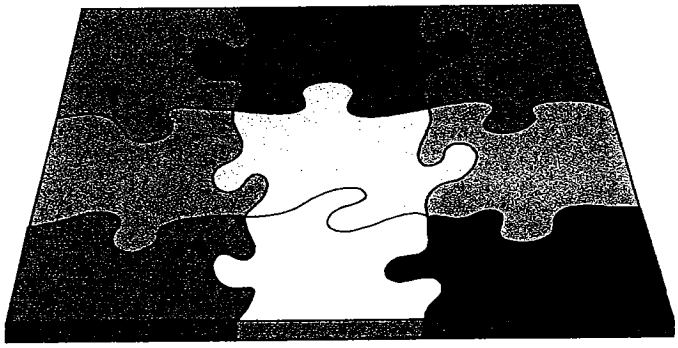
AZ – Marketing & Sales Business Policies and Guidelines

#2

AstraZeneca Business Policies

Partners in Policy



Confidential

AstraZeneca

March 2003

Dear AstraZeneca Colleagues:

The pharmaceutical industry has undergone an unprecedented level of change this past year. Industry practices have received significant attention from the press, state legislatures, and Congress. In July of 2002, CEOs of the leading pharmaceutical manufacturers issued a new code of conduct through our trade association, PhRMA. In October of 2002, the Office of the Inspector General of Health and Human Services issued a proposed draft of its ninth healthcare industry guidance, this time for the pharmaceutical industry.

AstraZeneca is committed to conducting its business with a high level of ethical conduct and integrity. The enclosed AstraZeneca Business Policies, also found on the AZ US Policies Site, apply to all personnel who engage in interactions with customers, including field personnel, headquarters-based personnel dealing with customers, and individuals deployed from skill centers that support our TAs. These Business Policies supplement corporate-wide policies established by AstraZeneca.

The AstraZeneca Business Policies are the result of significant work from cross-functional teams across the business, both at headquarters and from the field sales organization.

Adherence to all of the AstraZeneca Policies and Guidelines is necessary in order to maintain our commitment to ethical business practices. Furthermore, a policy violation may have legal implications and consequences for the Company and/or individual employees. Consequently, a violation of these policies may result in disciplinary action up to and including termination of employment. If you have any questions about the policies and guidelines or concerns about compliance with them, you should ask your supervisor for direction or you may call the Code of Conduct Helpline by dialing (888) 244-1769.

As a world leader in the pharmaceutical industry, we are committed to operating our business in a manner based on high ethical conduct, integrity, and trust. We appreciate your commitment to and support of this fundamental principle.

Sincerely,

David R. Brennan
President and CEO

Glenn Engelmann
Vice President, General Counsel and Secretary

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I. Legal Standards

I-1 Ethical and Professional Conduct

AstraZeneca

Ethical and Professional Conduct

Policy No.: **I-1**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **AZ employees must strictly adhere to Federal and state law and all AZ policies;**
- **Employees should assume they are acting as AZ's agent in all of their business-related interactions;**
- **All written agreements must be in a form approved by AZ's Legal Department;**
- **AZ employees are prohibited from using or disclosing nonpublic material information in selling or acquiring securities for personal gain;**
- **No record, report, entry, or document shall be falsified, distorted, misdirected, deliberately misleading, incomplete, or suppressed;**
- **No employee should seek or accept a personal "gift," which might have an influence on their business judgment;**
- **AZ employees should avoid actual or potential conflict of interest between their own activities and the interests of AZ;**
- **AZ employees have the duty to come forward and identify any situation in which he or she believes AZ or an employee of AZ is in violation, or is in danger of violation, of any applicable law, regulation, or AZ policy.**

2. Purpose

To state AZ's commitment to a high level of ethical conduct in the service of patients and other customers, and to establish procedures to guide employees in adhering to all applicable legal standards and AZ policies.

3. Policy

3.1. Responsibilities of AZ Employees

3.1.1. The primary objective of TA Support Functions and Sales personnel is to conduct business activities with Healthcare Professionals (HCPs) and other customers resulting in benefit to patients and enhancement of the practice of medicine. TA Support Functions, Sales personnel, and other AZ employees act as principal contacts for AZ with identified national and regional customers and, as such, must conduct themselves in a highly ethical and professional manner at all times.

3.1.2. AZ employees must strictly adhere to Federal and state law and all corporate policies established by AZ, specifying in a variety of contexts the roles and responsibilities of AZ employees who may come into contact with HCPs.

3.2 Agents of AZ

In many instances, when AZ employees engage in discussions with customers, they are acting as the agents of AZ. AZ may be responsible for, and bound by, statements or promises made by such personnel. In order to best protect AZ's interests, employees should assume they are acting as AZ's agent in all of their business-related interactions with customers and others outside of AZ.

3.3. Written Communications, Contracts, and Agreements

3.3.1. Written communications between AZ employees and our customers must be reviewed and approved through AZ's applicable quality review and approval process before being used. From time to time, AZ may issue written guidance regarding certain types of communications that do not require prior review.

3.3.2. In order to provide appropriate controls regarding financial commitments of AZ to outside parties, AZ employees must adhere strictly to delegations of authority established by AZ. Any contract, letter agreement, or proposal for any type of agreement that does not have prior approval, must be submitted to a person with a sufficient delegation of authority for review and approval. All written agreements must be in a form approved by AZ's Legal Department.

3.3.3. Oral agreements with consultants are expressly prohibited. Personnel who believe it is necessary to retain a consultant for any reason, but do

not have the authority to enter into a consulting agreement, must confer with their supervisor before beginning discussions with any potential consultant.

4. Specific Areas of Concentration

Included within our business ethics policy are the following specific types of activities:

4.1 Conflicts of Interest

AZ employees are required to observe a duty of loyalty to AZ and may not permit any self-interest (financial or otherwise) to interfere with that duty. If an employee believes that there is an actual or potential conflict of interest between his or her own activities and the interests of AZ, they should review that situation with their management.

4.2 Insider Trading

4.2.1. AZ employees are prohibited from using or disclosing nonpublic material information (information which is not publicly available and is of such a nature that a reasonable investor would view it as important in determining whether or not to buy or sell a security) obtained while in AZ employment.

4.2.2. Specifically, Federal law prohibits any fraudulent activity in connection with the purchase or sale of any security. This principle has been interpreted to include trading a security on the basis of such nonpublic material information. Trading in a particular security by any employee who is aware of such nonpublic material information and who uses such information for personal gain prior to its disclosure to the trading public would be a violation of both this Policy and Federal law.

4.3 Standards of Documentation

AZ employees are required to maintain and comply with established internal control standards and procedures to ensure that AZ assets are protected and properly used and that financial records and reports are accurate and reliable. No record, report, entry, or document shall be falsified, distorted, misdirected, deliberately misleading, incomplete, or suppressed. Improper accounting and documentation and fraudulent financial reporting are not only contrary to AZ policy, but also may be in violation of law or government regulations.

4.4 Gifts, Entertainment, or Hospitality

4.4.1. No AZ employee should seek or accept a personal gift, personal favor, entertainment, or hospitality, which might reasonably be believed to have an influence on his or her business judgment. Any offer of entertainment or hospitality must not be accepted unless the offer is within the bounds of acceptable and customary business entertainment and hospitality. Any questions regarding whether a personal gift, personal favor, entertainment, or hospitality is appropriate must be reviewed with Sales Management.

4.4.2. No AZ employee should place himself or herself under an actual or apparent obligation to anyone that is intended, or appear to be intended, to influence his or her business judgment. Gifts or favors must not be accepted if they would be construed as a bribe or a payoff or if they seek to interfere with your business judgment or decision-making.

4.4.3. Likewise, AZ employees must never use gifts, favors, entertainment, or hospitality in return for obtaining specific favorable business decisions or treatment from a customer.

5. Personal Responsibilities

5.1 Obligation to be Informed

AZ employees have an obligation to be informed of the principal legal requirements applicable to their activities on behalf of AZ. TA Support Functions and Sales personnel are expected to take the initiative to consult with the Legal Department (or where appropriate, the Human Resources Department) to resolve any questions or uncertainty they may have with respect to the applicability or interpretation of any law or regulation or the legality of any conduct or intended course of action with respect to AZ's business.

5.2 Duty to Come Forward

AZ employees have the duty to come forward and identify any situation in which he or she believes AZ is in violation, or is in danger of violation, of any law or regulation applicable to AZ, its assets, business, or operations. Ordinarily, an employee should raise such an issue with his or her supervisor. If, however, he or she believes that such reporting would be ineffective, he or she must bring such issue to the attention of the Legal Department (or, where appropriate, to the Human Resources Department). All such issues must be reviewed and investigated as necessary.

6. Penalties for Noncompliance

Compliance with this Policy is essential to maintain the high legal and ethical standards established by AZ. Violation of this Policy will result in disciplinary action up to and including termination.

AZ employees should recognize that in addition to disciplinary action under this Policy, violation of these policies might also subject such persons to other penalties that may include fines, imprisonment, and loss of professional standing and/or licenses.

AstraZeneca

Antitrust Laws

Policy No.: **I-2**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **AZ employees must comply with all applicable antitrust laws without exception;**
- **Consult with a Legal Representative early when dealing with matters that may have antitrust implications, ie, trade association meetings;**
- **An employee's involvement in conduct that violates the antitrust laws will be subject to appropriate discipline, including possible dismissal;**
- **Under no circumstances is information regarding competitive pricing and trade policies to be obtained directly from or provided to a competitor;**
- **The Legal Department should be consulted with respect to any questions regarding the appropriateness of any specific practice.**

2. Purpose

To state AZ's commitment to compliance with all applicable antitrust laws, and to provide guidelines to ensure that AZ employees conduct their professional activities lawfully. (This policy is intended to supplement AZ corporate policy on this subject.)

3. Policy

3.1. General Policy

3.1.1. AZ believes that the antitrust laws of the United States and other countries have contributed substantially to economic growth and that full compliance with them is in the best interest of AZ. It will continue to be our policy to comply in every respect with all applicable antitrust laws, and there will be no exception or deviation from this policy.

3.1.2. AZ employees must familiarize themselves with these laws by reviewing this policy and all other AZ materials addressing compliance with antitrust laws. Managers are responsible for assuring that all personnel under their supervision know and understand AZ policy on this matter and that all such personnel fully comply.

3.1.3. Any questions regarding the propriety of any contemplated action should be referred to the Legal Department for advice and guidance. Antitrust difficulties may best be avoided by following the practice of full and early discussion with Legal Counsel on all matters, which may have antitrust implications. The members of the Legal Department are available at any time to discuss day-to-day problems with employees.

3.2. Failure to Comply

3.2.1. The penalties for failure to comply with the antitrust laws may be severe for AZ, for individual employees participating in any violation, and for supervisory personnel and officers responsible for the actions of these employees. For instance, a company convicted of violating the Sherman Act may be fined up to $10,000,000 per offense. An individual employee, officer, or director of a company who authorizes or participates in a violation of the Act may also be convicted of a felony and punished by a fine of up to $350,000 and a prison term of up to three years. Even greater fines may be assessed against individuals or companies under other applicable legislation.

3.2.2. If antitrust difficulties arose, AZ could be subjected to significant adverse publicity, as well as substantial legal fees. In addition to the criminal penalties already mentioned, a violation of the antitrust laws could subject AZ to a court order limiting its activities and placing it at a serious competitive disadvantage. Other businesses injured by any antitrust violations may be able to recover three times their proven damages, plus attorneys' fees.

3.2.3. Additionally, an employee's involvement in conduct that violates the antitrust laws will be subject to appropriate discipline, including possible dismissal.

3.3. General Purpose of Antitrust Laws

The antitrust laws are intended to prohibit unreasonable restraints of trade, price discrimination, and unfair trade practices and, thereby, preserve a competitive economy. The antitrust laws are, for the most part, broadly worded and adaptable to changing business and economic practices with legal issues largely decided on a case-by-case basis through the application of general principles to specific facts. These laws represent a compromise between possible abuse of economic power by industry and strict regulatory control of business activities by government. Exhibit A attached to this policy contains a basic description of specific federal antitrust laws.

3.4. Employee Responsibilities

All of the possible activities that might violate the antitrust laws are not catalogued here. However, the following list provides some important examples of activities that must be strictly avoided, and also provides context for evaluating other similar activities that are also prohibited.

3.4.1. AZ employees must *never* discuss or agree with a competitor about anything relating to any of the following topics:

- Product pricing (including future prices or pricing policies) or any other matter affecting or related to price;
- Marketing or sales policies;
- Terms or conditions of sale or doing business with customers;
- Discounts, rebates, free goods offers;
- Profits, profit margins, or costs;
- Market shares information;
- Distribution practices;
- Bids or plans to bid (or refrain from bidding) for particular business;
- Sales territories;
- Recognition or termination of customers;
- Strategies for dealing with common customers, or for dividing customers between the Company and a competitor;
- Negative or derogatory comments about any supplier, wholesaler or customer.

3.4.2. In the event that an AZ employee is present at a trade association meeting, trade show, medical symposia, or other meeting, or is otherwise participating in a conversation with employees of competitor companies, and one or more competitors reveal or

discuss any of the topics outlined above, an AZ employee must immediately state his/her objection to that topic and leave the meeting or terminate his/her participation in that conversation. Promptly inform the Legal Department of any such occurrence. The AZ employee will receive further directions from the Company's lawyers as to what additional actions, if any, he/she should take.

3.4.3. Useful commercial information may be collected, consistent with the antitrust laws, from non-competitive third-party sources, such as customers, if the following guidelines are followed:

- AZ employees must document information they receive regarding competitive pricing and trade policies, particularly information that will form the basis of a pricing strategy intended to meet competitive terms. Such documentation must clearly specify when and from whom the information was obtained (eg, pharmacist or specific trade publication);
- If the information obtained is in the form of an already existing document, the employee must note on the document when and from whom the document was obtained. In the event that a document is marked as "Business Confidential" or "Secret," or words to that effect, you are not to review it, or to remove it from the third-party premises, without the explicit consent of that third party, ie, from an individual whose position, responsibilities, etc, within that third-party organization make it appear reasonable and appropriate that the individual is authorized to provide such consent;
- *Under no circumstances is information regarding competitive pricing to be obtained from or provided to a competitor.*

3.4.4. AZ employees must provide accurate information regarding the nonprofit status of customers and affiliates.

3.4.5. Employees should also refrain from discussing with our wholesalers their resale prices.

3.4.6. The Legal Department should be consulted with respect to any questions regarding the appropriateness of any specific practice.

4. Exhibits

A. Federal Antitrust Laws

EXHIBIT A

Federal Antitrust Laws

1. **Sherman Act**

The Sherman Act declares that every contract, combination, or conspiracy in restraint of interstate or foreign commerce is illegal. This law also prohibits monopolization, attempts to monopolize, or conspiracies to monopolize such commerce. For example, agreements between competitors to control prices, allocate territories, allocate customers, restrict output, or boycott third parties are illegal. Agreements between buyers and sellers to maintain resale prices and certain conduct by a single competitor, which might create or maintain an unlawful monopoly, also are prohibited.

2. **Clayton Act**

The Clayton Act declares unlawful any agreements, which have the effect of preventing or otherwise foreclosing a purchaser from dealing in the goods of a competitor, where the effect of such agreement may be to substantially lessen competition. This Act also prohibits acquisitions, mergers, and joint ventures where the effect of such transactions may be to substantially lessen competition or tend to create a monopoly.

3. **Robinson-Patman Act**

The Robinson-Patman Act, an amendment to the Clayton Act, is directed against price discrimination and other related discriminatory practices. This Act makes it illegal to grant or knowingly receive from a common supplier a difference in price for goods of like grade and quality, if such prices are offered at about the same time and if the effect may be substantially to lessen competition. It also makes it illegal to pay for sales services furnished by a customer, or to furnish sales services to a customer, unless such sales services are made available on proportionately equal terms to all competing customers.

This Act forbids the payment or acceptance of a commission, brokerage, compensation, allowance, or discount except for services rendered in connection with the sale or purchase of goods to the other party or its agent. There are exceptions and ramifications to these prohibitions. *Any arrangement in which it appears that one customer may be receiving more favorable prices or other terms than another customer, or in which a party other than the buyer and the seller is involved, must be cleared in advance with the Legal Department.*

There are two exceptions to the Robinson-Patman liability, which are of particular importance -- the nonprofit institutions exemption and the "meeting competition" defense. *The Legal Department must approve any determination that an exception to the prohibitions of the Robinson-Patman Act applies.*

Nonprofit Institutions Exemption

This exemption applies to purchases of products by certain nonprofit charitable institutions for their own use. In order to determine whether and to what extent this exemption is available for a particular customer, it is necessary to have information regarding the nonprofit status of the customer, its affiliations, if any, with for-profit entities, and uses for which the customer is purchasing products.

"Meeting Competition" Defense

The "meeting competition" defense allows a seller to offer a lower price to a customer when the seller can show based upon reasonable reliance that the lower price was established in good faith to meet an equally low price of a competitor. In order to determine whether this defense is available in connection with a particular customer, it is necessary to have information regarding the details of the competitive offer. Relevant information includes the name of the person who provided information regarding the competitive offer, the name of the company making the competitive offer, the price, availability of free goods, volume to be purchased, time period during which price is available, any other factors affecting value of competitive offers or prices to a customer, and documentation of the competitive offer, all of which should be provided by an appropriate source (typically the customer to whom the competitive offer or price was extended). *Note that under no circumstances may information regarding competitive offers be sought from or provided to competitors.*

4. Federal Trade Commission Act

The Federal Trade Commission Act makes it illegal to engage in unfair methods of competition and unfair or deceptive acts or practices. The practices and activities that may be reached by the Federal Trade Commission are considerably broader than those prescribed by other antitrust laws. This Act gives the Federal Trade Commission flexible power to condemn new unfair practices as they develop, and has been interpreted to condemn practices such as commercial bribery and false advertising.

I-3 Enforcement Inspections

AstraZeneca

Law Enforcement Inspections and Investigations

Policy No.: **I-3**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Immediately contact the Legal Department if a government official requests access to inspect AZ premises or property;**
- **If presented with a search warrant, AZ employees are to comply with its terms as provided in the warrant and contact the Legal Department immediately;**
- **If contacted by a government investigator, AZ employees have the right to agree to be interviewed or to decline; AZ employees are not required to give any statement unless they receive a subpoena;**
- **AZ recommends that AZ employees consult with counsel before agreeing to speak with an investigator;**
- **If an AZ employee decides to be interviewed by a government investigator, he/she *must* provide full and truthful information.**

2. Purpose

To describe the inspection authority of the FDA and other law enforcement agencies, and to assist Field Personnel in handling situations involving a government inspection or investigation.

3. Policy

3.1. Inspection Powers of FDA, DEA, and State Pharmacy Boards

3.1.1. The Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and State Pharmacy Boards are empowered to inspect, with certain exceptions, all equipment and records at AZ offices. They may also inspect vehicles used to transport drugs in interstate commerce.

3.1.2. Request for Inspection of Company Premises by a Government Agent without a Search Warrant

It is AZ policy to cooperate reasonably with requests by government authorities for access to AZ premises or property. In the event that a government agent, having properly identified himself/herself and displayed his or her identification credentials, requests access to inspect AZ premises or property or to otherwise obtain AZ information or property, AZ employees are to contact the Legal Department immediately. It will be the responsibility of AZ lawyers to facilitate an appropriate process for such an inspection. In the alternative, AZ employees may request that the investigator direct his/her inquiry to the Legal Department.

3.1.3. In either event, AZ employees must report any such contact with government authorities to the Legal Department.

3.1.4. Search Authorized by a Warrant

In the event that the government agent presents an AZ employee with a search warrant authorizing such an inspection, he/she is to comply with its terms as provided in the warrant. The AZ employee should obtain a copy of such warrant and contact the Legal Department immediately, transmitting the search warrant by fax as soon as possible. The AZ employee will receive further instructions from AZ lawyers. If the government agent removes any AZ property, the AZ employee must seek to memorialize in writing the materials that are removed from the premises.

3.2. Answering Questions

3.2.1. We ask that AZ employees advise the Legal Department if any government investigator in connection with any matter involving AZ contacts them.

3.2.2 If any government investigator contacts an AZ employee, he/she has the right to agree to be interviewed by the investigator or to decline to be interviewed. AZ employees are not required to give any statement (unless they receive a subpoena to testify in a formal proceeding).

3.2.3. If an AZ employee is contacted by a government investigator and decides to speak with the investigator, he/she has the right to consult an attorney before each conversation. The AZ employee is also entitled to have an attorney present during any conversation with the investigator.

3.2.4. It may be appropriate for AZ counsel to represent AZ employees and be present during their interview with the investigator. It also may be appropriate for other counsel to be engaged to represent AZ employees at AZ expense.

3.2.5. If an AZ employee decides to be interviewed by a government investigator, he/she *must* provide full and truthful information in response to all questions he/she chooses to answer. AZ employees should be aware that providing investigators with untruthful or misleading information could subject them to criminal prosecution.

3.2.6. Whether to speak with a government investigator or be represented by counsel is the AZ employee's decision. AZ does recommend, however, that AZ employees consult with counsel before agreeing to speak with an investigator.

AstraZeneca

Intellectual Property Claims

Policy No.: I-4

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2001**

Contents

1. Key Learnings

- **If approached by anyone outside of AZ with an idea, invention, suggestion for a new product, etc;**
  - **Avoid all discussion about the concept;**
  - **Do not accept any documents of any kind;**
  - **Advise the person to write directly to AZ's Licensing and Business Development group regarding the idea in nonconfidential terms.**
- **If an AZ employee receives a communication indicating that AZ material infringes on a copyright or trademark, he/she must not comment on the subject but should record the information, including the name, telephone number, and the address of the person who communicated with them, and transmit it to the Legal Department.**

2. Purpose

To guide AZ employees in managing situations, which may potentially give rise to intellectual property claims against AZ.

3. Policy

3.1. General Policy

In the course of the professional activities on behalf of AZ, AZ employees may encounter situations that involve the intellectual property rights of AZ and/or third

parties. To avoid situations, which potentially may incur liability for AZ, AZ employees should familiarize themselves with and follow this policy.

3.2. Unsolicited Disclosures

3.2.1. This procedure is intended to avoid having any unsolicited disclosure completely revealed to AZ before we have had an opportunity to develop the proper intellectual property groundwork. The full revelation of a disclosure without such groundwork could lead to Legal complications if, for example, an unsolicited idea were disclosed at a time when AZ was actually in the process of adopting an identical or very similar idea. This could lead to disputes about whether AZ misappropriated another's intellectual property for its own use and is obligated to compensate the other financially.

3.2.2. If a physician, pharmacist, or any other individual or organization outside AZ makes any unsolicited offer to disclose any idea, invention, specific suggestion for a new product (such as different medical uses or combination therapy), marketing or promotional technique, etc, the following procedure must be followed:

- Avoid all discussion of the details of the disclosure;
- Do not accept any documents, drawings, sketches, models, etc;
- Advise the person offering the disclosure to write directly to the AZ Licensing and Business Development, stating in very general, nonconfidential terms the nature of the disclosure.

3.2.3. Disclosures pertaining to the discovery, development, or use (alone or in combination) of pharmaceutical products or related technologies will be processed and reviewed by Licensing. All subsequent contacts regarding these types of disclosures are between the disclosing party and Licensing. Disclosures pertaining to other matters will be handled by the Legal Department.

3.2.4. A letter acknowledging receipt of the submission and confirming its nonconfidential nature will be sent to the disclosing party. If AZ has any preliminary interest in the disclosure, the disclosing party will be asked to agree in writing to the conditions under which AZ will accept and consider the disclosure.

- If this agreement is signed, full disclosure will be accepted and will be circulated to appropriate persons at AZ for consideration;
- If AZ is interested in using the disclosure, an effort will be made to enter into an agreement for such use;
- If AZ is not interested in the submission, the disclosing party will be advised in writing and any original documents returned. A copy may be kept in AZ files for record keeping purposes.

3.3. Patent, Trademark, and Copyright Claims

Persons outside AZ may suggest that a communication or material produced by AZ infringes on a trademark or copyright, or that one of our products infringes the patent held by some third party, or that we otherwise have acted inappropriately regarding another party's intellectual property rights. If an AZ employee receives such a communication, he/she must not comment on the subject. Instead, the AZ employee should record the information, including the name, telephone number, and the address of the person who communicated with him/her, and transmit it to the Legal Department.

I – 5 Product Liability Claims

AstraZeneca

Product Liability Claims

Policy No.: **I-5**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **When engaging in product discussions with healthcare professionals (HCPs), AZ employees are perceived as acting as AZ's agent;**
- **AZ may be responsible for, and bound by, any statements or promises AZ employees make;**
- **Do not make any statements about product claims or risks that are not consistent with our prescribing information and approved promotional materials;**
- **If served with a Legal document pertaining to AZ products or activities, such as a summons or complaint initiating a lawsuit against AZ, AZ employees must immediately call the Legal Department.**

2. Purpose

To assist AZ employees in handling certain situations which may have Legal implications for AZ under product liability law.

3. Policy

3.1. General Policy

In the course of any professional activities on behalf of AZ, an AZ employee will encounter a variety of situations, which have Legal implications for AZ. The AZ employee is not expected to know about all the ramifications of applicable laws

and regulations; however, the AZ employee should be able to (1) handle routine situations, which may have Legal implications; and (2) identify situations in which Legal advice should be sought. To this end, the AZ employee should familiarize his/herself with and follow the guidelines provided in this policy. If any of the material is not clear, or if he/she has questions regarding the Legal implications of his/her activities, seek clarification through his/her designated supervisor.

3.2. Legal Status of AZ Employees

When AZ employees engage in product discussions and other interactions with healthcare professionals (HCPs), they are **perceived as** acting as AZ's agent. AZ may be responsible for, and bound by, any statements or promises AZ employees make.

3.3. Potential Product Liability Claims

3.3.1. AZ employees should be aware that their activities may influence or even cause product liability claims. A product liability claim arises when a patient asserts that he or she has had an adverse reaction from an AZ product and files a claim or lawsuit against AZ under such theories as negligence, breach of warranty, or strict liability.

3.3.2. AZ is generally protected against such lawsuits because our full prescribing information and promotional materials carefully define the limitations of our product claims and the various risks associated with the use of the product. However, any statements AZ employees make to the claimant's attending physician (or other HCP), which tend to *extend the claims* or to *minimize the risks* may **arguably** nullify the effect of the limitations or warnings in our promotional materials. For example, if an HCP used an AZ product for an unapproved claim based on an AZ employee's recommendation and the patient experienced a side effect, AZ could be vulnerable **to claims that we failed** to adequately warn the HCP. Therefore, AZ employees should not make any statements about product claims or risks that are not consistent with our prescribing information and approved promotional materials. All promotional activities must *always* comply fully with AZ policy entitled **Product Promotion** (II-1). In addition, AZ Personnel must *never* participate in, or create the appearance of participating in patient treatment.

3.4. Service of Process

If AZ employees are ever personally served with a Legal document pertaining to one or more of AZ products or activities, such as a summons or complaint initiating a lawsuit against AZ, they must immediately call the **Legal Department** and then notify their designated supervisor. In most jurisdictions, we have only a very limited time (10-20 days) in which to respond to a complaint. Failure to respond in time may result in a default judgment, which means AZ loses the lawsuit without having an opportunity to defend itself.

3.5. Notice of Potential Claims

If AZ employees become aware of a potential Legal claim against AZ (for example, if a patient engages an attorney or threatens a lawsuit), they should

make no comment on the substance of the claim, but immediately bring the matter to the attention of their designated supervisor.

4. References

4.1 AZ Business Policies

Product Promotion (II-1).

I - 6 Patient Privacy

AstraZeneca

Patient Privacy

Policy No.: **I-6**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2001**

Contents

1. Key Learnings

- **The privacy of the relationship between the patient and the HCP must be respected at all times;**
- **AZ employees must not participate in the treatment of any patient;**
- **AZ employees may not examine prescription files, patient records, or other documents with respect to individual patients.**

2. Purpose

To express AZ policy that all AZ employees must respect the privacy of the relationship between patients and healthcare professionals (HCPs).

3. Policy

3.1. General Statement

The privacy of the relationship between the patient and the HCP must be respected at all times. AZ employees may not examine prescription files, patient records, or other documents, or otherwise obtain access to specific information about prescribing practices, with respect to individual patients. AZ employees also must not participate in the treatment of any patient.

This policy is not intended to preclude disclosure of patient information during the course of Adverse Event Reporting, clinical investigation, or training, or under any other circumstances when consent has been granted.

3.2. General Market Information

General information regarding the extent of usage of specific products by HCPs may be collected by AZ and distributed to TA Support Functions and Sales Personnel. Persons who receive such data are strictly bound by the AZ policy entitled **Sales Prescriber Data** (V-6).

3.3. Discussions with HCPs

During discussions with HCPs, it is permissible for AZ Personnel to discuss HCP's product preferences for categories or types of patients. It is not permissible to discuss specific patients with HCPs in a way that allows a patient's identity to be revealed.

4. References

4.1. AZ Business Policies

Sales Prescriber Data (V-6).

II. Product Promotion

AstraZeneca

Product Promotion

Policy No.: **II-1**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents:

1. Key Learnings

- **All promotional materials and reminder items used by an AstraZeneca (AZ) employee involved in the sale or marketing of an AZ product must be approved through the eSTaR Process prior to their use;**
- **All promotional presentations must be objective, balanced, and include information on the risks as well as the benefits of the product being discussed;**
- **Full prescribing information must be offered for every product for which an indication is discussed;**
- **AZ employees may not initiate any discussion involving comparisons with competitive products unless specifically instructed to do so by AZ.**

2. Purpose

To reinforce AZ's commitment to comply with all applicable legal and regulatory requirements governing all AZ employees when involved in product promotional activities.

3. Policy

3.1. General Statement

As representatives of AZ, all employees involved in promotional activities must adhere to all applicable laws and regulations. To that end, and to help ensure that AZ products are prescribed and administered in the best interests of the patient by Healthcare Professionals (HCPs) who are thoroughly knowledgeable about product attributes and characteristics, all employees involved in any promotional activities with HCPs must familiarize themselves with the legal and regulatory standards applicable to their promotional activities and must adhere to the practices outlined in this policy.

TA USDD personnel (ie, Scientific Commercialization) have the potential to be involved in the scientific exchange of information and/or promotional activities. This policy applies only to their promotional role in discussions of AZ products.

This policy applies to all advertising and promotional discussions or activities, regardless of the medium used. Activities under the scope of the policy include, but are not limited to, product promotion conducted over the Internet or other electronic media, direct-to- consumer promotion, or promotion via fax, telephone, or at convention exhibits.

3.2. Conformance to Full Prescribing Information (PI)

3.2.1. HCPs should receive complete and accurate information about AZ products as is appropriate to their role in healthcare delivery. The full prescribing information (also called package insert, product circular, or directions for use) is the basis for all of the company's communications about its products. AZ personnel must not promote a new product or a new indication for an existing product to HCPs until they receive the official direction to do so.

3.2.2. When engaging in a product discussion with an HCP, AZ employees are acting as AZ's agent. AZ may be responsible for, and bound by, any statements or promises made by the employee. Any claim made orally that does not conform to the product's full prescribing information, may render the product misbranded and could jeopardize AZ's ability to market that particular product. Also, statements extending claims or minimizing risks may expose AZ to product liability claims. Therefore, the AZ employee must stay strictly within approved claims and never minimize any of the risks associated with the use of any AZ product.

A copy of the current full prescribing information (PI) for each product discussion initiated must be offered, including discussions in which there are references to non-leave-behind promotional materials. If the HCP initiates a discussion about a product that the AZ employee was not planning to discuss and for which no current full PI is at hand, the AZ employee must offer to obtain a copy.

3.2.3. If an HCP mentions a use of a product that is not an approved indication, or mentions using it in ways not recommended in the full PI (such as administering the product in higher-than-recommended dosages), the AZ employee must clearly state that the product is not indicated for use in that way and provide a copy of the current full PI. If the HCP indicates that he or she would like further information about such usage, offer to assist the professional in submitting a Professional Information Request (PIR) (*see* **Professional Information Requests [PIRs]**, VI-8).

3.2.4. If the AZ employee is drawn into a discussion on product information about which he/she is not certain, the employee should inform the HCP that they do not have that knowledge and offer to assist the HCP in obtaining information through a PIR (*see* **Professional Information Requests [PIRs]**, VI-8). This will help the employee avoid inadvertently making statements beyond the product's approved labeling. The AZ employee should be certain to offer to obtain a copy of the current full prescribing information.

3.3. Balanced Presentation

3.3.1. In addition to discussing product information in conformance with the full prescribing information, AZ employees must also give an ***objective*** and ***balanced*** presentation of both the benefits and risks of the product. This does not mean, however, that every single product communication must include a full recitation of all contraindications, warnings, precautions, and adverse reactions; the employee may take into account the scope and frequency of previous communications, the HCP's experience with the drug, and the context in which the product is discussed. For example, when a new product is introduced, it is not enough to single out an indication and a few precautions and adverse reactions. To use the product in the best interests of the patient, the HCP must know as much as possible about it. Therefore, the AZ employee should strive to engage the HCP in a complete discussion of the product, including all product characteristics.

3.3.2. In sum, the balanced presentation requirement means that AZ employees must make sure that the sum total of their presentations to any HCP on a given product adds up to full awareness of the product's benefits and the risks associated with its use. While not exhaustive, the following list sets forth some examples of activities ***that must be strictly avoided***:

- Making statements that tend to diminish the warnings in the full prescribing information. *Example: "As you know, Doctor, with almost any drug, hematological problems might result, but they usually don't:";*

- Presenting a side effect as if it were a clinical benefit;

- Failing to point out the limits of a product's indications when the HCP advises you that he or she is using, has used, or intends to use the product beyond its claim structure;

- Marking up promotional materials or reprints. Highlighting, marking, or underlining points the AZ employee wishes to stress could be construed as an attempt to distract attention from or diminish information that the HCP should know;

- Lifting statements out of context from the full prescribing information or approved promotional materials in any way that might distort their meaning;

- Abbreviating your discussion, because of an interruption or other constraints, after covering only the benefits or advantages of a product and not offering to leave a copy of the full prescribing information with the HCP.

3.3.3. There is no requirement to give a complete, balanced statement or to offer the prescribing information if a product is simply mentioned in passing without reference to any indication. Of course, if such a mention leads to further discussion of the product, the provisions of this policy must be followed.

Discussions of contract terms with an HCP by an Account Director or other appropriate AZ representative for a product are not considered promotional if the discussion is focused on the requirements and responsibilities of the parties to the contract and not the indications or prescribing information of the AZ product or its competitive products.

3.4. Promotional Materials

3.4.1 The law requires that any promotional materials given to an HCP contain "full disclosure" (also known as full prescribing information): adequate directions for use, along with a complete statement of all the product's benefits and risks. To ensure compliance with the law, all materials used in promotion (including reprints, reference texts, patient education pieces, display and exhibit materials, and reminder items) must have prior approval through the AZ PRA review process. AZ employees have access to a variety of currently approved promotional materials via Sales InSite, MarketPro, the National QuickList, and/or their designated management support. Homemade materials must never be used for promotion (including cutting or pasting approved materials), use or distribute unapproved journal articles or reference texts, write notes to HCPs containing product information, use approved material outside of the scope of its intended use, or provide copies of non leave-behind pieces to HCPs.

3.4.2. The AZ employee is responsible for ensuring that they always use the most current approved promotional materials and related current full prescribing information in accordance with the AZ guidance or directions accompanying such materials (including directions about dates of use). Never use outdated materials (typically, the approval period for promotional materials is one year) or materials that the employee has been directed to stop using. The approval date will be found on the back of most AZ developed pieces. The approval status of promotional materials may be confirmed by consulting Sales InSite, MarketPro, the National QuickList, and/or your designated management support.

3.4.3. Consistent with the policies set forth above in Sections 3.2 and 3.3, AZ employees may only use approved materials in a way that is consistent with the relevant full prescribing information and within the framework of a balanced presentation.

3.4.4. Consistent with the policies set forth above in Section 3.3.2, approved reprints and printouts that are left behind must not be underlined, highlighted, annotated, or otherwise marked by any AZ employee.

3.5. Comparisons with Competitive Products

3.5.1. AZ employees may not initiate any discussion involving comparisons with competitive products unless specifically instructed to do so by AZ. In such case, approved materials and training will be provided to the employee. As with all product discussions, all such product comparisons may be made only in the context of an objective, balanced presentation. The benefits of one product and the shortcomings of another may not be singled out.

3.5.2. In the event of a misunderstanding on the part of an HCP regarding a competitive product that does ***not*** involve safety, efficacy, and/or tolerability (*eg*, dosing frequency), refer to that product's ***current*** prescribing information to dispel confusion. Any such reference must offer only a factual accounting of points in the full prescribing information. If the AZ employee must refer to another company's full prescribing information, the employee must take reasonable precautions to ensure that it is current. Full prescribing information in the latest edition of the *Physician's Desk Reference* or in its most recent supplements, generally, may be assumed to be current. Of course, if the employee has actual knowledge or reason to believe that the prescribing information is not current, he/she may not use that source.

3.5.3. If asked a question requiring a product comparison, which is not answered within the foregoing policy guidelines, offer to assist the HCP in obtaining information through a PIR (*see* **Professional Information Requests [PIRs]**, VI-8).

3.6. Medical Information Scientists (MISs)

3.6.1. Medical Information Scientists have strong backgrounds in medicine, pharmacology, or other scientific disciplines. By virtue of their training and expertise, MISs serve a vital role providing scientific and therapeutic information to HCPs. This includes, but is not limited to, information regarding AZ products.

3.6.2. **All MISs must adhere to the provisions of the AZ Promotion Policy, as well as all other Business Policies, to the same extent as all other AZ employees involved in product promotion unless otherwise stipulated in this policy. The roles of other members of the Scientific Commercialization group (Product Development Scientist [PDS], Medical Marketing Leader [MML], Field Medical Director [FMD]) will be covered in the policies on Scientific Exchange of Information (see USDD Policies) due to their clinical rather than promotional focus.**

3.6.3. In response to a bona fide, unsolicited request from an HCP about an AZ approved or investigational drug, an MIS may provide an oral or written response and may include copies of published literature or unpublished information such as "data on file." If the request is on an unapproved drug or unapproved indication, the MIS must clearly state as such, and must ensure that the response is limited to the question being asked, is complete, unbiased, balanced, and does not make stated or implied claims of safety and/or efficacy.

3.6.4. MISs and other members of the Scientific Commercialization group must adhere to the following rules regarding computer searches of biomedical databases, regardless of whether the searches relate to a topic that is within or off-label:

- A computer database search may be performed only in response to a ***specific*** and ***unsolicited*** request by an HCP;
- Only databases approved by AZ for use by the Scientific Commercialization group may be searched;
- Searches must be performed in a completely neutral and objective manner. No manipulation or screening of any kind is permitted. For example, confining a search to articles on a particular topic written in or after 1998 is not permitted if the searcher knows that a series of unfavorable articles on the same topic appeared in 1996;
- Upon completion of the search, the MIS or other Scientific Commercialization representative must inspect the search and determine if it contains data of an off-label nature relating to an AZ product. If the search does contain data of an off-label nature, the MIS must document the following:

- The name and address of the HCP requesting the search;
- The date of the inquiry; and
- The specific inquiry and search strategy used by the MIS in executing the search.

- This information must be archived in accordance with applicable guidelines;

- All citations generated by a search must be provided to the requesting HCP;

- Full text copies of one or more of the cited articles may be provided to the HCP only if:

  - The HCP makes a specific and unsolicited request for such articles after reviewing the citation list;
  - The selection of articles was not influenced by the Scientific Commercialization representative in any respect; and
  - Copies are made only with the permission of the copyright owner and/or do not otherwise violate US copyright laws.

- Printouts of requested searches and articles may be delivered by the MIS or other Scientific Commercialization representative in person, by the PSS or Account Director through whom the request was directed (provided that the search did not involve the off-label use of an AZ product or produce off-label information), or by mail and must include the following legend in legible and conspicuous print on the first page of each document:

  THE INFORMATION CONTAINED IN THIS DOCUMENT IS BEING SUPPLIED TO YOU AT YOUR SPECIFIC UNSOLICITED REQUEST. THIS MATERIAL IS NOT INTENDED AS LABELING OR AS A RECOMMENDATION FOR USE AS TO ANY PRODUCTS OR THERAPEUTIC CLASSES OF PRODUCTS IT DISCUSSES. FOR SUCH INFORMATION, YOU SHOULD CONSULT THE CURRENT FULL PRESCRIBING INFORMATION FOR THE PARTICULAR PRODUCT(S). ASTRAZENECA CAN OBTAIN A COPY OF THE FULL PRESCRIBING INFORMATION FOR ANY ASTRAZENECA PRODUCT FOR YOU. ASTRAZENECA MAKES NO REPRESENTATIONS OR WARRANTIES CONCERNING THE ACCURACY OR COMPLETENESS OF THE DATABASE SEARCH THAT WAS CONDUCTED PURSUANT TO YOUR REQUEST, OR OF THE INFORMATION GENERATED BY THE SEARCH.

- Printouts must not be underlined, highlighted, annotated, or otherwise marked by the Scientific Commercialization representative, except with the legend quoted above;

- No discussion may be initiated with an HCP of issues raised by information generated through a database search, except in strict conformance with this policy;

- MISs or other Scientific Commercialization representatives may attach a brief letter to the information provided to an HCP as a result of a search, indicating where the answer to the HCP's question is found in the search material.

4. References

4.1 AZ Business Policies

Gaining Access to Healthcare Professionals (II-3); **Professional Information Requests (PIRs)** (VI-8); **Product Samples** (VI-7).

II – 2 Development of Promotional Material

AstraZeneca

Development of Promotional Materials & Related Items

Policy No.: **II-2**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Only promotional pieces approved through the eSTaR Process are permitted to be used for product promotion;**
- **Promotional materials approved through the eSTaR Process must not be altered, highlighted, or otherwise modified;**
- **Reminder Items must have a fair market value(FMV) less than $35 and must have patient, medical, or professional relevance. Items valued at $35 or more must be classified as Patient or Medical Solutions.**

2. Purpose

To state AstraZeneca's (AZ's) commitment to comply with all applicable legal, ethical, and FDA requirements for the creation of AZ product promotional pieces and related items (eg, Reminder Items).

3. Policy

3.1 Promotional Regulatory Affairs Policy

The Promotional Regulatory Affairs (PRA) department designed the eSTaR Process to ensure AZ's compliance with its medical, legal, and regulatory requirements as they pertain to activities and materials used in marketing, sales, and promotional activities that occur in the US. This also includes materials used

to train any AZ sales force. Specifically, this process will ensure that promotional, educational, and marketing materials and activities are:

a) Medically and scientifically sound and responsible
b) Compliant with FDA regulations pertaining to Prescription Drug Advertising and Promotions;
c) Compliant with laws governing Fraud and Abuse, unfair competition, product liability, best price, anti-trust, intellectual property, and privacy issues;
d) Compliant with AZ policies.

Originators or sponsors of promotional items, sales training materials, press releases, and/or other materials that meet the requirements described in Table 1 below, must submit their materials for review and approval through the eSTaR Process prior to their distribution or use. The following table lists those items requiring eSTaR submission and approval prior to production and promotional use of the items.

Table 1 - Items Requiring eSTaR Submission

- Any item or communication that mentions a product name or contains product or medical information that is intended for use with, or dissemination to, the public, including, but not limited to
  a) Any item with statements regarding the safety, effectiveness, and/or use of a pharmaceutical product;
  b) Any item which makes claims about a pharmaceutical product;
  c) Any item which serves as a reminder item;
  d) Any item that provides information on a disease state.

- Any item or communication that mentions a product name or contains product or medical information that is intended for use with, or dissemination to, the AZ sales force or any AZ personnel who interact with the public, including, but not limited to:
  a) Training materials containing product or medical information;
  b) Training materials containing selling model information;
  c) Communications providing direction regarding products.

Note: This list is not comprehensive as pharmaceutical promotion and regulations continue to evolve. See your PRA Manager for any questions about whether an item requires PRA Review through eSTaR.

3.2. Participants in the eSTaR Process

3.2.1. Participants in the eSTaR Process fall into three main categories
- Originators
- PRA Reviewers
- Other Reviewers

- Legal
- Clinical Research Physician
- Medical Resource/Product Scientist

3.2.2. Originator

Originators are the main customers of the eSTaR Process. They create and/or sponsor materials that require PRA review. Originators are located at Headquarters (HQ) and in the Field. HQ Originators typically come from the following groups: Central Promotions, Sales Training, Public Affairs, Corporate Communications, Knowledge Management, E-Commerce, and Managed Care Promotions. Field Originators typically come from the following groups: Customer Support/Solutions Managers, Promotions Managers, Managed Care, and Field Sales Training.

3.2.3 PRA Reviewer

The PRA Reviewer is the regulatory reviewer who is responsible for ensuring that materials meet FDA regulations pertaining to Prescription Drug Advertising and Promotions. Specifically, they:

- Review the promotional material and marketing activities for compliance to applicable FDA regulations and identify potential regulatory issues;
- Provide promotional regulatory consultation and advice to the enterprise to ensure a high level of compliance to FDA regulations and AZ Policy;
- Manage the eSTaR and approval process that effectively supports centralized and decentralized product promotion;
- Facilitate the team meetings between legal, medical, regulatory, and marketing representatives for the review and approval of promotional materials and marketing activities;
- Provide comprehensive skill development and continuing education programs for the enterprise, regarding compliance of promotional and regulated activities with applicable laws and regulations;
- Effectively manage the relationship between AZ and the FDA Division of Drug Marketing, Advertising, and Communications (DDMAC).

3.2.3. Other Reviewers

The other reviewers are responsible to review and approve materials submitted to the eSTaR Process. They bring specific expertise to the process. Other reviewers come from various areas of the company, including Legal, Clinical Research, Medical Resource, Quantitative Sciences and Marketing Promotions (editor). With few exceptions, reviewers are located in HQ. The other reviewer roles in the eSTaR Process are described below.

Legal – Legal counsel will be responsible for the following:

- In conjunction with PRA, provide advice with respect to those FDA advertising and promotional issues that are novel, ambiguous, and/or likely to draw the attention of the FDA;
- Provide advice with respect to applicable laws, in particular those governing:
  - Fraud and abuse
  - Unfair competition (deceptive trade practices and consumer protection)
  - Product liability
  - Anti-trust
  - Intellectual property (copyright, trademark, and rights to data)
  - Privacy
- Ensure compliance with applicable AZ policies

Clinical Research Physician – The Clinical Research Physician (CRP) is the key medical reviewer responsible for verifying the medical and scientific integrity of the item by ensuring that the:

- Promotional themes are supported by scientific data;
- Promotional pieces are consistent with labeling in light of all available medical information;
- Message is truthful, balanced*, and not misleading so that a practicing HCP would understand how to use the product safely and effectively in the context of the full prescribing information;
- Sales training and promotional pieces are medically correct;
- Comparisons to other products are fair, balanced*, and fulfill regulatory and legal requirements;
- Graphics or presentations have no unintended (expressed or implied) medical implications.

* *Ensures risks, benefits, and limitations of treatment are fairly represented.*

Medical Resource TA Leader/Product Scientist – The Medical Resource TA Leader and Product Scientist are responsible for ensuring that the:

- Sales training and promotional pieces are scientifically correct;
- Literature references are accurate, supportive, and representative of what is in the literature;
- Promotional themes are supported by scientific data;
- Scientific content of the promotional pieces are consistent with labeling;
- Comparisons to other products are scientifically valid, fair, balanced, and fulfill regulatory and legal requirements
- Graphics or presentations have no unintended medical implications;
- Message is truthful, balanced, and not misleading so that a practicing

HCP would understand how to use the product safely and effectively in the context of the full prescribing information.

3.3 PRA Escalation Process

The optimum time to use the PRA escalation process is during the development period. The optimum time to seek TALT (Therapeutic Area Leadership Team) approval is during the development period. Waiting until it is too late in the process will only cause further delays.

3.3.1 If an Originator does not agree with the results of an eSTaR review, he or she should first seek resolution with the eSTaR Review Team responsible for reviewing the item. If the issue cannot be resolved in a satisfactory manner, the Originator may elect to seek resolution via the PRA Escalation Process. These steps are described below (See Figure 1). The Escalation Process may also be used to obtain oversight as appropriate from the Product CoreTeams, the Therapeutic Area Leadership Team (TALT) or the Operations Portfolio Management Team (OPMT).

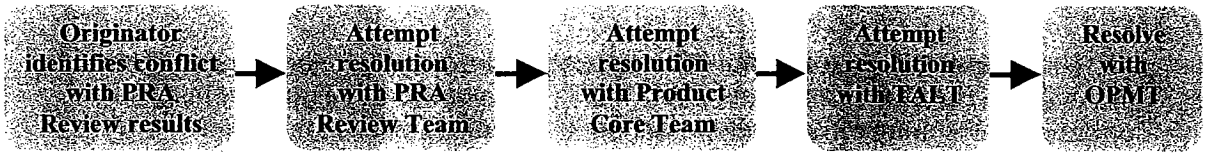
Product Core Team Oversight
If agreement cannot be reached with the eSTaR review Team, the Originator or any party may escalate to the next level--the Product Core Team. A resolution meeting with the Product Core Team may include the following roles: eSTaR Review Team, Product Director, Product Manager, and Regulatory Affairs Director.

Therapeutic Area Leadership Team (TALT) Oversight
If agreement cannot be reached with the Product Core Team, any party may escalate the issue to the next level--the Therapeutic Area Leadership Team (TALT). A meeting to attempt resolution at the TA level may include the following roles: TA Leader, Marketing Director, Product Director, National Sales Director, PRA Director and/or PRA Senior Director, TA Medical Leader, Legal Leader, and TA Regulatory Leader.

Criteria for mandatory TALT approval:
- New product/indications launch
- New comparative claims
- Broadcast Direct To Consumer (DTC) Advertising
- Off-label reprints with scripts

Operations Portfolio Management Team (OPMT) Oversight
If agreement cannot be reached with the TA Leadership Team, any party may escalate the issue to the OPMT level, which will make any final decision(s) on the issue. A meeting to resolve at the OPMT level should include the following roles: Senior VP C&PM, Senior VP USDD, VP Marketing, VP Sales, VP Regulatory Affairs, and the VP General Counsel.

Figure 1 – PRA Escalation Process



4. Reminder Items

Reminder items play an important role in overall promotion and in increasing company and brand awareness. They also play a significant role in AZ's public image. Consequently, all reminder items, must be approved through the eSTaR Review Process and must comply with all applicable laws, regulations, and business policies, including **Gaining Access to Healthcare Professionals** (II-3). In addition, all reminder items must follow the applicable corporate identity standards and the branding requirements for the specific product(s) referenced, and comply with the following requirements below:

Reminder items must have a fair market value (FMV) less than $35 and have patient, or medical relevance (ie, patient education materials, medical text books, stethoscopes, other diagnostic tools, etc.) Items with professional relevance (ie, pens, scratch pads, penlights, etc) must be of minimal value. All reminder items must be branded with the AstraZeneca or a product logo and must be approved through the eSTaR Process.

5. References

5.1. AZ Business Policies

Gaining Access to Healthcare Professionals (II -3).

AstraZeneca

Gaining Access to Healthcare Professionals (HCPs)

Policy No.: **II-3**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

For Field Sales, excluding the MCBG, references to HCPs for this policy is limited to prescribers only.

Contents

Exhibits

1. Key Learnings

- **There are four approved Access Tools available for gaining time with HCPs to promote AstraZeneca products (a fifth exists for the Managed Care Business Group);**
- **Because the use of Access Tools is governed by a variety of laws, generally known as the "anti-kickback" or "fraud and abuse" laws, it is essential that AZ employees adhere to the letter and spirit of this Policy;**
- **Dollar limits outlined in Exhibit A should also serve as the definition of "modest" meals described in other business policies (ie, Advisory Board or other consulting meetings).**

2. Purpose

To establish standards, consistent with all relevant legal obligations, governing the use of meals and "solutions" **to gain access to a difficult-to-see Healthcare Professional's (HCP's) time and attention in order to appropriately and effectively promote AZ products based upon their safety, efficacy, and benefit characteristics** (hereinafter "the Policy").

3. Policy - Background and Overview

3.1. Introduction

AZ seeks to inform and educate HCPs regarding the safety and efficacy of AZ's products, through the use of appropriate product discussions and other promotional activities.

AZ also recognizes that HCPs are often extremely busy and have a limited ability to provide sales reps and TA support teams with a sufficient amount of time and attention to permit an adequate and effective opportunity for discussing, or otherwise promoting, our products.

To help facilitate this access in appropriate ways, AZ has developed this Policy permitting a number of different activities (or "Access Tools"), which may be used to assist in gaining an HCP's time and attention.

Because these activities are governed by a variety of laws, generally known as the "anti-kickback" or "fraud and abuse laws," which will be described more fully below, it is essential that AZ employees adhere to the letter and spirit of this Policy. AZ never wants to be in the position where these Access Tools have been misused or could be misconstrued to be for the purpose of "buying" an HCP's business or "inducing" an HCP, institution, or organization to use AZ's products or put them in a favorable formulary position.

Generally, each of these Access Tools consists of a specific activity or solution. Access Tools have been assigned specific dollar and/or frequency limits, as appropriate, per activity or solution per AZ employee per HCP.

Each of these Access Tool limits is attributable to a specific activity or solution and may not be transferred from one activity or solution to another. For all solutions, sound business judgment and a standard of reasonable behavior should guide the use of these tools. If an AZ employee is unsure of or has questions regarding the appropriateness of an Access Tool he/she wishes to employ, they should contact their manager before moving forward with the idea.

Because the Managed Care Business Group (MCBG) is involved in business-to-business relationships with its customers, a unique solution is available for their use only. **Healthcare Service Solutions** (Exhibit J) relate to the management or delivery of healthcare services, and provide an opportunity for AZ to provide healthcare-related tools or information to a MCBG customer with the primary purpose of improving the provision of healthcare to patients. Special legal and management approvals are required in order to implement these solutions.

4. Fundamentals of Federal and State Laws and Regulations

Any AZ activity (including goods or services) that provides "value" to HCPs or office staff is subject to various Federal and state laws prohibiting "kickbacks," bribery, false claims, or "fraud" if even ONE purpose of providing the value is, in whole or in part, to induce the purchase, use, or recommendation of AZ products. In this context, "value" also includes paying cash to an HCP, institution, or organization, or providing them with the opportunity to earn money.

These laws, which include both civil and criminal penalties, are very broad in scope and govern the entire range of goods or services that AZ provides to HCPs, institutions, and organizations including meals, patient, medical and healthcare service solutions, in order to gain access. (These laws also govern the provision of samples to HCPs and contract services with HCPs for consulting arrangements, clinical trial programs, advisory boards, etc).

4.1. Federal Law

The Federal Fraud and Abuse Laws (also known as the Anti-Kickback Laws) cover all products or services that may be reimbursed, in whole or in part, by Medicaid, Medicare, and many other healthcare programs funded by the Federal government (such as CHAMPUS). These federal laws are enforced by the Office of the Inspector General (OIG) within the Department of Health and Human Services.

The OIG will analyze each arrangement to determine whether ONE purpose of the item or service of value is to induce prescriptions, inclusion on an organization's formulary, or the purchase of our products. The courts have held that the law is violated if only one purpose is inducement, even if there are other (legitimate) purposes as well. (This is the so-called "one purpose" rule.)

To be considered an inducement, the "value" provided must either be large enough or frequent enough, or be intended by the giver to be large enough or

frequent enough, to influence the judgment of an HCP or a member of his or her staff. The OIG takes the position that there need not be a direct quid pro quo (ie, "I will give you an educational grant if you agree to prescribe our products.") for there to be a violation of the fraud and abuse laws. Rather, it will look at all of the facts and circumstances surrounding our relationship with an HCP to determine if the Company violated the law. Put another way, the OIG will ask whether the value offered is sufficient to interfere with the judgment of an HCP as to whether to prescribe a drug or make it available on a formulary based on such legitimate considerations as the cost, quality, and safety of our products or because of the fact that he or she has received, or hopes to receive in the future, items of value from the Company.

In addition, any remuneration offered or paid for services provided to an HCP by AZ that exceeds the reasonable fair market value (FMV) of those services, may be viewed as intended to induce the use of AZ products. If an AZ employee has questions regarding the FMV of a solution, service, or other item of value, they should contact their Customer Solutions/Support Manager (CSM), Promotions Manager, or Promotional Regulatory Affairs (PRA) representative. Inferences regarding AZ's intent may be drawn from the structure of the transaction and/or the interrelationship between the value provided and the volume of prescriptions or sales.

Evidence showing over use of AZ's products or reduced quality of services to patients is also considered evidence of whether the incentive offered was intended to be an inducement. However, the OIG may conclude that there is a violation of the law even if the arrangement does not result in a direct increase in Medicare or Medicaid costs.

It is important to understand that the fact that a type of arrangement or practice is common in the industry does not constitute a defense to an alleged Fraud and Abuse Law.

4.2. State Laws on the Provision of Gifts

There are also state laws that cover state-funded programs, and, in several states, any product reimbursed, in whole or in part, by any third-party payer, such as an insurance company (state all-payer laws). Generally, these laws also prohibit the use of money, gifts, goods, or services to bribe an HCP or to induce or influence the purchasing behavior of AZ's customers.

There are presently a few states (ie, Minnesota, Vermont, and Georgia), which have adopted special state rules. AZ employees dealing with HCPs in these jurisdictions need to understand and follow policies specific to these states (see Exhibit N).

Because of the state "all payer" laws and other potentially applicable statutes, AZ generally seeks to comply with the Federal anti-kickback statutes, regardless of whether drugs covered by Medicaid or Medicare are involved.

4.3. The Law Permits the Use of Access Tools

It is entirely appropriate to provide HCPs with modest meals or solutions, so long as the sole and exclusive purpose of that modest meal or solution is to gain and/or facilitate access to the time and attention of an HCP in order to inform him or her about the safety, efficacy, and benefits of AZ products. It is essential, however, that the purpose of any good, service, or solution is solely and exclusively to gain and/or facilitate access to HCPs and that the purpose is not to induce the use of our products because of the "value" we are providing to the HCP. If an AZ employee already has adequate access, Access Tools may not be used (see Exhibit H for specific issues surrounding Patient Solutions).

Because the purpose of such access involves a promotional dialogue between the HCP and the AZ employee, the term "access," as used in this Policy, is not the same as obtaining HCP "goodwill" or building a "relationship" with an HCP. While developing an excellent relationship with AZ customers is important to effectively conducting business and may be an incidental benefit resulting from an effective promotional presentation facilitated through the use of an Access Tool, building goodwill alone can never justify the use of those Access Tools permitted, pursuant to this Policy. It is not appropriate, for example, to take an HCP to dinner if the purpose is merely to socialize and, thereby, strengthen the relationship between the HCP and the AZ employee.

This Policy does not govern compensation to an HCP in conjunction with any contract that an HCP might have for the provision of services to AZ (including meals). However, when engaging in activities covered by Exhibit A of this policy, in conjunction with contracted services (see **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services,** III-1), the same dollar limits apply.

5. Specific Access Tools

For purposes of this Policy, these Access Tools consist of the following five activities or types of solutions:

1. Providing lunch, or other refreshments, to one or more HCPs, and their staff members, *on an HCP's premises* while providing product information to the group (see "Lunch & Learns" – Exhibit F)

2. Taking an HCP out of the office for a modest meal at a local restaurant engaging in a product discussion with the HCP or otherwise promoting AZ products (see "Access Meals" – Exhibit G)

3. Providing a "patient-related" solution (See **Patient Solutions** - Exhibit H)

4. Providing a "medical-related" solution (See **Medical Solutions** - Exhibit I)

5. MCBG only providing a Healthcare Service solution (See **Healthcare Service Solutions** – Exhibit J)

With regard to the items listed above, it is expected that the AZ representative will spend the majority of time discussing and providing product information to the HCP(s), for whose benefit the Access Tool is being provided.

"eBusiness" solutions will be classified as either a Patient-, Medical- or Healthcare Service Solution and will need to follow the associated limits found in Exhibit A of this policy. If, for example, an "eBusiness solution" is classified as a Medical Solution, the difference between the FMV of the solution and the value AZ gets back in data or other information may not exceed $100. At this time, development and implementation of "eBusiness" solutions can only be handled centrally due to the extensive FMV evaluation and legal review that must be undertaken. All "eBusiness solutions" will be reviewed and approved by the Legal Department and the corresponding TA and Sales groups.

The dollar limits, and additional policy requirements, for each of these Access Tools are set forth below in Exhibits F through J. Community Health Fairs, where AZ sponsors local health fairs in conjunction with a physician group practice or hospital, shall be administered as a form of patient-related solutions and are addressed in Exhibit K. The dollar limits for each of these Access Tools are also summarized, for ease of reference, in Exhibit A. Exhibit B provides a quick reference of key principles and standards of good practice that must be followed by all AZ employees when using these Access Tools.

6. Exclusions From The Policy

This Policy does not govern collateral meals that are provided to an HCP in the context of, and incidental to, a **Professional Education and/or Consulting Program**.

This Policy does not govern the provision of social activities, hospitality, or compensation to an HCP in conjunction with any contract that an HCP might have with AZ for the provision of services to AZ, such as consulting agreements, clinical trial agreements, etc. Consulting Agreements are covered by a separate policy entitled **Engaging Healthcare Professionals, Institutions, & Organizations in Consulting Services** (III-1).

This Policy does not govern the provision of charitable donations to charitable causes. This is covered by the **Charitable Contributions and Sponsorships Policy** - (VI -3).

Contract Sales Organizations (CSOs) are subject to the same dollar and frequency limits with regard to the use of Access Tools.

7. PhRMA Code on Interactions with Healthcare Professionals

The Executive Committee of the Pharmaceutical Research and Manufacturers of America (PhRMA) unanimously adopted a new marketing code to govern the pharmaceutical industry's relationships with physicians and other healthcare professionals (see **PhRMA Code on Interactions with Healthcare**

Professionals – Exhibit D). The voluntary code took effect on July 1, 2002. AZ has committed to supporting and adhering to the principles contained in The PhRMA Code its activities involving HCPs.

The new code makes very clear that the interactions of company sales representatives with healthcare professionals are to benefit patients and enhance the practice of medicine. It explicitly spells out that all interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education. The code provides that our interactions with HCPs should not be perceived as inappropriate by patients and/or the public at large. The code is based on the principle that an HCP's care of patients, should be based, and should be perceived as being based, solely on each patients medical needs and the HCP's medical knowledge and experience.

The Code permits informational presentations and discussions that provide valuable scientific and educational benefits by industry representatives and others speaking on behalf of a company. The Code states that in connection with such presentations and discussions, meals (but no entertainment/recreational events) may be offered so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value. Inclusion of a healthcare professional's spouse or other guest is not appropriate. And offering "take-out" meals or meals to be eaten in the absence of a company representative is inappropriate.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

8. AMA Guidelines on Gifts to Physicians from Industry

On December 3, 1990, the American Medical Association's (AMA's) Council on Ethical and Judicial Affairs issued its "Guidelines on Gifts to Physicians from Industry." These guidelines were reviewed by the AMA in June of 2001 and reaffirmed. They have been incorporated in the AMA's Code of Ethics for the Medical Profession. A summary of the AMA Guidelines is attached as Exhibit E.

AZ is committed to supporting and adhering to the principles contained in the AMA Guidelines in its activities involving HCPs.

9. Adherence to Policy and Good Judgment/Substantial Compliance

In order to permit AZ to employ all of these Access Tools appropriately, it is important that all AZ employees adhere to the letter and spirit of these policies. Additionally, because AZ employees have been entrusted with this flexible menu of Access Tools, it is essential that all employees use common sense and good judgment when employing these tools.

Each and every employee who uses and supports the use of these Access Tools is responsible and accountable to AZ for complying with this Policy.

It is the desire and the intention of AZ that all dollar limits set forth in Exhibit A are followed.

AZ expects good faith compliance with these rules. For example, an HCP may order all of the most expensive items on a menu that could result in a bill exceeding the guidelines for one meal. If the excess cost is significant, AZ expects that the employee will modify his or her plans in the future to take reasonable account of that HCP's behavior, perhaps by changing the type of restaurant used or by employing a different Access Tool.

10. Appropriate Planning

Prior to employing any of these Access Tools, an AZ employee should work with their management (and cylinder if appropriate) to prepare a plan for using these tools strategically, effectively, and in a manner that conforms with AZ Business Policy.

11. Call Reports

Each promotional opportunity arising as a result of employing an Access Tool must be recorded in Compass/NorthStar with a specific entry accurately describing the promotional efforts actually undertaken with respect to the use of that Access Tool.

12. Expense Reporting

The AZ employee must ensure that all expense-related information, submitted in support of reimbursement and including the identity of the HCPs receiving the goods or services provided, is complete and accurate. AZ employees are expected to follow all frequency and spending limits established for each activity and to accurately and completely document those activities in Compass/NorthStar. If more than one AZ employee participates in an access activity, the expenses should be reported only once by the same individual recording the call in the expense reporting system.

13. Spouses

Because AZ's access policy is intended to facilitate meaningful product discussions, spouses, family members, and other guests may not be invited to attend any access activity covered by this Policy.

Consistent with the PhRMA Code and AMA Guidelines, AstraZeneca may never pay for a spouse, guest or family member. Employees should make every effort when inviting an HCP to participate in a company function to clearly state--both verbally and in writing--AstraZeneca's policy on spouses and guests. In the event

that an HCP arrives at a function in the company of his or her spouse, family member, or other guest, AZ employees must not pay for the guest, and should inform the HCP that if the guest stays, the HCP will be responsible for the expenses of the guest. Employees should use good judgment and professional courtesy in managing the circumstance.

Additionally, AZ is cognizant of the fact that there may be occasions when an AZ employee may feel reluctant to employ an Access Meal with an HCP without an escort. In that event, the Company recommends that the employee's manager, an employee counterpart, or one additional HCP also be invited to attend the function.

14. Milestone Events and Greeting Cards

AZ policy prohibits the provision of gifts to HCPs.

AZ employees may provide an HCP with a holiday or birthday card. Product messages may not be included.

Additionally, on the occasion of a Milestone (a birth or death) Event in an HCP's immediate family, or the immediate family of an HCP's staff member, an AZ employee may donate money to a designated charity. The value of the donation shall not exceed $50 per occasion. (The purpose of the expenditures and the identity of either the recipient or the individual on whose behalf the donation was made, shall be expressly noted in Compass/NorthStar and on the expense report submitted to the appropriate manager for reimbursement.)

15. References

15.1 AZ Business Policies

Product Promotion (II-1); **Promotional Education Programs** (IV-2); **Engaging Healthcare Professionals, Institutions & Organizations in Contracted Services** (III-1), **Charitable Contributions and Sponsorships** (VI-3).

Exhibits

EXHIBIT A

Access Activity Limits

Access Activity	Frequency per AZ employee per HCP (or customer)	Dollar Limit per Event *
Patient Solution	Reasonable	Minimal value
Medical Solution	Reasonable	$100 maximum per solution
Lunch and Learn		The lesser of:
PSS/MIS	Reasonable	$25 maximum per person including staff; or, $100 maximum per HCP.
Institutions	Reasonable	$15 maximum per person
AD	Reasonable	$25 maximum per person
Access Meal		
PSS	3 per HCP per year per PSS	$50 maximum per HCP including all food and beverage (COLA applies)
MIS	1 per HCP per year per MIS	
AD	12 per HCP per year	$100 maximum per HCP including all food and beverage
MCGB only:		
Access Entertainment	4 per HCP per year	$200 per event including food and beverage

**Per person maximum applies to prescribers and AstraZeneca employees.*

EXHIBIT B

Essential Principles/Standards of Good Practice

In implementing our access policy, remember the following essential principles and standards of good practice:

1. AstraZeneca (AZ) is committed to a high standard of business ethics and compliance to the law.

2. **Managers are always responsible for the conduct of the employees they supervise.**

3. AZ is committed to and follows the PhRMA Code on Interactions with Healthcare Professionals and supports the principles of the AMA Guidelines.

4. The purpose of this Policy is to provide a set of tools that may be used to gain access to difficult-to-see HCPs. If an AZ employee already has adequate access to an HCP, these tools may not be used. It is not appropriate to use an Access Tool merely to socialize with an HCP, even if the opportunity to socialize may help build goodwill or rapport with them. If the use of an Access Tool does increase your rapport with a customer, it will be as an incidental benefit to the primary purpose of engaging in a product discussion.

5. Modest meals or solutions as defined by this Policy may be used by AZ employees to assist them in gaining access to a difficult-to-see HCP's time and attention in order to effectively educate that HCP regarding AZ's products' efficacy, safety, and benefits and, thereby, to promote our products. This also includes engaging in business-to-business discussions with institutions or organizations.

6. AZ employees must familiarize themselves with their obligations under this Policy, including the Fraud and Abuse Laws, by directing questions to their designated supervisors or to the Legal Department.

7. Access Tools should always be provided in a way that allows AZ to compete for business based on the efficacy, safety, and benefits of our products.

8. Meals or solutions may **never** be used as an inducement to, influence, or in consideration for an HCP's current or future prescribing habits or the recommendation, favorable formulary placement, purchase, or use of our products by any HCP or their staff.

9. Access Tools may never be used in a way that could be considered lavish or excessive in value (for example, combining Access Tools for multiple HCPs in a way that appears extravagant).

10. Access Tools must be used singularly, and not in combination with multiple Access Tools, in order to maximize the frequency of achieving promotional access with an HCP.

11. Access Tools may not be provided on such a regular or routine basis that they act as, or appear to be, an inducement.

12. Access Tools must not be provided to HCPs because of their prescribing habits or volume of purchases in any way. They must not be provided to institutions or organizations because of the formulary status of AZ products or tied to the volume purchased in any way.

13. Access Tools may not be used to "reward" an HCP for his or her current or past prescribing habits or institutions or organizations for their past use or formulary position of AZ products.

14. Any Access Tool must be entirely professional in tone and appropriate to the serious business of Healthcare and must not be perceived as inappropriate by patients or the public at large.

15. When employing an Access Tool, an AZ employee must use that opportunity to educate HCPs and to promote our products. In other words, a promotional dialogue must take place as part of and at the same time as the access-related benefit is provided to the HCP.

16. AZ employees must always attend an Access Meal in order to promote our products.

17. Whenever possible, AZ employees must use the lowest dollar value tool within any one category possible to achieve the access required.

18. Never, even in jest, should an AZ employee suggest or hint at an improper motivation, as to the reason why we are providing goods or services to an HCP, institution, or organization.

19. Only Access Tools covered by an approved written policy are permissible; the provision of any other goods or services not explicitly authorized by a written policy is not permitted.

20. AZ has other policies that govern compensation to HCPs for the provision of consulting services, such as service on advisory boards, etc. Consulting arrangements, including those relating to clinical trials, are intended to obtain necessary services and are not to be used for the purpose of gaining access. Likewise, AZ's policies on charitable donations and the provision of samples may not be used for the purpose of gaining access.

21. Spouses, family members, or other guests may not be invited to Access Meals. This tool is for the sole purpose of gaining the time and attention of the difficult-to-see HCP to have a promotional discussion about AZ products; therefore, it is inappropriate to invite a spouse or other guest.

22. Spouses and other guests may not benefit from any "value" provided to an HCP as part of an Access Tool.

23. AZ employees may not pay for meals or solutions with cash or personal checks but always with a corporate credit card or an authorized company check.

24. All documentation by employees regarding the use of such Access Tools must be complete and accurate, and must fairly characterize the nature of the activity described in the promotional discussion. They must follow the frequency and spending limits contained in Exhibit A.

25. All of the possible activities that might violate the Anti-Kickback Laws are not catalogued here. However, the following list provides some important examples of activities that must be strictly avoided:

    - Providing, or offering to provide, cash, goods, or services to any physician, pharmacist, managed care executive, or other person in a position to influence the use of AZ products in exchange, or as a quid pro quo, for prescribing an AZ product, switching a prescription to an AZ product, or placing an AZ product on formulary.

    - Paying, or offering to pay, physicians to participate as investigators in a clinical trial, unless the trial has a valid research purpose, the AZ drug being investigated is supplied without charge, and physicians are selected as investigators for valid purposes unrelated to historical or anticipated prescribing volume.

    - Making, or offering to make, any payment to any HCP in the absence of the performance by the HCP of bona fide services.

    - When bona fide services are actually performed by HCPs as investigators, speakers, or in other consulting capacities, paying, or offering to pay, compensation that is greater than the fair market value of the services provided.

    - Providing cash, goods, or services to any person in a position to influence utilization of AZ products if the cash, goods, or services are valuable enough to affect the person's independent judgement, are likely to cause inappropriate utilization of AZ Products, or are likely to increase costs to Medicaid or other governmental or private insurers.

Exhibit C

(No exhibit)

EXHIBIT D

PhRMA Code on Interactions with Healthcare Professionals

Preamble

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.

Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient healthcare. This document focuses on our interactions with healthcare professionals that relate to the marketing of our products.

Effective marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to:

- Inform healthcare professionals about the benefits and risks of our products,
- Provide scientific and educational information,
- Support medical research and education, and
- Obtain feedback and advice about our products through consultation with medical experts.

In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large. This Code is to reinforce our intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

Therefore, PhRMA adopts, effective July 1 2002, the following voluntary Code on relationships with healthcare professionals. This Code addresses interactions with respect to marketed products and related pre-launch activities. It does not address relationships with clinical investigators relating to pre-approval studies.

PhRMA Code on Interactions with Healthcare Professionals

1. BASIS OF INTERACTIONS

Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

2. INFORMATIONAL PRESENTATIONS BY OR ON BEHALF OF A PHARMACEUTICAL COMPANY

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits. In connection with such presentations or discussions, occasional meals (but no entertainment/recreational events) may be offered so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value. Inclusion of a healthcare professional's spouse or other guests is not appropriate. Offering "take-out" meals or meals to be eaten without a company representative being present (such as "dine & dash" programs) are not appropriate.

3. THIRD-PARTY EDUCATIONAL OR PROFESSIONAL MEETINGS

a. Continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies is permissible. Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor who, in turn, can use the money to reduce the overall conference registration fee for all attendees. In addition, when companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

b. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference's sponsor (except as set out in section 6 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

c. Financial support for meals or receptions may be provided to the CME sponsors who in turn can provide meals or receptions for all attendees. A company also may provide meals or receptions directly at such events if it complies with the sponsoring organization's guidelines. In either of the above situations, the meals or receptions

should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting.

d. A conference or meeting shall mean any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentations(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

4. CONSULTANTS

a. It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- A written contract specifies the nature of the services to be provided and the basis for payment of those services;
- A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- The criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- The retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- The venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.

b. It is not appropriate to pay compensation for services, travel, or lodging expenses to non-faculty and non-consultant attendees at company-sponsored meetings including attendees who participate in interactive sessions.

5. SPEAKER TRAINING MEETINGS

It is appropriate for healthcare professionals who participate in programs intended to recruit and train speakers for company sponsored speaker bureaus to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses, when (1) the participants receive extensive training on the company's drug products and on compliance with FDA regulatory requirements for communications about such products, (2) this training will result in the participants providing a valuable service to the company, and (3) the participants meet the criteria for consultants (as discussed in part 4.a. above).

6. SCHOLARSHIPS AND EDUCATIONAL FUNDS

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

7. EDUCATIONAL AND PRACTICE-RELATED ITEMS

a. Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value ($100 or less). For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a VCR or CD player does not. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Providing product samples for patient use in accordance with the Prescription Drug Marketing Act is acceptable.

b. Items of minimal value may be offered if they are primarily associated with a healthcare professional's practice (such as pens, notepads, and similar "reminder" items with company or product logos).

c. Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) should not be offered.

d. Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in parts 4 and 5). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

8. INDEPENDENCE OF DECISION MAKING

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

9. ADHERENCE TO CODE

Each member company is strongly encouraged to adopt procedures to assure adherence to this Code.

Frequently Asked Questions

a. **Question**
Under the Code, may items such as stethoscopes be offered to healthcare professionals?

Answer
Yes, because these items primarily benefit patients, so long as the items are not of substantial value and are only occasionally offered to the healthcare professional. Items that are of more than minimal value and do not primarily benefit patients are also not permitted even if they bear a company or product name.

b. **Question**
Under the Code, may golf balls and sports bags be provided if they bear a company or product name?

Answer
No. Golf balls and sports bags, even if of minimal value, do not primarily entail a benefit to patients and are not primarily associated with the healthcare professional's practice, even if they bear the name of a company or product.

c. **Question**
Under the Code, may healthcare professionals be provided with gasoline for their cars if they are provided with product information at the same time?

Answer
No. Items intended for the personal benefit of a healthcare professional should not be offered.

d. **Question**
The Code says that informational presentations and discussions may be accompanied by occasional, modest meals. What types of presentations and meals would this include?

Answer
An informational presentation or discussion may be accompanied by a modest meal provided that the venue and manner of presentation/discussion is conducive to a scientific or educational interchange. For example, if a medical or scientific expert (who is a consultant to or employee of the company) is providing information about recently obtained study data to an audience of healthcare professionals, this could be done over lunch or dinner at a quiet restaurant providing the meal is of modest value as judged by local standards.

Following the same logic, if a sales representative is providing substantial scientific or educational information regarding a company's products to one or a few healthcare practitioners, this could also be done during a modest meal which could be at or outside of a physician's office.

However, if the nature or location of the meal would not facilitate communication of the information, then a meal would not be appropriate. Further, the use of modest meals on more than an occasional basis would not be appropriate.

e. **Question**
A representative of Company X provides pizza for the staff of a medical office. Is this consistent with the Code?

Answer
This would be consistent with the Code if the representative will provide an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the presentation is conducive to a scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the Code.

f. **Question**
A representative of Company X invites physicians to meet to hear a scientific and educational presentation about a new drug at the café at a nearby bookstore. Coffee and cake are provided by the representative and, following the presentation (which is in small groups), each physician is given a gift certificate for books in the amount of $30. Does this conform to the Code?

Answer
No. While the presentation may present scientific or educational information and the coffee and cake may appropriately be provided, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value.

g. **Question**
Company C invites 30 physicians to a corporate suite at a professional baseball game for a 45-minute scientific and educational presentation followed by a buffet and the three-hour game. Does this conform to the Code?

Answer
No. A modest buffet meal accompanying a scientific or educational would be acceptable. However, the provision of entertainment and/or recreational activities,

including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Code.

h. **Question**
Under what circumstances would the Code permit a company to provide entertainment or recreational activities directly to healthcare practitioners?

Answer
Companies may provide modest entertainment or recreational activities to healthcare practitioners in a context where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at a speaker-training meeting.

Companies should generally not provide entertainment or recreational activities to healthcare practitioners. Thus, companies should not invite healthcare professionals to sporting events, concerts, or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are used to facilitate informational interchanges between the company representative and the healthcare professional. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.

i. **Question**
Company A retains a small group of 15 nationally known physicians regarding a therapeutic area relevant to Company A's products to advise on general medical and business issues and provide guidance on product development and research programs for those products. These physicians are paid significant fees, but those fees are typical of the fees paid to thought leaders in this therapeutic area. They normally meet once or twice a year at resort locations to discuss the latest product data, research programs and Company plans for the product(s). Does this comply with the Code? If it does, is it appropriate to pay for the spouse of the healthcare professional to attend, as well?

Answer
This arrangement appears to comply with the Code. The number of advisors seems reasonably small. The advisors seem to have been selected based on their expertise in the areas where advice is needed. While the consultants are paid significant fees, these appear to be reasonable under the circumstances. Finally, while holding consultant meetings at resort locations is not prohibited, the facilities chosen should be conducive to the services provided as well as reasonable and appropriate to the conduct of the meeting.

It would not be appropriate to pay for the cost of the spouse of the advisor. If the spouse attends, it should be at the cost of the advisor.

j. **Question**
Company A invites 300 physicians/consultants to a two-day and one-night speaker-training program at a regional golf resort. All attendees are compensated for their participation and their expenses are reimbursed. Prospective speakers are selected based on recommendations of the Company's district managers and an assessment of their qualifications by the Company's medical or scientific personnel. Each of the

attendees is required to sign an agreement in advance covering the services they will provide. They are educated by a faculty on the full range of data surrounding the disease state and the Company's drug product, on presentation skills, and on FDA regulatory requirements. The Company plans to use at least 280 participants as speakers over the coming year, and it needs to train 300 speakers in order to ensure that 280 will actually be available when needed. Training sessions take both days, and the Company provides for a few hours of golf and meals. Does this program conform to the Code? If so, is it appropriate to pay for a spouse of the healthcare professional, as well?

Answer
This arrangement appears to comply with the Code. Speaker training is an essential activity because FDA holds companies accountable for the presentations of their speakers. In this case, the participants undergo extensive training that will result in a valuable service being provided to the company, and the arrangement meets reasonable indicia of a bona fide consulting relationship. While resort locations are not prohibited, the Company may want to consider whether it would be more appropriate to hold the training session at a non-resort location. In this case, the number of speakers being trained is important; if significantly more participants were trained than were to be used as speakers, this arrangement would not comply with the Code.

The amount of time spent training speakers should be reasonable in relation to the material that has to be covered. The compensation offered to prospective speakers, including the value of any entertainment, should be evaluated to assure that it is reasonable compensation for that time.

It would not be appropriate to pay for the cost of the spouse of the healthcare professional. If the spouse attends, it should be at the cost of the healthcare professional.

k. **Question**
A sales representative invites a physician out for a round of golf and lunch following the golf. The physician is very busy and is difficult-to-see in her office. The cost of the golf and the lunch combined are $65. Does this comply with the code?

Answer
No. It is inconsistent with the Code to provide entertainment or recreational activities such as golf.

EXHIBIT E

AMA Guidelines Summary

General: **The AMA's Guidelines suggest the following standards in providing items or services of value to physicians and those who have the potential to influence a physician's prescribing patterns:**

- Any items provided to individual physicians should primarily benefit patients and should not be of substantial value (substantial value defined as a fair market value of $100);
- Textbooks and modest meals are appropriate if they serve a genuine educational function and have a fair market value of $100 or less;
- Cash payments are never appropriate;
- Individual reminder items of minimal value are permissible as long as they are related to the physician's work (eg, pens and notepads);
- No items of value should ever be provided to a physician with "strings attached." In accordance with this principle, no employee shall give any item of value to a physician related to that physician's prescribing habits;
- When AZ underwrites medical conferences or lectures organized by third parties, responsibility and control over the selection of content, faculty, educational methods, and materials must belong to the organizers of the conferences or lectures;
- Subsidies to underwrite the costs of continuing medical education conferences or professional meetings may be given only to the conference's sponsor, who may use the money to reduce the conference's registration fee;
- Payments to defray the costs of a conference should never be provided directly to physicians attending the conference.

Conferences and Meetings: The following policies apply to conferences for which Continuing Medical Education (CME) accreditation has been granted, as well as other medical, educational, or promotional meetings;

- Subsidies, either direct or indirect, should not be provided to pay for the costs of travel, lodging, or other personal expenses of a physician attending a conference or meeting;
- Subsidies should not be provided to compensate for a physician's time in attending a conference or meeting;

- Subsidies should not be provided for hospitality outside of modest meals or social events that are held as part of a conference or meeting;

- Program content, as well as invitation design, must focus more on the educational piece of any conference or meeting than on the social aspects;

- Faculty at conferences or meetings may receive reasonable compensation for services and reimbursement for reasonable travel, lodging, and meal expenses. (Such payments must also comply with all applicable AZ policies and guidelines.);

- Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses;

- Scholarships or other special funds to allow medical students, residents, and fellows to attend certain educational conferences are permissible if the academic or training institution selects the beneficiaries of the funds;

- Sponsorship of a professional society's charitable event or other charitable donations may be permissible, but must comply with AZ corporate policies on charitable contributions.

EXHIBIT F

Lunch & Learns

Contents

1. Definition

As used herein, the "Lunch & Learn" activity includes any occasion at which an AZ employee provides one or more HCPs and their staff with a lunch or other refreshments (such as breakfast fare or snacks) while on the HCPs premises during ordinary business hours **for the purpose of gaining access to facilitate a product discussion or as it relates to Managed Care, undertaking some other promotional or business activity.**

2. Criteria

These events are always conducted on the HCP's premises.

The Lunch & Learn must be organized and implemented in such a way as to maximize the AZ employee's opportunity to promote AZ products and to facilitate a product discussion.

Whenever office or medical staff personnel share in the lunch, the cost of providing their food and drink must be included in the aggregate total for the HCP for whom they work. If they support multiple HCPs, the cost will be included in the aggregate total for one of the attending HCPs. Alcohol may never be served at a Lunch and Learn.

3. Dollar Limits (See Exhibit A)

A. Pharmaceutical Sales Specialist (PSS) and Medical Information Scientist (MIS):

The lesser of 2

1: The total dollar value of food and drink provided for any one individual (whether an HCP or staff member) must not exceed $25 (excluding tax and gratuity) for a single Lunch & Learn event, **OR**

2: The total dollar value of food and drink for any one HCP and his or her associated staff members (ie, office manager, nursing staff, etc) must not exceed $100 in the aggregate for a single Lunch & Learn event.

Examples: If one HCP attends a Lunch & Learn alone, the total maximum value of the lunch is $25 excluding the cost of the AZ employee's meal. If the HCP attends with three staff members, the value of the lunch, for the individual HCP and the three other individuals may not exceed $25 per person, and the aggregate value of the lunch may not exceed $100 for those four individuals.

If the value of each lunch served is only $20, then one HCP and up to four staff members may attend ($20 X 5 = $100).

If two HCPs attend a Lunch & Learn costing $25 per person, a total of eight personnel (two HCPs and six support staff) may attend for a total aggregate cost of $200 (8 X $25 = $200).

A list of attendees must be included in the expense report sent to the manager for approval.

B. PSS Institutional Promotion Spending Limits:

The total dollar value of food and drink provided for any one individual (whether an HCP or staff member) may not exceed $15 for a single Lunch & Learn event.

A list of attendees must be included in the expense report sent to the manager for approval.

C. Managed Care Business Group (MCBG):

The total dollar value of food and drink provided for any one individual may not exceed $25 for a single Lunch & Learn event.

A list of attendees must be included in the expense report sent to the manager for approval.

4. Reviews and Approval

Managers must review Lunch & Learn expenditures at the time a PSS, MIS, or Account Director submits an expense report for approval.

Managers must satisfy themselves that their direct report has complied with this Policy and that the documentation submitted is complete and accurate (including the listing of those attending the event).

5. Reasonableness and Good Business Judgement

It is expected that Lunch & Learns will be used only to access difficult-to-see HCPs and not as an inducement or reward for past, current, or future use or favorable formulary position of any AZ product.

Lunch & Learns should be used judiciously and not in every instance that an AZ employee wishes to have a product discussion with an HCP.

EXHIBIT G

Access Meals

Contents

1. Definition

As used herein, "Access Meals" include any activity where an AZ employee invites a difficult-to-see HCP to a breakfast, lunch, or dinner, served at a restaurant, **for the purpose of gaining access to facilitate a product discussion or as it related to Managed Care, undertakings some other promotional or business activity.**

2. Criteria

- At least one AZ employee must attend the Access Meal;
- The venue chosen for an Access Meal must be modest and reasonable based on local standards, and the venue's atmosphere must be appropriate and conducive to promotional activities;
- This Policy does not encompass dinners, etc, which may be provided to HCPs in the context of, and incidental to, a continuing education course, a professional education program, or any program for which the HCP is contracted as a consultant or service provider. These are covered in **Engaging Healthcare Professionals, Institutions & Organizations in Contracted Services** (III-1), **Independent (Non Promotional) Education Programs & Related Grants** (IV-1), **Promotional Education Programs** (IV-2), and **Services and Data Purchase Agreements** (III-3);
- AZ Employees may not invite an HCP's spouse, family member or other guest to attend an Access Meal.

3. Frequency and Dollar Limits (See Exhibit M)

1: The total dollar value of food and drink (excluding tax and tip) provided to a single HCP by an AZ employee may not exceed the amount specified in Exhibit M per HCP for any one meal. When providing a meal to an HCP, the meal must be modest and reasonable based on local standards. These limits do not include the cost of the meal for the AZ employee.

2: The total number of Access Meals that may be provided by a PSS to an HCP is **3** per HCP per year.

3: The total number of Access Meals provided to a single HCP by an Account Director must not exceed **12** per HCP per year. In those cases where more than one Account Director calls on an account, it is expected that they will coordinate their activities so as not to exceed the limit of **12** Access Meals per HCP per year.

4: The total dollar value of food and drink (excluding tax and gratuity) provided to a single HCP by a member of the TA USDD teams shall not exceed **1** Access Meal per HCP per year.

4. Guidelines When Alcohol is Served

In the event that alcohol is consumed during the course of the Access Meal, an AZ employee should use good common sense in ensuring that the function ends safely and appropriately.

The AZ employee should monitor liquor consumption and seek to prevent intoxication by any attendee.

Reasonable steps should be followed to avoid intoxication, (ie, the timing of food and drink and the type of alcohol served, if possible). Alternative transportation should be provided if an attendee becomes intoxicated.

5. Reviews and Approval

The Manager must review Access Meal expenditures at the time an employee submits an expense report for approval.

Managers must satisfy themselves that the AZ employee has complied with this Policy, that the meal was in fact modest and reasonable by local standards, and that the documentation submitted is complete and accurate.

Reports of these activities will become available through the Compass/NorthStar system. Each HCP in attendance must be entered into Compass. If more than one AZ employee is involved in the Access Meal, only one entry should be made in Compass/NorthStar. The same person reporting the activity in Compass/NorthStar must enter the expense for the meal into the expense reporting system.

EXHIBIT H

Patient Solutions

Contents

1. Definition

For this Policy, "Patient Solutions" are those goods or services provided to a patient by an HCP whose purpose is to benefit patients in the knowledge, understanding, and management of a disease state or disorder. Examples of Patient Solutions include, but are not limited to:

- Patient educational brochures;
- Disease, product, procedure, or anatomical instructions sheets;
- Diaries or wallet cards to track medical information.

Patient Solutions are used to facilitate access to HCPs in order to provide product information or have a business discussion on AZ products.

2. Criteria

The process for employing Patient Solutions can be obtained by consulting the National QuickList, Customer Solutions/Support Manager and/or Customer Solutions Standard Operating Procedures. Patient Solutions created in consultation with individual HCPs or a group practice should be made available for use with other HCPs, as appropriate.

3. Dollar Limits, Approvals, & Frequency (See Exhibit A)

Because Patient Solutions are designed to be educational aids that an HCP may use with a patient and then have the patient take them home for further study or reference, it is anticipated that the cost of these brochures, tear sheets, charts, etc will be of minimal value. PSSs, Account Directors, and other AZ employees providing these materials to HCPs should use good business judgment and provide them at a reasonable frequency based on the size of the practice.

It is expected that each AZ employee, in consultation with their manager, will provide a reasonable and appropriate number of Patient Solutions to any one practice, institution, or organization relatively proportionate to the specific needs of that practice or group. It is appropriate to work with individual HCPs or practices to develop Patient Solutions that are not currently available through other AZ resources (ie, National QuickList items), so long as AZ obtains the right

to use the materials with other HCPs. These new solutions should be available for use with any HCP or practice, as appropriate, as a Patient Solution.

MCBG

For Patient Solutions delivered to Managed Care Organizations (MCO), there are no specific dollar limits, however, they must be reasonable, appropriate, and delivered in a quantity that reflects the number of covered lives in the health plan. The MC Legal representative, PRA, and the MC Sales Director or Segment Director, must approve these solutions.

Programs or items that have been approved within the Managed Care Resource Guide are suitable to provide to institutions and organizations within the MCBG customer base. These programs or items may be provided in an amount of up to $5,000 fair market value (FMV). Programs or items provided in amounts that exceed an FMV of $5,000 and programs or items that are not approved and currently in the Resource Guide will need to be submitted through the MC CSM and approved by the MC Legal representative, PRA and the MC Sales Director or Segment Director.

TA Marketing

TA Marketing teams may create Patient Solutions designed for PSSs to facilitate access to HCPs. When developing these solutions, members of the TA Marketing teams must make sure that they follow all policies for Patient Solutions.

4. Reviews and Approval

Because Patient Solutions may contain product or disease information, as well as AZ logos, they must go through the PRA Approval Process as outlined in **Development of Promotional Material and Related Items** (II-2).

5. Reports

Reports of these activities will be available through the Compass/NorthStar system.

EXHIBIT I

Medical Solutions

Contents

1. Definition

For this Policy, "Medical Solutions" are those goods or services whose primary purpose is to benefit a HCP's practice of medicine (delivery of medical care), such as a medical textbook, or a Managed Care Organization's physician network (ie, training program, disease management program, algorithm, etc). Medical Solutions are used to gain access to difficult-to-see HCPs to provide product information or have a business discussion on AZ products.

For Medical Solutions that are educational in-service programs (ie, Frontline Services, "Calming the Upset Patient") and held in an HCP's office, a meal may be provided to attendees following the Institutional Lunch & Learn guidelines set forth in Exhibit F.

2. Criteria

The process for employing Medical Solutions may be obtained by consulting the Customer Solutions/Support Manager and Customer Solutions Standard Operating Procedures.

3. Dollar Limits & Approvals (See Exhibit A)

The dollar limit associated with the distribution of Medical Solutions to HCPs is $100 fair market value (FMV). Fair market value (FMV) is the reasonable cost to an institution, organization, physician, or physician's practice of obtaining goods or services from a third party in the open market in that particular geography. For example, an anatomical model of the heart delivered to an individual HCP must not exceed $100 FMV.

The fair market value (FMV) of authorized Medical Solutions may be obtained by consulting the Customer Solutions/Support Manager or Promotions Manager.

MCBG

For Medical Solutions delivered to individual HCPs within a Managed Care Organization (MCO) or individual physicians within their network, the FMV dollar limit is $100. There are no specific dollar limits for Medical Solutions provided to

an MCO, however, they must be reasonable, appropriate, and delivered in a quantity that reflects the number of covered lives in the health plan. The MC Legal representative, PRA, and the MC Sales Director or Segment Director, must approve these solutions.

Programs and items that have been approved within the Managed Care Resource Guide are suitable to provide to institutions and organizations within the MCBG customer base. These programs or items may be provided in an amount of up to $5,000 FMV. Programs or items from the Resource Guide provided in amounts that exceed an FMV of $5,000, and programs or items that are not currently approved and in the Resource Guide, will need to be submitted through the MC CSM and approved by the MC Legal representative, PRA and the MC Sales Director or Segment Director.

TA Marketing

TA Marketing teams may create Medical Solutions designed for PSSs to gain access to difficult-to-see HCPs. When developing these solutions, members of the TA Marketing teams must make sure that the items do not exceed an FMV of $100 and that they follow all policies for Medical Solutions.

4. Reviews and Approval

Because Medical Solutions may contain product or disease information, as well as AZ logos, they must go through the PRA Approval Process as outlined in **Development of Promotional Materials and Related Items** (II-2).

5. Reports

Reports of these activities will be available through the Compass/NorthStar system.

EXHIBIT J

Healthcare Service Solutions (MCBG ONLY)

Contents

1. Definition

For this Policy, "Healthcare Service Solutions" are business-to-business initiatives (goods or services) that relate to the management or delivery of healthcare services, such as:

- "e"Healthcare software;
- NCQA/HEDIS Seminars;
- Tufts Understanding Managed Care CDs.

These initiatives involve AstraZeneca (AZ) providing healthcare-related tools or information to a Managed Care Business Group (MCBG) customer with the primary purpose of improving the provision of healthcare to patients.

2. Criteria

The process for employing Healthcare Service Solutions may be obtained by consulting the Customer Support Manager (CSM). Healthcare Service Solutions will be provided only to institutions or organizations and NOT to individuals. The focus of Healthcare Service Solutions involves subject matter that is educational in nature and related to improving the overall quality of healthcare delivered to patients; they must never involve expenditures that covers the business expenses of a customer.

Programs and items that have been approved within the Managed Care Resource Guide are suitable to provide to institutions and organizations within the MCBG customer base. These programs or items may be provided in an amount up to $5,000 fair market value (FMV). Programs or items from the Resource Guide provided in amounts that exceed an FMV of $5,000, and programs or items that are not currently in the Resource Guide, will need to be submitted through the MC CSM and approved by the MC Legal representative, PRA, and the MC Sales Director or Segment Director.

3. Dollar Limits

There are no specific dollar limits for Healthcare Service Solutions within the MCBG customer base. Healthcare Service Solutions that have been approved (see "Criteria" above) must be reasonable and appropriate based on the number of covered lives in the organization.

4. Reviews and Approval

See "Criteria" above.

Reports of these activities will be available through the Compass/NorthStar system.

EXHIBIT K

Community Health Fairs

Contents

1. Definition

AstraZeneca recognizes two types of community health fair support:

First, AZ may be asked to support nationally recognized disease awareness events sponsored through national organizations, charities, or health coalitions. Support for these activities, often in the form of grants, shall be administered as part of the **Charitable Contributions and Sponsorships Policy** (VI-3).

Second, AZ may also sponsor health fairs that AZ initiates or for which we provide specific Company support in conjunction with an organization or institution (not owned by a physician or physician group). These local activities must be administered as a form of Patient Solutions, as set forth in Exhibit H.

2. Criteria

There are several general criteria an AZ employee should consider in conducting a patient-related health fair.

There are substantial FDA issues involved anytime AZ becomes involved in activities that are targeted to consumers or potential consumers and AZ employees must consult their Promotional Regulatory Affairs Field Partners (PRAFPs) for further guidance before engaging in community health-fair-related activities.

- Programs must be oriented towards patient and/or public health issues;
- Any donation may acknowledge AZ support for the program, but may not advertise or promote specific Company products;
- Contributions/support may not provide any personal benefit to an HCP;
- Programs may not provide direct billing opportunities for HCPs;
- Community Healthcare or awareness programs may not be used as an inducement for any HCP, institution, or organization to use, prescribe, or place on formulary any AZ products.

EXHIBIT L

Institutional/Organizational Promotion

Contents

1. Definition

As used herein, "Institutions" shall include hospitals, surgery centers, and residents' clinics, psychiatric facilities, correctional institutions. "Organizations" shall include Pharmacy Benefit Managers (PBMs), Health Maintenance Organizations (HMOs), Retail Pharmacies, Physician Practice Management Groups, and other Managed Care Organizations. While the terms of the Policy generally apply to such activities at these designated facilities, there are certain unique features to gaining access to HCPs in the institutional/organizational context that require special rules.

2. Dollar Limits (See Exhibit A)

Institutions

1: When conducting or supporting on-premises in-service, Lunch & Learn or related functions at an institution, the total dollar value of food and drink provided for any one individual (whether an HCP or staff member) may not exceed $15 for a single function.

2: A list of individuals attending an institutional function must be submitted with the expense report capturing the expenses for that function.

3: The AZ employee also must ascertain that the use of such Access Tools does not violate any applicable institutional policy.

Organizations

1: When conducting or supporting on-premises in-service, Lunch & Learn or related functions at a Managed Care Organization, the total dollar value of food and drink provided for any one individual may not exceed $25 for a single function.

2: A list of individuals attending an institutional function must be submitted with the expense report capturing the expenses for that function.

3: The AZ employee must ascertain that the use of such Access Tools does not violate any applicable organizational policy.

3. Reviews and Approval

When submitting an expense report pertaining to on-premises, in-service functions, the AZ employee must identify the name of the institution where the activity took place and must attach the sign-in sheet of attendees to the expense report submitted for reimbursement.

EXHIBIT M

Maximum Allowable Meal Costs Per Person With Cost-of-Living Adjustments

Contents

1. Definition

The maximum allowable meal cost per person for AstraZeneca (AZ) is $50. This limit is based on a meal being defined as three courses (ie, appetizer, entrée and dessert), two glasses of wine, and coffee or tea. Tax and gratuity are not included in this limit. This exhibit contains the cost-of-living adjustments to the AZ limit for Access and Collateral Meals (those associated with educational programs, consultant programs, investigators meeting, etc) by city (or county) within a state.

These adjustments are based on the premise that meals must be "modest, as judged by local standards" as specified in AZ policy and the PhRMA Code. This list will be reviewed every 18-24 months.

2. Criteria

2.1 PSS

Each PSS will have a single maximum allowable cost per person for Access and Collateral Meals for their entire territory. PSSs are expected to comply with their territory limit. Any AZ employees accompanying a PSS in their territory shall comply with the PSS's Access and Collateral Meal limit.

2.2 All Other AstraZeneca Employees

For all other AZ employees hosting a meal for a Healthcare Professional (HCP), the following Table will be utilized.

Per Person Maximum Meal Costs And Cost-of-Living Adjustment Guidelines

Alabama	**$50**

Alaska	**$50**
Arizona	**$50**
Mesa, AZ	$65
Phoenix, AZ	$65
Tucson, AZ	$65
Arkansas	**$50**
Little Rock, AR	$65
North Little Rock, AR	$65
California	**$50**
Fairfield, CA	$65
Fresno, CA	$65
Lompoc, CA	$65
Long Beach, CA	$85
Los Angeles, CA	$85
Napa, CA	$65
Oakland, CA	$75
Orange County, CA	$75
Riverside, CA	$65
Sacramento, CA	$65
San Bernardino, CA	$65
San Diego, CA	$75
San Francisco, CA	$85
San Jose, CA	$85
Santa Barbara, CA	$65
Santa Cruz, CA	$65
Santa Maria, CA	$65
Santa Rosa, CA	$75
Vallejo, CA	$65
Ventura, CA	$65
Watsonville, CA	$65
Colorado	**$50**
Boulder, CO	$65
Colorado Springs, CO	$65
Denver, CO	$75
Longmont, CO	$65

Connecticut	**$50**
Bridgeport, CT	$65
Danbury, CT	$65
Hartford, CT	$65
Meriden, CT	$65
New Haven, CT	$65
Norwalk, CT	$85
Stamford, CT	$85
Waterbury, CT	$65
Delaware	**$50**
Newark, DE	$75
Wilmington, DE	$75
District of Columbia	**$85**
Florida	**$50**
Boca Raton, FL	$75
Bradenton, FL	$75
Clearwater, FL	$65
Daytona Beach, FL	$65
Fort Lauderdale, FL	$75
Jacksonville, FL	$65
Miami, FL	$85
Naples, FL	$75
Orlando, FL	$75
Sarasota, FL	$75
St. Petersburg, FL	$65
Tampa, FL	$65
West Palm Beach, FL	$75
Georgia	**$50**
Atlanta, GA	$75
Savannah, GA	$65
Hawaii	**$50**
Honolulu, HI	$65

Idaho	**$50**
Boise City, ID	$65
Illinois	**$50**
Chicago, IL	$85
Indiana	**$50**
Bloomington, IN	$65
Indianapolis, IN	$65
Iowa	**$50**
Kansas	**$50**
Kansas City, KS	$65
Kentucky	**$50**
Louisville, KY	$65
Louisiana	**$50**
Baton Rouge, LA	$65
New Orleans, LA	$75
Maine	**$50**
Rochester, ME	$65
Maryland	**$50**
Baltimore, MD	$75
Massachusetts	**$50**
Barnstable, MA	$65
Boston, MA	$85
Brockton, MA	$65
Lowell, MA	$65
Yarmouth, MA (Cape Cod)	$65

Michigan	**$50**
Detroit, MI	$65
Flint, MI	$65
Minnesota	**$50**
Minneapolis, MN	$65
St. Paul, MN	$65
Mississippi	**$50**
Missouri	**$50**
Kansas City, MO	$65
Montana	**$50**
Nebraska	**$50**
Nevada	**$50**
Las Vegas, NV	$65
Reno, NV	$75
New Hampshire	**$50**
Nashua, NH	$65
Portsmouth, NH	$65
New Jersey	**$50**
Atlantic City, NJ	$75
Bergen County, NJ	$75
Cape May, NJ	$65
Hunterdon County, NJ	$65
Jersey City, NJ	$65
Middlesex County, NJ	$65
Monmouth County, NJ	$65
Newark, NJ	$65
Ocean County, NJ	$65
Passaic County, NJ	$75
Somerset County, NJ	$65
Trenton, NJ	$65

New Mexico	**$50**
Albuquerque, NM	$65
Santa Fe, NM	$65
New York	**$50**
Bronx, NY	$85
Brooklyn, NY	$85
Buffalo, NY	$65
Manhattan, NY	$100
Nassau County, NY	$75
Newburgh, NY	$85
Niagara Falls, NY	$65
Queens, NY	$85
Staten Island, NY	$85
Suffolk County, NY	$75
North Carolina	**$50**
Chapel Hill, NC	$65
Charlotte, NC	$65
Durham, NC	$65
Gastonia, NC	$65
Greensboro, NC	$65
High Point, NC	$65
Raleigh, NC	$65
Winston-Salem, NC	$65
North Dakota	**$50**
Ohio	**$50**
Akron, OH	$65
Cincinnati, OH	$65
Cleveland, OH	$85
Columbus, OH	$65
Dayton, OH	$65
Elyria, OH	$85
Lorain, OH	$85
Springfield, OH	$65

Oklahoma	**$50**
Oregon	**$50**
Portland, OR	$65
Pennsylvania	**$50**
Erie, PA	$65
Philadelphia, PA	$85
Pittsburgh, PA	$65
Reading, PA	$65
Puerto Rico	**$50**
Rhode Island	**$50**
Pawtucket, RI	$65
Providence, RI	$65
Warwick, RI	$65
South Carolina	**$50**
Anderson, SC	$65
Charleston, SC	$65
Greenville, SC	$65
Myrtle Beach, SC	$65
North Charleston, SC	$65
Rock Hill, SC	$65
Spartanburg, SC	$65
South Dakota	**$50**
Tennessee	**$50**
Nashville, TN	$65
Texas	**$50**
Arlington, TX	$65
Dallas, TX	$75
Fort Worth, TX	$65
Houston, TX	$65
San Antonio, TX	$65

Utah	**$50**
Ogden, UT	$65
Salt Lake City, UT	$65
Vermont	**$50**
Virginia	**$50**
Charlottesville, VA	$65
Washington	**$50**
Bellevue, WA	$85
Everett, WA	$85
Seattle, WA	$85
Tacoma, WA	$65
West Virginia	**$50**
Wisconsin	**$50**
Milwaukee, WI	$65
Wyoming	**$50**

EXHIBIT N

State Legislation Effecting AstraZeneca Promotion

Contents

1. GAINING ACCESS TO PHYSICIANS IN MINNESOTA

1.1. Introduction. Minnesota state law imposes additional prohibitions and reporting requirements relating to the provision of gifts or other items of value to healthcare professionals (HCPs). AstraZeneca (AZ) therefore has a separate, more restrictive policy regarding meals, promotional/reminder items, and educational grants in Minnesota.

1.2. Summary of the Law. The statute's prohibitions and reporting requirements may be summarized as follows:

A. No gifts of any value may be offered or given to any licensed practitioner by any drug manufacturer or wholesale distributor. Licensed HCPs include MDs, DOs, podiatrists, DDSs, PAs, NPs and veterinarians. Gifts include free food, meals, pens, scratch pads, and any such giveaways or items of value not specifically excluded from the term "gift" (see paragraphs B, C and D below). Also note that this applies to HCPs who receive gifts outside of the context of their medical practice (for example, an HCP who has a business position within a HMO). This also applies to giveaways of food or gifts at conventions, as well as to social activities and recreational expenses.

B. The statutory definition of "gift" does not include:

1. Items with a total combined retail value in any calendar year of not more than $50; or

2. Publications and educational materials.

C. The statutory definition of "gift" does not include the following Professional Education Programs:

Payment to a sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;

Reasonable compensation for services and payment of the reasonable expenses of an HCP who serves on the faculty at a Professional Education conference or meeting;

The policies for Professional Education Programs are set forth in section IV of the AZ Business Policies.

D. The statutory definition of "gift" does not include compensation for the substantial professional or consulting services of an HCP in connection with a genuine research project. The policies and guidelines for Engaging HCPs as Consultants are set forth in Section III of the Business Policies.

Manufacturers are required to file with the Board of Pharmacy an annual report identifying all payments, compensation for services, reimbursements, or other compensation authorized under the statute as described in C and the first paragraph of D above. The report, which becomes a public record, must identify payments totaling $100 or more to a particular HCP and must identify the HCP, the address, the amount, and the nature of the expenditure.

E. The Legal Department has responsibility for filing the annual report identifying all payments, compensation for services, reimbursements or other compensation authorized under the statute as described in 1.2. (C) and (D) above and provided pursuant to the policies on Professional Education Programs (IV) or Engaging Healthcare Professionals, Institutions & Organizations in Contracted Services (III). It is imperative that all such payments are duly recorded.

F. A violation of the statute is a misdemeanor, punishable by fine and/or jail.

1.3. AstraZeneca Policy On Use Of Access Tools In Minnesota.

In light of the strict prohibitions in the Minnesota statute, **AstraZeneca employees may not provide Access Meals to Minnesota HCPs.** Only the following items of value are to be provided to Minnesota prescribers in order to gain access to their time and attention:

A. Lunch & Learns with a cumulative value of no more than $50 per year per prescriber. In order to ensure that the law is not violated, where

multiple teams call upon an HCP, the teams must plan the provision of Lunch & Learns in advance.

B. The Hospital Sales Representatives in Minnesota may also provide Lunch & Learns. The Hospital Sales Representative must document (by receipt) the total cost of food and keep a sign-in sheet listing the name, specialty, time, date, and name of the customer account. A list of individual HCPs must be maintained along with the prorated cost of their meal. If and when any HCPs of any customer account approaches the $50 limit for such food or snacks, the Hospital Representative may no longer provide any additional Lunch & Learns in that customer account.

C. Patient Solutions, limited to publications and educational materials, and subject to the limitations set forth in Exhibit H of this policy.

D. Medical Solutions, limited to publications and educational materials, and subject to the limitations set forth in Exhibit I of this policy.

* * *

2. GAINING ACCESS TO STATE EMPLOYED PHYSICIANS IN GEORGIA

2.1. Summary of the Law. In Georgia, gifts to state employees, including medical personnel, are subject to annual reporting to the State Board of Pharmacy. Failures to report are subject to legal penalties. No regulations or guidelines have been issued, but the Attorney General's Office has indicated that the statute should be read in conjunction with the state's Public Officials Bribery Act.

2.2. AstraZeneca Policy. No item of value may be given to state employed healthcare professional in Georgia. The only exceptions to this policy are Lunch & Learns at state hospitals. These are permitted but must be reported to Sales Management.

* * *

3. DISCLOSURE OF VALUE PROVIDED TO PHYSICIANS IN VERMONT

3.1. Summary of the Law. In Vermont, the value, nature and purpose of any gift, fee, payment, subsidy, or other economic benefit of $25 or more provided in connection with product discussions, or other marketing activities by the

Company, by our sales teams, or directly through our marketing teams, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs must be reported annually to the state. This would include payments made (including meals, lodging, travel, etc.) to the aforementioned individuals acting as consultants, advisors, speakers, etc, as well as promotional materials with a value of $25 or more that may be sent directly to them.

3.2. **AstraZeneca Policy.** To assure compliance, AZ employees must document and maintain records on all expenditures of $25 or more on the aforementioned activities. For Field Sales, this will be accomplished through the Compass/Northstar tool. For all other functions, this information will be summarized by AZ's Finance representatives at the end of each year and submitted to the Senior Director of Corporate Compliance for submission to the state.

III. Engaging HCPs

AstraZeneca

Engaging Healthcare Professionals As Speakers & Educators

Policy No.: **III-4**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Issued: **07/01/2002**

Contents

1. Key Learnings

- **Engagement of Healthcare Professionals (HCPs), as speakers and educators must be done to fulfill a bona fide and necessary business need;**
- **It is not appropriate to engage more individuals than AZ would need to conduct speaker programs or other educational programs;**
- **Those HCPs being engaged must have the requisite expertise and skills necessary to provide the services they are being trained for;**
- **Speakers and educators should never be retained as an inducement to, or in any way in consideration of, current or potential prescribing, purchasing, formulary position, use, or dispensing of AZ products.**

2. Purpose

To provide a policy to govern AstraZeneca's (AZ's) engagement of healthcare professionals (HCPs) as speakers or educators to skillfully present information on behalf of AZ. In addition to the policies contained herein, all activities in which AZ retains HCPs as speakers and educators are also subject to all provisions of the policy on **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1)

3. Policy

3.1 Types of Speaking and Faculty Activities

AZ often requires the services of HCPs for speaking purposes, to conduct Tutorials, lead Preceptorship Programs or otherwise provide educational services to third-parties or AZ employees on behalf of AZ. HCPs engaged in these types of activities are subject to AZ policy on **AZ Employee Education by HCPs: Tutorial & Preceptorship Programs** (III-5), **Faculty Update Programs & Other HCP Training** (III-6) and policies governing the conduct of **Independent (Nonpromotional) Education Programs** (IV-1) and **Promotional Education Programs** (IV-2).

Examples of activities for which AZ may retain an HCP as a speaker or educator include the following:

- Scientific presenter of clinical trial results;
- Moderator for an Advisory Board;
- Moderator for a consultant's panel;
- Convention/Symposia presenter;
- Peer Dinner Meetings;
- Case Study Programs;
- Clinical Lecture Series;
- Grand Rounds (for nonaccredited programs);
- Speaker Programs;
- Roundtables;
- Visiting Professorships;
- "Doctor-to Doctor" Preceptorships;
- Media spokesperson for radio, TV or the press on issues related to AZ therapeutic areas;
- Tutorials;
- Preceptorships.

3.2 Services Provided Must Be Bona Fide

HCPs may only be engaged as speakers or educators for services that are rooted in and meet a bona fide business need. Guidelines to be observed in order to ensure that engagement of HCPs is appropriate and conform to applicable legal and company standards include the following:

- Gaining access to the HCP, in and of itself, no matter how valuable to the company, is not a bona fide business need;

- The company must have a genuine business need for the services to be provided by all of the HCPs being utilized;
- "Token" services by HCPs are not permitted. For example, asking an HCP to explain the meaning of an approved promotional resource in exchange for compensation would not be a bona fide business need;
- Those serving as speakers and educators must be qualified to perform the speaker or educational services;
- The intended services must actually be provided by those trained;
- The amount of compensation for services must be determined by the fair market value (FMV) of the services being provided and the ability of the individual to deliver the expected level of quality by virtue of their speaking ability and professional training. Target level, potential to prescribe, and/or prescribing level are not appropriate factors for determining compensation for services.

4. Compensation for Services

The amount of compensation paid to the speaker or educator must be reasonable, set in advance, and based on the fair market value (FMV) of the services provided. The amount to be paid to the speaker or educator must not be in return for, as an inducement to, or in any way in consideration of, current or potential prescribing, purchasing, use, formulary positions or dispensing of AZ products.

See Compensation for Services sections (5.3. & 6.2.3., respectively) of **AZ Employee Education by HCPs: Tutorial & Preceptorship Programs** (III-5) and **Faculty Update Programs & Other HCP Training** III-6) for particular types of **Promotional Educational Programs** (IV-2) and **Independent (Nonpromotional) Educational Programs** (IV-1) for further information on compensation rates.

Compensation for Services must be paid with an AZ check using approved AZ financial payment systems and coded as such; consultants must never be paid by a third party.

5. References

5.1 AZ Business Policies

Gaining Access to Healthcare Professionals (II-3); **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1); **Independent (Nonpromotional) Educational Programs and Related Grants** (IV-1); **Speaker Programs** (IV-5); **Faculty Update Programs and Other HCP Training** (III-6), **AZ Employee Education by HCPs: Tutorial & Preceptorship Programs** (III-5).

AstraZeneca

Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services

Policy No.: **III-1**

Issued by: **AZ Business Policy Group**
Date Issued: **07/01/2002**
Date Revised:

Contents

1. Key Learnings

- **This policy applies to all forms of engaging healthcare professionals (HCPs), institutions, and organizations for contracted services;**
- **Engaging HCPs, institutions, and organizations should never be used to gain access to HCPs;**
- **Engaging HCPs, institutions, and organizations should never be used to promote unapproved products or claims;**
- **A third-party vendor must be used to facilitate discussion sessions and to prepare a Conclusions and Recommendations Document;**
- **All services must meet bona fide and necessary business needs;**
- **An HCP, institution, or organization should never be selected to provide contracted services in return for, as an inducement to, or in any way in consideration of the current or potential prescribing, purchasing, using, formulary status, or dispensing of AZ products;**
- **The number of consultants required for a given service should not exceed a bona fide need; if more consultants are contracted than necessary, the activities could be viewed as promotional or as not having a legitimate business need;**

- **A signed agreement must be in place before any services are provided or any payments are made; compensation should never be paid with a personal check, credit card, cash or other means of remuneration;**
- **All input as a result of consulting services must be documented and transferred to appropriate individuals and teams within AZ who will take appropriate actions.**

2. Purpose

To provide a policy to govern AstraZeneca's (AZ) retention of healthcare professionals (HCPs), institutions, and organizations for contracted services in exchange for some form of remuneration in a manner that complies with all applicable laws and relevant AZ policies. This policy applies to the retention of HCPs, institutions, and organizations by any AZ entity including foreign affiliates. This policy is not intended to apply to the retention of these groups for conducting clinical trials. For such activities, please consult company policies on clinical trial programs.

3. Types of Contracted Services

AZ often retains HCPs, institutions, and organizations for the provision of contracted services in exchange for financial remuneration. Although the types of contracted services for which AZ retains these groups can vary, generally, they involve the HCP, institution, or organization providing input and valuable information to AZ, or educating and training AZ personnel or other HCPs designated by the company. As to institutions or organizations, they can also involve executing services on behalf of AZ or providing data to AZ. It is important to understand that regardless of the term used to describe a particular relationship or contracted service, if a US HCP, institution, or organization is engaged to provide services and AZ provides financial remuneration, the provisions of this policy apply. This policy also applies to the retention of foreign affiliates by the US business, as does **Engaging Healthcare Professionals in Global Activities** (III-9).

This Policy applies to ***all*** types of contracted services (excluding clinical trials). Those policies particular to a specific activity are described in the accompanying policies (III-2 to III-6):

- Advisory Boards & Consultants (III-2);
- Services and Data Purchase Agreements (III-3);
- Speaking & Educational Faculty (III- 4 & III- 5);
- Faculty Update Programs & Other HCP Training (III-6).

4. Compliance With Contracted Services Policies

The following principles must be adhered to for any and all forms of contracted services with HCPs, institutions, or organizations.

If AZ were to characterize an engagement as a Contracted Service, but the engagement did not involve bona fide services for which the company has a legitimate business need, or if AZ properly characterized the engagement, but did not follow the requirements for such engagements set forth below and in applicable policies, AZ may subject itself to both civil and criminal actions by various government agencies and to civil actions by private parties. Therefore, it is of critical importance to determine whether the engagement for Contracted Services of an HCP, institution, or organization is based on a bona fide business need for Contracted Services, and, if so, to assure that all requirements of this policy are met. AZ Legal and Regulatory contacts are available to advise AZ employees on these matters.

4.1 Services Provided Must Be Bona Fide

An HCP, institution, or organization may only be retained for services that are rooted in and meet a bona fide business need for such services. Guidelines to be observed in order to ensure that consulting arrangements or other arrangements with HCPs, institutions, or organizations are appropriate and conform to applicable legal and company standards include the following:

- Gaining access to the HCP, institution, or organization in and of itself, no matter how valuable to AZ, is not a bona fide business need;
- If more than one HCP, institution, or organization is retained to provide the same services, the company must have a genuine business need for the same service to be provided by all of the consultants in the aggregate;
- Providing "token" service is not permitted. For example, mere interactive exchange, attendance at an educational program, or mere completion of a simple questionnaire would not constitute genuine consulting services;
- The services must actually be provided.

4.2 Purpose of Services

It is critical that the intent of any programs involving the retention of HCPs, institutions, or organizations is clear both to AZ employees and those being contracted to perform services or provide data. These groups are retained and compensated for the time and the bona fide, necessary services being provided to AZ. Specifically, everyone must understand that these programs are not:

- Promotional Programs;
- Independent (Nonpromotional) Education Programs (accredited or nonaccredited);
- An opportunity to entertain customers.

4.3 Selection of Consultants

HCPs, institutions, and organizations must be selected based on their ability to provide the service for which they are being retained. They should never be selected to provide contracted services in return for, as an inducement to, or in any way in consideration of their current or potential prescribing, purchasing, use, formulary status, or dispensing of AZ products. An exception to this prohibition would be that one may consider a physician's medical experience, including his/her experience with our products and the relevant disease state, in considering whether to retain them as a consultant. For example, whether an HCP was a prescriber would be relevant in selecting an HCP as a consultant where the purpose of the consultation is to evaluate a proposed advertisement directed to nonprescribers.

4.4 Capture and Dissemination of Input

All Contracted Services that involve AZ receiving input, advice, consulting services, data, or other information must incorporate and implement a predefined process for collecting, disseminating and acting upon the information, input and services received. Individuals used to facilitate input sessions and to compile the information gathered in a Conclusions and Recommendations Document must have the requisite skills to accomplish these tasks. The use of a third-party vendor is highly recommended to ensure that qualified individuals run the input sessions and produce the Conclusions and Recommendations Document. All input must be adequately documented and transferred to appropriate teams and individuals (ie, Group Directors, PRA Managers and Field Partners, Legal, etc) within AZ such that it prompts relevant and appropriate action.

If the individuals or group involved in retaining the Contracted Services could not potentially act upon the advice or data received or effect some change in current business strategy or tactics, then that individual or group does not have a bona fide need and should not be engaging the HCP, institution, or organization to provide services. In such circumstances, the value provided to the consultant could be considered an illegal inducement under the Fraud and Abuse laws.

4.5 Contractual Agreements

Any time an HCP, institution, or organization is retained to provide contracted services, a written agreement signed by both AZ and the consultant is required prior to the provision of services. No compensation for services will be distributed without a fully executed contract in place. The agreement must include the following **(any exceptions must be approved by an AZ Legal Representative)**:

- A complete description of the services to be provided;
- The terms of the agreement;
- The total compensation to be paid for the services;
- Federal Tax ID number;

- Individual or Corporation designation.

If the services are to be provided on a periodic, sporadic, or part-time basis, the agreement must specify the schedule on which services will be provided, the length of each service period, and the exact charge for each period. If a retainer fee is part of the agreement, the agreement must specify which services are to be paid by the retainer fee and which services are compensated on an incremental basis, determined by the pre-defined fee schedule.

A variety of contract templates meeting these requirements are available. Your Legal Representative can guide you in selecting the appropriate contract for your needs or provide you with an appropriate contract/agreement to meet special requirements not covered by the currently available contract templates.

4.6 Meeting and Travel Logistics

To the extent it is necessary to convene a meeting of HCPs performing consulting or other services, the provisions of this section, as well as any applicable AZ Travel Policies (V-3, V-4, and V-5) apply.

4.6.1 Duration

The meeting should be only as long as needed to reasonably perform the service and to accommodate reasonable travel requirements (see Company Wide Policies – US Travel and Meetings - http://travel.us.astrazeneca.net/publiccontent/policy.asp).

The overwhelming majority of time spent for all organized meeting activities must be spent on the services that the consultant is providing.

4.6.2 Venue, Travel, Entertainment, and Meals (for Advisory Boards and Faculty Update Programs only)

Meetings held outside the continental US and in Canada must be reviewed and approved by the TA Lead or the National Sales Director of the relevant Therapeutic Area or MCBG and Legal (except for a regional meeting held within its own region which is located outside the continental US and Canada, eg, Puerto Rico). Meetings for audiences that are primarily US based may not be held outside of the US.

Travel by air and rail must be by coach class for travel within and outside of the US. Travel by car will be reimbursed for mileage traveled at standard rates set by the IRS. Any exceptions must be approved by the appropriate TA Lead or National Sales Director of the relevant TA or MCBG and Legal.

Meals and any entertainment provided must follow the following guidelines:

- The provision of a modest meal based on local standards in conjunction with contracted services is acceptable providing it does not exceed $100;
- The cost of a modest entertainment activity in conjunction with contracted services must not exceed $125, including a modest meal.

The majority of the meeting time must be spent on the services that the consultant is providing. It is critical to keep in mind that the goal of the meeting is to obtain the benefit of the consultants' services, not to entertain them or provide them with information about AZ or its products.

Appropriate accommodations would be those with no more than a number 4 Mobil Travel Guide® rating or equivalent. This would include properties such as Starwood, Hilton, Hyatt, and Marriott. AZ's Purchasing Meeting Services Department can provide AZ employees with a complete list of properties that meet this requirement. Accommodations with a rating above 4 are not permissible. A facility suitable for the purpose of the meeting should be selected. It should be conducive to accomplishing the purpose of the meeting and should ensure necessary privacy.

It is appropriate to reimburse consultants for necessary and reasonable business expenses actually incurred as part of providing contracted services. Expenses including parking, transportation, and, if required, lodging will be reimbursed upon submission of documentation (receipts required for all expenses $25 or more) on an AZ Reimbursement Form.

In the event that travel, meals, accommodations, entertainment, or other incidentals provided to participants are unreasonable, the Fraud and Abuse laws could consider the value of such items an illegal inducement under the Fraud and Abuse laws.

For all travel associated with programs described in this policy, please contact the Purchasing Meeting Services Department. For a listing of preferred suppliers and discounted rates, refer to their website at www.meetingsatoz.com.

4.7 Compensation for Services

The amount of compensation paid to the HCP, institution, or organization must be reasonable, set in advance, and based on the fair market value (FMV) of the services provided.

The amount to be paid to the HCP, institution, or organization must not be determined in a manner that takes into account the their current or potential prescribing, purchasing, use, formulary status, or dispensing of AZ products (eg, prescriptions written by a physician).

See specific policies (III-2 – III-6) for particular types of consultant programs for AZ-approved compensation rates.

Compensation for services should be paid with an AZ check or by a company designated by AZ; cash or personal checks must not be used.

4.8 Number of Consultants and Number of Consultant Meetings

The number of HCPs, institutions or organizations retained for consulting, as well as the number of meetings held with consultants, should be determined by legitimate business needs for the services. Further guidelines specific to each type of contracted service can be found in the appropriate policy (III-2 – III-6).

5. References

5.1 AZ Business Policies

Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services (III-1); **Advisory Boards** (III-2); **Services and Data Purchase Agreements** (III-3); **Engaging Healthcare Professionals as Speaking and Educational Faculty** (III-4); **AZ Employee Education by HCPs: Tutorials & Preceptorship Programs** (III-5); **Faculty Update Programs & Other HCP Training** (III-6);**Independent (Nonpromotional) Education Programs & Related Grants** (IV-1); **Promotional Education Programs** (IV-2).

All policy information pertaining to Advisory Boards is located on the AstraZeneca Intranet Policy site at:

http://legal.us.astrazeneca.net

III – 3 Services & Data Purchase Agreements

AstraZeneca

Services and Data Purchase Agreements

Policy No.: **III-3**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Issued: **07/01/2002**

Contents

1. Key Learnings

- **This policy applies only to the Managed Care Business Group (MCBG) and TA Support Functions wishing to contract for services, data, or other materials with institutions and organizations;**
- **Contracting for services or data must meet a bona fide business need and must not be duplicative of other services or data currently obtained by AZ or required to be provided to AZ by an existing contract;**
- **AZ should not receive patient identifiable data. To the extent any patient data is obtained as a result of these services or data agreements, it must be with the patient's consent, must be held strictly confidential, and must not be shared with parties outside of AZ (internal distributions must be limited/controlled). Appropriate adherence to privacy laws by all parties is required;**
- **Selection of a service or data provider may not be used as an inducement to use or contract for AZ products;**
- **A signed agreement which has proper legal approvals must be signed by AZ and the service or data provider;**
- **The provision of services or data must follow policies set forth in Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services (III-1).**

2. Purpose

To expand on policies stated in **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1) and provide a specific policy to govern AstraZeneca's (AZ's) purchase of services or data from institutions, or organizations in a manner which complies with all applicable laws and relevant AZ policies. When institutions and organizations are customers of AZ, they are subject to specific legal requirements, some of which are distinct from the requirements relating to HCPs and non-customer institutions and organizations. *Any contract with a managed care organization or other healthcare institution that is a customer or potential customer of AZ, must be reviewed in advance with the Managed Care Legal Representative and Managed Care Promotions group. All such requests must be directed through the Customer Support Manager (CSM) responsible for that market segment or business center. All such engagements must be reviewed and approved by the MCBG Legal Representative.*

3. Policy

This policy applies to transactions with institutions and organizations by any AZ entity, including foreign affiliates. This policy is not intended to apply to the retention of institutions or organizations for Clinical Trial Pgrams. For such activities, please consult the company policies on Clinical Trial Programs. In addition to the policies contained herein, all activities in which AZ retains institutions or organizations for services and data purchases are also subject to all applicable provisions of the policy on **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1).

3.1. Types of Services, Data, and Other Materials

AZ often purchases services, data or other materials from institutions and organizations that are customers. Although the types of purchases may vary considerably, generally, they involve the institution or organization providing a service, material, and/or valuable information to AZ (for purposes of this policy this will be referred to as "Services"). It is important to understand that, regardless of the term used to describe a particular relationship or service, if an institution or organization is engaged to provide services or data, the provisions of this policy apply.

3.1.1. Services & Other Materials

Examples of Services for which AZ may contract with an institution or organization include but are not limited to the following:

- Development and implementation of patient education programs;
- Development and implementation of professional education programs;
- Development and implementation of medical quality improvement programs;

- Development and implementation of compliance and persistency programs;
- Development of electronic healthcare management tools;
- Implementation of Drug Utilization Review programs;
- Professional in-servicing training programs;
- Professional detailing programs.

Terms previously used to describe types of Services include but are not limited to the following:

- Professional Service Agreements;
- Customer Service Agreements;
- Data Purchase Agreements;
- Disease Management Partnerships/Programs;
- Customer Capability Agreements;
- Business Development Support.

3.1.2. Data Purchases

Examples of data that AZ may purchase from institutions and organizations include but are not limited to:

- Drug utilization data for a covered population to assess market share changes across products or therapeutic categories, either "real time" or otherwise;
- Healthcare delivery data to assess and benchmark current medical practice for a given population, type of institution, or geographic area;
- Disease epidemiological data;
- Patient outcomes data;
- Patient and professional awareness data.

3.1.3. Data as a Result of a Program Provided by AZ

In some circumstances, AZ can obtain valuable data or information from customer institutions or organizations as part of a program provided by AZ (generally, the data or information is generated as a result of the program). In such circumstances, the value of the data or information received is evaluated to determine its fair market value (FMV) in exchange for the value of the program provided by AZ. Of course, the program provided must meet AZ policy requirements and involve legitimate healthcare subject matter.

It is anticipated that situations outlined above will be rare and will not be the result of any pre-approved programs contained in the Managed Care Resource Guide. Programs that result in the generation of data must be reviewed and approved by the MCBG Legal Representative.

3.2. Services and Data Provided Must Be Bona Fide

3.2.1. An institution or organization may only be retained for Services that are rooted in and meet a bona fide and otherwise unmet business need for such services. Similarly, data purchased must also meet a bona fide and unmet business need and must not be duplicative of data currently available through other data sources, purchased or otherwise. Guidelines outlined in Engaging Healthcare Professionals, Institutions, and Organizations in Contracted Services (III-1) are to be observed in order to ensure that service arrangements with HCPs, institutions, and organizations are appropriate and conform to applicable legal and company standards including but not limited to the following:

- For purposes of this policy, gaining access to the institution, organization or members of their staff in and of itself, no matter how valuable to AZ, is not a bona fide business need;
- Payment for services or data is not a means of providing additional discounts or rebates on product purchases;
- The need for, and use of, the acquired material, service, or data must be identified and documented in advance of the transaction;
- A signed written agreement with a term of at least one year specifying the services to be performed and the payment terms is required;
- If more than one organization or institution is retained to provide the same services, AZ must have a genuine business need for the services to be provided by all of the parties in the aggregate;
- "Token" services are not permitted;
- The institution or organization must be qualified to perform the services and must never be selected based on their current or potential utilization, purchasing volumes, or formulary position of AZ products;
- The services must actually be provided;
- AZ will not pay for services, data, or materials which the institution or organization is obliged to perform or provide by law or contract, such as certain counseling services by pharmacists to Medicaid patients concerning their medications;
- Payment for services, data, or materials will be based on fair market value (FMV) determined by reference to objective market conditions (ie, an evaluation against comparable remuneration for similarly situated materials, services, or data);
- A process for reviewing, processing, reporting, and disseminating purchased data must be established and implemented;
- Any contract for services, data, or materials must not be made part of, or incorporated into, any agreement for the purchase of AZ products.

3.2.2. Patient Confidentiality

When data is purchased, patient confidentiality must be maintained. That is, data provided to AZ must either not include information that could reveal individual patient identities (de-identified), or explicit consent must

be given by the patient in order for the data to be revealed to AZ. In the case where AZ obtains patient identifiable health information, AZ must have adequate safeguards around it to ensure that it remains confidential and that it not be shared with parties outside of AZ.

More definitive policies will be created to address patient privacy issues as they pertain to AZ as more clarity is obtained regarding the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that goes into effect April 15, 2003. For now, AZ must maintain confidential patient information as such and not release it to any party outside AZ without explicit patient consent. Additionally, access to and use of this data must be limited and approved by your Legal Representative. The exception to this is when AZ has a legal obligation to disclose adverse drug information to the FDA. Additionally, all AZ employees must understand and comply with the policy on Patient Privacy (I-6).

3.3. Inappropriate Application of this Policy and/or Failure to Comply

If AZ were to characterize a transaction as a service agreement or data purchase but the transaction did not involve bona fide services for which the company has a legitimate business need, or if AZ properly characterized the transaction but did not follow the requirements for such transactions set forth herein and applicable company guidelines, the company could subject itself to both civil and criminal actions by various government agencies, and to civil actions by private parties. Therefore, it is critically important to determine whether a meeting or other interaction with an institution or organization is legitimate and necessary for providing contracted services, data, or material and, if so, to assure that all requirements of this policy are met. AZ Legal and Regulatory Representatives are available to advise AZ employees on these matters.

4. Requirements for Services, Data & Material Purchases

4.1. Selection of Service Providers

Service providers should be selected based on their ability to provide the service for which they are being retained. **An institution or organization should never be selected as a provider in return for, as an inducement to, or in any way in consideration of the current or potential purchasing, using, formulary position or dispensing of AZ products.**

4.2. Services Agreement

Any time an institution or organization is retained as a service provider, a written agreement signed by both AZ and the provider is required. The agreement must include the following **(any exceptions must be approved by an AZ Legal Representative)**:

- A description of the services or data to be provided;
- The term of the agreement;

- The total compensation to be paid for the services;
- Applicable confidentiality agreement;
- Statement on protection of privacy rights;
- Ownership of intellectual property, if any, as a result of the services contract and the application of the trademark and copyright laws to the services, data or materials to be contracted for;
- Provisions relating to eSTaR Process of materials disseminated pursuant to an agreement.

If the services are to be provided on a periodic, sporadic, or part-time basis, the agreement must specify the schedule on which services will be provided, the length of each service period, and the exact charge for each period. If a retainer fee is part of the agreement, the agreement must specify which services the retainer fee pays for and which services are compensated on an incremental basis, determined by the predefined fee schedule.

AZ Legal Representatives can provide AZ employees with an appropriate agreement template meeting these requirements.

4.3. Services Agreement Logistics

To the extent it is necessary to convene a meeting of members of institutions or organizations performing services, the provisions of **Engaging Healthcare Professionals, Institutions, & Organizations for Consulting Services** (III-1) apply.

5. References

5.1 AZ Business Policies

Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services (III-1) **Gaining Access to Healthcare Professionals** (II-3); **Independent (Nonpromotional) Education Programs & Related Grants** (IV-1).

III – 4 Engaging HCPs as Speakers

AstraZeneca

AZ Employee Education By HCPs: Tutorial & Preceptorship Programs

Policy No.: **III-5**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Educational programs in which HCPs are engaged must meet a bona fide business need;**
- **Learning objectives for educational programs must be established by training or management or approved by an AZ manager;**
- **All patient healthcare information disclosed during a Preceptorship or Tutorial must be held in the strictest confidence;**
- **Contracts must be fully executed prior to any Tutorial or Preceptorship taking place;**

- **Compensation for services checks will not be cut unless the fully executed contract is on file at the Lecture Bureau and the services have been performed.**

2. Purpose

To provide a policy for the training of AstraZeneca (AZ) employees by healthcare professionals (HCPs) to supplement their AZ training so they may better understand approaches to diagnosis, treatment, and other healthcare related issues from an HCP's perspective.

3. Tutorial Policy

3.1 General

A Tutorial consists of an interactive discussion with two or more AstraZeneca (AZ) employees, led by an HCP Tutor, usually considered a thought leader within the relevant territory.

Medical thought leaders are usually physicians, but may also be other HCPs (eg, managed care specialists, pharmacy consultants, etc). A Tutorial may be held in an HCP's office, at a company meeting, or in a restaurant setting. Since AZ is retaining these thought leaders to provide bona fide services to the employees of AZ, these programs are subject to the AZ policy **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1).

3.2. Content of Program

Tutorials are designed to expand an AZ employee's current knowledge of the practice of medicine (diagnosis and treatment) and/or expose you to the various healthcare issues that HCPs deal with on a daily basis. Managers or regional training specialists play a crucial role in coaching AZ employees on establishing learning objectives for the Tutorial.

The learning objectives that AZ employees establish should be discussed in advance with potential Tutors in order to determine who will best be able to meet those objectives. To ensure participants derive the greatest possible benefit from the program, everyone should make a list of questions or topics they are interested in so the value of the Tutorial is enhanced for all.

3.3. Tutor Selection Criteria

Tutors should be selected based on their ability to educate AZ employees. They may never be selected in return for, as an inducement to, or in any way in consideration of the current or potential prescribing, purchasing, use, formulary position, or dispensing of AZ products. When selecting a Tutor, they must be qualified to train AZ employees on the subject matter referenced in the learning objectives. Factors to be considered in determining qualifications include the following:

- Strong familiarity/expertise in the presentation subject matter;
- Participation in or affiliation with academia, editorial boards, related associations, clinical/healthcare management, and/or managed care;
- Speaking/teaching ability;
- Peer rapport in presentation topic;
- Ability to answer reasonable questions on the presentation topic;
- Ability to provide quality, ethical, and balanced presentations;
- Participation in Editorial boards.

3.4 Tutorial Set-Up

Follow the guidelines listed in the Compass & NorthStar Reference Manual to create, submit, review, and approve Tutorial requests or consult the Professional Education department.

All Tutorials must be based on learning objectives established with an AZ employee's manager or a member of Sales Training and approved by his/her manager.

Occasionally, in preparation for the launch of a new AZ product or a new indication, it may be appropriate to schedule Tutorials that may discuss information that is considered outside of labeling. These Tutorials may be focused on a disease state that is new to AZ and the soon-to-be launched product, or an indication that is not yet approved, in anticipation of approval. The Therapeutic Area, Sales Training and/or the MCBG often recommend Tutorials to support these events. In these situations, the appropriate TA and Sales Training or the MCBG must create and approve the learning objectives for this training. Promotional Regulatory Affairs (PRA) must approve the training materials and information that will be used to perform this training (*see* **Product Promotion,** II-1).

3.5 Tutorial Program Limits

Tutorial programs are designed to meet specific educational objectives that have been agreed to between a PSS and their manager. Because these programs provide additional clinical knowledge that was not specifically detailed during AZ sales training programs, the number of Tutorial Programs that a PSS may attend OR host is one per product per year for a maximum of three.

4. Preceptorship Policy

4.1 General

Preceptorships provide an opportunity for an AstraZeneca (AZ) employee to spend a half or full day with a Healthcare Professional (HCP) (the Preceptor) in their clinical or business environment to learn about disease states, clinical practices and procedures, therapeutics issues, managed care segment issues, and other pertinent information. Since AZ retains Preceptors to provide bona fide services to the employees of AZ, these programs are subject to the AZ policy **Engaging Healthcare Professionals, Institutions, and Organizations in Contracted Services**(III-1).

4.2 Content of Program

Preceptors must be prepared to allow AZ employees to accompany them in the conduct of patient visits, administrative duties, medical consults, and other activities pertaining to their normal daily routine.

AZ employees must not initiate product promotional discussions during a Preceptorship. If the employee receives a question about an AZ product during the Preceptorship, the employee must keep all comments within product labeling, in accordance with the policy **Product Promotion** (II-1) and provide full prescribing information for that product to the Preceptor.

4.3 Patient Confidentiality

During the course of a Preceptorship, the AZ employee may be privy to physician/patient interactions, charts or records, and healthcare issues related to patients that would normally be considered to be private and confidential. At all times before, during, and after the Preceptorship, the confidentiality of physician/ patient interactions must be respected and protected (*see* **Patient Privacy**, I-6).

Prior to participating in the Preceptorship, the Preceptor and the AZ employee must sign a Preceptorship Agreement, including, among other things, the obligation to maintain patient privacy and the confidentiality of patient information disclosed during the Preceptorship. This agreement is available to be printed automatically through Compass upon completion of the Preceptorship request and must be executed prior to the Preceptorship occurring.

Physicians should be directed to inform patients that the AZ employee is not a healthcare practitioner and obtain the consent of the patient(s) for having the employee present during the Preceptorship.

If at any time a patient is not comfortable with the Preceptorship, the AstraZeneca employee must not participate in any activity or discussions relating to that patient.

4.6 Preceptor Selection Criteria

Preceptors must be selected based on their ability to educate the AZ employee on the identified objectives. The Preceptor must not be selected in return for, as an inducement to, or in any way in consideration of the prescribing, purchasing, use, formulary position or dispensing of AZ products. Preceptors should possess the ability to answer questions on a variety of topics related to the objectives identified for the AZ employee. The HCP should also be willing to allow the AZ employee to be present during the normal activities of his or her day.

During the course of selecting a Preceptor, the identified learning objectives should be shared with the potential Preceptor in advance of the Preceptorship to ensure they are comfortable in their ability to fulfill those objectives. When an HCP has been identified and confirmed for the Preceptorship, the AZ employee must sign the Preceptorship Agreement and the Preceptor must sign it as well. This executed agreement must be provided to the AZ Lecture Bureau in order for the compensation for services check to be cut.

On the day of the Preceptorship, the AZ employee should review the learning objectives again to ensure those objectives are achieved.

4.5 Preceptorship Set-Up

Follow the guidelines listed in the Compass & NorthStar Reference Manual to create, submit, review, and approve Preceptorship requests. Contact the Professional Education Department (PED) or the Lecture Bureau if you need assistance.

Preceptorships are also used in preparation for the launch of a new AZ product or a new indication. Refer to section 3.4. for Tutorial Set-Up and follow the same procedures.

4.6 Preceptorship Program Limits

Preceptorship programs are designed to meet specific educational objectives that have been agreed to between a PSS and their manager. Because these programs provide additional clinical knowledge that was not specifically detailed during AZ sales training programs, the number of Preceptorship Programs that a PSS may participate in is limited to the following:

- PSSs may attend OR host one Preceptorship per product per year for a maximum of three.
- A PSS may attend one additional Preceptorship if required by the launch of a new product or a new indication for an existing product.

5. Administrative Information

5.1 Requests and Required Contracts

Submit compensation for services requests through Compass using Preceptorship or Tutorial "Type of Program" under Speaker Programs. There should not be expenses associated with the Tutorial or Preceptorship. Any out-of-pocket expenses (eg, lunch for an AZ employee and tutor/preceptor only) should be submitted on an AZ employees' expense report to his/her manager via the expense reimbursement system.

A Tutorial/Preceptorship contract should be on file for each program. The contract must be signed and received by AZ and the services provided prior to the Tutorial/Preceptorship check being disbursed.

5.2. Expense Reimbursement for Tutors and Preceptors

AZ will reimburse Tutors and Preceptors for properly documented and reasonable expenses directly related to the services they provide in conjunction with the Tutorial (ie, parking, tolls, travel, meals).

Expenses will be reimbursed upon receipt of a completed expense reimbursement form with original receipts. Original receipts are required by the IRS for all expenses in excess of $25. The Lecture Bureau does not automatically supply reimbursement forms for

Preceptorships, as Preceptors do not typically have expenses associated with these programs. Should the Preceptor otherwise require an expense reimbursement form, contact the Lecture Bureau.

Speaker travel and lodging expenses must never be paid for by any AZ employee and submitted as a personal expense for reimbursement.

5.3. Compensation for Services

Compensation for services for Tutorials/Preceptorships must be paid directly to the Tutor/Preceptor using their social security number or federal tax identification number if they are legally incorporated. If using an organization, practice, or corporation tax identification number, the payee must be the name that the IRS has registered to that number. Failure to do so will result in inaccurate reporting to the IRS and AZ may incur fines to the IRS.

If the compensation for services is paid to an organization, it must be paid to the organization for which the Tutor/Preceptor directly works. According to IRS regulations, compensation for services may not be paid directly to a charitable organization on behalf of the Tutor/Preceptor. The Tutor/Preceptor must claim the compensation for services as income and then they may donate the money to the organization. An educational grant, payable to another organization, society, or group, may not be given as a substitute for the compensation for services to the Tutor/Preceptor. The Tutor/Preceptor may waive the compensation for services if they so choose, but a contract must still be signed.

The district, region, or MC segment responsible for the AZ employees attending the program will fund compensation for services and any expenses unless the program is initiated by the product team or by sales training.

5.3.1 Tutorials

The recommended compensation for services for a local Tutor is based on the FMV of the services rendered up to $500. The default compensation for services in Compass is set at $250. Increases or adjustments to this amount are allowable by the manager approving the request, provided that the amount does not exceed the upper limit of the recommended $500.

5.3.2 Preceptorships

The recommended compensation for services for a local Preceptor is up to $250 for a half day and up to $500 for a full day. A standard compensation for services amount is set as the default in Compass. Increases or adjustments to this amount are allowable by the manager approving the request, provided that the amount does not exceed the upper limit of the recommended $500.

5.4 Program Evaluations and Follow-Up

Following any Tutorial or Preceptorship, the AZ employee who requested the program must fill out an evaluation form and submit it within 10 business days. (The feedback feature in Compass for the PREP speaker request can be used for submitting the Tutor or Preceptor evaluation). The AZ requester should be responsible for ensuring that any follow up opportunities that arise from the program are communicated to the

appropriate persons in AZ (eg, mirrored counterparts, sales management, marketing or promotions managers, Medical Information Scientists, etc).

Relevant Tutor/Preceptor evaluation criteria should include:

- Knowledge of the topic and ability to present the material accurately;
- Fair and balanced presentation;
- Whether Tutor/Preceptor addressed the learning objectives outlined of the program;
- Ability of the Tutor to maintain attention of audience and facilitate question and answer session;
- Ability of the Tutor to field questions from the audience and answer with a professional and educational response;
- Overall presentation quality.

The program evaluation should include:

- Documenting the most important "take aways" from the meeting for the AZ employee(s);
- Best practices for conducting/structuring these programs.

5.5 Collateral Meals

It is appropriate to provide a modest meal for the Tutor or Preceptor. This meal is incidental to an educational program and therefore, an AZ employee must use the **Lunch & Learn Limits** referenced in **Gaining Access to Healthcare Professionals policy** (II-3, Exhibit A) as a reference.

6. References

6.1 AZ Business Policies

Gaining Access to Healthcare Professionals (II-3); **Independent (Nonpromotional) Educational Programs & Related Grants** (IV-1); **Promotional Education Programs** (IV-2); **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1).

For the Field: refer to the Sales Connection Newsflash of January 24, 2003 for Critical Guidelines and Clarifications regarding Preceptorships and Tutorials.

AstraZeneca

Faculty Update Programs & Other HCP Training

Policy No.: **III-6**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Faculty updates and other HCP training must fulfill a bona fide and necessary business need;**
- **It is not appropriate to train more individuals than the company will actually need to conduct speaker, educational, or other consulting programs;**
- **Those HCPs being trained must have the requisite expertise and skills to provide the services they are being trained for;**
- **HCPs must never be retained as an inducement to, or in any way in consideration of, their current or potential prescribing, purchasing, formulary position, use, or dispensing of AZ products.**

2. Purpose

To provide a policy governing AstraZeneca's (AZ's) training of healthcare professionals (HCPs) for speaker, educational or other related engagements. This policy applies to the training of HCPs by any AZ entity, including foreign affiliates.

3. Policy

3.1 Faculty Update Programs

By conducting Faculty Update Programs, AZ ensures that there is an adequate pool of national and regional speakers prepared to deliver presentations related to AZ marketed products and TA disease areas. These programs are typically held when there is new information for one of AZ's currently marketed products or when a new product is launched (eg, scientific update or slide kit training). It may also be appropriate to have an annual refresher course.

Since Faculty Update Programs involve consulting services, provisions of the **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1) apply. All provisions of Other Types of Training (3.2 of this policy) apply.

To ensure the successful outcome of a Faculty Update Program, they must be designed to be an interactive educational program with the goal of promoting consistent and measurable results. Faculty must be trained using the approved presentation materials they will use in their presentations. Additionally, frequently asked questions covering off-label information is appropriate for presentation and discussion during training sessions. Faculty must not use this off-label material when conducting Speaker Programs. If asked, they may answer questions pertaining to off-label information, but they must state that the product is not currently indicated for such use by the FDA after answering the question.

These programs must not be used to train more speakers than are reasonably needed to meet the goals of the speaker program they will support. The number trained must not exceed the number of speakers anticipated to be used on a regular basis. If a larger group than required is trained, the program could expose the company to legal and/or regulatory consequences.

3.1.1 Medical Information Scientists (MIS) Responsibilities

- Identify speakers for the programs;
- Submit participating speaker information to Professional Education Department (PED) (regional program) or communicate to regions to promote speaker utilization (national programs);
- Review approved slides, talk titles, and program details with speakers;
- Attend workshops;
- Complete payment request spreadsheet (national program);
- Confirm completion of speaker contract by each speaker;
- Submit PREP speaker requests (one per speaker) in Compass (regional program);
- Confirm participating speakers;
- Provide support to speakers prior to presentation in venue ready rooms;
- Provide speaker scientific support during workshop preparation, when appropriate;

- Present off-label scientific information approved by PRA and the Clinical Research Physician (the CRP may present this information);
- Deliver program opening and closing remarks;
- Perform assessment of scientific accuracy of speakers;
- Meet with speakers after the program to follow up on scientific topics that need further MIS support.

3.1.2. Regional Business Manager (Regional Programs Only); TA PED Manager (National TA Programs) Responsibilities

- Work with MIS (regional program) or TA (national program) to identify appropriate individuals as potential speakers based on speaker criteria;
- Craft invitation from approved template;
- Document with MIS or AZ Lecture Bureau that speakers have participated in programs and identify according to TA;
- Assure that only the appropriate number of speakers attend each program (only enough to fulfill a bona fide need).

3.1.3. Promotional Regulatory Affairs (PRA) Responsibilities

- Ensure all speaking materials including program titles, program outlines, program invitations, slides, speaker notes, are those that have been approved through the eSTaR process;
- Must give the "Speaker's Regulatory Responsibilities" presentation at every Faculty Update Program

3.1.4. PSS Responsibilities

- Work with DSM/MIS to create a list of potential speakers;
- Deliver invitations (if appropriate);
- Follow-up to ensure speaker's receipt of invitation (if appropriate).

3.1.5. Miscellaneous Responsibilities

- Choose presentation skills vendor identified by PED or an alternate vendor who will develop a program (see Attachment A for Sample Objectives of Optional Speaking Skills Session) (MIS /RSD/Customer Solutions);
- Mail sufficient invitations with the goal of confirming desired number of speakers;
- Contact vendor to confirm date of program and local venue (PED);
- Coordinate venue (PED).

Speakers must be selected based on their ability to educate HCPs and should never be selected in consideration of, as an inducement to, or in return for their past, current, or potential prescribing, use, formulary status, or dispensing of AZ products. They must be qualified to speak on the subject matter and be able to do so in a succinct, authoritative and interesting manner.

3.2 Other Types of Training

AZ also requires the services of HCPs to provide employee training or to provide other educational services on behalf of AZ. HCPs engaged in these types of activities are subject to AZ policy on **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1), **Advisory Boards** (III-2), or **Engaging Healthcare Professionals as Speakers and Educators** (III-4).

In addition to being trained as a speaker, HCPs may be trained for a variety of other activities. Some of the more common activities include, but are not limited to, training as a:

- Scientific presenter of Clinical Trial results;
- Moderator for Advisory Board;
- Media spokesperson to be interviewed by radio, TV or the press on issues related to AZ therapeutic areas;
- A forum designed to educate and/or update company speakers on topics (such as AZ products) on which they might be consulted by AZ or on which they might speak on behalf of the company;
- Preceptor and/or Tutor for employees to learn about disease states, clinical practices and procedures, and other pertinent information in a real-life clinical setting;
- Facilitator of a program designed for the exchange of clinical information between HCPs.

Terms used to describe types of HCP training in the past include, but are not limited to the following:

- Faculty Workshops;
- Tutorial Programs;
- Preceptorship Programs (national sponsored programs);
- Speaker/Faculty Update Meetings;
- Media Training.

4. Components of Providing Training to HCPs

There are several requirements that must be met when planning the training of HCPs for employee training or to provide other educational services. In all cases, the primary intent is to prepare an HCP to provide educational or related services to AZ employees or other HCPs on behalf of AZ.

In those instances, the following criteria apply:

- There must be a bona fide business need, good faith, and legitimacy (non-duplicative) to have the HCP/HCPs trained;
- Training may include off-label information so that the individual can adequately address the broadest range of possible issues and unsolicited questions;

- Training must include the regulatory issues and their responsibilities as speakers/trainers on behalf of AZ.

When discussing off-label information, it must be clearly stated and understood by all that the off-label information is being presented as background information only and that it is not to be used as part of any speaker or other educational presentation. If asked about an off-label indication during the course of a speakers program or other educational program, the presenter is to answer the question then clearly indicate that the product is not approved by the FDA for that particular use.

4.1 Services Provided and Company's Need for Services Must Be Bona Fide

HCPs may only be trained to provide employee training or to provide other educational related services that are rooted in and meet a bona fide business need for such services. Guidelines to be observed in order to ensure that training programs for HCPs are appropriate and conform to applicable legal and company standards include the following:

- Gaining access to the HCP, in and of itself, no matter how valuable to AZ is <u>not</u> a bona fide business need;
- AZ must have a genuine business need for the services to be provided by all of the HCPs being trained for a specific speaker or educational activity. For example, the training of a group of HCPs on results of a clinical trial would not be appropriate if only one or two individuals were required to perform the desired speaker/educational activity;
- "Token" training of HCPs is not permitted;
- Those being trained must be qualified to perform the services;
- The intended services must actually be provided by those trained.

5. Inappropriate Application of this Policy and/or Failure to Comply

If AZ were to characterize the training of an HCP for Speaker/Employee Training but there was no bona fide business need, or if AZ properly characterized the training but did not follow the requirements for such training events set forth below and applicable AZ Guidelines, AZ could subject itself to both civil and criminal actions by various government agencies, and to civil actions by private parties. Therefore, it is of critical importance to determine whether training of an HCP(s) is legitimately necessary for educational services and if so, to ensure that all requirements of this policy are met. AZ's Legal and Regulatory Representatives are available for advice on these matters.

6. Requirements for Training HCPs and Training Meetings

6.1. Selection of HCPs for Training

HCPs should be selected for training based on their ability to provide the service for which they are being trained. An HCP must never be selected in return for, as an inducement to, or in any way in consideration of current or potential, prescribing,

purchasing, formulary position, use, or dispensing of AZ products. An exception to this prohibition would be that one might consider a physician's medical experience, including his/her experience with our products and the relevant disease state, in considering whether to train him/her for speaking purposes, to provide employee training, or to provide other educational services if such experience is relevant.

6.2. Training Meeting Logistics

To the extent it is necessary to convene a meeting of HCPs or thought leaders to train them for speaking or other educational services, the provisions of this section, as well as any other applicable Company-wide policies apply.

6.2.1. Duration

The meeting should be only as long as needed to reasonably perform the training and to accommodate reasonable travel requirements. The overwhelming majority of the training program must be spent training the HCPs.

6.2.2. Venue, Travel, Entertainment, and Meals

Meetings held outside the continental US and Canada must be reviewed and approved by the TA Lead or the National Sales Director of the relevant TA or the Managed Care Business Group (MCBG) except for a regional meeting held in Puerto Rico. **Meetings for audiences that are primarily US based may not be held outside of the US.**

Travel by air and rail must be consistent with the current AZ travel guidelines for travel within and outside of the US. Travel by car shall be reimbursed for mileage traveled at standard rates set by the IRS. Any exceptions must be approved by the TA Lead or National Sales Director of the relevant TA, the MCBG, or designate.

Meals and any entertainment provided must follow these guidelines:

- The provision of a modest meal based on local standards in conjunction with contracted services is acceptable providing it does not exceed $50;
- The cost of a modest entertainment activity in conjunction with contracted services must not exceed $125, including a modest meal.

The overwhelming majority of the training program must be spent training the HCPs. It is critical to keep in mind that the goal of the meeting is to provide training to the HCPs, not to entertain them.

Appropriate accommodations would be those with a number 4 Mobil Travel Guide® rating or equivalent. This would include properties such as Sheraton, Westin, Hyatt, and Marriott. The company's Meeting Services Group can provide AZ employees with a complete list of properties that meet this requirement. Accommodations with a rating above 4 are not permissible. A facility suitable for the purpose of the training and conducive to that goal should be selected and should ensure the necessary privacy.

It is appropriate to reimburse participants in training for necessary and reasonable business expenses actually incurred such as travel and accommodations.

6.2.3. Compensation

Compensation for individuals trained to provide a service for AZ must be based on fair market value (FMV) for their time out of the office. As stated above, it is appropriate to provide meals and accommodations and/or reimburse them for reasonable expenses associated with attending the program.

The acceptable compensation for services for an attendee at a regional Faculty Update Program is $500. Compensation in excess of this amount must be approved by the NSD for that TA.

The acceptable compensation for services for an attendee at a national Faculty Update Program is $1000 - $2000. The TA Leader must approve compensation in excess of this amount.

6.2.4. Attendees from AZ

Attendance by AZ employees, or particular groups of AZ employees, is limited to those individuals required to conduct the training or provide the specific scientific, media, strategy or other applicable information. Other AZ employees may attend associated meal or social functions at the invitation of those conducting the training program and with the approval of their manager. PSSs may not attend these programs.

6.2.5. Number of Trainees Required

The number of HCPs required to be trained to provide employee training or to provide other educational services should be determined by legitimate business needs. The number of HCPs being trained should not exceed what would be considered legitimate for the specific business service they are intended to provide.

7. References

7.1 AZ Business Policies

Gaining Access to Healthcare Professionals (II-3); **Independent (Nonpromotional) Education Programs & Related Grants** (IV-1); **Government Employees and Agencies** (III-8); **AZ Employee Education by HCPs: Tutorial & Preceptorship Programs** (III-5); **Engaging Healthcare Professionals as Speakers and Educators** (III-4); **Advisory Boards** (III-2); **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1).

AstraZeneca

Marketing Research Projects

Policy No.: **III-7**

Issued by: **AZ Business Policy Group**
Date Issued: **07/01/2002**
Date Revised:

Contents:

1. Key Learnings

- **Marketing Research Projects are used to collect healthcare information directly from HCPs generally in an anonymous fashion to avoid bias;**
- **Marketing Research Projects must follow the guidelines established by the Council of American Research Organizations (CASRO) and the Pharmaceutical Marketing Research Group (PMRG) and should be conducted by a third party;**
- **Marketing Research Projects must never be used as a means to promote to our current or prospective customers;**
- **There must be a clear, compelling, and bona fide business need AND intent to use the findings to influence a specific business decision in order to conduct Marketing Research Projects.**

2. Purpose

To elaborate on the provisions in **Engaging Healthcare Professionals in Contracted Services** (III-1) to govern AstraZeneca's (AZ) policy on conducting Marketing Research (MR) Projects in a manner which complies with all applicable laws and relevant company policies.

3. Policy

There may be times when TA Support Functions or Field Sales Leadership may have a legitimate business need to collect and then act on information obtained directly from healthcare professionals (HCPs). MR Projects are conducted to collect this information, generally in an anonymous fashion so as not to cause a bias in the results. Sometimes, small qualitative MR Projects are conducted to check a hypothesis or are used as the basis for designing large, quantitative MR Projects. Regardless of the research design, the following are general principles to be followed when conducting MR Projects.

3.1 Fundamental Principles

The following policies mirror guidelines published by the Council of American Research Organizations (CASRO) and the Pharmaceutical Marketing Research Group (PMRG), two major market research societies that have established the norms for conducting research. These guidelines are applicable for all research, whether qualitative or quantitative. AZ conducts MR Projects in a way that conforms to the norms set by these societies.

Similar to other policies on Engaging Healthcare Professionals, MR Projects:

- Should only be conducted if there is a clear, compelling, and bona fide business need AND if there is intent to use the findings to influence a specific business decision;
- Should never be used as a means to promote current or investigational products or off-label indications to our current or prospective customers.

3.2 Study Design

MR study designs should reflect the goals of the study. This must be addressed in how the sample population for a study is selected. For example, to understand issues facing a specific district or region would require the inclusion of a random sample of physicians from the target list for that particular area. The sample size should only be as large as required to effectively answer the proposed questions, and no larger. If one were to utilize a sample size significantly larger than required, regulating bodies could view the research project as promotion or, worse yet, a sham, designed to induce an HCP to use or favor AZ products when making prescribing or formulary decisions. Likewise, the decision of whether to use qualitative or quantitative, telephone or in-person, focus group or mini group, should all be based on study goals.

A third-party MR supplier should always conduct research projects. By using a third party, AZ may ensure that:

- The methodology will be appropriate and strong;
- The questionnaire or discussion guide is unbiased;
- The report is thorough and unbiased.

In order to collect feedback, there is often a need to present information to the respondent about AZ products, or competitive products, or about findings from scientific studies. The time spent presenting this information should be kept to a minimum. At the very most, no more than 25% of the time with the respondent should be spent presenting information. Typically, when the Business Analysis and Intelligence group conducts MR Projects, these presentations take no longer than 10-15 minutes out of a one-hour, one-on-one meeting, or 15-20 minutes out of a two-hour focus group.

3.3 Study Goals

MR Projects differ in their goals from Advisory Boards in that there is a promise and commitment to confidentiality. This means that the final report is communicated at a summary level, never with HCP level responses, with associated names, or with identifying information. Additionally, individual responses should never be reported to anyone in a selling role, and information gained about a particular HCP should never be used in a sales call. Finally, to avoid bias, respondents should not know who is sponsoring the research.

4. Conducting Qualitative Research

Qualitative research is typically used to understand the range of responses to a question, but not to quantify the percentage of respondents who actually feel that way. Qualitative research is also used when budgets are limited and the TA support functions or sales groups need a quick temperature check, but cannot afford the time or the resources to get a more refined view.

Business Analysis and Intelligence conducts qualitative MR on the same topics that may be required at a regional level. There are a variety of methodologies that can be used. The methodology selected can be based on a variety of factors including but not limited to:

- Budget;
- Amount of background information to be shared;
- Timelines.

The methodology selected will also vary depending on the study objective and can include but is not limited to:

- Telephone interviews;
- One-on-one in person interviews;
- Mini groups;
- Focus groups;
- Internet- based tools.

The number of respondents generally targeted for a regionally based MR Project should be up to about 20 HCPs per specialty, although, in rare

instances, it may go as high as 45. The basic rule of thumb is to start with 10-15 interviews, and, if the same basic information is heard repeatedly from respondents, there is no need to continue with further interviews. Conversely, if there is a lack of consistency across critical issues, interviews should continue until an understanding of the range is obtained. Enough information should be gathered so that if follow-up quantitative research is planned, it can be designed to address the divergence found in the qualitative results. More often than not, by the twentieth interview, most needs should have been adequately addressed.

MR Projects, including all recruiting, should be conducted by a by a third party MR vendor. The length of time required to conduct the research varies based on the methodology chosen. All times below are inclusive of time to present materials or data:

- One-on-one discussion either in person or over the phone is usually under one hour;
- Mini groups or focus groups are 1-2 hours in length.

At times, there is a business need to get reactions to new information that might take more than 15 minutes to present. For example, AZ may need reactions to unpublished data, or to a new class of drugs. These cases may demand longer presentations, however, in total, including research time, these discussions should last no longer than four hours. Further, given the business need, it is expected that the sample size for this research would be relatively small, perhaps with no more than 100 doctors across the country.

Research should be conducted in a research facility, or a private meeting room. Respondents can only be paid fair market value (FMV) for their service. When utilizing national or international experts, a higher compensation for services may be required to ensure their participation.

5. Conducting Quantitative Research

As noted above, qualitative studies may help us to know the range of responses to particular issues. Quantitative studies help us to know how many respondents actually hold that belief. Like qualitative studies, a third party market research vendor who can assist on study and questionnaire design, sampling, interviewing and report generation should conduct these studies. The following describes key elements of quantitative research which differ from those used in qualitative research:

- Used to quantify the percentage of respondents who actually feel a certain way about a topic;
- Sample size is large enough to make the responses projectable across a large audience with some degree of statistical significance.

6. References

6.1 AZ Business Policies

Advisory Boards (III-2); **Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services** (III-1).

AstraZeneca

Government Employees and Agencies

Policy No.: **III-8**

Issued by: **AZ Business Policy Group**
Date Revised : **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Those engaging government employees (GE) as consultants must be familiar with all laws and regulations applicable to such activities;**
- **AZ may not pay a consulting fee or compensation for services to a GE if such arrangement would create a conflict of interest and if it is unreasonable in relation to the effort required;**
- **Before providing consulting services or participating in an AZ-supported educational program, a GE must complete the AZ Federal Provider Form;**
- **Grants payable to government agencies or individuals within those agencies are only permitted where specifically authorized by statue and regulation;**
- **Gifts to a GE must not violate the "Standards of Conduct" of the Executive Branch**
  -Any single item must not exceed $20 FMV;
  -The yearly limit for a GE from any company is $50 FMV;
  -Paid attendance at widely attended events if authorized and not exceeding $250 FMV.

2. Purpose

To state AstraZeneca's (AZ's) commitment to comply with all applicable legal requirements and ethical standards with respect to the participation of government employees in AZ-sponsored educational activities and gifts to officers, officials, or employees of the executive branches of Federal and state governments, and to provide guidelines to ensure such compliance.

3. Policy

3.1. General Policy

3.1.1. AZ may engage government officers, officials or employees (GEs) as speakers, consultants, or participants in connection with preceptorships, tutorials, and other training activities only if these activities do not violate government ethics rules. AZ employees engaged in the planning and implementation of educational activities involving GEs must be familiar with and follow all applicable laws and regulations pertaining to such activities. For example, Federal employees are subject to standards set forth in 5 Code of Federal Regulations, Part 2635 Subparts D and H, 5 C.F.R. Part 2636 Subpart B, and any supplemental regulations adopted by the government agency for which the GE works. This policy provides only a general overview of these requirements and should not be relied upon as a comprehensive source for the applicable legal standards. Please consult with your Legal Representative when engaging government employees in contractual services.

3.1.2. AZ may not pay for a Preceptorship, compensation for services, or consulting fee to a GE, or pay the expenses of a GE, if such arrangement would create a conflict of interest for the GE or constitute an unlawful payment or compensation for the GE's official duties.

3.1.3. All consulting fees, Preceptorships, and compensation for services must be reasonable in relation to the time and effort required.

3.1.4. No AZ employee may offer anything of value to any GE in violation of any law or regulation applicable to that GE (see 3.6. of this policy). The ethics rules covering personal gifts, however, do not apply to gifts, in-kind donations, or voluntary contributions to agencies authorized to accept them. Thus, AZ may pay a GE's expenses if requested by the Department of Veterans Affairs (VA) or Department of Defense (DOD) and not solicited by the GE.

3.2. Conflicts of Interest

3.2.1. Applicable standards of ethical conduct prohibit GEs from engaging in any outside employment or activities, including seeking or negotiating for employment, that conflict with their official duties.

3.2.2. AZ may not enter into a consulting arrangement with a GE, pay compensation for services or speaker fee to a GE, or enlist a GE's participation in an AZ-supported program, if the arrangement creates a "disqualifying financial interest" for the GE. In very general terms, a GE may not enter into an arrangement with AZ *if the GE's government activities could have a direct and predictable effect on AZ and thus on the GE's opportunity to earn money through the arrangement. Such arrangements are prohibited because they could create a financial interest for the GE that would impermissibly conflict with the GE's official duties, requiring disqualification from such duties. A GE may also not receive payment for speaking about matters within his or her official duties or for Preceptorships including official duties because the GE is already paid for that work by the government.*

3.2.3. For full-time GEs, these restrictions usually preclude most work for industries having business with or regulated by their agencies. Special part-time employees may be less restricted due to the relationships arising out of their primary non-government business and fewer conflicts with official government duties.

3.2.4. Special restrictions apply to Presidential appointees and full-time non-career employees on sources of outside income. As a general rule, these individuals may not accept compensation from outside sources for consulting or speaking.

3.3. Consulting Arrangements

Potential consulting agreements with GEs must be evaluated on a case-by-case basis and must receive the advance approval of the AZ Legal Department. Generally, in addition to the requirements of the **Engaging Healthcare Professionals, Institutions, and Organizations in Contracted Services** (III-1) policy, four basic principles must be considered in determining the propriety of a consulting arrangement. AZ must:

- Ensure that the arrangement does not present a conflict of interest;
- Ensure that the arrangement is a genuine consulting arrangement and not a prohibited payment for teaching, speaking, or writing, which relates to the GE's official duties;
- Obtain proof that the appropriate official from the government agency with which the GE is affiliated has approved the consulting arrangement;
- Require certification in a consulting agreement that the arrangement does not violate the ethics rules of the GE's agency.

The AZ Federal Provider Form (see Section 3.5. below) is designed to ensure that the above requirements are met.

3.4. Teaching, Speaking, and Writing

3.4.1. AZ must ensure that any arrangement with a GE does not violate ethics laws or standards, such as the Federal Office of Government Ethics regulations that prohibit any form of compensation to a government employee for teaching, speaking, or writing, that relate to the employee's official duties. Compensation for speaking includes travel expenses and business courtesies as well as the speaker fee. Generally, the arrangement will be prohibited if:

- The activity is undertaken as part of the GE's official duties;
- The invitation to participate in the activity was extended because of the GE's official position rather than his or her expertise on the particular subject matter;
- The invitation to participate in the activity was extended by a person whose interests may be substantially affected by performance or nonperformance of the GE's official duties;
- The activity would require disclosure of nonpublic information.

3.4.2. GEs may have their expenses paid to speak at conferences, symposia, and similar events if the agency has determined that it is in the government's interest. However, in these situations, the GE may not be paid for his or her time or effort.

3.5. AstraZeneca Federal Provider Form

3.5.1. Before providing consulting services or participating in an AZ-supported educational program, a GE must complete the AZ Federal Provider Form (the Form). The Form confirms that

- The GE's participation in the proposed activity does not create any apparent or real conflict of interest with the GE's employment with, or services to, the Federal government;
- Any compensation given to the GE does not constitute compensation or payment to the GE for performing his or her official duties;
- Any compensation given to the GE does not constitute a prohibited gift or otherwise violate the Federal ethics regulations.

3.5.2. Before completing the Form, the GE must verify, with the appropriate authorized government personnel, the accuracy of the information submitted. AZ may not pay an compensation for services to a GE, or compensate or reimburse a GE for consulting services or related expenses, unless AZ has received the Form with the appropriate approvals and verification.

3.6. Gifts to Employees of the Executive Branch (Military or Civilian)

3.6.1. The Executive Branch of the Federal government has adopted standards for its employees' acceptance of gifts, entertainment, or other items having monetary value. While these standards vary under a particular Executive Branch agency's gift statute, the Standards of Ethical Conduct for Employees of the Executive Branch ("Standards of Conduct") clearly restrict the type and value of gifts that government employees may accept. AZ employees doing business with Executive Branch employees should be aware of, and must comply with, all such restrictions and honor them.

The Standards of Conduct define the term "gifts' broadly to include any gratuity, favor, discount, entertainment, hospitality, loan, forbearance or other item having monetary value. It includes services as well as training, transportation, lodging and meals, or other things of value, whether provided in-kind, by payment in advance, or by reimbursement after the expense has been incurred. The definition does not include modest refreshments, such as soft drinks, coffee, and donuts, offered other than as part of a meal. Similarly, greeting cards, plaques, and other items of little intrinsic value are not considered gifts under the Federal ethic regulations.

3.6.2. Under the general terms of the Standards of Conduct, an HCP or any other employee in the Department of Veterans Affairs (VA), Department of Defense (DOD), or other Executive Branch agency may not accept personal gifts offered by any persons or organizations doing business or seeking to do business with the employee's agency. There are exceptions under limited conditions. For example, VA physicians or other agency employees may accept infrequent, unsolicited gifts in-kind having an aggregate market value of $20 (this includes meals, reminder items, solutions, etc) or less per occasion, provided that the aggregate market value of individual gifts received does not exceed $50 FMV in a calendar year from any one prohibited source (eg, contractor or supplier). Gifts from a particular corporate entity, its officers, and employees must be aggregated for purposes of applying the yearly $50 FMV limitation on gifts of $20 FMV or less. **AZ policy prohibits the provision of gifts to any HCP. AZ provides corporate or product reminder items or medical or patient solutions.** The Standards of Ethical Conduct will consider these items gifts for employees of the Executive Branch.

3.6.3. GEs may accept free attendance at widely attended gatherings if the agency determines it is in its interest and the value does not exceed $250 FMV. For example, an agency may permit a GE to accept a seat at an AZ-sponsored table at a dinner honoring a public official. If the guest is employed by an agency with which AZ does business or which regulates AZ's business, the agency authorization must be in writing, and AZ should obtain assurances from the GE that his or her attendance has been approved. GEs may accept travel expenses and conference

fees from a sponsor if speaking on behalf of an agency. AZ may also pay a GE's attendance and travel expenses if requested by the agency and not the GE. Free attendance and travel expenses are authorized if received from non-profit organizations under 5U.S.C. § 4111. Therefore, educational grants to such organizations are generally the best way to subsidize GE attendance at events. (See section 3.7) GEs may not accept travel expenses to attend promotional events. Please consult your Legal Representative if attendance by a GE at an event is desired.

3.6.4. Any exceptions under the Standards of Conduct do not apply to gifts offered under circumstances having the appearance of impropriety, such as in return for the purchasing, prescribing, recommending, use, formulary status, or dispensing of AZ products.

3.6.5. Any AZ employee providing a Lunch & Learn; Medical, or Patient Solution; or a Reminder Item to an HCP or other employee of the VA, DOD, or any other Executive Branch agency must inform the proposed recipient that AZ policies require that the recipient of any of the above comply with the Standards of Conduct and regulations adopted by the recipient's particular agency. In addition, AZ employees must document the cost, name, title, and organization of the recipient in order to ensure that the calendar year $50 FMV limitation is not exceeded.

3.7. Grants to Government Agencies

3.7.1. AZ may not make grants payable either to government agencies or individuals within those agencies except when such grants are specifically permitted by statute. For example, under applicable law, the VA and medical centers in the VA are permitted to accept grants from pharmaceutical companies (and others). In general terms, such grants are made payable to the Department of Veterans Affairs, General Post Fund, and evaluated by the VA on a case-by-case basis. Educational grants to a particular VA medical center should be arranged with the intended recipient and made payable to the General Post Fund accounts designated for that particular VA medical center.

When no statute expressly governs or permits a grant to be made to a government agency or official, grants must be made payable to a company-approved third party (eg, the Henry M. Jackson Foundation) authorized to receive such payments and direct them to the appropriate government agency.

3.7.2. The Henry M. Jackson Foundation

The Henry M. Jackson Foundation (the Foundation) provides an avenue for corporations to provide funding for visiting speakers or consultants at Federal facilities. Grants to the Foundation may be used to fund the services of either GEs or non-GEs, although the procedures relating to GEs and non-GEs differ. AZ employees must adhere to the Foundation's specific guidelines governing the provision of grants.

3.7.3. Sponsorship grants may not designate specific GEs to be invited to attend events, although it is permissible to make recommendations.

4. References

4.1. AZ Business Policies

Engaging Healthcare Professionals, Institutions, and Organizations in Contracted Services(III-1).

4.2 AZ Federal Provider Form

AstraZeneca

Engaging Healthcare Professionals in Global Activities

Policy No.: **III-9**

Issued by: **AZ Business Policy Group**
Date Issued: **07/01/2002**
Date Revised:

Contents

1. Key Learnings

- **When engaging foreign physicians and other healthcare professionals (HCPs), contact AZ product team counterparts from that/those country/countries early in the planning process to review applicable policies;**
- **When contracting with individual HCPs or inviting them to other programs, the value or compensation they receive, must be based on fair market value (FMV) for the services provided;**
- **US Policies are aligned with the PhRMA Code and must be followed when engaging US Physicians;**
- **If travel and accomodations are provided, there must be a bona fide need for the travel.**

2. Purpose

To provide:

a. A policy for the US business to govern AstraZeneca (AZ) retention of foreign healthcare professionals (HCPs) in US activities in exchange for some form of compensation in a manner which complies with all applicable laws and relevant company policies;

b. Guidance on US policies to global teams must comply with engaging US HCPs in the US or elsewhere;

c. Policy that governs the creation, use or distribution of promotional materials intended to support international conventions, symposia or other promotional events.

This policy applies to the retention of US HCPs by any AZ entity, including foreign affiliates and the retention of foreign HCPs by the US business. This policy is not intended to apply to the retention of HCPs for clinical trial programs. For such activities, please consult company policies on clinical trial programs.

3. Policy

3.1 Global Interactions

AstraZeneca (US and Global teams) often invites or retains HCPs, recognized nationally or internationally as influential experts for a variety of contracted services or for participation in US or international events. Although the types of contracted services and events for which AstraZeneca invites/retains these HCPs can vary, generally, they involve either the HCP providing input and valuable information to the company or speaking on behalf of the company or being invited to a promotional or educational event by AZ. These services and events are hosted almost exclusively by the TAs and supporting functional areas. Therefore, *this policy does not apply to US Field Sales.*

3.2 Compensation/Value for US HCP Interactions

When engaging US HCPs, value can take many forms including
- Meals;
- Entertainment;
- Compensation for services.

Guidelines exist that must be followed when engaging US HCPs in contracted services, or inviting them to conventions, symposia, or to participate in other functions. Guidelines also exist on providing gifts, reminder items, meals, entertainment and compensation for services in conjunction with these activities. Whether a US HCP receives compensation or value from services performed or other engagements or events in the US or on foreign soil, the Access Limits contained in **Gaining Access to Healthcare Professionals** (II-3, Exhibit A) and other compensation guidelines must be followed.

All limits on value provided must be based on fair market value (FMV) of the materials, not the cost to AZ to acquire them. For example, if AZ provides an HCP with a medical textbook that AZ pays $75 for but would cost the HCP $100 to purchase, the FMV is $100. If a dinner is hosted for a group of HCPs, the value of that meal must not exceed the Access Meal limits established for the TA Support Functions in **Gaining Access to Healthcare Professionals** (II-3, Exhibits A and M).

In order to ensure that US AZ policies on Engaging Healthcare Professionals for Consulting Services and other policies are not violated, the US business expects

that a the Global TA team enlisting the services of a US HCP will communicate with the US TA Promotional Regulatory Affairs (PRA) Director (http://pra.us.astrazeneca.net/web/ContactList.asp) early in the planning stages of anticipated programs or services which would provide value to a US HCP. It is the responsibility of the US TA PRA Director to inform the Global team of the policies and guidelines that must be followed (see, **Engaging Healthcare Professionals, Organizations, & Institutions in Consulting Services** [III-1] and **Gaining Access to Healthcare Professionals** [II-3]).

3.3 Value Limits and Reporting Responsibilities for Global HCP Interactions

There is a trend Globally to monitor and limit the value/compensation that HCPs receive. For example, France has very specific rules governing the types and amount of compensation physicians may receive. Just as it is the responsibility of a Global or other non US team member to contact the US TA PRA Director to insure applicable policies are understood and followed when involved with US physicians, the same applies for US product teams enlisting the services of foreign physicians.

Because it is impossible to be aware of all the various policies that exist, it is always critical to contact the national Nominated Signatory for the country concerned: (http://ma.psl.astrazeneca.net/ma_businesstools/prom_help/review_procedures/Nominated%20Sigs%List.htm) early in the planning process to ensure valuable efforts are not wasted planning an event or engagement that would violate an AZ Global or other international policy. The Global TA Medical Affairs Manager (http://ma.psl.astrazeneca.net/who_are_we/pages/mams_in_the_tas.xls) is an alternative contact for consultation when appropriate.

3.4 Creation and Distribution of Promotional and Enduring Educational Materials

To ensure compliance with FDA regulations, all materials used in the US with US based attendees for promotional or educational (including reprints, reference texts, patient education pieces, display and exhibit material, and reminder items) activities must have prior approval through the eSTaR Process (see **Development of Promotional Materials** [II-2]). The use or distribution of unapproved journal articles or reference texts, use of approved materials outside the scope of its intended use, or providing copies of non-leave pieces to HCPs are prohibited.

Any promotional materials given to a US based HCP must contain "full disclosure": adequate directions for use (also known as full prescribing information), along with a complete statement of all the product's benefits and risks (http://pra.us.astrazeneca.net/web/PO_Overview.asp).

4. Travel and Accommodation Expenses

Travel and accommodation expences associated with consulting services or other programs must follow the policies on **Engaging Healthcare Professionals in Consulting Services** (III-1), **Independent (Nonpromotional) Educational Programs** (IV-1), **Promotional Education Programs** (IV-2) and the **Company Wide Travel & Meeting Policy**. These require that the venue and location be conducive to accomplishing the purposes of the meeting, that it not be lavish, and that there be a bona fide and legitimate business need for the services and travel.

AZ may not pay for travel, lodging, meal, social or any other ancillary expenses of spouses or guests of the US HCPs whose services we have contracted for.

5. References

5.1 AZ Policies

Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services (III-1); **Advisory Boards (& Other Consultant Meetings)** (III-2); **Gaining Access to Healthcare Professionals** (II-3); **Services and Data Purchase Agreements** (III-3); **Engaging Healthcare Professionals as Speakers & Educators** (III-4); **Independent (Nonpromotional) Education & Related Grants** (IV-1); **Promotional Education Programs** (IV-2), the **Company Wide Travel & Meetings Policy**, and http://pra.us.astrazeneca.net/web/Conv_Exhibits.asp

IV. Professional Education

AstraZeneca

Independent (Nonpromotional) Education & Related Grants

Policy No.: **IV-1**

Issued by: **AZ Business Policy Group**
Date Revised: **03/31/2000**
Date Revised: **07/01/2001**

Contents

1. Key Learnings

- **Educational grants are designed to support independent, *nonpromotional,* education to HCPs, ultimately focused on enhancing patient care;**
- **For programs to qualify as independent (*nonpromotional*) they must meet qualifications set forth in the "FDA's Guidance" in Attachment I, ensuring that the programs are free from commercial bias;**
- **If programs concern commercial products, they must present objective information and be based on generally accepted scientific methods;**
- **Educational grants *may not* be used to support programs that are *promotional* in nature (see Promotional Education Programs, VI-2);**

- **Continuing Education Grants may be used to support CME (*accredited)* or *non-accredited* educational programs;**
- **For programs to qualify as *accredited*, they must meet qualifications set forth in the accrediting organization's guidelines;**
- **Contact the TA Professional Education or Field Professional Education representative when planning to support or develop any educational programs;**
- **Medical and Pharmacy Education Grants are used to support Independent (Nonpromotional) Education Programs;**
- **These grants may only be used to fund programs with an educational purpose;**
- **AZ may not provide grants with "strings attached;"**
- **AZ must not direct or influence the content of the educational program, selection of speakers/presenters;**
- **An AZ Grant Letter of Agreement contract must be completed for each Medical or Pharmacy Education Grant.**

2. Purpose

To state AstraZeneca's (AZ's) commitment to providing financial support for *Independent (Nonpromotional) accredited* or *nonaccredited* Continuing Education Programs without influencing the content of these activities, describe the types of educational grants provided by AZ for this purpose and the applicable standards related to the conduct of these activities. ***If educational grants are made in accordance with FDA guidelines on independent education and the American Council on Continuing Medical Education (ACCME) or the American Council on Pharmaceutical Education (ACPE) Guidelines, these programs will typically be considered product promotion and are generally not regulated as such by the FDA.*** Programs of a promotional nature are covered under **Promotional Education Programs** (IV-2).

Educational grants may be used to fund only activities or programs with an *educational* purpose. They may be *accredited* or *nonaccredited* by approved-provider organizations (see below).

2.1 Introduction

The purpose of Continuing Education (CE), HCP's or other independent (nonpromotional) educational programs is to enhance an HCP's ability to provide care for patients. These educational programs can be accredited or nonaccredited, but regardless of accreditation status they must adhere to the **FDA's Guidance: Industry-Supported Scientific and Educational Activities,** otherwise they will be considered promotional. Accredited programs provide the participant with a number of credit hours based on the time and scope of the topics being discussed. HCPs are generally required to achieve a certain number of CE hours every year or two in order to maintain their licensure. A variety of accrediting bodies exist depending on the HCP's role in health care and the specialty to which they belong:

- ACCME – Accreditation Council for Continuing Medical Education;
- ACPE – American Council on Pharmaceutical Education;
- ACHE – Accreditation Council for Healthcare Executives.

Continuing education programs can be directed at:
- Physicians (ACCME)
  - Medical students
  - Residents
  - Postgraduate Fellows
- Pharmacists (ACPE)
- Nurses (varies by state)
- Health Care Administrators (ACHE)

Some of these groups have their own accrediting standards that must be followed when developing and designing educational programs. For example, the Essentials and Standards of the Accreditation Council for Continuing Medical Education (ACCME) govern activities providing CE credits to physicians. If planning an accredited program for one of the above groups, the AZ PREP (Professional Relations and Education Programs) representatives have the specifics on how to support a program, what information may or may not be provided by AZ, and the appropriate letter of agreement. For pharmacy programs, contact the Director of Pharmacy Affairs.

AZ may support accredited activities through designation of a medical education grant to an accredited organization. Employees involved in such educational activities must be familiar with and adhere to the standards provided in the following documents: **FDA's Guidance: Industry-Supported Scientific and Educational Activities (the "FDA Guidance")** (Attachment I), and in policies or guidelines that accrediting organizations have established such as the ACCME or ACPE guidelines (Attachments II and III).

3. Policy

3.1 Independent (Nonpromotional) Education Programs

Independent (Nonpromotional) Education Programs may be *accredited* or *nonaccredited*. If they are accredited, guidelines of the accrediting body must be followed. In order for these programs not to be considered promotional, FDA guidelines on independent education must also be followed (Attachment I – **FDA Guidance: Industry-Supported Scientific and Educational Activities and Attachment II – ACCME Internet Policy http://www.accme.org/incoming/pol_12_internet.pdf**).

Grants covered by this policy include but are not limited to
- Medical Education;
- Pharmacy Education;
- Postgraduate Education.

Independent (Nonpromotional) Educational Grants may only be made payable to institutions, organizations, societies, or groups, consistent with FDA and accrediting

organization standards. They may NOT be paid to individuals, group practices or physician-owned practices.

3.2 Grand Rounds Activities

Grand Rounds activities are a special kind of educational program. These programs are generally held in hospitals for medical students and residents. Attending and Staff physicians are welcome to attend and usually do. Generally, students or residents are selected to present interesting or unusual patient cases and then lead a discussion on treatment options and, if applicable, outcomes. In other instances, guest speakers may be invited to address the group on a particular disease state, therapeutic area, or surgical intervention.

Because of the variety of topics and objectives, Grand Rounds Programs fall into all three categories of educational programs

- Independent, accredited;
- Independent, nonaccredited;
- Promotional (see Promotional Education Programs IV-2).

The category that a Grand Rounds Program falls into will determine which policies apply and whether or not a grant may be provided. If the program is independent and nonpromotional, then this policy applies and all funding must be provided via a Medical Education Grant. If the program is deemed promotional, then the AZ employee requesting the program should follow the **Promotional Education Programs** (IV-2) policy.

3.3 Standards for Support of Accredited Activities

Accredited activities may be supported through the provision of an independent educational grant to an accredited organization. Activities providing Continuing Education (CE) credits to HCPs are governed by the specific standards for the accrediting organization or institution.

3.3.1. Independence and the FDA

The FDA (Federal Drug Administration) continually evaluates the independence of educational and scientific programs and has issued a list of factors intended to furnish guidance on the design and conduct of educational activities to determine if they constitute *promotion*. These factors will be considered by the agency as part of an overall evaluation of an activity, though no individual factor by itself is likely to stimulate agency action based on lack of independence. The twelve factors are:

(1) Control of content and selection of presenters and moderators;
(2) Disclosures (Ties to Industry);
(3) Focus of the program;
(4) Relationship between provider and supporting company;
(5) Provider involvement in sales and marketing;

(6) Provider's demonstrated failure to meet standards;
(7) Multiple presentations;
(8) Audience selection;
(9) Opportunities for discussion;
(10) Dissemination of product information;
(11) Ancillary promotional activities;
(12) Complaints.

The FDA Guidance also notes that one means of documenting the measures taken to ensure independence of an activity is to have a written agreement between the provider and the supporting company, which reflects that the provider has sole responsibility for designing and conducting the activity. The FDA Guidance states that a written agreement provides "valuable evidence" of whether a program is independent or promotional. **AZ Policy requires that a written agreement be signed for all continuing education programs.**

If AZ influences the content of an AZ-supported educational program directly or indirectly, then the program is subject to FDA regulation as a *promotional activity*. The information included in such programs must be consistent with product labeling. Please refer to the policy on **Promotional Education Programs** (IV-2) for additional guidance on programs that are deemed to be promotional.

3.3.2. Exhibits at Accredited Programs

- Company exhibits may only be displayed during symposia or conventions with the consent of the accrediting provider or appropriate third party organization (*see* **Convention/Symposia Exhibits**, IV-3).

- Exhibits must not be in the same room as the medical education activity. The FDA guidance must be observed as it relates to the *independence* of the medical education program.

- When exhibits are displayed in conjunction with accredited programs, additional consideration must be given to ensure compliance with applicable guidelines of the accrediting organization.

- Independent education grants may not be used to fund an exhibit or display booth. Accredited providers may, however, waive exhibit fees at their discretion (whether or not continuing education credits are provided) for related medical education programs.

3.4 Enduring Materials

Distribution of enduring materials, invitations, or business reply cards for independent CE programs must be in accordance with AZ's policy on **Distribution of Enduring Materials from Independent Educational Programs** (IV-6).

4. Independent (Nonpromotional) Education Grants

Independent (Nonpromotional) Education Grants may only be used to support activities or programs with an *educational* purpose that are not promotional. They may not be used to support individual interests or expenses. AZ may not provide grants with "strings attached." Receipt of a grant should never be contingent upon the recipient's activities with respect to AZ or AZ products. Grants should never be offered or provided, either directly or indirectly, in exchange for current or potential prescribing, purchasing, use, formulary inclusion, or dispensing of AZ products.

4.1 Program Standards

If a grant is used to fund an *accredited* educational program, AZ must adhere to both the FDA standards for independent medical continuing education programs *and* the standards of the accrediting body for which the program is being developed, eg ACCME's Standards for Commercial Support of Continuing Medical Education ("ACCME Standards") or similar standards of another representative accrediting body (eg ACPE, ACHE). These standards generally prohibit AZ from controlling the selection of specific topics for the program, selecting speakers, identifying prospective attendees, and otherwise engaging in conduct that would control program content. If requested in writing by the provider, AZ may suggest speakers or topics to the independent accredited provider; however, the accredited provider must retain control over the speaker and topic selection and program content.

If a grant is used to fund a *nonaccredited* educational program, **AZ must still adhere to the FDA standards for independent continuing education programs**. Again, the FDA standards prohibit AZ from controlling the selection of specific topics for the program, selecting speakers, identifying prospective attendees, and otherwise engaging in conduct that would control the content of the program.

4.2. Accredited & Nonaccredited Programs

Independent education grants may be used to support either *accredited* or *nonaccredited* educational programs.

Accredited educational programs include, but are not limited to:

- Regional CME symposia;
- Monographs for CME (physician) or ACPE (pharmacist);
- Educational seminars for physicians;
- Development of CE programs on Internet or CD-ROM;
- Third-party accredited educational programs;
- Grand Rounds Programs;
- Educational seminar development for physicians/pharmacists;
- Development of CME programs on Internet or CD-ROM;
- Third-party accredited educational programs;
- Patient Centered Asthma Care Education;
- Interactive Workshop for Success Program;
- Regional Medical or Pharmacy Educational Symposia.

Nonaccredited, independent educational programs include, but are not limited to:

- Community education programs;
- Customer-initiated health fairs conducted by institutions, organizations, clinics, or hospitals;
- Funding for customers to create, produce, or distribute a patient education newsletter on their own;
- Physician training programs at academic institutions;
- "Doctor to Doctor" or "Pharmacist to Pharmacist" preceptorship programs conducted by academic institutions;
- Grand Rounds Programs without CME credit.

4.3 Prohibited Activities

Activities, **which may not be funded by an education grant,** include, but are not limited to:

- Exhibit or display booths at conventions/conferences (use Regional Exhibit type of funds request instead of grant request; see **Convention/Symposia Exhibits**, [IV- 3]);
- Research or Health Economics studies;
- Charitable contributions;
- General/miscellaneous education funds (support promotional education programs);
- Parties or social events for HPCs;
- Testimonial dinners;
- Medical missions to foreign countries;
- Medical school yearbook advertisements;
- Requests for medications;
- Travel, registration, or lodging expenses for nonfaculty HCPs to attend CE programs (accredited or non accredited);
- Private schools/colleges attended by physicians or their families.

Independent education grants must never be used to support charitable events, such as fund-raiser golf outings, tennis tournaments for charity, the American Heart Ball, etc. Please see the corporate **Charitable Contributions & Sponsorships Policy** (VI-3) and **AZ Representation at Charitable Fund-Raisers** (VI-2) for specific guidelines regarding support for these types of events.

4.4 Postgraduate Grants

Postgraduate grants are specific types of educational grants to institutions that allow medical students, residents, or fellows to attend carefully selected national conferences. The institution receiving the grant must choose the medical students, residents, or fellows who attend the conference. Postgraduate grants must be administered in accordance with the PhRMA Code on Interactions with Healthcare Professionals and the AMA Guidelines on Gifts to Physicians from Industry, (see **Gaining Access to Healthcare Professionals** [II-3; Exhibits D & E]).

Postgraduate grants may not be used to provide funding for practicing physicians, pharmacists, nurses, or other HCPs to attend conference

5. Requests for Independent (Nonpromotional) Education Grants

5.1 Grant Approval

The direct manager or other appropriate member of AZ management, up to the limits of their delegation of authority, must first approve all independent education grants. Grants exceeding the direct manager's delegation of authority limit are subject to approval according to the requirements in the Delegations of Authority database.

Independent (nonpromotional) education grants must be made payable to institutions, organizations, societies, or groups consistent with the FDA and the standards of the accrediting body. When a third party (eg, medical communications company) is involved, the accredited provider must be paid--**not** the third party.

Educational grants may not be used to fund an exhibit or display booth. However, the accredited provider may provide complimentary exhibit space when a grant is provided for the educational program. It is permissible for AZ to accept these offers.

5.2 Grant Processing

The amount requested for an Independent Educational Program may cover only those expenses directly related to the cost of the program including, but not limited to:

- Speaker compensation for services;
- Speaker expenses;
- Invitation creation and printing;
- Audio/visual equipment;
- Meeting room rental;
- Modest meal by local standards (see **Gaining Access to Healthcare Professionals** [II-3; Exhibit M]).

The grant recipient should return any unused money from the grant to AZ.

In order to adhere to standard accounting principles regarding prepaid expenses, grants are typically not processed more than 90 days before the date of the program or activity supported by the grant, unless specifically requested by contacting the AZ Lecture Bureau.

Education Grant requests must be received at least 45 days prior to the date of the educational program date in order to be processed by that program date. All requests that are received without a 45-day lead-time will be processed with all others according to standard first in, first out procedure. Furthermore, requests that are submitted without the 45-day lead-time will typically not be rushed ahead of those with proper lead-time. Should extenuating circumstances require that a request be processed more expeditiously, please notify the AZ Lecture Bureau of the situation. The Lecture Bureau will then make every reasonable effort to accommodate the request.

6. Letter of Agreement

AZ has developed letters of agreement to be used when arranging a grant with a recipient organization, society, or group. These letters of agreement have been tailored to the type of grant at issue. *Checks for grants will not be issued unless the grant recipient has signed the appropriate letter of agreement and the AZ Lecture Bureau has received it.*

An AZ grant letter must be signed for each education grant. Only TA Professional Relations Managers and Field Professional Education Managers may sign a grant letter of agreement from any other organization. If a member of field sales encounters a situation in which the organization requires that their letter of agreement be signed, the letter must be forwarded to the field Professional Education Department (PED) (via the AZ Lecture Bureau) for review and an appropriate signature.

AZ education grant letters of agreement have been developed to support a broad range of independent education programs that AZ may support. The language of these agreements must never be altered without review and approval of the appropriate persons within the Professional Relations, Professional Education, and Legal departments.

7. References

7.1. AZ Business Policies

Gaining Access to Healthcare Professionals (II-3); **Distribution of Enduring Materials from Independent Educational Programs** (IV-6); **Promotional Education Programs** (IV-2); **Speaker Programs** (IV-5); **Conventions/Symposia Exhibits** (IV-3); **Medical & Pharmacy Education Grants** – IV-7; **Library Grants** – IV-8; **Post-graduate Grants** – IV-9.

7.2 Attachments

Attachment 1: FDA Guidance
Attachment 2: ACCME Guidelines

Attachment I

FDA Guidance: Industry-Supported Scientific And Educational Activities[1]

I. Background: Promotion, Education, and Independence

Two important sources of information on therapeutic products (human and animal drugs, biological products, and medical devices regulated by the Food and Drug Administration [FDA]) for health care professionals are (1) Activities (programs and materials) performed by, or on behalf of, the companies that market the products; and (2) activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company. Although both provide valuable and sometimes vital information to health care professionals, the programs and materials performed and disseminated by companies are subject to the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act (the act), whereas the truly independent and nonpromotional industry-supported activities have not been subject to FDA regulation.[2]

This jurisdictional line is important because the constraints on advertising and labeling,[3] when applied to scientific and educational activities, can restrict the freedom of participants to discuss their data or express their views. In particular, discussions of unapproved uses, which can be an important component of scientific and educational activities, are not permissible in programs that are or can be (because the provider is not functionally independent) subject to substantive influence by companies that market products related to the discussion. Thus, the agency has traditionally sought to avoid regulating activities that are produced independently from the influence of companies marketing the products. The agency recognizes that industry-supported activities can be both nonpromotional and educational.

Demarcating the line between activities that are performed by or on behalf of the company, and thus subject to regulation, and activities that are essentially independent of their influence has become more difficult due to the increasing role industry has played in supporting postgraduate and continuing education for health care professionals.

The agency traditionally has recognized the important public policy reasons not to regulate all industry-supported activities as advertising or labeling. To permit industry support for the full exchange of views in scientific and educational discussions, including discussions of unapproved uses, FDA has distinguished between those activities supported by companies that are non-promotional and otherwise independent from the substantive influence of the supporting company and those that are not. Those activities that have been deemed by the agency to be independent from influence by the supporting company and nonpromotional have not been treated as advertising or labeling and have not been subjected to the agency's regulatory scrutiny.

In determining whether an activity is independent of the substantive influence of a company, the agency examines whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle. FDA is concerned that companies may influence the content of educational programs both directly and indirectly. Directly by being involved in the selection of speakers or in the treatment of

topics, indirectly through the nature of the relationship between the company and the provider (eg, if the provider has reason to believe that future financial support from the company depends upon producing programs that promote the company's products.)

FDA is responsible for seeing that scientific and educational activities that are not intended to be promotional are designed to be truly independent from substantive influence by the marketers of regulated products. The agency recognizes, however, that the primary responsibility for overseeing the process of postgraduate and continuing professional education and scientific exchange lies with the scientific and health care communities and accrediting organizations. Accordingly, FDA will work closely with scientific and professional health care communities and accrediting organizations to help ensure that provider activities are independent.

The agency is providing this guidance to describe the agency's enforcement policy with regard to scientific and educational activities supported by industry. The guidance seeks to clarify the distinction drawn by the agency between scientific and educational activities that FDA considers nonpromotional and those that the agency considers promotional and provides guidance on how industry may support such activities without subjection to regulation under the labeling and advertising provisions of the act.

This guidance applies only to those company-supported activities that relate to the supporting company's products or to competing products. A company-supported educational activity or part thereof that does not relate to the company's products or a competing product, or suggest a use for the company's products, would not be considered a promotional activity under this guidance.

II. Guidance: Industry-Supported Scientific and Educational Activities

FDA has not regulated and does not intend to regulate, under the labeling and advertising provisions of the act, industry-supported scientific and educational activities that are independent of the influence of the supporting company. Companies and providers who wish to ensure that their activities will not be subject to regulation should design and carry out their activities free from the supporting company's influence and bias, based on the factors considered in evaluating activities and determining independence as described below. These factors are provided to furnish guidance on the design and conduct of such activities so that they will be educational and non-promotional in nature. These factors will be considered as part of an overall evaluation of an activity; no individual factor is likely by itself to stimulate an action based on lack of independence.

A. Factors Considered in Evaluating Activities and Determining Independence

FDA will consider the following factors in evaluating programs and activities and determining independence:

(1) Control of Content and Selection of Presenters and Moderators

The agency will consider whether the provider has maintained full control over the content of the program, planning of the program's content, and over the selection of

speakers and moderators. In so doing, the agency will look at whether the supporting company has engaged in scripting, targeting points for emphasis, or other actions designed to influence the program's content. In addition, the agency will consider if the company has suggested speakers who are or were actively involved in promoting the company's products or who have been the subject of complaints or objections with regard to presentations that were viewed as misleading or biased in favor of the company's products.

(2) Disclosures

The agency will consider whether there was meaningful disclosure, at the time of the program, to the audience of (1) the company's funding of the program; (2) any significant relationship between the provider, presenters or moderators, and the supporting company (eg, employee, grant recipient, owner of significant interest or stock); and (3) whether any unapproved uses of products will be discussed.

(3) The Focus of the Program

The agency will consider whether the intent of the company and the provider is to produce an independent and nonpromotional activity that is focused on educational content and free from commercial influence or bias. The agency will also consider whether the title of the activity fairly and accurately represents the scope of the presentation.

The agency also will look at the focus of the activity to determine if the central theme is based on a single product marketed by the company or a competing product, except when existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies. This is not to suggest that each treatment option must be discussed with precisely equal emphasis. However, emphasis on a newer or, in the view of the presenter, more beneficial treatment modality should be provided in the context of a discussion of all reasonable and relevant options.

(4) Relationship Between Provider and Supporting Company

The agency will consider whether there are legal, business, or other relationships between the company and the provider that could place the company in a position whereby it may exert influence over the content of the activity (eg, a provider that is owned by, or is not viable without the support of, the company supporting the activity).

(5) Provider Involvement in Sales or Marketing

The agency will consider whether individuals employed by the provider and involved in designing or conducting scientific or educational activities are also involved in advising or otherwise assisting the company with respect to sales or marketing of the company's product.

(6) Provider's Demonstrated Failure to Meet Standards

The agency will consider whether the provider has a history of conducting programs that fail to meet standards of independence, balance, objectivity, or scientific rigor when putting on ostensibly independent educational programs.

(7) Multiple Presentations

The agency will consider whether multiple presentations of the same program are held.[4]

(8) Audience Selection

The agency will consider whether invitations or mailing lists for supported activities are generated by the sales or marketing departments of the supporting company, or are intended to reflect sales or marketing goals (eg, to reward high prescribers of the company's products or to influence "opinion leaders").

(9) Opportunities for Discussion

In the case of a live presentation, the agency will consider whether there was an opportunity for meaningful discussion or questioning provided during the program.

(10) Dissemination

The agency will consider whether information about the supporting company's product presented in the scientific or educational activity is further disseminated after the initial program, by or at the behest of the company, other than in response to an unsolicited request or through an independent provider as discussed herein.

(11) Ancillary Promotional Activities

The agency will consider whether there are promotional activities, such as presentations by sales representatives or promotional exhibits, taking place in the meeting room.

(12) Complaints

The agency will consider whether any complaints have been raised by the provider, presenters, or attendees regarding attempts by the supporting company to influence content.

B. Additional Considerations

The foregoing list of factors is not intended to be exhaustive and other factors may be appropriate for consideration in a particular case.

One means of documenting the measures taken to ensure independence of an activity is to have a written agreement between the provider and the supporting company. This document should reflect that the provider will be solely responsible for designing and conducting the activity, and that the activity will be educational, nonpromotional, and free from commercial bias. While not required, a written agreement, coupled with the factors described above, can provide valuable evidence as to whether an activity is independent and nonpromotional.

III. FDA's Cooperation with Major Accrediting Organizations

FDA recognizes the important role accrediting organizations can play in ensuring that industry-sponsored educational activities are independent and nonpromotional. The agency also recognizes the importance of avoiding undue Government interference in postgraduate and continuing education for health care professionals, as the agency seeks to ensure that company promotional activities meet applicable legal requirements. Thus, the agency will continue to work with major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers.

End Note:

1 62 Fed. Reg. 64074 (Dec. 3, 1997). This guidance has been prepared by FDA's Intra-Agency Working Group on Advertising and Promotion. This guidance represents the Agency's current thinking on industry-supported scientific and educational activities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the industry. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

2 In this context, the terms "independent" and "nonpromotional" are not mutually exclusive. The agency views independence as an indication of whether an activity is nonpromotional.

3 These provisions require the company to ensure that the content does not promote unapproved uses, and that discussions of the company's products are not false or misleading and do not lack fair balance.

4 FDA recognizes that some repeat programs can serve public health interests. The Department of Health and Human Services sometimes actively encourages multiple presentations on selected urgent topics.

Attachment II

ACCME Standards

The Accreditation Council for Continuing Medical Education (ACCME) has published guidelines governing industry support for CME programs. The ACCME standards are reprinted below, followed by ACCME Questions and Answers interpreting the guidelines.

STANDARDS FOR COMMERCIAL SUPPORT OF CONTINUING MEDICAL EDUCATION (March 20, 1992)

Preamble

The purpose of continuing medical education (CME) is to enhance the physician's ability to care for patients. It is the responsibility of the accredited sponsor of a CME activity to assure that the activity is designed primarily for that purpose.

Accredited sponsors often receive financial and other support from nonaccredited commercial organizations. Such support can contribute significantly to the quality of CME activities. The purpose of these Standards is to describe appropriate behavior of

accredited sponsors in planning, designing, implementing, and evaluating certified CME activities for which commercial support is received.

STANDARDS

1. General Responsibilities of Accredited Sponsors

Accredited sponsors are responsible for the content, quality, and scientific integrity of all CME activities certified for credit. Identification of continuing medical education needs, determination of educational objectives, and selection of content, faculty, educational methods, and materials is the responsibility of the accredited sponsor. Similarly, evaluation must be designed and performed by the accredited sponsor.

a. Basic Design Requirements for CME Activities

In designing educational activities, the accredited sponsor must assure that the activities have the following characteristics: they must be free of commercial bias for or against any product; if the activities are concerned with commercial products, they must present objective information about those products, based on scientific methods generally accepted in the medical community.

b. Independence of Accredited Sponsors

The design and production of educational activities shall be the ultimate responsibility of the accredited sponsor. Commercial supporters of such activities shall not control the planning, content or execution of the activity. To assure compliance with this standard, the following requirements must be adhered to:

(1) Assistance with Preparation of Educational Materials

The content of slides and reference materials must remain the ultimate responsibility of the faculty selected by the accredited sponsor. A commercial supporter may be asked to help with the preparation of conference related educational materials, but these materials shall not, by their content or format, advance the specific proprietary interests of the commercial supporter.

(2) Assistance with Educational Planning

An accredited sponsor may obtain information that will assist in planning and producing an educational activity from any outside source whether commercial or not. However, acceptance by an accredited sponsor of advice or services concerning speakers, invitees, or other educational matters, including content, shall not be among the conditions of providing support by a commercial organization.

(3) Marketing CME Activities

Only the accredited sponsor may authorize a commercial supporter to disseminate information about a CME activity to the medical community. However, the content of such information is the responsibility of the accredited

sponsor, and any such information must identify the educational activity as produced by the accredited sponsor.

(4) Activities Repeated Many Times

Accredited sponsors that offer commercially supported educational activities that repeat essentially the same information each time they are given, must demonstrate that every iteration of that activity meets all of the Essentials and Standards.

(5) Educational Activities or Materials Prepared by Proprietary Entities

When accredited sponsors offer educational activities consisting of concepts or materials prepared by proprietary entities, such activities must adhere to the Essentials and Standards in all respects, especially with regard to the provisions concerning the independence of the accredited sponsor in planning, designing, delivering, and evaluating such activities.

2. Enduring Materials

The accredited sponsor is responsible for the quality, content, and use of enduring materials for purposes of CME credit. (For the definition, see ACCME "Standards for Enduring Materials.")

3. Identifying Products, Reporting on Research, and Discussing Unlabeled Uses of Products

a. Generic and Trade Names

Presentations must give a balanced view of therapeutic options. Faculty use of generic names will contribute to this impartiality. If trade names are used, those of several companies should be used rather than only that of a single supporting company.

b. Reporting Scientific Research

Objective, rigorous, scientific research conducted by commercial companies is an essential part of the process of developing new pharmaceutical or other medical products or devices. It is desirable that direct reports of such research be communicated to the medical community. An offer by a commercial entity to provide a presentation reporting the results of scientific research shall be accompanied by a detailed outline of the presentation, which shall be used by the accredited sponsor to confirm the scientific objectivity of the presentation. Such information must conform to the generally accepted standards of experimental design, data collection, and analysis.

c. Unlabeled Uses of Products

When an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose, is discussed during an educational activity, the accredited sponsor shall require the speaker to disclose that the product is not labeled for the use under discussion or that the product is still investigational.

4. Exhibits and Other Commercial Activities

a. Exhibits

When commercial exhibits are part of the overall program, arrangements for these should not influence planning or interfere with the presentation of CME activities. Exhibit placement should not be a condition of support for a CME activity.

b. Commercial Activities During Educational Activities

No commercial promotional materials shall be displayed or distributed in the same room immediately before, during, or immediately after an educational activity certified for credit.

c. Commercial Supporters at Educational Activities

Representatives of commercial supporters may attend an educational activity but may not engage in sales activities while in the room where the activity takes place.

5. Management of Funds from Commercial Sources

a. Independence of the Accredited Sponsor in the Use of Contributed Funds

The ultimate decision regarding funding arrangements for CME activities must be the responsibility of the accredited sponsor. Funds from a commercial source should be in the form of an education grant made payable to the accredited sponsor for the support of programming. The terms, conditions, and purposes of such grants must be documented by a signed agreement between the commercial supporter and the accredited sponsor. All support associated with a CME activity, whether in the form of an educational grant or not, must be given with the full knowledge and approval of the accredited sponsor. No other funds from a commercial source shall be paid to the director of the activity, faculty, or others involved with the supported activity.

b. Payments to Faculty

Payment of reasonable compensation for services and reimbursement of out-of-pocket expenses for faculty is customary and proper.

c. Acknowledgment of Commercial Support

Commercial support must be acknowledged in printed announcements and brochures; however, reference must not be made to specific products.

d. Accountability for Commercial Support

Following the CME activity, upon request, the accredited sponsor should be prepared to report to each commercial supporter, and other relevant parties, information concerning the expenditure of funds each has provided. Likewise, commercial supporters should report to the accredited sponsor information concerning their expenditures in support of the activity.

6. Commercially Supported Social Events

Commercially supported social events at CME activities should not compete with nor take precedence over the educational events.

7. Policy on Disclosure of Faculty and Sponsor Relationships

a. Disclosure Policy for All CME Activities

An accredited sponsor shall have a policy requiring disclosure of the existence of any significant financial interest or other relationship a faculty member or the sponsor has with the manufacturer(s) of any commercial product(s) discussed in an educational presentation. All certified CME activities must conform to this policy.

b. Disclosure in Conference Materials

CME faculty or sponsor relationships with commercial supporters shall be disclosed to participants prior to educational activities in brief statements in conference materials such as brochures, syllabi, exhibits, poster sessions, and also in postmeeting publications.

c. Disclosure for Regularly Scheduled Activities

In the case of regularly scheduled events, such as grand rounds, the moderator of the activity shall make disclosure after consultation with the faculty member or a representative of the supporter. Written documentation that disclosure information was given to participants shall be entered in the file for that activity.

8. Financial Support for Participants in Educational Activities

a. Expenses of Non-Faculty Attendees

In connection with an educational activity offered by an accredited sponsor, the sponsor may not use funds originating from a commercial source to pay travel, lodging, registration fees, compensation for services, or personal expenses for non-faculty attendees. Subsidies for hospitality should not be provided outside of modest meals or social events that are held as part of the activity.

b. Scholarships for Medical Students, Residents, and Fellows

Scholarship or other special funding to permit medical students, residents, or fellows to attend selected educational conferences may be provided, as long as the selection of students, residents, or fellows who will receive the funds is made either by the academic or training institution or by the accredited sponsor with the full concurrence of the academic or training institution.

HYPOTHETICAL QUESTIONS AND ANSWERS ON THE ACCME STANDARDS FOR COMMERCIAL SUPPORT OF CME (MARCH, 1993)

Preamble

The ACCME Standards for Commercial Support of Continuing Medical Education, which became effective May 1992, are an attempt to prevent undue interference and control of continuing medical education by commercial interests. The Food and Drug Administration, which has a legislative mandate to regulate the pharmaceutical industry, has had the perception that a substantial amount of product promotion occurs under the guise of continuing medical education. The FDA apparently believed that regulation of CME also would control these promotional activities. The ACCME, and others, have been negotiating with the FDA to modify their original concepts. These Standards are an expansion of previous ACCME Guidelines for Commercial Support (1984 and 1991) and address many of the FDA's specific concerns so that independent continuing medical education activities can continue to receive commercial support without interference from the FDA. There are three basic concepts that recur throughout the Standards:

1. The accredited sponsor is responsible for every aspect of an activity it certifies for credit.

2. Education and promotion should not be mixed, either in design or in publicity materials.

3. The audience is entitled to know if funds have been supplied by a commercial source and whether there is any relationship between the speakers and the company/companies supporting the activity. The audience is also entitled to know if a speaker has a "significant" relationship with any commercial company.

Following are a series of hypothetical questions and answers addressing some of the issues that may arise when implementing the Standards for Commercial Support.

Hypothetical Questions

1. ***Question:*** In the case of medical schools, what is considered the accredited entity, the entire medical school or the office of continuing medical education? Who is held responsible for compliance with the Standards?

   Answer: The medical school is the accredited institution. The Guidelines to Essential #6 state that the sponsor (the accredited entity) "must designate an entity responsible for CME and delineate its authority." The "keeper of quality" in a medical school is the CME

unit, which must be able to demonstrate its involvement in all aspects of the medical school's continuing education program, including compliance with the Standards.

2. ***Question:*** What's wrong with an accredited sponsor selecting a speaker from a "speaker's list" provided by a company if the sponsor has an identified need for a speaker on that particular subject?

   Answer: When the sponsor has identified the need for a particular topic, the sponsor can seek information from one or more sources, including commercial companies, about appropriate speakers for the identified need [Standard 1.b(2)]. However, the initiative should not come from a company representative or third party agency, which presents a list of speakers and asks the sponsor to "pick one." Input from multiple sources will contribute to objectivity and balance.

3. ***Question:*** Is it appropriate for a representative of the company that is supporting a CME activity through an educational grant to pick up faculty members at the airport, transport them to the meeting site, take them out to dinner, etc?

   Answer: Generally, no. If the company representative establishes a relationship with a speaker, that speaker then may have some sense of obligation toward the company rather than toward the accredited sponsor that is presenting the CME activity.

4. ***Question:*** What must an accredited sponsor do to assure that a CME activity is free of commercial bias?

   Answer: The sponsor must maintain complete control over all aspects of the educational planning and implementation process, including selection of topics and speakers and control of funding. The likelihood of a biased presentation will be greatly minimized because the program director and/or the sponsor's planning committee will be "in control" of all aspects of the activity.

5. ***Question:*** Who makes the decision about the amount of an honorarium, the company or the accredited provider?

   Answer: Decisions about the amount of honorarium to be paid to a speaker are the responsibility of the accredited sponsor. The sponsor should determine what constitutes a "reasonable honorarium" for invited speakers and negotiate directly with the speaker. If the speaker does not wish to accept the amount offered, an alternate speaker should be identified. It is not appropriate for the supporting company to determine the size of the honorarium.

6. ***Question:*** CME sponsors will be paying speakers' honoraria more than in the past when commercial companies paid the speaker. Where can they get information or help on what are reasonable fees?

   Answer: There is no directory or guide on appropriate honoraria and the amount will vary according to the amount of time and effort expected from the speaker, specialized knowledge of the speaker (could someone else give the presentation?), location of the activity (distance and time away), and budget. A suggestion might be to contact

colleagues in similar institutions to determine what others are offering for similar presentations.

7. ***Question:*** Is it appropriate for company representatives/communication companies to contact faculty about logistical details and content of presentations? To what extent must the accredited sponsor be involved with the logistics of the CME activity?

   Answer: The accredited sponsor is expected to control all aspects of the educational part of an activity, which would include contacts with faculty, design of promotional materials and handouts, collecting registration fees, and paying speakers. Logistical details, such as printing of promotional materials and handouts, hotel arrangements, planning social events, etc may be handled by any agency the sponsor chooses to employ, but all such activities must be directed and controlled by the accredited sponsor.

8. ***Question:*** Do the Standards apply only to AMA/PRA Category 1 or do they also apply to Category 2 credits?

   Answer: The AMA has stated that the Standards apply to all CME activities designated for AMA/PRA credit.

9. ***Question:*** Is it necessary to have a document on file for every faculty member who participates in a program receiving commercial support?

   Answer: Yes, a disclosure statement from every faculty member is necessary. Standard 7a. requires accredited sponsors to "have a policy requiring disclosure of the existence of significant financial interest or other relationship with the manufacturer(s) of any product(s) discussed in an educational presentation." The sponsor must be able to document that faculty were asked about possible relationships and that the audience was informed when such relationships were found to exist. Disclosure to the audience may be either oral or written.

10. ***Question:*** Is there a written statement that discourages (or forbids) the use of third parties to provide speakers (*ie*, speakers bureaus)?

    Answer: Yes, Standard 1.b (5) addresses third parties. As in all other relationships with industry, direct or indirect, the initiative must come from the accredited sponsor, which may ask for suggestions, but a speakers list should not be offered without such prior request [see 1.b (2)].

11. ***Question:*** Must grant money be paid directly to the accredited sponsor to cover speaker expenses or can it be paid to the speaker by a third party?

    Answer: A third party company is considered to be an agent of the organization that contracts for its services. If it is an agent of a commercial company, then it is not appropriate to pay speakers directly. If it is an agent of the sponsor, the sponsor may choose to designate another entity to handle logistics, including payment of expenses related to the CME activity, always, of course, under the sponsor's direction and control.

12. ***Question:*** Are there instances where it is appropriate for the pharmaceutical company to pay a speaker's expenses directly?

Answer: Commercial support should always be in the form of an educational grant made payable to the accredited sponsor. The only exception is when it is impossible for the sponsor to accept grants or to directly pay a faculty member. In that case, the sponsor must document one or more compelling reasons that prevent receiving commercial funds as a grant. For institutions that are prohibited from accepting grant support, the decision on how support will be paid must always be made by the accredited sponsor, not by the company supplying the funds.

13. ***Question:*** Commercial support sometimes is not actually received until the last minute, or even after the meeting. On the other hand, faculty are usually contacted and committed well in advance. Is it necessary to recontact faculty for disclosure statements in such situations?

    Answer: The determining factor is the principle that "the audience is entitled to know." Standard 7(a) requires disclosure of a financial interest or other relationship a faculty member has with the manufacturer of any product(s) discussed in the presentation, not only with the supporting company (if any).

14. ***Question:*** If one of our attending staff speaks at our own CME activity, such as grand rounds, is a disclosure statement required?

    Answer: Yes, as in the above question, the audience is entitled to know, and the speaker has an obligation to disclose, any significant financial relationship with a company; therefore, disclosure statements should be requested from all speakers at all CME activities. With in-house faculty, one disclosure statement could cover a number of CME activities on the same subject at the same institution.

15. ***Question:*** If a CME provider receives no commercial support for a CME activity, is the faculty still required to complete a disclosure statement?

    Answer: Yes, Standard 7(a) states that "all certified CME activities" shall conform to the sponsor's policy on faculty disclosure.

16. ***Question:*** Does disclosure apply only to faculty relationships with pharmaceutical companies or does it also apply to relationships with other companies, eg, medical device manufacturers, malpractice insurance companies, etc?

    Answer: If the company supplying an educational grant sells a product or provides a service for which compensation is received, faculty disclosure of relationships is required.

17. ***Question:*** Does faculty disclosure apply only to current relationships or should sponsors try to determine past relationships also?

    Answer: Disclosure should be requested of any relationships that may be perceived as having potential conflict of interest.

18. ***Question:*** Can grant support be used to reduce registration fees? If so, by how much?

Answer: Not directly. Grant support can be used to offset the total costs of a CME activity so the sponsor may choose to reduce registration fees. Decisions about the use of grant support must be that of the sponsor, without grantor designation or allocation for a specific purpose such as reduced registration fees. Support may also be used to provide scholarships for students and residents for appropriate, carefully selected educational activities.

19. ***Question:*** If commercial support is provided for an activity relating to a nonclinical topic, eg, risk management, does the faculty disclosure Standard still apply?

Answer: Yes. If the speaker has a relationship to any service or product relevant to the subject under discussion, it must be disclosed. When in doubt, it is always wiser for the sponsor to require faculty disclosure.

20. ***Question:*** Is it acceptable to use a product name in a CME activity title if there are no competing products on the market?

Answer: No. Generic names are acceptable, but trade names should not be used in CME activity titles unless the activity is intended to be promotional. Trade names may be used as part of a balanced (ie, discussion of other drugs and/or therapeutic options) educational presentation for that particular disease or problem.

21. ***Question:*** In joint sponsorship, what is the responsibility of the accredited sponsor with regard to soliciting or receiving grants from industry or assistance from third parties?

Answer: The responsibility for handling all funds rests with the accredited sponsor; the nonaccredited joint sponsor should not be soliciting support for an activity controlled by the accredited sponsor, except with the knowledge and approval of the accredited sponsor, which has the ultimate responsibility and accountability.

22. ***Question:*** Must generic names always be used in discussions of products and treatments?

Answer: In general, yes. In order to decrease the chances of promotional intent, generic names are preferred. In practice, it is sometimes necessary to use generic and product names because generic names may not be recognized by the audience. Nevertheless, presentations must be balanced, with discussion of both benefits and risks of the treatment, as well as alternative products and therapies.

23. ***Question:*** May scholarships for residents or fellows be paid directly or must these funds also be in the form of a grant? Who decides what meetings residents or fellows may attend?

Answer: Scholarships may not be paid directly. All commercial support, for any purpose, should be in the form of a grant. The decision regarding which meetings are appropriate for residents or fellows to attend must be made by their academic institution or by the accredited sponsor. The important words in Standard 8.b are "selected educational conferences" (eg, the annual meeting of their national specialty society). Support may not be used to send residents or fellows to meetings selected by the supporting company.

24. ***Question:*** Why does Standard 3.c require disclosure about off-label or unlabeled use of products? Doesn't this restrict the flow of scientific information?

Answer: The Food and Drug Administration, which has the legislative mandate to regulate the pharmaceutical industry, is concerned about the possible public health consequences of unrestricted discussion of off-label uses of drugs and/or devices. The ACCME Standard requiring disclosure of unapproved uses during presentations or discussions has caused the FDA to modify their original position thus permitting continued discussion of important and valuable off-label uses of products, provided the audience is advised that the use under discussion has not yet been approved in the United States.

25. ***Question:*** Are commercial exhibits at meetings considered commercial support?

Answer: Yes, commercial exhibits at educational events are an important source of income for sponsors. However, since exhibits are usually solicited by the sponsor and it is an arrangement for which the company receives something tangible in return, it is not the same as an unrestricted educational grant. The Standards require that a grant in support of the educational portion of the program must not be contingent upon permission for an exhibit.

26. ***Question:*** Is it acceptable to use grant money to provide a meal function for spouses/guests that is served separately from meeting participants?

Answer: No, because the grant is in support of the educational activity.

27. ***Question:*** Could a spouse luncheon be interpreted as a modest social event as part of a CME meeting?

Answer: No, unless the physician/registrants attend the luncheon and it occurs in conjunction with the meeting.

28. ***Question:*** Is it acceptable for a company to provide dinner cruises, theater tickets, basketball tickets, etc for participants and guests, following an educational activity?

Answer: In general, no. The AMA's Guidelines on Gifts to Physicians from Industry state that social events should be conducive to discussion and exchange of ideas, thus basketball games and theater events do not fit that description. The cost of the social activity should be "modest" and the number of hours devoted to the educational portion of the program should substantially outweigh the number of hours of the social event. Any social activities held in conjunction with an educational program should be approved in advance by the accredited sponsor to avoid a possibly embarrassing situation.

29. ***Question:*** What can ACCME do about nonaccredited institutions that sponsor promotional activities and advise physicians to claim Category 2 credit?

Answer: Credit issues are the responsibility of the AMA and are not within the authority of the ACCME, nor does ACCME have any control over nonaccredited sponsors. However, the AMA has revised the PRA so that Category 2 credit for formal instruction

may only be designated by accredited sponsors. Therefore, promotional programs cannot be designated or self-claimed for credit. Promotional CME activities, whether sponsored by an accredited or nonaccredited provider, fall under the jurisdiction of FDA regulations regarding promotional activities.

30. ***Question:*** If the sponsor selects the speakers, topics, etc and follows all of the essentials, why can't a company pay the speaker directly?

Answer: Direct payment of an honorarium or expenses establishes a relationship between the speaker and the company. This relationship creates the potential (conscious or unconscious) for bias in a presentation. It is in the best interest of both the sponsor and the faculty speaker to avoid even the appearance of a conflict of interest.

31. ***Question:*** If commercial support is provided for a series of short activities (eg, grand rounds), is a separate letter of agreement and disclosure information required for each or can they be combined?

Answer: Separate disclosure statements are required from each faculty member. If one company is supporting the series, the letter of agreement should specify the topics to be covered in the series, but a separate letter of agreement for each activity may not be necessary.

32. ***Question:*** Is it permissible for the company providing support to purchase airline tickets for speakers to reduce the need for a small institution to handle these funds?

Answer: In general, no. However, if a sponsor agrees to permit the supporting company to purchase airline tickets, the tickets should be sent to the speaker by the sponsor, not by the company, to minimize contact between the speaker and the supporting company.

33. ***Question:*** In the case of regularly scheduled events (eg, grand rounds) where verbal disclosure by the moderator would be appropriate, what should be included in the disclosure?

Answer: The moderator can state that the speaker has a financial relationship with Company X. The nature of the relationship is not necessarily relevant but can be disclosed if the speaker wishes. A note can be inserted in the CME activity file that the speaker was asked and disclosure was made to the audience.

34. ***Question:*** In determining faculty relationships to commercial companies, what constitutes a "significant financial interest"?

Answer: The ACCME has not defined "significant financial interest," preferring to leave that determination to sponsors, based upon each institution's own ethical guidelines. Some organizations have set an arbitrary dollar amount; others make case-by-case decisions. The individual faculty member should consider what others might perceive to be a conflict of interest, such as ownership of stock, research grants, honoraria, or consulting fees.

AstraZeneca

Promotional Education Programs

Policy No.: **IV-2**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Since AstraZeneca (AZ) may exert control over certain aspects of these programs, they are considered promotional by the FDA and cannot be accredited for CE;**
- **Only PRA approved topics can be the subject of a Speaker Program;**
- **Any references to AZ products or those manufactured by competitors must be made in an objective and balanced manner and consistent with the approved product label;**
- **Full prescribing information (PI) for any AZ product discussed must be offered to each program attendee;**
- **Compensation for services check requests for Speaker Programs must be entered into COMPASS;**
- **All speakers must have signed a current speaker contract prior to speaking on AZ's behalf and the original signed contract must be on file with the Lecture Bureau in order to process compensation for services requests;**
- **All moderators for Case Study programs must sign a corresponding contract for each Program in which they participate prior to the program occurring.**
- **PSSs must not encourage speakers to discuss off-label topics.**

2. Purpose

To state AZ's commitment to conducting or underwriting *promotional* education programs for its customers in accordance with all applicable laws, guidelines, and regulations and to generally describe AZ professional education programs. Since AZ may have control over certain aspects of these programs, such as subject matter/topic, audience selection, and/or speaker selection, these programs will typically be viewed as promotional by the FDA and subject to FDA regulations. These programs will have to comply with FDA promotional guidelines.

3. Policy

3.1. General Policy

3.1.1. AZ provides a means to provide financial support for high quality, ethical and scientifically sound medical education activities for the healthcare community. **Since AZ has control, whether it is partial or full control, over certain aspects of such an educational program, the program will typically be regarded as promotional by the FDA and is, therefore, subject to FDA regulation.**

3.1.2. Continuing education credits are not available for speaker programs categorized as promotional. If AZ seeks to maintain control over the content of the program or the selection of the audience or speaker, CE credit may not be provided. Nonpromotional programs, including CE, are discussed in the policy on **Independent (Nonpromotional) Education & Related Grants** (IV-1).

3.1.3. The opportunity to be a speaker or otherwise participate in AZ promotional education programs must never be offered to a provider (ie, physician, pharmacist or other healthcare professional (HCP), including a pharmacy director, PBM executive or other personnel of a managed care organization, hospital, etc.) with "strings attached" (eg, in exchange for, or in consideration of, current or future prescribing, use, formulary inclusion, or favorable status, or recommending of AZ products, *see* **Gaining Access to Healthcare Professionals**, [II-3]).

3.2. Speaker Programs

3.2.1. Promotional medical education programs are typically programs for which a speaker delivers a lecture or facilitates a discussion on a preapproved topic to an audience of HCPs. These programs include a variety of formats where an AZ employee organizes the speaking event and selects the audience and speaker. Only talk topics approved by PRA for promotional purposes may be used for these professional education

programs. Programs must not be conducted using talk topics that are not approved for promotional speaker programs disguised as approved titles (ie, conducting an unapproved talk but using an approved talk title on the program request).

3.2.2. It is not the role of a speaker to draw specific attention to any AZ product during a presentation. Any references to AZ products or those of competitors must be made in an objective and balanced manner and consistent with the approved product label. Any AZ employee who learns that a speaker has failed to give a balanced presentation and has failed to remain consistent with the approved product label must report this information to AZ. If a speaker repeatedly fails to give a balanced presentation that remains within labeling, AZ will no longer use that speaker for Company-sponsored programs. AZ employees involved in conducting a program must ensure that full prescribing information (PI) for any AZ product discussed is offered to each program attendee.

3.3. Compensation for Services

3.3.1. AZ has determined standard compensation for services for speakers at each type of promotional education program. Compensation for services should be determined according to the appropriate AZ standard for the role of the speaker and type of program being delivered. No commitment should be made to pay any non-standard compensation for services without prior approval by the Professional Education Department (PED). Reasons for compensation for services outside the standard ranges include, but are not limited to the following criteria:

- The program requires more preparation for the speaker than most programs, eg, A/V presentation where slides are not provided by the company or easily accessible;
- The size of the program is smaller or larger than most programs;
- The program involves discussion of unusually complex subjects;
- The program requires additional travel time that will keep the speaker away from the office for an extended period;
- The actual Fair Market Value (FMV) of that speaker's time is less than or greater than the standard amount.

Compensation for services must never be determined based on the speaker's current or potential prescribing levels or ability to influence prescribing choices of other HCPs. Target status of an HCP is never appropriate justification for increasing or modifying compensation for services.

3.3.2. Compensation for services for promotional education programs should be paid directly to the speakers using their social security numbers or Federal tax identification numbers if they are legally incorporated.

- If compensation for services is paid to an organization, it must be paid to the speaker's own organization or to the organization for which the speaker directly works;

- **In order to maintain compliance with IRS regulations, AZ may not pay a speaker's compensation for services directly to a charitable organization on behalf of that speaker.** Speakers must claim their compensation for services as income and then they may donate the money to the charitable organization. Speakers may waive the compensation for services if they so choose (but they still must sign an AZ speaker contract to meet other program requirements);

- An educational grant, payable to another organization, society, or group as discussed in the policy **Independent (Nonpromotional) Education & Related Grants** (IV-1), may not be given as a substitute for the compensation for services payment to the speaker;

- For programs that AZ cancels 14 days or less prior to the program date, AZ will honor the commitment to pay the speaker or moderator compensation for services provided that a written agreement (speaker or moderator contract) has been completed prior to the program being cancelled.

3.3.3 Compensation for services may only be paid to the speaker who is providing bona fide services. Attendees of programs may not receive compensation for services, unless they are also participating in the program as a speaker or presenter and are rendering bona fide services.

3.4. Reimbursement of Speaker Expenses

AZ will reimburse speakers for properly documented and reasonable travel, lodging, and meal expenses directly related to the services they provide in conjunction with the speaker program. AstraZeneca may also arrange for travel and lodging for the speaker through Carlson WagonLit and have the charges directly billed to AZ. Travel and lodging assistance should be arranged by contacting the AZ Lecture Bureau. Travel, lodging and individual meal expenses for participants in Case Study Programs and for attendees at all other speaker programs are not reimbursable by AZ.

3.5 Contracts

3.5.1. AZ has prepared contractual agreements for use with all types of promotional education programs. These contractual agreements must be completed prior to the program being held. AZ will not pay compensation for services or reimburse expenses to speakers unless the designated agreement has been signed by both AZ and the speaker and has been received by AZ.

3.5.2. For speaker programs, one speaker agreement must be signed for the time period designated in the agreement. This agreement will be valid for all speaker programs conducted during this time period.

3.5.3. For Case Study Programs, one agreement must be signed every time an HCP moderates a Case Study Program.

3.5.4. If a speaker is a Federal government employee (full time or part time), he or she must also complete an AZ Federal Provider Form. This agreement is valid for the time period specified in the agreement for all bona fide services provided to AZ for which they are eligible to receive compensation for services.

3.5.5. Changes or modifications to the AZ contractual agreements are not allowed unless reviewed and approved by the Professional Education (PED) and Legal departments.

3.6 Event-Related Material

All material distributed in association with any AZ supported speaker programs (invitations, promotional items, flyers, handouts, etc.) must be approved through the eSTaR Process (see **Development of Promotional Materials & Related Items** [II-2]). Reminder items may also be distributed as part of the event related materials but they must be company-approved reminder items.

In addition to a collateral meal (see 4. Collateral Meals), items may be provided to attendees in recognition of their participation providing they are primarily for the benefit of patients and are not of substantial value (FMV of $100 or less). Items of minimal value (less than $35 FMV) may be offered if they are primarily associated with an HCP's practice (such as pens, notepads, and similar reminder items). These items may be branded with the Company logo or appropriate product logo. No cash payments or gift certificates are acceptable as a giveaway or reminder item. Items intended for the personal benefit of the HCPs may not be offered.

Payments in cash or cash equivalents (such as gift certificates) may not be offered to HCPs either directly or indirectly, except as compensation for bona fide services.

4. Collateral Meals

Meals which are modest by local standards (see **Gaining Access to Healthcare Professionals** [II-3; Exhibit M]) and designed to increase attendance at a program may be provided at Speaker and Case Study Programs; however, the speaker/educational portion of any program must dominate the agenda and any meal must be incidental to the overall program. These types of meals are called "Collateral Meals" since they are in conjunction with a speaking or other educational event. The perception of engaging customers in "token" educational activities as a means to provide a meal must be avoided in all instances. The educational portion of the program must be dominant on any invitation or flyer distributed for the program, not the meal. If a speaker program has a collateral meal associated with it, the cost of the meal may not exceed a total of $50 per HCP excluding tax and tip (COLA applies) The inclusion of these types of activities in conjunction with a speaking or other educational program will not count against the frequency limits under the policy on **Gaining Access to Healthcare Professionals** (II-3; Exhibit A).

Because of the educational focus of these programs, spouses, other family members, and/or guests may not be invited to speaker programs or any collateral meal. If a spouse/guest is an HCP (pharmacist, nurse, etc) who may benefit from the content of the speaker program, then he/she may be invited to the program.

5. References

5.1. AZ Business Policies

Patient Privacy (I-6); **Product Promotion** (II-1); **Gaining Access to Healthcare Professionals** (II-3); **Independent (Nonpromotional) Education & Related Grants** (IV-1).

IV – 3 Convention/Symposia
Exhibits

AstraZeneca

Convention/Symposia Exhibits

Policy No.: **IV-3**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2001**

Contents

1. Key Learnings

- **All product specific promotional and scientific exhibits/activities at conventions held in the US are under the jurisdiction of the US FDA;**
- **Commercial exhibits must conform to the regulations listed under 21 CFR § 202 Prescription Drug Advertising and can only include information on products approved in the US;**
- **Scientific exhibits must conform to the regulations listed under 21 CFR § 312.7 (a) Promotion of an Investigational Drug;**
- **Participation at a convention pre-briefing is MANDATORY for all AZ employees staffing exhibits and recommended for other AZ attendees; the assigned PRA representative must review the important points with any AZ employee who misses this briefing.**

2. Purpose

To provide the ability to fund and staff exhibits held in the US in a variety of available venues, whether the exhibit is related to a symposium, convention, or other program type, or the exhibit is freestanding without a related program.

3. Policy

This policy is applicable to conventions, local meetings, symposia, and hospital displays held in the US. For US participation in conventions held outside of US, the rules of the specific country would apply except for those policies and guidelines that cover US Healthcare Professionals (HCPs) and related spending guidelines. Reasonable efforts must be made to follow all US Policy spending guidelines for meals in **Gaining Access to Healthcare Professionals** (III-3, Exhibit A) and **Engaging Healthcare Professionals in Global Activities** (III-9). Market Research activity conducted independently by a third-party provider independent from commercial or scientific activity is not covered in this policy (see **Marketing Research Projects** [III-7]).

3.1 Overview

All product specific promotional and scientific activities at conventions held in the US, whether from non-US or US sources, are under the jurisdiction of the US FDA. Therefore, US-specific regulatory requirements must be followed. US exhibit booths at conferences held outside the US with US attendees are expected to follow FDA guidelines and regulations as well. The AZ Promotional Regulatory Affairs and Legal departments must be consulted on a case-by-case basis for exceptions.

AZ has identified two categories of exhibits: scientific and commercial. Each category serves a different and unique purpose and should have a different focus. It is critical that all materials and activities taking place in the exhibits preserve the integrity of each exhibit category, that they are "separate and distinct," and that the distinction between the two are not blurred. Commercial exhibits must conform to the regulations listed under 21 CFR § 202 *Prescription Drug Advertising*, and scientific exhibits must conform to the regulations listed under 21 CFR § 312.7 (a) *Promotion of an Investigational Drug*. While only information on products approved in the US may be provided in the commercial exhibits, exchange of scientific information on investigational products is allowed at the scientific exhibits. However, representation that the investigational product is safe and effective for the indication/use discussed is not permitted.

3.2 National Conventions and Meetings

For national conventions and meetings, all floor plans, activities, prebrief training, and information/material/items to be disseminated at all exhibits must be reviewed and approved through the eSTaR Review Process. Items primarily for the benefit of patients may be offered to HCPs if they are not of substantial value (FMV $35 or less). Items of minimal value may be offered if they are primarily associated with an HCP's practice (such as pens, notepads, and similar reminder items with company or product logos). These items must also be less than $35 FMV.

It is strongly recommended that all AZ attendees at national conventions attend a pre-convention briefing before being able to work at the convention. This pre-convention briefing is MANDATORY for all personnel staffing the exhibits. If for some reason the AZ employee misses the briefing, he/she must contact the PRA representative to review the important points. A PRA representative should attend all conventions in which AZ is participating or be on call at headquarters.

3.3 Local Conventions and Hospital Displays

AZ exhibits may be displayed during symposia or conventions with the consent of the accredited provider or appropriate third-party organization. Exhibits may also be displayed at hospitals or institutions with the permission of the institution, regardless of whether there is a specific program event.

All convention/symposia and hospital/institution rules for displaying must be observed. Items primarily for the benefit of patients may be offered to HCPs if they are not of substantial value (FMV $100 or less). Items of minimal value may be offered if they are primarily associated with an HCP's practice (such as pens, notepads, and similar reminder items with company or product logos). These items must be less than $35 FMV.

ACCME, ACPE, ACHE, etc Standards or Guidelines should be observed for exhibits during CE events (*see* **Independent (Nonpromotional) Education & Related Grants** [IV-1]).

These displays are considered to be Commercial Exhibits and must conform to the Promotional Regulatory Affairs (PRA) Guidelines on Commercial Exhibits (see http://pra.us.astrazeneca.net/web/Conv_Exhibits.asp).

3.3.1 Administrative Information

- Exhibit fees may not be paid through an educational grant. Instead, they may be paid through submission of a Regional Exhibit Funds Request. **In certain instances, an organization or institution may require an unrestricted educational grant for a CE program, which includes complimentary display space as well as other program expenses such as speaker compensation.** In these instances, only a Medical or Pharmacy Grant Request may be submitted. If Exhibit fees are waived because of an associated Educational Grant, see **Independent (Nonpromotional) Education & Related Grants,** (IV-1). If only the cost of display space is being requested, still submit a Regional Exhibit Funds Request;

- Regional Exhibits or display fees under $100 may be paid directly to the organization or institution and reimbursed through the expense reimbursement system. Exhibit fees over $100 must be submitted on a Regional Exhibit Request form in Compass. For expenses over $25, original receipts are required;

- For Tier II displays within the Managed Care Business group, all exhibit paperwork (exhibitor prospectus, etc.) must be forwarded to the Managed Care Conventions Coordinator (MCCC). The MCCC will process all exhibit selections, fees, logistics, etc;

- No contracts are required for Regional Exhibits or Displays. If the display is in conjunction with a CME program and the organization requires the signing of their letter of agreement, this must be submitted to the Lecture Bureau for signing by an authorized member of the Field Professional Education Department (PED);

- Requests submitted for exhibits should be initiated at least 4 to 6 weeks prior to program date;

- Accounts Payable will cut the check and send it to the Lecture Bureau, which will mail the check with the appropriate correspondence to the person specified by the request originator. If correctly processed, the check should reach the appropriate person 4 to 6 weeks after being submitted by the request originator.

4. Types of Exhibits

AZ has identified two types of exhibits within each of the two categories and developed guidelines for each. These guidelines will be maintained by the Promotional Regulatory Affairs (PRA) Department on the Intranet USRA Web Page (http://usra.us.astrazeneca.net/web/PRA.asp).

4.1. Scientific:

Scientific Exhibits – Non-US and US
The purpose is to exchange scientific information regarding investigational products or marketed products.

Institutional Research Exhibits – Non-US and US
To highlight research being conducted in a specific disease area without providing information on the investigational compounds being researched.

4.2 Commercial:

Commercial Exhibits – US
The purpose is to promote products and the uses as approved in US.

Commercial Exhibits – Non-US
The purpose is to promote products approved in countries outside of US to non-US attendees attending US conventions.

5. References

5.1. AZ Business Policies

Product Promotion (II-1); **Gaining Access to Healthcare Professionals** (II-3); **Independent (Nonpromotional) Education & Related Grants** (IV-1); **Conventions/Symposia Exhibits** (IV-3); **Regulatory Considerations for Information Dissemination at Scientific and Commercial Exhibits at Conventions/Meetings Held in US** (http://pra.us.astrazeneca.net/web/Conv_Exhibits.asp).

AstraZeneca

Case Study Programs

Policy No.: **IV- 4**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **10/17/2002**

Contents

1. Key Learnings

- **Because AstraZeneca (AZ) exerts control over these programs, Case Study Programs are considered Promotional Education Programs;**
- **All responses not consistent with the approved product label must be disclosed as being unapproved;**
- **A maximum of eight HCPs may be invited to participate;**
- **Each HCP must prepare an interesting or challenging case related to the assigned topic;**
- **A modest collateral meal (by local standards) may be provided to participants (see Gaining Access to Healthcare Professionals – II-3; Exhibit M).**

2. Policy

2.1 General

Case Study Programs are designed to provide HCPs with an interactive educational forum on how to treat and manage challenging patient cases in therapeutic areas within AstraZeneca's portfolio. The format must include presentation and discussion of actual case studies prepared and presented by the attendees.

Case Study Programs are comprised of no more than eight HCPs within a PSS's territory. The PSS invites the appropriate HCPs, instructing them to prepare a presentation on a challenging and interesting case from their practice. The case studies must be based on therapeutic areas in which AZ has marketed products and participants must not proactively discuss off-label uses of AZ products.

Any references to AZ products or those of other companies, made by an employee, moderator, or presenter, must be done in an objective and balanced manner and within the approved labeling for the particular product. All comments not consistent with the approved product label must be disclosed by the moderator as being unapproved.

2.2 Moderator and Participant Criteria

Moderators must be chosen solely on the basis of their ability to provide the services required for these programs. Target status and/or prescribing volume are not appropriate factors for determining who is selected as moderator for a Case Study Program or the level of compensation for services they receive.

2.2.1. Moderator

- Specialist in subject matter;
- Peer recognition of expertise of subject matter;
- Teaching ability;
- Ability to moderate discussions within small groups.

2.2.2. Participants

- Healthcare professionals (HCPs) treating disorders within AZ's therapeutic areas;
- HCPs with patient cases that are relative to the subject matter;
- HCPs able to prepare patient cases for discussion with other HCPs;
- HCPs that are willing to participate in an interactive educational discussion on interesting or challenging cases.

2.3 Case Study Program Format

2.3.1. Participants

- No more than eight local physicians, physician assistants, nurse practitioners, oncology nurses, or pharmacists may participate in a Case Study Program;
- One local HCP specialist (moderator);
- MIS or DSM may assist moderator with facilitation of the meeting, if requested.

2.3.2 Meeting Location

- Restaurant, office, or other suitable location that ensures privacy and provides an atmosphere for meaningful discussion.

2.3.3 Content

- Educational content is the focus of this program. As such, a modest meal may be provided in conjunction with the program;
- Each participant must prepare an interesting or challenging patient case and present it to the group;
- The cases must be related to the chosen topic;
- Patient identities must not be disclosed;
- Allow for 15 - 20 minutes per case for presentation and discussion.

2.3.3 Case Study ProgramTopics

- All Case Study Programs must be conducted using one of the therapeutic areas currently marketed by AZ;
- The topic of the program must be within the product labeling for AZ products.

2.3.5 Compensation for Services

- Compensation for services for speakers presenting at speaker programs should fall within the approved range for the type of services that are being provided. Although a single standard compensation amount is automatically chosen via the electronic request process in Compass, the approving manager with a corresponding delegation of authority may adjust the compensation amount provided that the amount is within the approved range of fair market value (FMV) for the qualifications of the speaker and the services being provided;
- Since these programs are designed to use local moderators, the Fair Market Value (FMV) of the services being provided have been valued at $750;
- Compensation for service amounts may not be changed by writing the adjusted amount on the contract, as this will invalidate the contract;
- Compensation for services will be funded locally by the District or Region responsible for the AZ employee requesting the program;
- If AZ cancels the program 14 days or less prior to the program, AZ will honor the commitment to pay compensation for services to the moderator.

2.3.6. Speaker Expenses

Since Case Study Programs are designed to utilize local or regional thought leaders, there should not typically be speaker travel and lodging expenses. However, there are occasions when good business reasons dictate the need to utilize a national thought leader or moderator that will require travel. In this case, contact the PED to obtain an appropriate expense reimbursement form and a moderator agreement that includes information on travel, lodging, and expenses

2.3.7. Collateral Meals

Since Case Study Programs are usually conducted after normal office hours, it is appropriate to provide a modest collateral meal (by local standards) to those participating in the program. The meal should be modest and follow the Access Meal dollar limits outlined in **Gaining Access to Healthcare Professionals** (II-3, Exhibit M). Although meals may be provided for Case Study Programs, other social or entertainment activities are never permitted.

2.3.8. Patient or Medical Solutions

It is acceptable to provide participants of Case Study Programs a Patient or Medical Solution with a fair market value (FMV) of not more than $100. These items must be designed to primarily benefit patient healthcare.

3. Required Contracts/Documentation

- AZ Moderator Contract – one required per program

4. References

4.1. AZ Business Policies

Ethical and Professional Conduct (I-1); **Product Promotion** (II-1); **Independent (Nonpromotional) Education & Related Grants** (IV-1); **Promotional Education Programs and Related Grants** (IV-2).

AstraZeneca

Speaker Programs

Policy No.: **IV-5**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Issued: **07/01/2002**

Contents

1. Key Learnings

- **Speaker Programs are presentations given by thought leaders on behalf of AstraZeneca (AZ) to customers about AZ products and related to AZ therapeutic areas;**
- **Speakers should use slide kits (if available) and speak only on approved talk topics/titles;**
- **Speakers must provide balanced presentations that are consistent with the approved product label;**
- **All talk titles/topics must be accompanied by complete program outlines;**
- **Speakers should not be selected in any way for consideration of, as an inducement to, or in return for their current or future prescribing, purchasing, use, formulary inclusion or favorable position, or dispensing of AZ products;**
- **A Speaker Evaluation form must be filled out by the AZ contact following any paid speaker program;**
- **PSSs must not encourage speakers to discuss off-label topics;**

- **Package inserts must be available to all attendees and faculty.**

2. Policy

Speaker Programs are presentations given on behalf of AstraZeneca (AZ) by a national, regional, or local healthcare thought leader to an audience of HCPs. Speakers may also be AZ personnel such as Medical Information Scientists (MISs) or other company scientists. The following policy and related policies (**Independent [Nonpromotional] Education & Related Grants** [IV-1] and **Promotional Educational Programs & Related Grants** [IV-2]) apply whether or not the speaker is an AZ employee.

Professional Medical Education Programs allow AZ to provide the service of medical education for small to medium sized groups of customers. **Although speaker programs provide a form of continuing education, these programs are promotional in nature; therefore CE credits are not available for these programs. Because AZ has influence over these programs, they are subject to the same laws and regulations that govern other forms of promotional activities and must be within current approved product labeling.** These programs are not venues for providing information on AZ, competitor, or independent (customer) current investigational research, unapproved uses, or studies other than those approved by the FDA for inclusion in package inserts.

The speaker must give a balanced presentation that remains within labeling for any AZ product that is discussed. A question and answer session with the attendees may immediately follow the presentation. All responses related to off-label use of any product discussed must be disclosed during the presentation immediately after they occur as being unapproved.

2.1 Goals/Objectives

- Provide high-quality, ethical, and scientifically-accurate medical education programs;
- Increase customer exposure to AZ products and facilitate interactive, educational discussions;
- Provide medical education to customers on AZ products, topics related to AZ therapeutic areas of interest, and related healthcare areas of interest.

2.2 Types of Speaker Programs

There are several types of Speaker Programs available to meet various strategic and tactical objectives. While each is slightly different, all are designed to provide educational opportunities for HCPs and all are considered promotional because AZ has control over topics, content, speakers, and/or audience.

2.2.1 National and Regional Speaker Programs

These programs provide the opportunity for nationally or regionally recognized experts to present information on the therapeutic categories or diseases that AZ has an interest in. These presentations are given in a lecture format with limited time for Q&A sessions. Speakers may use slides or other eSTaR-approved materials provided by AZ or may develop their own materials. In either case, presentations must be balanced, be on label, and follow all FDA promotional regulations. Topics for national or regional speakers programs must be from the approved talk title list.

2.2.2 Roundtables

Roundtable Discussions are a more intimate form of speakers program for several reasons. First, the total number of participants is limited to eight. Secon, the small size provides a much greater opportunity for interaction with the speaker and more time for Q&A sessions. Generally, the speaker utilizes his or her own presentation materials rather than formal slide presentations developed by AZ. Even though the presentation materials are not eSTaR approved, the speaker must provide a balanced, truthful, and not misleading presentation. Additionally, the speaker must not proactively present information that is off-label.

2.2.3 Visiting Professorships

In certain circumstances, bringing a key opinion leader or recognized subject matter expert into a territory may be very appropriate in providing an educational opportunity for a small group of HCPs. Visiting Professorships provide the opportunity for one-on-one interactions in a clinical setting with a recognized subject matter expert. It may be in the HCPs office or in an institution such as a hospital. Visiting Professors can provide expert advise on challenging cases or demonstrate new diagnostic or procedure techniques. Even though the presentation materials are not eSTaR approved, the speaker must provide a balanced, truthful, and not misleading presentation. Additionally the speaker must not proactively present information that is off-label.

2.3 Speaker Criteria

Speakers should be selected based on their expertise in the therapeutic area (TA) and their ability to educate other HCPs. Speakers should not be selected in any way for consideration of, as an inducement to, or in return for the current or future prescribing, purchasing, use, formulary inclusion or favorable position, or dispensing of AZ products. When selecting a speaker, the speaker must be qualified to speak on the subject matter. Factors to be considered in determining qualifications include the following:

- Strong familiarity/expertise in the presentation subject matter;

- Participation in or affiliation with academia, editorial boards, related associations, clinical/healthcare management, and/or managed care;
- Speaking/teaching ability;
- Peer rapport in presentation topic;
- Ability to answer reasonable questions on the presentation topic;
- Ability to provide quality, ethical and balanced presentations.

Whenever possible, individuals chosen as speakers should be those recommended by product teams, MISs, and Regional Sales Management. These speakers should also have participated in an AZ Speaker Training or a Faculty Update Program to ensure that they have received up to date and accurate clinical data and available slide kits. AZ employees should consult with their DSM to obtain guidance in choosing an appropriate speaker or to discuss reasons for using a nonrecommended, nontrained speaker.

2.4 Adding Faculty

There will be many occasions where AZ wants to add speakers to the approved list. In addition to a national speakers bureau organized by a product team, there may be local or regional thought leaders who would be very appropriate to speak on AZ's behalf.

The DSM should ensure that speaker candidates meet the minimum criteria set forth above. They should also review the candidate's curriculum vitae (CV). If the prospective speaker meets with the DSM's approval, their recommendation and the CV are forwarded to the local MIS.

The MIS should meet with the candidate to discuss their qualifications. The MIS is responsible for composing a memo to the AZ Lecture Bureau, requesting that the candidate be added to the list of approved speakers. The Lecture Bureau will forward a packet of information to the speaker and arrange for any training needs or appropriate product information.

2.5 Titles and Presentation Topics

Only topics approved through the eSTaR Process may be used as the subject matter for Speaker Programs. Any AZ employee may submit new talk topics/titles for approval by Promotional Regulatory Affairs by contacting their PRA representative:

- All new topics/titles **must** include a full outline;
- When possible, slide kits should be developed for new talk topics/titles;
- New talk topics/titles are not restricted to AZ products but they should be relevant to the therapeutic area, the healthcare industry and the customers' practice of providing healthcare to patients;
- Lists of current approved talk topics matched to products and Therapeutic Areas are available on the AZ Speaker Directory.

2.6 Speaker Evaluation

A Speaker Evaluation Form must be filled out by the AZ program requester following any paid speaker program. This form is available electronically in Compass and on-line via the AZ Speaker Directory at http://speakerdirectory.us.astrazeneca.net. Speaker Evaluation Forms should also be completed by the attendees and returned to the Lecture Bureau upon completion of the Speaker Program. Templates for printing these forms are available to download on the Speaker Directory. In addition, the list of attendees must be documented and submitted by the AZ program requester with their expense report for the expenses related to the program.

Relevant speaker evaluation criteria should include whether the

- Presentation was consistent with the product label;
- Presentation was fair and balanced;
- Speaker stayed within the approved topic guidelines;
- Speaker was able to maintain attention of audience and facilitate question and answer session;
- Speaker was able to field questions from the audience and answer with a professional and educated response;
- Overall presentation was of high quality;
- Speaker had the knowledge of topic and ability to present the material accurately.

2.7 Removing Faculty

Recommendations for the removal of a speaker from the AZ pool of approved speakers can be made by contacting the Professional Education Department (PED) and describing the specific reasons for recommendating the speaker be removed. The recommendation will be handled as follows:

- The Professional Education Department (PED) will evaluate the recommendation for removal and contact any others in AZ who need to be involved in the removal decision;
- Final decision will be made jointly by the Professional Education department and the appropriate member(s) of Sales Management responsible for that customer;
- After a decision has been made to remove a speaker from the AZ pool of approved speakers, the Professional Education department will remove the speaker's name from the database.

Speakers may be removed for any sound reason, including but not limited to:

- Not adhering to product labeling;
- Not keeping within presentation guidelines (unbalanced/biased presentation);
- Hostility towards audience;
- Lack of preparation;

- Inappropriate behavior;
- Poor presentation quality.

2.8 Speaker Expenses

AZ will reimburse speakers for properly documented and reasonable travel, lodging, and meal expenses directly related to the services they provide in conjunction with the speaker program. For national speakers or those requiring direct travel assistance, arrangements should be made by contacting the Lecture Bureau for AstraZeneca and requesting speaker scheduling and travel assistance.

- Expenses will be reimbursed upon receipt of a completed expense reimbursement form with original receipts. The IRS requires original receipts for any expense over $25.
- Expenses should not be paid for directly by AZ unless there are extenuating circumstances and prior approval is obtained from PED.
- Speaker travel and lodging expenses must never be paid for by any AZ employee and submitted as a personal expense for reimbursement.
- Speaker travel and lodging may be arranged and direct billed to the corresponding AZ cost center when speakers are scheduled through the AZ Lecture Bureau.
- Speaker expenses related to upgrades, personal travel and activities, entertainment, in-room movies, and other expenses not directly related to the provision of services are not reimbursable, in accordance with IRS regulations

2.9 Compensation for Services

Compensation for Services for speakers presenting at speaker programs should fall within the approved range for the type of services that are being provided. Although a single standard compensation amount is automatically chosen via the electronic request process in Compass, the approving manager with a corresponding delegation of authority may adjust the compensation amount provided that the amount is within the approved range of Fair Market Value (FMV) for the qualifications of the speaker and the services being provided.

Approved FMV ranges are as follows:

- National Faculty Speaker Dinner Program - $750-2500 (standard $1500)
- Regional or Local Speaker Dinner Program - $500-1500 (standard $750)
- Roundtable discussion, small group discussion, 5 to 8 attendees, local speaker - $200-500
- National Faculty Visiting Professorship - $725-2500 (They should not be paid per number of appointments that they make each day. Only the speaking or teaching physician may receive an compensation for the program.)

- Attendees for a speaker program do not receive compensation.
- Compensation for services should first be based on the type of program and level of services being provided by the speaker, and then based on the expertise of the speaker.
- Compensation for services in excess of the high end of the approved range may only be approved by the NSD for the corresponding sales team responsible for the program or the Vice President of the TA for the product team sponsoring the program
- If multiple programs occur, compensation will be received for each presentation. If adjustments are necessary, prior managerial approval is required.
- Compensation for services should be paid directly to the speaker, using their social security number or Federal tax identification number if they are legally incorporated.
- **Compensation for services for speakers must be paid by AZ Accounts Payable department, never by a third party organization or an AZ employee.**
- The Region responsible for the AZ employee requesting funds will fund compensation for services locally.
- **No compensation for services will be paid unless a fully executed contract is in place.**

3. Collateral Meals

Modest and reasonable meals designed to increase attendance to a program may be associated with Speaker Programs; however, the speaker portion of any program must dominate the agenda and any meal must be incidental to the overall program. These types of meals are called "collateral meals" since they are in conjunction with a speaking or other educational event. The perception of engaging customers in "token" educational activities as a means to provide meals or other social opportunities must be avoided in all instances. The educational portion of the program must be dominant on any invitation or flyer distributed for the program, not the meal.

If a Speaker Program has a collateral meal associated with it, the cost of the meal cannot exceed a total of $50 per HCP in attendance at the program (Cost of Living Adjustment may apply). The costs involved for the collateral meal will not count towards the frequency limits under the **Gaining Access to Healthcare Professionals** (II-3; Exhibit A & M) policy.

4. Invitations and Promotional Items

PRA approved invitations and promotional items may be distributed.

- Pre-approved invitations may be obtained via the Lecture Bureau and the invitation template in MS Excel on the hard drive (printed on paper obtained

through the National Quick List). Other invitations may be utilized only after submission to PRA and subsequent approval.

- Approved promotional items may be provided to attendees and faculty, although they should not distract from the educational content of the program
- Package Inserts (PIs) must be available to attendees and faculty of all programs, regardless of whether promotional items are provided

5. Administrative Information

- Submit request for compensation for services through Compass using appropriate type of program under Speaker Programs
- AZ will maintain all speaker contracts and dispense as well as maintain speaker expenses

6. Required Contracts

- AZ Speaker Contract (one speaker contract per time period valid for all lecture speaker programs)

7. References

7.1. AZ Business Policies

Gaining Access to Healthcare Professionals (II-3); **Independent (Nonpromotional) Education & Related Grants** (IV-1); **Promotional Education Programs** & Related Grants (IV-2).

AstraZeneca

Distribution of Enduring Materials from Independent Educational Programs

Policy No.: **IV- 6**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Distribution of continuing education (CE) accredited materials and other materials for independent education programs (Enduring Materials) must be requested in writing by the organization providing the educational credits (accrediting sponsor) or the hosting organization for non-accredited programs.**
- **The accrediting sponsor or hosting organization must have an additional independent marketing effort for the program. AstraZeneca (AZ) may not be the sole source of marketing activities for the program.**
- **Enduring Materials must have been developed by the accrediting sponsor or hosting organization in accordance with the FDA Guidance for Independence (see Policy IV-1, Attachment I) and the appropriate accrediting organization guidelines (ACCME, ACPE, ANE, etc) when credits are awarded.**
- **AZ may not add any promotional information to the Enduring Materials.**
- **Dissemination of Enduring Materials by AZ personnel must be follow instructions in 3.3 of this policy and be separate and distinct from product discussions through the use of the following transitioning statement, "AZ supports many educational offerings that you may**

find of interest. Here is some information on one of those programs."

- **While invitations disseminated in sealed envelopes do not require eSTaR approval, all content material and invitations disseminated outside of a sealed envelope do require eSTaR approval.**

2. Purpose

To provide the ability for AZ personnel to distribute Enduring Materials resulting from the development of Independent (Nonpromotional) accredited and non-accredited Continuing Education (CE) Programs to healthcare professionals.

3. Policy

3.1. Enduring Materials

3.1.1. CE Enduring Materials are any printed, recorded, or computer-assisted materials, which contain information about, act as delivery mechanisms for, or contain educational content pertaining to an Independent (Nonpromotional) Educational Program. Enduring Materials may be used over time at various locations. They are divided into two types: invitation materials and content materials.

3.1.2. Below are examples of Enduring Materials. This is not an exhaustive list:

Invitation Materials:

- Invitations to a program including live, CD, print or web-delivered Programs;
- Business Reply Cards to receive other content materials (BRC);

Content Materials:

- Programmed texts;
- Cassette tapes;
- Computer-assisted instructional materials (CD-ROMs, web-based programs, etc);
- Videotapes;
- Journal Supplements;
- Unabridged abstracts on disc from national professional meetings.

3.2 General Requirements

- Both the program and Enduring Materials must meet all guidelines for the accrediting organization corresponding to the type of credits being offered (if any) and AstraZeneca Business Policies for Independent (Nonpromotional) Educational Program development;

- All Enduring Materials must be developed by the Accrediting Sponsor or hosting organization. They must include reference to AZ sponsorship of the program;
- A written request for AZ distribution of Enduring Materials must be received from the Accrediting Sponsor or hosting organization and kept on file by AZ prior to Enduring Materials being developed. It may be included in the original proposal from the Accrediting Sponsor or hosting organization that is the basis for the medical education grant awarded by AZ;
- The Accrediting Sponsor or hosting organization must have an independent marketing effort for the program. Distribution of Enduring Materials by AZ or its personnel must not be the sole marketing effort;
- The sales force must be provided with guidance on their responsibilities for the distribution of the Enduring Material.

3.3 Distribution Requirements

3.3.1 AZ personnel may deliver invitation materials to healthcare professionals without eSTaR review provided the following process has been met:

- The Accrediting Sponsor or hosting organization will place each piece of invitation material in a sealed envelope. The envelope may be labeled "An educational activity offering xxx # category X credit hours" or the envelope may be blank.
- The accrediting sponsor will ship sealed invitation material to an AZ designated distribution center.
- AZ must prepare a cover letter to the field sales force outlining ACCME guidelines as well as time sensitivity for distribution of the sealed envelopes. The AZ template for distribution of invitation materials should be used (see Appendix I).
- Modifications may be made to the above template by obtaining the approval of the AZ Marketing Communication Director.
- Field sales force personnel must distribute the sealed envelope at the close of their product discussions. They are to transition from the product discussion in the following manner, " Dr. _____, AstraZeneca supports many educational offering that you may find of interest. Here is a brochure for one of those programs."
- Field sales personnel are not permitted to discuss the Independent (Non-promotional) Educational Program or answer questions about the program from the healthcare professional. All questions from the healthcare professional are to be directed to the accrediting sponsor.
- All invitations to field-based Independent Education Programs must comply with the above process with one exception. If the Accrediting Sponsor or hosting organization does not provide the invitations in sealed envelopes, AZ must place them in plain, sealed envelopes prior to delivery. No additional promotional material may be included. If any printing will appear on the envelope, review with the PRAFP prior to printing and distribution.

3.3.2 Invitation Materials delivered outside of sealed envelopes and distribution of content materials must be approved through the eSTaR process prior to distribution.

3.3.3 All content material to be distributed by AZ personnel must be approved through the eSTaR process.

4. References

4.1 AZ Business Policies

Independent (Nonpromotional) Education & Related Grants (IV-1); Convention/Symposia Exhibits (IV-3)

4.2 Other References

Appendix I: Template for Invitations

APPENDIX I

Template: "Delivery of invitations for an independent educational activity to customers"

MEMO

To:

Cc: Designated team members and Marketing Communications Director for TA

From:

Subject: Delivery of invitations for an independent educational activity to customers

"AZ is supporting an independent educational activity in the area of "Disease State or TA." XXX, the (continuing education Accrediting Sponsor or hosting organization), has asked the AstraZeneca field representatives to participate in the recruitment efforts by distributing invitations to our customers. We are inviting all members of the XXX (i.e. GI/CV sales team) to join in this effort. **Attached you will find xx (number) invitations for delivery to your customers. Because of the quickly approaching dates, we ask that you deliver these invitations immediately or by (insert date) to your (healthcare provider type).**

As you visit your healthcare professional, CME invitations are to be handed out at the close of your discussion. You are to transition from the discussion in the following manner:

> "Dr. XXX, AstraZeneca supports many educational offerings that you may find of interest. Here is some information for one of those programs."

AstraZeneca representatives are not permitted to discuss the independent activity or answer questions from the healthcare professional concerning the activity. All questions are to be directed by the healthcare professional directly to (the name of the Accrediting Sponsor or hosting organization).

We appreciate your participation in helping us reach your target customers. If you have any questions or require additional information, please fee free to contact (PREP Manager) at (direct phone number).

Thanks for your efforts

AstraZeneca

Medical & Pharmacy Education Grants

Policy No.: **IV-7**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Medical & Pharmacy Education Grants are used to provide financial support for Independent (Nonpromotional) Education Programs;**
- **These grants may only be used to fund programs with an educational purpose;**
- **AZ may not provide grants with "strings attached;"**
- **AZ may not direct or influence the content of the educational program or selection of speakers/presenters;**
- **An AZ Grant Letter of Agreement contract must be completed for each Medical or Pharmacy Education Grant.**

2. Policy

Through educational grants, AstraZeneca (AZ) financially supports Independent (Nonpromotional) Medical and Pharmacy Education Programs without influencing the content of these activities. If educational grants are made in accordance with FDA guidelines on independent education and American Council on Continuing Medical Education (ACCME) or American Council on Pharmaceutical Education (ACPE) Guidelines, these programs will not be considered product promotion and will not be regulated as such.

Educational grants may be used to fund only activities or programs with an educational purpose. They may be accredited or non-accredited by approved-provider organizations (see below).

2.1. Accredited Medical & Pharmacy Education Programs

2.1.1. Content Development

AZ must not direct or influence the content of the educational program or activity supported by the grant and should not play a role in the selection of speakers or presenters other than responding to unsolicited independent provider written requests for suggestions of presenters, sources of possible presenters, or assistance with educational planning and otherwise in compliance with applicable ACCME or ACPE guidelines. The ACCME and ACPE guidelines are set forth as Attachments to these policies, along with FDA laws and regulations.

2.1.2. Grant Contingencies

AZ may not provide grants with "strings attached." Receipt of a grant should never be contingent upon the recipient's activities with respect to AZ or AZ products. For example, grants should never be offered or provided, either directly or indirectly, in exchange for current or future prescribing, purchasing, using, formulary inclusion, or dispensing of AZ products.

2.1.3. Payment

Educational grants should be made payable to organizations, societies, or groups consistent with FDA, ACCME, and ACPE standards. When a third party (eg, medical communications company) is involved, the accredited provider should be paid--not the third party. If the third party is actually the accredited provider, AZ may pay them directly. Educational grants may not be used to fund an exhibit or display booth (see Convention/Symposia Exhibits).

2.1.4. Turnaround Time

In order to adhere to standard accounting principles regarding prepaid expenses, grants are typically not processed more than 60 days before the date of the program or activity supported by the grant, unless specifically requested by contacting the AZ Lecture Bureau.

Medical and Pharmacy Education Grant Requests must be received at least 45 days prior to the date of the educational program date in order to be processed by that program date. All requests that are received without a 45 day lead time will be processed with all others according to standard FIFO (first in, first out) procedure. Furthermore, requests that are submitted without the 45 day lead time will typically not be rushed ahead of those with proper lead time. Should extenuating circumstances require that a request be processed more expeditiously, please notify the AZ Lecture Bureau of the situation. The Lecture Bureau will then make every reasonable effort to accommodate the request.

2.1.5. Letter of Agreement

AZ has developed letters of agreement to be used when arranging a grant with a recipient organization, society, or group. These letters of agreement have been tailored depending on the type of grant at issue. *Checks for grants will not be cut and distributed unless the grant recipient has signed the appropriate letter of agreement and the AZ Lecture Bureau has received it.*

An AZ grant letter must be signed for each Post-Graduate Grant. AZ employees should not sign a grant letter of agreement from any other organization. If the organization requires that their letter of agreement be signed, the letter should be forwarded to the field Professional Education Department (PED) for review and an appropriate signature. Other letters of agreement will **not** substitute for AZ's letter of agreement.

2.1.6. Grant Approval

The District Sales Manager (or appropriate corresponding member of AZ management) must first approve all Medical and Pharmacy Education Grants up to their Delegation of Authority. Grants exceeding the manager's Delegation of Authority limit are subject to approval according to the requirements in the Delegations of Authority database.

2.1.7. Fundable Activities

Activities that may be funded by a Medical or Pharmacy Education Grant, include, but are not limited to:

Accredited programs, such as:

- Educational seminars for physicians/pharmacists;
- Development of CME programs on Internet or CD-ROM;
- Third-party accredited educational programs;
- Patient Centered Asthma Care Education;
- Interactive Workshop for Success Program;
- Regional Medical or Pharmacy Educational Symposia.

Non-accredited programs, such as:

- Health Fairs conducted by institutions, clinics, or hospitals;
- Physician/Pharmacist training programs at academic institutions;
- "Doctor to Doctor" or "Pharmacist to Pharmacist" preceptorship type programs conducted by academic institutions.

2.1.8. Non-Fundable Activities

Activities, **which may not be funded by a Medical or Pharmacy Education Grant,** include, but are not limited to:

- Exhibit or display booths at conventions/conferences *(see* **Convention/Symposia Exhibits**, [IV-3]);
- Research or Health Economics studies;
- Charitable contributions;
- General/miscellaneous education funds;
- Parties or social events for physicians/pharmacists;
- Testimonial dinners;
- Medical missions to foreign countries;
- School yearbook advertisements;
- Requests for medications;
- Purchase of tickets for physicians/pharmacists (or AZ employees) to play golf or tennis, to take trips, or to participate in similar activities;
- Private schools/colleges attended by physicians/pharmacists or their families.

Grants should never be used to support charitable events, such as fund-raiser golf outings, tennis tournaments for charity, American Heart Ball, etc. Please see the Corporate **Charitable Contributions and Sponsorship Policy** (VI-3) and **AstraZeneca Representation at Charitable Fund-Raising Events** (VI-2) for specific policies regarding support for these types of events.

2.2 Non-accredited Medical & Pharmacy Education Programs

Non-accredited Medical or Pharmacy Education Programs must follow similar guidelines as accredited programs and must be independent (nonpromotional). However, they do not need to adhere to the ACCME or ACPE standards for Independent Education Programs. A letter of agreement is required for non-accredited Medical Educational Programs.

Although the ACCME or ACPE standards do not apply, AZ will still follow FDA standards to ensure that these programs are independent and not promotional.

3. Required Contracts

An AZ Grant Letter of Agreement contract must be completed for each Post-graduate Grant.

4. References

4.1. AZ Business Policies

Product Promotion (II-1); **Gaining Access to Healthcare Professionals** (II-3); **Independent (Nonpromotional) Education & Related Grants** (IV-1); **Convention/Symposia Exhibits** (IV-3); **Charitable Contributions and Sponsorships** (VI-3); **AstraZeneca Representation at Charitable Fund-Raising Events** (VI-2).

4.2. Other Sources

ACCME Guidelines
ACPE Guidelines
ACHE Guidelines
AstraZeneca's Delegations of Authority Database

AstraZeneca

Library Grants

Policy No.: **IV- 8**

Issued by: **AZ Business Policy Group**
Date Revised: **04/30/2001**
Date Issued: **07/01/2002**

Contents

1. Key Learning

- **Library Grants may only be provided to institutions or organizations, not individual physicians or physician groups;**
- **Library Grants must never be offered in return for, as an inducement to or in consideration of, the current or future prescribing, purchasing, use, dispensing, or formulary status of AZ products;**
- **Library Grants must be first approved by the appropriate managers up to their delegation of authority;**
- **A Library Grant Contract is required for each library grant.**

2. Policy

Through the provision of Library Grants, AstraZeneca (AZ) financially supports the provision of medical education and/or medical reference materials and the updating of medical libraries for institutions and organizations, which includes:

- Medical textbooks;
- Trade journal subscriptions;
- Medically-related computer software (eg, Mosbey's);
- Internet access fees for medically-related web sites.

Educational grants may be used to fund only materials with an *educational* purpose and may only be provided to institutions and organizations, not individual physicians or physician groups.

2.1.1. Library Grants must be given through a grant request; materials should not be purchased and submitted as an expense. **The customer must control the selection of the materials.**

2.1.2. Library Grants must never be offered in return for, as an inducement to or in consideration of, the current or future prescribing, purchasing, use, dispensing, or formulary inclusion or favorable position, of AZ products.

2.1.3. Library Grants are limited to $5,000 per institution. Any proposed library grants that exceed the foregoing limitation may only be made if approved by the next level manager above your direct manager and follow the requirements in the Delegation of Authority database.

2.1.4. Library Grants may be funded locally by the District/Region/MCBG responsible for the AZ employee submitting the request or centrally by a TA Team .

2.1.5. All Library Grants must first be approved by the appropriate managers up to their Delegation of Authority. Grants exceeding that individual's Delegation of Authority limit are subject to approval according to the requirements in the Delegation of Authority database.

2.1.6. Library Grants may be used to support development or maintenance of medical educational or reference web sites or portion of the web sites; specifically, funds may be used:

- For the patient education portion of the web-site;.
- To provide information that serves as a reference for other HCPs.

Funds may not be used for the purpose of directly marketing the organization, practice, or physicians in the practice/organization.

2.1.7. Library Grants may only be used to support web sites when the grant recipient controls the content. For instance:

- A department of an institution may use funds to support the posting of published studies or research to be accessed by industry (nurses, physicians, pharmacists, etc) or nonindustry parties (patients) when the content of the posting is controlled by the institution;
- A web site may provide an educational service to patients by posting disease prevention measures or other medical education information provided that the grant recipient has control over the content that is posted.

2.1.9. Library Grants must never be used to support charitable events, such as fund-raiser golf outings, tennis tournaments for charity, American Heart Ball, etc. Please see Corporate **Charitable Contributions and Sponsorships** (VI-3) and **AstraZeneca Representation at Charitable Fund-Raiser** (VI-2) for specific guidelines regarding support for these types of events.

2.1.9. Library Grants must never be used to fund the purchase of durable goods, including, but not limited to, televisions, VCRs, diagnostic equipment, or office equipment.

3. Required Contracts

A Library Grant Contract is required for each Library Grant.

4. References

4.1. AZ Business Policies

Product Promotion (II-1); **Gaining Access to Healthcare Professionals** (II-3); **Independent (Nonpromotional) Education & Related Grants** (IV-1); **Charitable Contributions and Sponsorships** (VI-3); **AstraZeneca Representation at Charitable Events** (VI-2).

4.2. Other Sources

AstraZeneca's Delegation of Authority Database

AstraZeneca

Post-Graduate Grants

Policy No.: **IV-9**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Post-Graduate Grants are used to provide financial support to medical students, residents, and fellows to attend carefully selected national educational conferences or professional meetings. These grants may only be used to fund programs with an educational purpose;**
- **Funds may only be provided to the academic institution or accrediting sponsor of the meeting;**
- **AZ may not provide grants with "strings attached;"**
- **An AZ Grant Letter of Agreement contract must be completed for each Post-Graduate Grant.**

2. Purpose

Through the provision of Post-Graduate Grants, AstraZeneca (AZ) financially assists in underwriting the costs for medical students, residents, fellows and other HCPs in training to attend carefully selected national continuing education conferences or professional meetings such as ACPE, AAPF, ACC, ACHE, etc.

3. Policy

3.1 Provision of Post-Graduate Grants

Providing scholarships and other special funds to assist in underwriting educational programs is permissible if the beneficiaries of the funds are selected by the academic or training institution. They must be given to the academic institution or the accredited sponsor, who may use the money to reduce the conference's registration fees for medical students, residents, fellows, or other healthcare professional trainees, but not for any one individual attendee. Such payments to defray the costs of a conference may never be provided directly to the HCPs-in-Training attending the conference.

Grants should never be used to support charitable events, such as fundraiser golf outings, tennis tournaments for charity, American Heart Ball, etc. Please see **Charitable Contributions and Sponsorships** (VI-3) for specific guidelines regarding support for these types of events.

3.2. Recipient Selection

The decision regarding which meetings are appropriate for students, residents, or fellows to attend must be made by their academic institution or by the accredited sponsor. Support may not be used to send residents or fellows selected by AZ.

The students, residents, or fellows must be chosen by the institution receiving the grant. Post-Graduate Grants must be administered in accordance with the ACCME Guidelines, which are in alignment with the PhRMA Code on Interactions with Healthcare Professionals and the AMA Guidelines on Gifts to Physicians, as referenced in Exhibits D and E in the policy **Gaining Access to Healthcare Professionals** (II-3) and Attachment II in the policy on **Independent (Nonpromotional) Education & Related Grants** (IV-1).

Post-Graduate Grants may not be used to support HCPs (eg, practicing physicians, pharmacists, nurse practitioners, managed care administrators, etc) attending the conference.

3.3. Grant Amount

Post-Graduate Grants may not be for an amount greater than travel, lodging, and registration fees for each student, resident, or fellow. Any expenses incurred outside of travel, lodging, and registration fees are not supported by Postgraduate grants.

All commercial support, for any purpose, should be in a form of a grant. Expenses of students, residents, or fellows should never be submitted to AZ for reimbursement. If expenses are submitted, they should not be processed. Cash payments are not allowed.

3.4. Grant Approvals

All Post-Graduate Grants must be first approved by the appropriate managers up to their Delegation of Authority. Grants exceeding an individual's Delegation of Authority limit are subject to approval according to the requirements in the Delegation of Authority database.

Post-Graduate Grants may be funded locally by the District/Region responsible for the AZ employee submitting the request, or centrally by a specific TA Team.

3.5. Required Contracts

Both parties must agree to and sign a Post-Graduate Grant Contract before a Post-Graduate Grant may be paid.

3.5.1 Turnaround Time

In order to adhere to standard accounting principles regarding prepaid expenses, grants are typically not processed more than 60 days before the date of the program or activity supported by the grant, unless specifically requested by contacting the AZ Lecture Bureau.

Post-Graduate Grant Requests must be received at least 45 days prior to the date of the educational program date in order to be processed by that program date. All requests that are received without a 45 day lead time will be processed with all others according to standard FIFO (first in, first out) procedure. Furthermore, requests that are submitted without the 45 day lead time will typically not be rushed ahead of those with proper lead time. Should extenuating circumstances require that a request be processed more expeditiously, please notify the AZ Lecture Bureau of the situation. The Lecture Bureau will then make every reasonable effort to accommodate the request.

3.5.2 Letter of Agreement

AZ has developed letters of agreement to be used when arranging a grant with a recipient organization, society, or group. These letters of agreement have been tailored depending on the type of grant at issue. *Checks for grants will not be cut and distributed unless the grant recipient has signed the appropriate letter of agreement and the AZ Lecture Bureau has received it.*

An AZ grant letter must be signed for each Post-Graduate Grant. AZ employees should not sign a grant letter of agreement from any other organization. If the organization requires that their letter of agreement be signed, the letter should be forwarded to the field Professional Education Department (PED) for review and an appropriate signature. Other letters of agreement will **not** substitute for AZ's letter of agreement.

3.5.3 Grant Approval

The District Sales Manager (or appropriate corresponding member of AZ management) must first approve all Post-Graduate Grants up to their Delegation of Authority. Grants exceeding the manager's Delegation of Authority limit are subject to approval according to the requirements in the Delegations of Authority database.

4. Required Contracts

An AZ Grant Letter of Agreement contract must be completed for each Post-Graduate Grant.

5. References

5.1. AZ Business Policies

Product Promotion (II-1); **Gaining Access to Healthcare Professionals** (II-3); **Independent (Nonpromotional) Education & Related Grants** (IV-1); **Convention/Symposia Exhibits** (IV-3); **Charitable Contributions and Sponsorships** (VI-3); **AstraZeneca Representation at Charitable Fund-Raisers** (VI-2).

5.2. Other Sources

ACCME Guidelines
ACPE Guidelines
ACHE Guidelines
AstraZeneca's Delegations of Authority Database

V. Company Property & Interest

V – 1 Safeguarding Company Interests

AstraZeneca

Safeguarding Company Assets

Policy No.: V-1

Issued by: AZ Business Policy Group
Date Issued: 03/31/2000
Date Revised: **07/02/2002**

Contents

1. Key Learnings

- **AZ employees have a responsibility to safeguard and preserve Company assets entrusted to them**
- **All electronic equipment, cellular telephones, and peripherals must be kept in good working order**
- **Expenses for which reimbursement is sought must be submitted accurately and in a timely manner in accordance with current policy on expense reporting**
- **The Corporate Credit Card is to be used for business expenses only**
- **All corporate records for which employees are responsible must be true, accurate and complete, and must be prepared in a timely fashion**
- **Any *unauthorized* use of AZ funds by an employee is a violation of AZ policy.**

2. Purpose

To state AstraZeneca (AZ) policy regarding the preservation and use of Company assets by all AZ employees.

3. Policy

3.3. General Policy

All AZ employees have a responsibility to safeguard and preserve assets entrusted to them for their use in conducting AZ business. This includes such items as sales equipment (*eg*, hospital display units, brochures, electronic devices,); computers, palm pilots, security access cards to buildings and computing systems, computer programs and software; company cars; Corporate charge cards; cellular telephones; telephone charge cards; fleet car service/fuel cards;; funding allocated for various programs (*eg*, speaker and lunch programs); videotapes; airline tickets provided for AZ-sponsored travel; and other equipment and supplies that may be issued from time to time. These assets are issued to employees for their use over an extended period of time, but remain AZ property and are recorded on AZ books as assets. These items must be returned promptly by the employee upon request by AZ or upon termination of employment.

3.2. Sales Equipment

3.2.1. Sales equipment must be kept in serviceable and presentable condition at all times. Promotional materials that have become outdated, soiled, or damaged must not be used; detail bags must be kept clean and neat so that they present a professional appearance and give the user a sense of pride and professionalism. All electronic equipment, cellular telephones, and peripherals must be kept in good working order. AZ-issued computers and software must be well maintained and safeguarded against theft or improper use.

3.2.2. Sales equipment placed inside a car must be kept in the trunk of the car at all times when the car is not occupied.

3.3. Company Car

All AZ employees must follow the standards and restrictions for AZ automobile use provided in the policy entitled **Fleet Vehicles** (V-4) and the Driver Assistance Handbook issued by Fleet Administration.

3.4. Expense Reporting

3.4.1. All AZ employees must honestly, accurately and promptly report expenses for which reimbursement is sought in accordance with current policy on expense reporting. Original documentation must be submitted for any single expense item according to the guidelines provided by AZ. Although not required in all instances, receipts should ordinarily be submitted. Expense reports must be filed no less frequently than once a month. However, very small expenditures that total less than $100.00 may be deferred and submitted quarterly so long as the delay does not impact your Amex credit status.

3.4.2. All AZ employees must familiarize themselves with AZ **Expense Reimbursement** (VI-4) policy.

3.5. Corporate Charge Cards

3.5.1. All AZ employees are required to use the AZ-provided Corporate Card for all travel expenses and local business expenses whenever possible.

3.5.2. The annual "Rewards" membership fee associated with the Corporate Amex Card is not reimbursable by AZ Financing, delinquency or other fees for this card and fees for other credit or charge cards are not reimbursable.

3.5.3. The Corporate Card is to be used for business expenses only. Personal expenses *cannot* be charged with the Corporate Card. No one other than the AZ employee named on the card is permitted to use the Corporate Card for any reason.

3.5.4. All original Corporate Card receipts and the detailed receipts from the selling establishment are to be submitted with the expense report.

3.5.5. Monthly statements are sent directly to the employee's home each month. All billing discrepancies should be resolved directly with the Corporate Card Vendor using the Customer Service Center number provided.

3.5.6. Payment of all charges is due immediately upon receipt of the monthly statement. Employees are liable for payment of all charges incurred on the Corporate Card. The amount of legitimate business charges will be reimbursed directly to Amex or as a direct deposit to the employee pursuant to the **Expense Reimbursement** (VI-4) policy. Employees will not be reimbursed for any late fees incurred for failure to pay the charges promptly and in full each month.

3.5.7. AZ management receives monthly account activity reports from the Corporate Card Vendor. The corporate **Expense Reimbursement** (VI-4) policy along with any other Company guidelines or other budgetary considerations governs spending.

3.5.8. If your card is lost or stolen, call the Vendor's Customer Service Center immediately. Customer service representatives are available 24 hours a day, seven days a week.

3.5.9 The Corporate Card is the property of both the vendor and AZ. Any abuse of the card (such as delinquencies or personal use of the card) may result in suspension of all privileges, forfeiture of the card or termination of employment.

3.6. Telephone Charge Cards

All AZ employees should use the telephone card provided by AZ for all business-related toll telephone communications to take advantage of favorable AZ-negotiated

rates.

3.7. Meeting Travel Expense and Airline Tickets

All AZ employees must follow the procedures relating to travel expenses and airline tickets provided in the AZ policy entitled { HYPERLINK "file:///C:/Web%20docs/Web%20docs%208-23/V-3%20-%20Travel.htm" } (V-3) and the **Expense Reimbursement** (VI-4) policy.

3.8. Cellular Telephones

AZ-provided cellular telephone is to be used for business purposes only.

3.9. Record-keeping and Reporting Systems

The integrity of AZ record keeping and reporting systems must be respected at all times. All corporate records for which employees are responsible must be true, accurate and complete, and must be prepared in a timely fashion. The financial records of AZ must accurately reflect and fairly represent AZ activities; therefore, they must be maintained in accordance with AZ policies and in a manner, which reflects the nature and purpose of each activity. No false or inaccurate entry is to be made in the records of AZ for any reason.

3.10. Unauthorized Use of AZ Funds

Any *unauthorized* use of AZ funds by an employee is a violation of AZ policy. Criminal charges may be pursued if, in the opinion of AZ, fraud or embezzlement is involved. In summary, all employees are responsible for using the many resources entrusted to them in the most efficient manner possible for the benefit of AZ.

3.11. Questions

Any questions pertaining to the application of this policy to a specific situation should be directed to your direct supervisor, who will consult with the appropriate Finance personnel if necessary.

4. References

4.1. AZ Business Policies

Electronic Communications and Devices (V-2); { **HYPERLINK "http://uspolicies.us.astrazeneca.net/marketing/V-3_-_Travel.htm"** } (V-3); { HYPERLINK "http://uspolicies.us.astrazeneca.net/marketing/V-4_-_Fleet_Vehicles.htm" } (V-4)

4.2. Finance Business Policies

Expense Reimbursement (VI-4)

4.3. Other Sources

Driver Assistance Handbook

Electronic Communication and Devices:

The current policy has not changed.
If changes occur, you will be notified electronically via a Sales Connection Newsflash.

Reminder: all current policy information is on the Policy Intranet Site.

AstraZeneca

Travel Meeting and Services Policy

Policy No.: V-3

Issued by: **AZ Business Policy Group**
Date Issued: **3/31/00**
Date Revised: **07/01/02**

Contents

1. Purpose of the Policy

This policy sets forth guidelines and established procedures for employees who incur business travel and entertainment expenses while acting on behalf of or for the benefit of AstraZeneca. Employees will be reimbursed for necessary and reasonable expenses that are related to the transaction of Company business.

This policy should be read in conjunction with the "Expense Reimbursement Policy" (Finance).

Please note that all airline contracts are approved for business purposes only. For personal travel needs, please contact Carlson Leisure Group at 877-429-8849, where special rates and discounts are available.

2. Objectives

- Ensure all US employees have a clear and consistent understanding of policies and procedures for business travel and entertainment.
- Provide business travelers with a reasonable level of service and comfort at the optimum cost.
- Maximize the company's ability to negotiate discounted rates with preferred suppliers and reduce travel expenses.
- Employees are expected to exercise prudent business judgment regarding expenses covered by this policy. Employees may only request reimbursement for amounts actually spent.

3. Responsibility and Enforcement

Employees are responsible for complying with this travel policy. Each manager is responsible and accountable for monitoring compliance with policy when reviewing requests, travel expense reports, or other travel management information reports. Any deviations must be noted and specifically approved by an *AZLT member or the Vice President, Research and Development Site General Manager.*

Employees submitting expenses that are not in compliance, risk delayed, partial or forfeited reimbursement. Violation of this policy will result in disciplinary action, up to and including termination. The Company assumes no obligation to reimburse employees for expenses that are not in compliance with this policy.

Management reports will be reviewed periodically with business heads to ensure adherence to policy.

Questions regarding this travel policy should be referred to the Leader, Travel, Meetings and Fleet Purchasing (302) 886-3556 or by e-mail.

4. Travel Authorization

The company will not reimburse travel and entertainment expenses incurred by a spouse or other individual accompanying an employee on business unless both of the following conditions have been met:

- There is a bona fide business purpose for taking the spouse or individual
- Such expenses have received prior approval by an *AZLT member or the Vice President, Research and Development Site General Manager.* Requests and approvals must use the "Travel Request for Spouses" authorization form (AM5627).

5. Travel Arrangements

As there are significant dollar savings to be gained by making travel arrangements, all travel arrangements including air, lodging and rental cars must be booked through Carlson Wagonlit, AstraZeneca's designated Travel Management Company:

Carlson Wagonlit Travel
1800 Concord Pike
Rollins Building – 1st Floor
P.O. Box 15437
Wilmington, DE 19850-5437

5.1 Domestic Business Travel (24x7):

Phone Reservations (888) 552-7790 (Option #2)

Horizon Electronic Booking: 888-552-7790 (Option #3)

Horizon Technical Support: (800) 333-4740 (Option #3)

5.2 International Business Travel (7:30 a.m. to 6:00 p.m.) (EST):

Phone Reservations: (888) 552-7790 (Option #1)

24-Hour Emergency Service (Continental USA): (800) 777-7999

ID Code: A/Q7L-AZ

6. Traveler Profile Forms

All employees expecting to travel at least once per year should submit a completed traveler profile form to Carlson Wagonlit to ensure that pertinent details and preferences are available for the reservation process. It is the responsibility of the traveler to keep profile information current by advising Carlson Wagonlit in writing of updates.

Horizon Users: Profiles are to be maintained by the traveler or travel arranger via Horizon, the electronic booking tool.

7. Preferred Suppliers

Preferred suppliers are those with whom AstraZeneca has negotiated advantageous agreements that provide benefits to both the Company and travelers. They should always be used in preference to their competitors unless reasonable business and personal considerations require otherwise. A list of preferred suppliers and discounted rates is available on the Travel Services intranet site under preferred suppliers.

8. Air and Rail Travel

Rail reservations should be made by calling Amtrak directly at (800-835-8725) or via their web site at http://www.amtrak.com. Rail reservations reserved through Carlson Wagonlit result in a higher transaction fee of $40.

Air Travel Parameters: Defined as flying time to the first business destination by the most direct route.

CLASS OF POLICY

DOMESTIC / NORTH AMERICA	COACH
INTERNATIONAL	
< 6 HOURS	COACH
> 6 HOURS	BUSINESS
RAIL	COACH
ACELLA	BUSINESS

*Business class of travel will normally be undertaken for international flights longer than 6 hours. When the "preferred carrier" reasonably meets the business need and is not used, coach class of travel will be undertaken.

Advance Itinerary Authorizations will be required for all transactions that are not charged to the employee's Corporate Amex Card. As circumstances allow, the Travel Management Company will take advantage of discounted fares. Frequent flyer programs will not influence carrier selections.

9. Travel Parameter Exceptions

Travel outside of policy limits requires authorization of an AZLT member or the Vice President, Research and Development Site General Manager. If employees who are eligible for different classes of travel wish to travel together, the Senior Staff should downgrade.

10. Parameters for Lowest fares

The following parameters have been established to allow for cost savings without a great inconvenience to the individual traveler:

1. Employees are expected to make air travel arrangements in a timely manner to obtain the lowest fare available. In order to take advantage of discounted fares, determining travel plans at least 7 days in advance is preferred.

2. Departure/Arrival Window - If a flight's departure/arrival is within 2 hours of the requested time (before or after) and does not add more than 2 hours to overall travel time, the lowest available fare will be considered.

3. One stop or connecting flights will be considered if substantial savings can be achieved.

4. Use of alternate airports and the use of penalty or non-refundable fares will be offered by the agent and should be considered to reduce overall air travel expense.

10.1 Upgrades of Service and Frequent Flyer Programs:

It is company policy to allow employees to accept free upgrades or use frequent flyer points that incur no additional expense to the Company and to retain frequent flyer bonuses earned while traveling on company business. Under no circumstances is an employee authorized to request a more expensive or extensive routing to obtain upgrades and/or frequent flyer points. Furthermore, annual fees for participation in awards programs are not reimbursable by AstraZeneca.

10.2 Unused Tickets and General Refunds:

All wholly or partially unused tickets must be returned to Carlson Wagonlit, who will process a credit to the employee's Corporate Amex account for the unused coupon. If for any reason a ticket or other travel related credit is refunded or exchanged for a lower-priced

alternative, the amount refunded or credited to the employee's Corporate Amex account by an airline or rail carrier must be returned to the Company as a credit transaction through AstraZeneca's Expense Reporting Sytem (AZER).

11. Risk Management

Situations arise where several employees from the same business or staff area may be traveling on the same flight or train. In order to minimize these occurrences, business areas and staff heads are responsible to determine the appropriate level of risk. The guideline is that no more than three (3) subordinates, or fifty percent (50%) of the group traveling, whichever is less, should travel with a principal.

12. Lodging

Hotel selection: Employees are expected to use the preferred hotel vendors as outlined in the hotel section of the Travel web site. Travel Purchasing will negotiate discounted rates with these hotels.

12.1 Room type

A single room with a private bath in a mid-level (three- or four-star) hotel is the Corporate standard. Periodic review of company lodging expenditures will be conducted for all travelers and provided to department management to ensure compliance to company standards.

12.2 Cancellation

The Travel Management Company will guarantee all rooms for late arrival. Employees must cancel room reservations by 6:00 p.m. on the expected day of arrival (4:00 p.m. at many resorts) to avoid a no-show charge. Employees should cancel by contacting the Travel Management Company directly. If a cancellation is made directly with a hotel, the cancellation number must be retained as documentation of the cancellation. **No-show charges are not reimbursable by the company to employees.**

12.3 Telephone Charges

Calls made through hotel switchboards are usually subject to substantial premiums and should be avoided by using a Company provided phone card.

13. Car Rental

Cars are to be rented by employees only when other means of transportation are unavailable, more costly, or impractical. The use of a rental car must be justified as a business need and not as a matter of personal convenience.

13.1 Rentals:

All rentals must be booked through Carlson Wagonlit using the Company's preferred vendor to take advantage of the large volume discounted rate, unlimited mileage (excluding one-way rentals) and enrollment in its preferred corporate customer program, which offers added convenience when renting. Automobile rentals should be for intermediate-size automobiles, although full-size automobiles may be used to meet business needs. When the preferred vendor is unavailable, Carlson Wagonlit will make arrangements with secondary car rental vendors.

13.2 Car rental insurance:

When renting a car for company business, use the following as a guideline for insurance:

	LDW – Loss Damage Waiver Coverage	PAI – Personal Accident Insurance	PEP – Personal Effects Protection	ALI – Additonal Liability Insurance
United States	**Decline**	**Decline**	**Decline***	**Decline**
United Kingdom	**Decline**	**Decline**	**Decline***	**Decline**
Canada	**Accept**	**Decline**	**Decline***	**Decline**
All Other Countries	**Accept**	**Decline**	**Decline***	**Decline**

* In the event of *In the event of carrying high value goods in the car, you may want to accept this coverage.

13.3 Refueling

Employees are encouraged to refuel rental cars before returning them to the vendor. This practice can save as much as 50% of the gasoline expense.

14. Other Transportation

14.1 To and from the airport

An airport limousine, hotel shuttle, personal car or a Company car (if available) may be used when traveling to and from the airport. The lowest expense must be considered in selecting the transportation.

Preferred limousine and car parking suppliers are listed on the Travel Services Intranet site under Preferred Suppliers.

14.2 Personal Automobile Expense and Mileage

Employees will be reimbursed for the business use of a personal automobile. Reimbursement rates change periodically. This covers all expenses incidental to the use of a personal automobile including gas, oil, insurance, wear-and-tear. Automobile mileage is measured from the employee's office, headquarters or home to the business destination. It is the employee's responsibility to maintain accurate records of all personal automobile business miles. When using a personal automobile for longer business trips, the total cost of the trip, including mileage, meals and lodging should not exceed the cost of public transportation.

14.3 Taxis and Other Local transportation

The cost of taxis to and from places of business, hotels, airports, or railroad stations in connection with business activities is fully reimbursable. Use of taxis is authorized only when a more economical service (i.e., hotel vans, shuttles) is not available or practical.

15. Quality of Service

Service standards are agreed with preferred suppliers. If travelers or travel organizers receive inferior service they should write to the supplier involved via the local travel professionals. The Companies will, in collaboration with the Travel Advisory Board and Meetings Advisory Board where appropriate, collect and use supplier performance information for continuous improvement purposes.

16. Meals and Entertainment

Personal meals are defined as meal expenses incurred by the traveler when dining alone on an out-of-town business trip.

Business meals are defined as meals with clients, prospects, or associates during which a specific business discussion takes place. Entertainment expenses include events such as clubs, theater, and sporting events, wherein a business discussion takes place during, immediately before, or after the event.

16.1 IRS Requirements

Please refer to the Expense Reimbursement Policy (Finance Dept.).

16.2 Other Reimbursable & Non Reimbursable Expenses

Please refer to the Expense Reimbursement Policy (Finance Dept.).

17. Payment Method - Corporate Card

It is **mandatory** to use the **Corporate Amex Card** as the payment method for travel and entertainment expenses where accepted. This will ensure insurance coverage, optimum

cash management and compilation of vendor data to maximize negotiating leverage. Exceptions to using the card are for small cash items under $25 and where the corporate card is not accepted. The Corporate Card must only be used for business purposes and employees are expected to submit their expense reports in the timeframe specified by AZER. Failure to submit timely expense reports will result in:

- Notification sent to employee and/or manager.
- Suspension or cancellation of charge privileges.
- Possible disciplinary action.

17.1 Issuance Criteria

All employees expecting to travel at least once per year or who will incur at least $500 per year in travel expenses should acquire a corporate card. Applications for the corporate card are available from the Corporate American Express desk at 302-886-2112 or by email to Elaine Webster.

17.2 Emergency Assistance

American Express Global Assist is available to all cardholders when traveling. It provides help with securing money, medical assistance, travel needs, any unusual service needed, and getting in contact with people in adverse conditions. The service is available 24 hours a day by calling 800-333-2639 in the United States or by calling collect 715-343-7977 from anywhere in the world.

18. Settlement of Expenses

Please refer to the Expense Reimbursable Policy (Finance Dept.).

19. Insurance

The Company provides insurance coverage for certain employees while traveling on Company business. For specific coverage benefits, contact either the Corporate Employee Benefits Department or the Insurance Department.

20. Safety

Employees should always use discretion to maximize personal safety when traveling to their destination.

The use of cellular phones while driving a company vehicle is strictly prohibited (see Motor Vehicle Safety (M&S-E-5) and Global AstraZeneca Safety Policy).

Employees shall not operate Company vehicles, or other vehicles, on Company business when their ability to do so has been impaired by alcohol or drugs. Seat belts must be worn by all passengers at all times when traveling on Company business. This includes the use of Company, rental, and personal vehicles.

When staying at hotels, employees are advised to use main or well-lighted entrances, close the room door securely and use all locking devices, not answer the door to strangers, and report unusual activities to hotel security.

21. Loss of Personal Property

21.1 Policy

The Company provides limited coverage in the event of loss or theft of an employee's money or other valuables either at Company locations or while traveling on Company business as specified below.

21.2 Personal Eye Glasses

The employee will be reimbursed for the cost of replacing or repairing eyeglasses that are damaged accidentally during the performance of job duties.

21.3 Baggage Indemnification

Coverage is provided to employees traveling Company business for loss of or damage to many personal effects, which are normally included as "accompanied" baggage on a business trip. The amount of coverage is as follows:

- The total amount indemnified for each employee shall not exceed $1,500.
- The indemnification for any single article will not exceed $300.
- The indemnification for cash will not exceed $250.

Certain property not related to the needs of travel will not be covered: e.g., stamp collections, manuscripts, medals, coins, bonds, securities, crockery, china, glass, sculpture, curios, pictures, musical instruments, antiques, plants or animals (or any personal purchases made during trip).
Since the intent of the Company's baggage indemnification is to provide limited protection to the employee for out-of-pocket costs not covered by personal insurance, only loss or damage not covered by other insurance will be considered.

Each employee is expected to take reasonable and proper care of his effects and to take all necessary steps to protect from loss, to minimize loss and to recover missing property.

21.4 Personal Automobiles

The Company will provide reimbursement to the employee for physical loss or damage to the employee's car while on Company business resulting from fire, theft or collision. Such reimbursement is reduced by any other available and collectible insurance or other reimbursement and by a $50 deductible.

21.5 Personal Effects in Cars

The Company will reimburse the employee for loss or damage to personal effects while contained in a Company automobile or the employee's personal car (or one temporarily hired or borrowed) while in use for Company business if such loss is caused by fire, Acts of God, explosion, vandalism or theft from the automobile. Such reimbursement is reduced by any other available and collectible insurance or other reimbursement and is subject to a limit of $250 which, in the case of theft, is payable only if the auto was properly locked.

Specifically excluded from this policy is theft, loss or damage relating to any and all types of electronic and computing devices and media, such as computers, cell phones, Personal Digital Assistance (PDA) devices, etc.; sound reproduction, transmitting and/or receiving devices, and peripheral equipment. Examples of excluded items are CB radios, AM/FM radios, tape decks, CD players, etc.

21.6 Employees Covered

This policy applies to all locations and to all employees.

21.7 Reference Source

For additional information or clarification contact the Manager, AstraZeneca Risk & Insurance Services, Wilmington.

**All reimbursement expenses under this Section will be charged to the employee's cost center.

22. Meetings and Group Travel Policy

22.1 Purpose of the Policy

This policy sets forth guidelines and established procedures for AstraZeneca personnel who have responsibilities for planning meetings and group travel. For interpretation of this policy, a meeting is any off-site gathering comprised of 10 or more people working for a common purpose.

22.2 Objectives

- Ensure all US employees have a clear understanding of policies and procedures for meeting and group travel.
- Ensure all US employees are familiar with the AstraZeneca Preferred Meeting Planning Suppliers.
- Ensure all US employees are familiar with the capabilities of the web-based Meetings Resource Center.

22.3 Group Travel and Meeting Logistics

Employees are responsible for complying with the Meetings Group Travel Policy, the Code of Conduct, and the applicable AstraZeneca Business Policies (see Engaging Healthcare Professionals, Institutions, & Organizations in Contracted Services – III-1). Each manager is responsible for monitoring compliance with these policies, when reviewing meeting plans. Any exceptions should be directed to the Manager of Meeting Services and Group Travel.

Logistics include:

- Group Travel
- Site Selection
- Budget Management which includes:

- Transportation – Airfare, Ground Transfers, Rental Car, Rail
- Lodging – Hotel guest rooms
- Food & Beverage – Hotel, Catering, and off-site Food & Beverage
- Meeting Rooms – Meeting Room Rental, Audio/Visual Equipment, Miscellaneous Supplies, Printing, Office Equipment

22.4 Preferred Suppliers

The Meeting Advisory Board representing product areas throughout AstraZeneca established a list of "PREFERRED SUPPLIERS" for our meeting arrangers. These suppliers should be the only suppliers used for any of your meeting planning needs. These suppliers are being held to very high standards; therefore, should you have any issues on quality or service, contact the Manager of Meeting Services and Group Travel.

The list of current Preferred Suppliers can be found within the Resource Center Web-based Meeting Resource Center @ **www.meetingsAtoZ.com**

22.5 Meeting Registration

Any off-site meeting comprised of 10 or more people or costing more than $5,000 should be registered with Meeting Services via this web-based Meeting Services Resource Center and include a budget summary.

Fleet Services:

The current policy has not changed. However, changes are expected so the decision has been made to wait and mail you the revised policy when it is complete.

Note that when changes are official, you will be notified via a Sales Connection Newsflash with the effective date.

Reminder: all current policy information is on the Policy Intranet Site.

Motor Vehicle Safety:

The current policy has not changed. However, changes are expected so the decision has been made to wait and mail you the revised policy when it is complete.

Note that when changes are official, you will be notified via a Sales Connection Newsflash with the effective date.

Reminder: all current policy information is on the Policy Intranet Site.

V – 6 Sales Prescriber Data

AstraZeneca

Sales Prescriber Data

Policy No.: **V-6**

Issued by: **AZ Business Policy Group**
Date Issued: **12/07/2001**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **All sales and prescriber data must be kept confidential**
- **AZ personnel must sign the "Statement of Policy on Confidentiality of Sales, Reporting and Prescriber Profiling Information".**

2. Purpose

To state the standards of confidentiality that Marketing and Sales Personnel must observe with respect to sales and prescriber data collected by or for AstraZeneca (AZ).

3. Policy

3.1. Sources of Sales and Prescriber Data

3.1.1. AZ purchases sales and prescriber data from various vendors, which collect and process sales activity from wholesalers and pharmaceutical manufacturers, as well as other sources across the United States. AZ also internally develops sales and prescriber data.

3.1.2. AZ distributes sales and prescriber data to TA Marketing and Sales Personnel for use in strategic assessment of business opportunities and performance evaluations.

3.2. Confidentiality

Any sales and prescription information collected either by or for AZ is strictly confidential and may be used only within AZ; under no circumstances may it be discussed with or revealed to anyone outside the AZ. The meaning is specific: ***The information an AZ employee receives about sales and market share may not be discussed with customers, with competitors, or with anyone else outside the AZ, with the exception of co-promotion and other contractual partners with whom AZ has entered into an agreement to share such information. This restriction applies throughout the employee's active employment with the AZ and continues after termination of the employment relationship.***

AZ personnel are expected to sign the "Statement of Policy on Confidentiality of Sales, Reporting and Prescriber Profiling Information". It states, "This is to confirm that I am fully aware of the responsibility I must exercise in the utilization of all sales tracking and profiling data provided by third party vendors. This information must remain highly confidential and cannot be disclosed to or discussed with anyone outside of AZ".

4. References

4.1. AZ Business Policies

Intellectual Property Claims (I-4); **Patient Privacy** (I-6); **Safeguarding Company Assets** (V-I)

VI. Other Policies

VI – 1 Advance Event Reporting

AstraZeneca

Adverse Event Reporting

Policy No.: **VI-1**

Issued by: **AZ Business Policy Group**
Date Issued: **02/08/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **All AZ employees are required to report adverse events to Drug Safety as soon as they become aware of an event associated with an AZ product.**
- **An adverse event must be reported whether or not the reported adverse event is described in the full prescribing information or the published literature and whether or not the reported adverse event is thought to be caused by the product.**
- **The HCP's assessment regarding the adverse event relationship to the AZ product does not determine the need to report that event. All adverse events (serious and non-serious) are to be reported to Drug Safety.**

2. Purpose

To ensure that AstraZeneca (AZ) complies with Food and Drug Administration regulatory requirements, all adverse event reports must be forwarded to Drug

Safety promptly and accurately in accordance with the applicable procedures explained in this policy.

3. Policy

3.1 Definition of Adverse Events

3.1.1. An adverse event is the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product.

An undesirable medical condition can be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver), or the abnormal results of an investigation (eg, laboratory findings, electro-cardiogram).

3.1.2. Adverse events may include, but are not limited to

- Unfavorable side effects
- Toxicity
- Injury
- Overdose
- Sensitivity reactions
- Pregnancy
- Drug Abuse & Misuse
- Suicide
- Drug Interaction
- Withdrawal effects
- Failure of the Drug to exhibit its expected pharmacologic/biologic effect, also known as lack of effect
- An exacerbation of any pre-existing condition(s) occurring during the use of an AZ product

3.2. Reporting Obligations

All AZ employees are required to report adverse events to Drug Safety as soon as they become aware of the event. An adverse event must be reported:

- Whether or not the reported adverse event is described in the full prescribing information or the published literature
- Whether or not the reported adverse event is thought to be caused by the AZ product.

3.3. What Should Be Reported

3.3.1. As much information as possible should be gathered concerning the details of the adverse event. **At a minimum, the following must be identified**

- **The date you were informed of the event**
- The Sales Specialist name and phone number
- The name and address of the reporting physician or other HCP

- Patient identifying information (such as age, sex, and initials)
- The adverse event
- The AZ product involved.

3.3.2. Forward any written reports, letters, or other documents that you may receive, related to the adverse event, to Drug Safety and retain a copy for your records.

3.4. Timeframe for Reporting

It is essential that you send your report to Drug Safety through electronic submission or fax on the SAME DAY you become aware of the event. If E-mail is not possible fax the report to Drug Safety as described in section 3.5.1 Methods of Reporting. If E-mail and fax are not possible report the event through the Information Center immediately by dialing (800) 236-9933, (8:00 AM – 7:00 PM ET), Monday through Friday, excluding holidays.

3.5. Methods of Reporting

3.5.1. Adverse events may be reported by either of these methods:

By Electronic Submission (preferred method):

- Use the tool and form available in Sales InSite.
- Open Sales InSite.
- On the Navigation Bar, select "Forms"
- Then select "Adverse Events."
- A new window will open with the Adverse Event form. Fill in the appropriate fields.
- When finished, click the Send button on the left side of the toolbar to send the information to the Drug Safety Department.

If you are working off line, ensure that you synchronize as soon as possible to transmit the information to the Drug Safety department.

By Fax (if unable to send electronically):
Complete the AstraZeneca (AZ) Adverse Event Report Form and fax the form to Drug Safety at (302) 886-4114. **It is no longer acceptable** to use the former Astra or former Zeneca legacy adverse event report forms. It is not necessary to obtain the physician or other healthcare professional's (HCP's) signature on the Adverse Event Report Form. Blank copies of the Adverse Event Form can be printed from the Sales InSite.

By Telephone (if unable to send electronically or Fax):
Telephone the Information Center at AZ at **(800) 236-9933.** The Information Center will document the information and forward the report to Drug Safety.

3.6. Emergencies

If you receive a report of an emergency about which a physician or other HCP wants immediate information

1. Ask the treating physician or other HCP to telephone the Information Center at AZ at **(800) 236-9933** so that communication between the treating physician or other HCP and the Information Center at AZ is established.

2. Immediately report the adverse event to Drug Safety.

3.7. Identifying the Treating Physician

If you receive a report of an adverse event from someone other than the treating physician (eg, nurse, pharmacist, patient, etc) make every effort to consult with the patient's treating physician. If you cannot consult with the treating physician promptly, make every effort to identify the physician and include their name, address, and telephone number in your report, along with the other information requested.

3.8. Comments and Potential Legal Involvement

If you have any information suggesting the adverse event being reported has or will lead to any legal involvement, this fact should be noted in your report. Otherwise, no comment regarding legal involvement should be made. Any other information reported should be limited to that which is medically relevant.

3.9. Enrollment in Clinical Studies

If the patient involved in the report is enrolled in an AZ clinical study, indicate this in your report and ask the physician or other healthcare professional to indicate this in his or her report.

3.10. Confidentiality

Do not discuss an adverse event report with anyone except the reporting physician or other healthcare professional, your designated supervisor and persons in Drug Safety, the Information Center at AZ, or the Legal Department. Questions directed to you by anyone else can be handled diplomatically by simply stating that, once you get the facts, you will refer the entire matter to Drug Safety.

3.11. Return of Drug

Do not accept the return of any containers of the AZ product involved, except upon specific request from the Company.

3.12. General Requests for Information

If HCPs ask for general information about adverse events on an AZ product with no indication of patient involvement, a Professional Information Request may be submitted. However, if the reporter indicates that a patient (or patients) has (have) experienced the adverse event, then this must be reported as an adverse event, even if specific details about the patient(s) are unknown. The procedure for reporting adverse events outlined in this document should be followed.

3.13. Questions

Any AZ employee who has any questions or concerns relating to the policy or procedures on Adverse Event Reporting should contact the Drug Safety Training Team at (302) 886-8364.

4. References

4.1 AZ Business Policies

Product Promotion (II-1); **Professional Information Requests (PIRs)** (VI-8)

VI – 2 Representation at Charitable Events

AstraZeneca

AstraZeneca Representation at Charitable Fund-Raising Events

Policy No.: VI-2

Issued by: **AZ Business Policy Group**
Date Issued: **10/01/2001**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **It is important for AstraZeneca to have a presence at charitable fund-raising events undertaken by non-profit organizations relating to our business interests -- that is, 501(c)(3) non-profit, healthcare-related organizations.**
- **Sponsorships of healthcare-related charitable fund-raising events undertaken by Sales or TA Support Functions must be funded from existing budgets within those groups.**

2. Purpose

To provide guidelines for AstraZeneca (AZ) employees for representing AZ at healthcare-related charitable fund-raising events.

3. Scope

This policy covers only charitable fund-raising events relating to healthcare non-profit organizations. Charitable contributions/grants to such organizations or sponsorships of programs other than fund-raising events are addressed under the corporate **Charitable Contributions and Sponsorships Policy** (VI-3), as are contributions/grants to non-profit organizations that are not healthcare-related

(eg, civic/community, education, arts/culture organizations in the regions surrounding AZ headquarters, R&D and manufacturing sites).

Charitable fund-raising events covered under this policy may include balls, galas, awards dinners, auctions, charity golf or tennis tournaments or other events where the primary purpose is to raise funds to benefit the non-profit organization. Charity walks, runs, dance-a-thons and other events aimed primarily at raising public awareness, but which may also have a fund-raising component (ie, through pledges to individual participants) are not addressed here, but are covered under the corporate **Charitable Contributions and Sponsorships Policy** (VI-3).

Charitable fund-raising events that may be supported by Sales and TA Support Functions are those that support ***healthcare-related non-profit organizations with 501(c)(3) tax-exempt status*** as public charities under the IRS code. (Organizations that have this status can easily demonstrate it. Most major non-profit health-care organizations—like the American Heart Association, American Cancer Society, Asthma & Allergy Foundation—are 501(c)(3) organizations; see attached list for other examples of 501(c)(3) organizations supported by AZ and aligned with our Therapeutic Areas.)

4. Policy

4.1. General Statement

It is important for AZ to have a presence at charitable fund-raising events undertaken by non-profit organizations relating to our business interests. Many of these organizations rely heavily on such events to generate funds for research, patient or public education, patient advocacy or services to their members. As a leading pharmaceutical company, AZ is frequently solicited to support such events--ranging from sponsorships to purchasing tables, serving on planning committees and attending the events. These events provide opportunities for AZ in terms of public relations, industry leadership and goodwill with important constituencies. It is common for AZ to purchase a table at a fund-raising gala or dinner or a foursome for a golf tournament. Although AZ may purchase an entire table to support the charitable organization, it is not appropriate to invite physicians or other healthcare professionals to join us at the table. The seats can only be used for AZ employees, or donated back to the sponsoring organization or other charitable organization to use (ie, raffle off or as part of a silent auction).

4.2. Coordinating and Approving Requests for Sponsorship of Charitable Fund-Raising Events

Requests for support of healthcare-related charitable fund-raising events may be addressed to any of a number of individuals or departments within AZ: Public Affairs, Therapeutic Areas or individual Product Teams, Business Centers, Managed Care Account Directors (ADs), DSMs or

PSSs, MISs and others. Before making a commitment to sponsor such an event, purchase a table, or enter a foursome, it is advisable to check with others in the company or to specifically ask the organization if other individuals or groups have been approached for support, to avoid duplication of sponsorships.

Within Sales and Scientific Commercialization, commitments for sponsorships of charitable fund-raising events may be approved by the PSS/AD/MIS if the sponsorship does not exceed $100. Requests for more than $100 must be approved by the appropriate manager, following existing Delegations of Authority. Frequently, these sponsorships will require the pooling of funds from more than one PSS, and may also involve funding from a Business Center or a TA.

Within the Managed Care Business Group and TA Support Functions, commitments for sponsorships of charitable fund-raising events should also be made according to existing Delegations of Authority. In some cases, requests for event sponsorships may come from the non-profit arm (often a foundation) of a for-profit managed healthcare organization or institutional customer; as long as the sponsorship is totally separate from AZ contracting or other business transactions, the sponsorship may be considered.

4.3. Supporting a Charitable Fund-Raising Event a Customer is Associated With

In some instances, an HCP may ask AZ to support a charitable fund-raising event because he or she is affiliated with the organization or is being recognized by the organization for service, research, etc. This is perfectly appropriate when the fund-raising event otherwise meets our criteria for sponsorship (ie, healthcare-related non-profit organization with 501(c)(3) status) and when the funds are available within the Sales and TA Support Functions organizations to support the event. However, it is not appropriate to support charitable fund-raising events recommended by HCPs when the events do not otherwise meet our criteria (eg, gala for a local symphony orchestra).

4.4. Auction Participation at Charitable Fund-Raising Events

If the charitable fund-raising event includes an auction, or sale of any type, any items purchased by AZ employees are to be paid for personally, not with company funds. These items are not reimbursable by AZ.

5. References

- **Gaining Access to Healthcare Professionals** (II-3); **Charitable Contributions and Sponsorships** (VI-3)
- Delegations of Authority Database

APPENDIX

Representative list of 501(c)(3) healthcare-related organizations supported by AZ:

The following are some of the major healthcare-related 501(c)(3) non-profit organizations already supported by AZ, both nationally and locally, because of their alignment with our business areas:

- American Heart Association (including American Heart Walks)
- Crohn's and Colitis Foundation of America
- American Cancer Society (including Relay for Life events)
- Susan G. Komen Breast Cancer Foundation (including Race for the Cure events)
- Y-ME
- US Too!
- National Alliance for the Mentally Ill
- National Mental Health Association
- American College of Allergy, Asthma and Immunology
- American Lung Association
- Asthma and Allergy Foundation of America
- National Patient Safety Foundation
- American Chronic Pain Association

Contributions and sponsorships need not be limited to these organizations, but these are the kinds of organizations where our contributions/sponsorships can have an impact on patients/families in the areas where we most want to be recognized for our leadership and our willingness to give back to the communities where we live and work.

VI – 3 Charitable Contributions & Sponsorship

AstraZeneca

Charitable Contributions and Sponsorships Policy No.: VI-3

Issued by: **AZ Business Policy Group**
Date Issued: **10/01/2001**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **Within Sales and the TA Support Functions, any charitable contributions/ sponsorships should be limited to 501(c)(3) non-profit healthcare-related organizations and should be funded from existing Marketing, Sales, or USDD budgets**
- **Within the Headquarters region, any charitable contributions/sponsorships made by Sales or TA Support Functions should be undertaken in consultation with Public Affairs**
- **Leaders within Sales or TA Support Functions are responsible for ensuring that charitable contributions/sponsorships made through their organizations are in compliance with all relevant AZ Business Policies, (AstraZeneca Representation at Charitable Fund-Raising Events (VI-2)) and are in compliance with the company-wide Charitable Contributions and Sponsorships (VI-3) Policy.**

2. Purpose

To establish standards, consistent with all relevant legal obligations governing charitable contributions and

- To outline organizational roles and responsibilities within the US business for making charitable contributions or sponsorship commitments on behalf of AZ
- To ensure that AZ's philanthropic resources are used strategically and in compliance with other business policies and relevant accounting/tax regulations. (This includes avoiding duplication in our contributions, since many organizations solicit support from more than one area within the company.)
- To describe the internal process for submitting requests for charitable contributions and sponsorships.

3. Definitions/Terms

501(c)(3): Section of the IRS Tax Code that designates an organization as charitable and tax-exempt. Organizations qualifying under this section are all private foundations (including corporate foundations) and all public charities [which are designated as both 501(c)(3) and 509(a)]. Most organizations seeking foundation or corporate contributions secure a Section 501 (c)(3) classification from the IRS. Proof of 501(c)(3) status is documented in a letter of determination, stating that the IRS has determined that the organization qualifies as a charitable entity. An organization with 501(c)(3) status can readily provide copies of its letter of determination and often automatically includes copies with requests for contributions or sponsorships.

Capital campaign: An organized drive to collect and accumulate substantial funds to finance major needs of an organization such as a building or major repair project or purchase of new equipment (for example, CT scan or laboratory equipment for a hospital). (Sometimes also known as "capital development campaign" or "building campaign".)

Charity: In its traditional legal meaning, the word "charity" encompasses religion, education, assistance to the government, promotion of health, relief of poverty or distress and other purposes that benefit the community. Non-profit organizations that are organized and operated to further one of these purposes generally will be recognized as exempt from federal income tax under Section 501(c)(3) of the Internal Revenue Code and will be eligible to receive tax-deductible charitable gifts.

Charitable Fund-Raising Event: An event where the primary purpose is to raise funds for a charitable organization or cause; frequently, a secondary purpose of these events is to increase awareness about the organization or cause with the public or with specifically targeted audiences. These events take many forms, including (but not limited to) gala dinners featuring awards programs or entertainment, auctions, charity golf tournaments, walks/runs/marathons/dance-a-thons. Increasingly, non-profit organizations are using these types of events to replace traditional "silent" fund-raising campaigns (such as direct mail or telephone solicitations) are are looking to corporations to sponsor the events.

Charitable Contribution: A contribution to a charitable organization that may be unrestricted (for general operating expenses) or may be designated to support a specific project or program, but does not generate significant publicity or marketing benefits to the organization or individual making the contribution. (See **Sponsorship of a Charitable Organization/Event** below for comparison.)

Corporate Foundation: A corporate (company-sponsored) foundation is a private foundation that derives its grant making funds primarily from the contributions of a profit-making business. The company-sponsored foundation often maintains close ties with the donor company, but it is a separate, legal organization, sometimes with its own endowment, and is subject to the same rules and regulations as other private foundations. (AstraZeneca has two corporate foundations, as described in the next section.)

Omnibus Budget Reconciliation Act of 1993: The Omnibus Budget Reconciliation Act of 1993 (OBRA) requires donors to charitable organizations to abide by two requirements in order to secure the maximum tax benefits for their gifts:

- **Substantiation of gifts of $250 or more:** Donors cannot claim deductions for gifts of $250 or more unless they have receipts from the charity to which donations are given. It is the responsibility of the donor organization to make sure that it has the receipt. A canceled check is *not* considered a receipt. [Note: AstraZeneca has a form that is mailed with charitable contributions of $250 or more to facilitate this documentation.]
- **Quid pro quo and gifts over $75:** When a donor receives goods or services for any payment of $75 or more to a charity, the charity must provide a receipt and a good-faith estimate of the value of goods and services (for example, meals, entertainment) received by the donor so that the donor can report the balance of the payment as a charitable contribution.

Sponsorship of a Charitable Organization/Event: A contribution or grant to a charitable organization for a specific project or program for which the organization or individual making the contribution receives significant publicity or marketing benefits (such as identification as a sponsor on invitations, advertising or marketing materials, signage, tickets/admissions to an event, opportunities to promote the contributing organization). For the purposes of this policy, sponsorships of charitable organizations/events in the name of AstraZeneca should be tracked as charitable contributions, whereas sponsorships associated with a specific product/brand should be considered promotional rather than charitable.

4. Overview of the Company's Charitable Contributions

AZ is a socially responsible, caring company, committed to maintaining a leadership presence and giving back to the communities in which our employees live and work. We do this in many ways, including financial support, product donations, employee volunteerism and board/leadership positions in support of charitable and civic organizations.

Our non-product charitable contributions and our sponsorships of events/programs on behalf of charitable organizations are made primarily through a direct giving program -- that is, through cash contributions from AZ to eligible non-profit organizations. In addition,

AZ sponsors a limited number of fund raising campaigns among employees on behalf of nonprofit organizations (ie, United Way), where payroll deductions or checks payable directly to the organization are coordinated through the company.

In addition, AZ has sponsored two corporate foundations in the US that support specific kinds of charitable contributions:

- The **AstraZeneca Foundation** provides our products at no cost to eligible patients who cannot afford to pay for their prescribed medications, through the **Patient Assistance Program**. The AZ Foundation also donates supplies of the company's products for humanitarian relief efforts in the US and elsewhere in the world.
- The **AstraZeneca Healthcare Foundation** provides the funding for National Breast Cancer Awareness Month, an extensive public health awareness and education campaign. The AZ Healthcare Foundation may also fund other public health awareness/education campaigns, as determined to be appropriate by the Legal and Tax departments of AZ.

Charitable contributions/sponsorships on behalf of AZ should always be coordinated with or through a legitimate nonprofit organization -- that is, an organization with documented 501(c)(3) tax-exempt status. AZ is not a charitable organization and employees are not authorized to independently organize charitable fund raising events on behalf of the company or to collect cash (or checks payable to the company) for charitable causes.

AZ also occasionally makes in-kind contributions of services (for example, publicity) to non-profit organizations through the Public Affairs department.

5. Scope and Exclusions

This policy addresses cash contributions made by the company to eligible 501(c)(3) organizations, regardless of whether they are unrestricted contributions or are intended to support specific programs/events, and whether or not AZ receives sponsorship benefits for these contributions.

This policy does not cover the following types of charitable contributions or grants, which are addressed elsewhere:

- **Product donations [USDD Medical Affairs policy on Patient Assistance and Charitable Donation; AZ Business Policies and Guidelines]**
- **Used computer equipment donations [Corporate & Community Affairs; R&D TCIS]**
- **Used scientific equipment donations [R&D site management]**
- **Employee-driven matching gifts to accredited colleges and universities [HR policy]**

The following do *not* qualify as charitable contributions and should not be coded/tracked as such:

- Grants to 501(c)(3) organizations that are earmarked for lobbying purposes [Note: Such grants may only be made by Government Affairs, but do not qualify for tax deductions either as charitable contributions or as business expenses.]

- **Educational grants**, as defined in AZ Business Policy **IV-7**
- Health fairs sponsored by a physician practice, hospital or managed care organization, defined under AZ Business Policy **Exhibit H, Patient Solutions** and **Exhibit K, Community Health Fairs** (Note: Contributions/sponsorships for those health fairs or community health/wellness outreach programs sponsored by 501(c)(3) organizations are considered charitable contributions and are covered under this policy.)

6. Policy

6.1. Roles & Responsibilities

6.1.1. Public Affairs

Public Affairs has overall responsibility for establishing policies and procedures relating to corporate charitable contributions and sponsorships; for developing a strategic framework for charitable contributions made by AZ within the US, for budgeting for and implementing charitable contributions and sponsorship strategies and plans within the Headquarters region, and for monitoring activities and expenditures in these categories throughout the US business. Three departments within Public Affairs support AZ's charitable contributions and sponsorships in the US:

- Corporate & Community Affairs
- Public Relations and Ally Development
- Government Affairs (Federal and State)

With the exception of the site managers and the Sales and TA Support Functions mentioned below (6.1.2 & 6.1.3), employees in any other areas of the business, including the headquarters-based functional areas, generally should not undertake charitable contributions and sponsorships on behalf of AZ. Requests for charitable contributions or sponsorships received by other individuals/groups should be forwarded to Corporate & Community Affairs for review. There are two exceptions to this general guideline:

- On occasion, it may be appropriate for an AZLT member to approve a charitable contribution/sponsorship for the philanthropic arm or foundation of a professional or trade association aligned with the AZLT member's functional area. The functional area should fund such contributions. However, as set forth in the company's Delegations of Authority, the Vice President, Public Affairs must concur with charitable contributions or sponsorships recommended by AZLT members.
- When a functional area or work team takes on a community service project (for example, clothing drive, holiday food/gift drive, neighborhood/facility fix-up), it may be appropriate to make a charitable contribution to the organization that is being helped. The functional area, should fund such contributions with the approval of the appropriate AZLT member and in consultation with the Vice President, Public Affairs. (Specifically in the Headquarters region, it is advisable before undertaking a community service project to contact Corporate & Community Affairs for recommendations about non-profit organizations already supported by the company or ongoing volunteer opportunities.)

6.1.2. Site Managers

Site managers at the following locations are responsible for establishing, budgeting for, and implementing local strategies appropriate to their community and business needs:

- Newark manufacturing site
- Westborough manufacturing site
- Wilmington R&D site (in close cooperation with Public Affairs, so as to avoid duplication of efforts)
- Waltham R&D site

6.1.3. Sales and TA Support Functions

Sales and TA Support Function leadership and are responsible for budgeting for and implementing charitable contributions and sponsorships that support 501(c)(3) healthcare-related organizations aligned with AZ business through the Therapeutic Areas, the regional Business Centers and the Managed Care Business Group. The leaders in these areas are also responsible for ensuring that charitable contributions and sponsorships made through their organizations are in compliance with all relevant AZ business policies, particularly when contribution or sponsorship requests are made by HCPs or institutional customers. Specifically:

- Charitable contributions may never be made to an HCP, institution, or organization in return for, as an inducement to, or in any way in consideration of, the current or potential prescribing, purchasing, use, formulary status or dispensing of AZ products
- Charitable contributions may only be made directly to the non-profit organization, not to or through an HCP, medical practice or other customer as a third party
- Charitable contributions may not be made by AZ "on behalf of" an HCP, medical practice or other customer. (The only exception, as noted in AZ Business Policy on Gaining Access to Healthcare Professionals (II-3), section 14, is when a contribution of no more than $50 is made to a designated charity on the occasion of a birth or death in the immediate family of an HCP or a member of an HCP's staff.)

Within the Sales and TA Support Function areas, individuals in the following roles are authorized to approve charitable contributions and sponsorships on behalf of AZ, consistent with the Delegations of Authority database:

PSS/AD, up to $100; for contributions of more than $100, the PSS/AD should seek approval from his/her manager

- DSMs, RSDs, ASDs, RBDs, NSDs (includes corresponding managed care functions)
- MISs, Regional Scientific Business Directors, Scientific Commercialization National Directors
- TA Leaders, Product Directors, PREP managers

6.1.4. Written Substantiation of Contributions of $250 or More

It is the responsibility of the AZ employee initiating the request for payment for a charitable contribution/sponsorship to ensure that the company receives written substantiation from the 501(c)(3) non-profit organization for any gift of $250 or more. The written substantiation should be forwarded to the appropriate individual in the AZ Tax department.

It is the responsibility of the Tax department to determine whether any given contribution/sponsorship is recorded, for tax purposes, as a charitable contribution or as a reasonable business expense.

6.2. Requirement for Written Requests

All requests for charitable contributions and sponsorships should be received in writing on the letterhead of the charitable organization and should include the following information:

- Name of the organization
- Complete mailing address
- Phone and fax numbers
- Name and title of the appropriate contact person
- Organization's tax ID number
- Description of the contribution/sponsorship being requested (including dollar amount, nature of program/event, timing and any other information that could be useful in reviewing the request).

  If the organization is requesting support from AZ for the first time, it will facilitate the review of the request if the following information is also included:
- Copy of the organization's 501(c)(3) determination letter from the IRS
- Financial statement for the most recently completed financial year, including current sources of income and amounts or percentages expended in program services, fundraising and administration
- Organization's most recent financial audit
- List of the principal staff members and members of the board of directors or trustees.

Requests should be submitted as far in advance as possible but certainly no less than 4 weeks prior to the time when the contribution/sponsorship is being sought.

6.3. Written Responses to Requests

AZ responds in writing to all written requests for charitable contributions/sponsorships. Standard letters to accompany contributions or to decline requests are available through Corporate & Community Affairs.

6.4. Types of Requests Not Supported

AZ does not support requests for charitable contributions from the following types of organizations, even when they do have 501(c)(3) status:

- Organizations that discriminate on the basis of age, race, color, religion, national origin, gender, sexual orientation, marital status, Veteran status, disability or other unlawful basis
- Sectarian or denominational religious organizations, missionary groups or projects serving religious purposes. However, on a case-by-case basis, the company will consider non-denominational activities operated by a church or religious group that serve a general community purpose or, for example, provide humanitarian relief.
- Fraternal, social, leisure, labor or political organizations
- Private foundations
- Public or private schools or scholarship funds (except in rare cases where a grant is made to support a specific science education initiative).
  AZ supports the education sector through a variety of non-profit organizations, such as Junior Achievement and the Delaware Valley Science Fairs. In addition to the above organizations, AZ does not support requests for the following types of grants or contributions:
- Capital campaigns
- Endowment campaigns
- Requests for loans or debt retirement
- Automatic renewal of grants
- Grants through which an AZ employee will receive any material benefit arising from the making of any portion of the grant
- Grants through which an HCP or other customer will receive any personal benefit
- Memorials
- Corporate promotional items for private events, school fairs/proms or other community programs, unless AZ is an official sponsor of the event or program.

In general, AZ does not make grants to individuals (for example, for travel, scholarships, camps) or sponsor individuals in fund-raising projects. However, it may sometimes be appropriate, especially in the Sales organization, for AZ to make a pledge to a non-profit organization when an individual HCP or team of HCPs requests support for participation in a walk, run or other healthcare-related charitable fund-raising event (for example, Race for the Cure, American Heart Walk). These pledges must be limited to $100, payable to the non-profit organization, not to the participant(s), and be funded from existing Sales or TA budgets.

6.5. Processing Payments for Charitable Contributions/Sponsorships

Charitable contributions and sponsorships should be processed using the Accounts Payable Request for Payment (RFP) form, available through the Finance department intranet site. Any time a contribution/sponsorship is made to a 501(c)(3) organization, the following General Ledger Code should be used on the RFP form: 43531100. This will allow the company to track its charitable activities for tax purposes as well as for business planning purposes. (In some instances, contributions/sponsorships from the Therapeutic Areas to 501(c)(3) organizations may be promotional or in support of CME programs and may be coded differently; Corporate & Community Affairs will periodically meet with TA PREP managers to track these types of grants.)

AZ employees must never write personal checks or use their Corporate American Express Cards and the expense-reporting system for corporate contributions or sponsorships on behalf of AZ.

6.6. Sales and TA Support Function Charitable Fund-Raising Events Policy

AZ frequently sponsors healthcare-related charitable fund-raising events, including balls, galas, awards dinners, auctions, charity golf or tennis tournaments or other events where the primary purpose is to raise funds to benefit the non-profit organization. It is important for AZ to have a presence at charitable fund-raising events undertaken by non-profit organizations relating to our business. When AZ Sales or TA Support Function employees represent the company at these events, there are some special considerations that must be observed. These are described in **AstraZeneca Representation at Charitable Fund-Raising Events** (VI-2).

6.7. Contribution/Sponsorship Requests From Organizations Where AstraZeneca Employees Volunteer

AZ recognizes that employees who serve as volunteers or volunteer board members for non-profit organizations may be asked by these organizations to solicit contributions, sponsorships or in-kind grants from the company. The company will consider such requests when they are consistent with our giving policies (that is, when the organizations are 501(c)(3) non-profit organizations, with an emphasis on healthcare-related organizations or, specifically in the headquarters region or near our other manufacturing and R&D sites in the US. 501(c)(3) non-profit organizations that fall into the other categories we support: civic/community, education/science education, arts and culture). However, there is no guarantee that these requests will be granted in every instance, as resources may not be available. Depending on where the employee volunteer works, such requests should be sent to Corporate & Community Affairs (Headquarters), local site management (Wilmington or Waltham R&D, Newark or Westborough manufacturing) or the appropriate Business Center (Sales).

6.8. Company Advertisings Related to Charitable Contributions/Sponsorships

Often a corporate sponsorship includes an opportunity for the sponsor to place a goodwill or courtesy ad in a program book for the event/program being sponsored. When the contribution/sponsorship is to a 501(c)(3) non-profit organization, the advertisement placed in a program booklet (or other promotional materials for the organization/event) should be a general corporate ad, with no reference to a specific product or products. It may be appropriate to mention AZ's commitment to a particular area of medicine (for example, cardiovascular for a Heart Walk), in which case it is appropriate to create a customized ad. Standard Promotional Regulatory Affairs (PRA)-approved ads are available through Corporate Communications in Public Affairs. Customized ads may be requested through the Production/Distribution group in Marketing Promotions; customized ads may require additional PRA review, so extra time should be allowed when requesting an ad. Employees should not design ads on their own or modify existing ads without consulting Corporate Communications or the Production/Distribution group to insure corporate identity guidelines are being followed.

7. Representative List of 501(c)(3) Healthcare-related Organizations Supported by AZ

Following are some of the major healthcare-related 501(c)(3) non-profit organizations already supported by AZ, both nationally and locally, because of their alignment with our business areas:

- American Heart Association (including American Heart Walks)
- Crohn's and Colitis Foundation of America
- American Cancer Society (including Relay for Life events)
- Susan G. Komen Breast Cancer Foundation (including Race for the Cure events)
- Y-ME
- US Too!
- National Alliance for the Mentally Ill
- National Mental Health Association
- American College of Allergy, Asthma and Immunology
- American Lung Association
- Asthma and Allergy Foundation of America
- National Patient Safety Foundation
- American Chronic Pain Association

Contributions need not be limited to these organizations, but these are the kinds of organizations where our contributions/sponsorships can have an impact on patients/families in the areas where we most want to be recognized for our leadership and our willingness to give back to the communities where we live and work.

8. References

8.1. AZ Business Policies

Gaining Access to Healthcare Professionals (II-3);
AstraZeneca Representation at Charitable Fund-Raising Events (VI-2)

Other AZ Policies:

- **USDD Medical Affairs policy on Patient Assistance & Charitable Donations**
- **HR policy on Employee-Driven Matching Gifts**
- **IS policy on donating used computer equipment**
- **R&D policy on donating used computer equipment**
- **Delegations of Authority Database**
- **Sample Letters-"Yes" and "No" responses to requests for charitable contributions; request for substantiation form to accompany all "Yes" letters when contributions are for $250 or more.**

ATTACHMENT I

September 11, 2002

Dear _____ :

On behalf of AstraZeneca, I am pleased to forward you a check in the amount of _____ in support of _____ .

Tax law requires that we receive written substantiation of contributions of $250 or more. We have prepared a simple form for this purpose. A copy is enclosed for your use. Once you have completed the form, please return it to our tax department to the attention of Bob Jenkins.

Sincerely,

[Name]

[Title]

Enc.

SUBSTANTIATION REQUIREMENT
CHARITABLE CONTRIBUTIONS

This is to certify that we have received from AstraZeneca, a charitable contribution in the amount listed below. If a non-cash donation was received, we hereby certify that it will be used by this organization and is not to be diverted into commercial channels. Please complete this form and return it to: AstraZeneca, ATTN: Robert Jenkins, Treasury Dept. 1800 Concord Pike, P. O. Box 15437, Wilmington, DE 19850-5437.

Signed: _____ _____
Authorized Individual (Print name) Date

_____
Authorized Individual (Signature)

_____
Title

_____
EIN #

_____
Organization

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_____

Street - P. O. Box Number

_____

City, State and Zip Code

_____

Amount of Cash Received

_____

Description (but not value) of any property other than cash contribution.

_____ yes _____ no Please mark whether you provided any goods or services in consideration for the property contributed.

_____ If yes to above, please provide a good faith estimate to the value of goods or services provided.

_____

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ATTACHMENT II

September 11, 2002

Dear _____ :

We have received your letter requesting support from AstraZeneca for _____ . We regret that we will not be able to provide financial assistance for this program. Most of our corporate contributions funds for this year are already committed to a variety of health initiatives in the community. We do our best to apply the limited discretionary funds we have available to other programs in the health areas throughout the year, but unfortunately we cannot support every request we receive.

We do wish you much success with your program.

Sincerely,

[Name]

[Title]

AstraZeneca

Expense Reimbursement

Policy No.:**VI-4**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **11/06/2002**

Contents

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1. Purpose

To provide guidelines to U.S. based AstraZeneca Employees regarding

- Reimbursable business travel and incidental individual operating expenses
- Purpose and use of the AstraZeneca AMEX Corporate Travel Card (AMEX)
- The AstraZeneca Expense Reimbursement application (AZER)
- Completion of the Travel Expense Report (ER)

2. Policy Overview

It is Company policy to reimburse employees for necessary and reasonable travel expenses and incidental operating expenses incurred on behalf of the Company. Specific overall limits have nc been established for each type of expense due to the varied circumstances surrounding each expenditure.

> Note: Neither the AMEX Travel card nor the AZER reporting system are to be used for large business purchases where it is appropriate to utilize a Purchase Order, Vendor
> Invoice or involve a purchasing specialist. Examples of such inappropriate purchases include, but are not limited to the following:
> - Promotional Items
> - Capital Purchases
> - Educational Reimbursement (tuition)
> - Prep Payment, honorariums, etc.

2.1. All employee travel expense reimbursement requests must be submitted through the AZER reporting system.

2.2. The Company provides employees with an AMEX card as the primary tool to pay for AZ business-related travel expenses. Each employee is liable for their respective AMEX account and each is responsible for maintaining their AMEX account in a current status and for paying AMEX for any non-reimbursable charges applied to the AMEX card.

- Use of the AMEX Corporate Card for Personal (non-business related) charges is strictly prohibited. Employees certify that they will not use AMEX for personal use when they log into AZER for the first time.
- Personal credit cards or cash should only be used when AMEX is not accepted.
- Employees are required to report (import) all AMEX charges and credits into AZER
- AZ will reimburse AMEX directly on behalf of the employee upon manager approval of the submitted report.
- AZ will utilize the total AMEX expenditure information to negotiate preferred travel rates.

2.3. Timely completion and recording of expense reports into AZER will permit prompt reimbursement of "out-of-pocket" expenses to the employee, AZ payment to AMEX covering employees' AMEX charges, and accurate reporting of business expenses. The following are the stipulated reporting frequencies however very small expenditures that total less than $100 may be deferred and submitted quarterly so long as the delay does not impact your AMEX credit position.

- Field sales employees must submit expense reports every two weeks.
- All employees may not submit more than 2 reports in any given month.

2.4. A hard copy of every AZER expense report with all original receipts must be promptly submitted to InterplX Technologies using the prepaid envelopes provided.

2.5. Managers have a fiduciary responsibility to the company to thoroughly and accurately review and approve their employees' expense reports online. Managers not doing so are subject to appropriate disciplinary action – up to and including termination of employment. The manager will either approve or reject the expense report electronically.

- The electronic approval indicates that the manager has reviewed the expense report and is approving expenses as legitimate business travel expenses within company policy.

2.6. Expense Reports will be audited. Employees violating this Policy are subject to appropriate disciplinary action – up to and including termination of employment. If an audit determines that the employee has been overpaid because this Policy has been violated, the amount overpaid will be deemed to be a debt that the employee owes the Company. The amount of the debt may be reduced from any award otherwise payable to the employee under the terms of the employee's Incentive Plan and in accordance with the terms of that Incentive Plan.

3. Expense Reimbursement Flow – AZER

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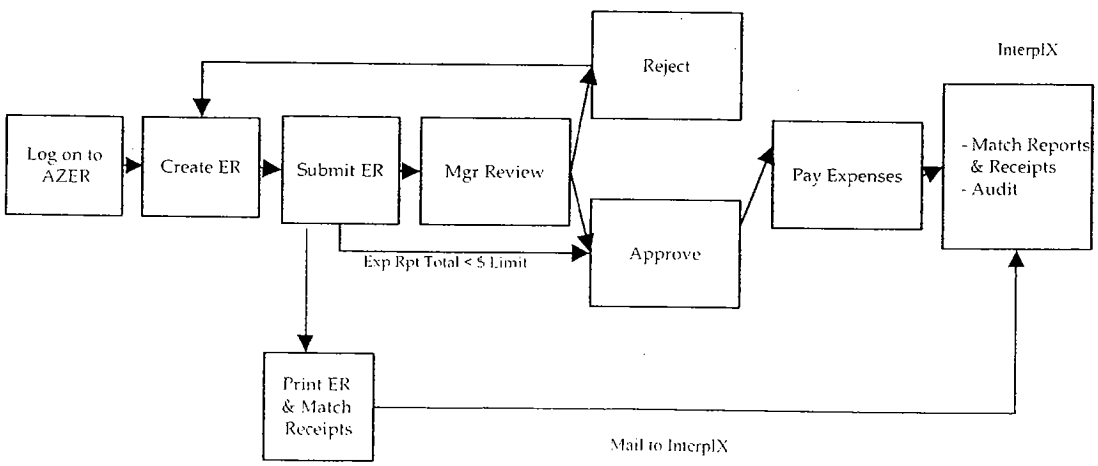

3.1. Employee enters expense report in AZER.
3.2. Employee electronically submits the expense report to his/her line manager for review and approval.
3.3. Promptly after submission, employee must print and mail their expense reports and original receipts in the pre-addressed, envelope (with only one expense report per envelope). Upon approval, employee expense report is processed for payment.
3.4. If expense report is rejected, employee must correct as necessary and resubmit for approval.

Employee expense reports submitted via AZER will be electronically routed to the employee's immediate manager. Depending on that manager's Delegation of Authority (DOA) level, the report may escalate up to the next manager with the appropriate DOA for approval. Certain expenses referenced in the AstraZeneca Travel Policy or in this policy require AstraZeneca Leadership Team (AZLT)-level or General Manager of US R&D approval.

4. General Documentation

Original receipts must be included with any single expense item $25 or greater. The IRS requires documentation in order to support both the deductibility of the expense for the Company, and the non-taxability of the reimbursement to the employee. However, it is recommended that all receipts are included with Expense Reports. (Unsubstantiated expenses in excess of $25 will not be reimbursed.)

Correct documentation is the original transaction receipt. Photocopies are not permissible

5. Responsibilities

Employees are responsible for:

5.1. Reviewing, understanding, and complying with AstraZeneca's Expense Reimbursement Policy and other related AstraZeneca policies (i.e., Marketing and Sales Business Policies and Guidelines and the Travel Policy)
5.2. Using the Corporate Card to pay for business related expenses only. Where a personal charge (such as non-reimbursable movie on a hotel bill or a personal day is combined on a car rental) is consolidated with a business expenditure it is permissible to use AMEX but this will require reporting and distributing the entire AMEX charge through AZER.

- Personal use of AMEX, other than in consolidated business/personal charges, is not permitted and will be subject to appropriate disciplinary actions that could include termination of employment. The company reserves the right to reimburse American Express for any unpaid employee AMEX account in arrears. Any amounts paid by AZ, in these circumstances, will be deemed to be an employee debt to AZ and the amount of the debt may be reduced from any Award otherwise payable to the employee under the employee's Incentive Plan.

5.3. Accurate and timely submission of expense reports. Employees must promptly provide hard copy documentation of the expense report and all receipts within sixty calendar days of the AZER submission).

- AMEX card privileges will be automatically suspended after 60 days of non-compliance with the expense report and receipts submission requirement.

Authorized Approvers are responsible for:

- Assuring the employee's compliance with the Expense Reimbursement Policy and other related AstraZeneca policies.
- Reviewing and approving all expense types, cost centers and project codes.
- Ensuring no large cash expenditures (>$100) are submitted without adequate explanation.

6. Audit

Expense Reports will be audited. Employees violating this Policy are subject to appropriate disciplinary action up to and including termination of employment. If an audit determines that the employee has been overpaid because this Policy has been violated, the amount overpaid will be deemed to be a debt that the employee owes the Company and the amount of the debt may be reduced from any Award otherwise payable to the employee under the terms of the employee's Incentive Plan and in accordance with the terms of that Incentive Plan.

7. AMEX – Corporate Card

AstraZeneca employees must use the AMEX Card as the payment method for travel, entertainment, and incidental operating expenses wherever AMEX is accepted.

- The AMEX Corporate Card is for business use only.
- Any credits applied to the AMEX card that relate to previously reimbursed expenses (price corrections, volume related rebates, discounts, etc.), are owed to the company and must be credited back through AZER utilizing the import functionality.
- Use of the AMEX Corporate Card for Personal (non-business related) charges is strictly prohibited.
- Employees are required to use the import functionality within the AZER application in order to record all AMEX charges or credits. This will ensure that all travel and incidental expenses applied to the AMEX card are paid directly to AMEX.
- Employees who allow their AMEX account balances to become delinquent, risk suspension or cancellation of their AMEX card and may be subject to disciplinary action.
- Employees must pay American Express for any non-reimbursable charges in a timely manner.
- AMEX delinquency or finance charges are not reimbursable by AstraZeneca

7.1. Foreign Currency

Foreign expenditures using AMEX will be automatically converted to US$ when the transaction is imported into AZER. Fees incurred for direct exchanges of currencies (cash) are a reimbursable expense. Valid exchange rate receipts for all direct exchanges of foreign currency must be included with the Expense Report.

8. Transportation - Air, Rail, and Auto

Please refer to the AstraZeneca Travel policy for travel arrangement details.

8.1. Air Travel

The original Carlson Wagonlit itinerary for air travel and Passenger Receipt coupon, if issued, must be included with the Expense Report.

8.2. Rail Travel

The original Passenger Receipts for rail tickets must be included with the Expense Report for reimbursement.

8.3. Taxis/Limos/Cars

Only the cost of taxis or carfare related to business activity is reimbursable. Receipts are required for fares over $25. Payment should be made with the Corporate Card whenever possible. (See AstraZeneca Travel Policy for more details.)

8.4. Personal Vehicles

There is no reimbursement to employees for commuting from home to place of employment and back.

The standard mileage allowance for use of a personal vehicle will be the Company rate in effect at the time of expenditure (as communicated periodically by the Finance Department).

It is the employee's responsibility to follow all traffic laws; therefore, the company will not reimburse employees for parking or moving violations in personal, rental, or company vehicles.

8.5. Rental Vehicles

Employees may use rental vehicles for company travel when the distance and time involved make good business sense.

The original transaction receipt must be included with the expense report form. Rentals submitted on the expense report are for business travel only.

8.6. Company Vehicles

Refer to the Motor Vehicle Policy in the Marketing and Sales (M & S) Business Policies and Guidelines and the Personal Use of Company Car Policy for details of submitted mileage with a company car.

Employees are responsible for recording both personal and business miles on a company car within the AZER expense reimbursement system

8.7. Tolls and Parking

Tolls and parking costs for business use are reimbursable expenses. EZ Pass monthly statements are acceptable documentation, but only current monthly charges per the usage statement may be reimbursed each month (NOT automatic replenish amount).

9. Loss of Personal Property

The Company provides limited reimbursement in the event of loss or theft of an employee's money or other valuables while traveling on Company business as specified below. Since it is the Company's intent to provide limited reimbursement to the employee for out-of-pocket costs not covered by personal insurance, only loss or damage **not covered** by other insurance will be reimbursed. All reimbursements under this Section will be charged to the employee's cost center.

9.1. Eyeglasses

Employees will be reimbursed for the cost of replacing or repairing eyeglasses, if they are damaged accidentally during the performance of job duties.

9.2. Baggage Indemnification

Coverage is provided to employees traveling on Company business for loss of or damage to some personal effects, which are normally included as "accompanied" baggage on a business trip. The amount of coverage is as follows:

- The total amount indemnified for each employee shall not exceed $1,500
- The indemnification for any single article will not exceed $300

Receipts will be needed to prove loss of an item over $50.00. Certain property unrelated to the needs of business travel will not be covered (e.g. cell phones, laptop computers, PDA's etc; TV's, CD players and/or other sound reproduction devices; cameras, stamp collections, manuscripts, medals, coins, bonds, securities, crockery, china, glass, sculpture, curios, pictures, musical instruments, antiques, plants, animals, or any personal purchases made during trip).

Each employee is expected to take reasonable and proper care of his/her effects and to take all necessary steps to protect them from loss, to minimize loss, and to recover missing property.

9.3. Damage to Automobiles

The Company will provide reimbursement to the employee for physical loss or damage to an employee's car while on Company business, if the damage results from **fire, theft or collision**. In the case of theft, reimbursement is payable only if the vehicle was properly locked. Such reimbursement is reduced by any other available and collectible insurance or other reimbursement and by a $50 deductible. A police report will be required in order to claim reimbursement.

9.4. Personal Effects in Cars

The Company will reimburse the employee for loss or damage to personal effects contained in a Company automobile or the employee's personal car (or one temporarily hired or borrowed) while in use for Company business if such loss is caused by fire, explosion, vandalism, or theft from the automobile. Such reimbursement is reduced by any other available and collectible insurance or other reimbursement and is subject to a limit of $250 which, in the case of theft, is payable only if the auto was properly locked. A police report will be required in order to claim reimbursement under this section.

Specifically excluded from reimbursement is theft, loss, or damage relating to any and all types of electronic and computing devices and media, such as computers, cell phones, Personal Digital Assistance (PDA) devices, etc., sound reproduction, transmitting and/or receiving devices, and peripheral equipment. Other examples of excluded items are CB radios, AM/FM radios, tape decks, CD players, etc.

Special note:

Do not submit these expenses through AZER. For information on how to submit a reimbursement request for loss of personal property, visit the Risk & Insurance Services web page and see "Expense Reimbursement – Loss of Personal Effects".

10. Hotel Accommodations

All hotel bills, with daily charges itemized, should be included with the expense report for reimbursement in the expense report. All charges must be broken down into individual categories (i.e. phone, meals, faxes, etc.). Acceptable documentation for hotels is the original hotel folio receipt, which shows proof of payment with a zero balance.

Any hotel accommodations outside the Travel Policy criteria are not reimbursable except when approved by an AstraZeneca Leadership Team (AZLT) member or General Manager of US R&D.

11. Meals

Meals must be charged on the AMEX card whenever possible. Employees must use good business judgment and not incur lavish or extravagant expenses. Questions regarding this policy must be directed towards your line manager first, then, contact the Expense Reimbursement Department.

11.1. Personal Meals

Personal meals are for the employee only and are paid for by the Company when the employee is traveling.

The Original itemized transaction receipt from the vendor must be included with the expense report. Tear tabs are not to be used as a receipt.

11.2. Business Meals

A business meal occurs when it takes place with clients, prospects, associates, or AstraZeneca employee(s) and a specific business discussion takes place. The most senior level AstraZeneca Employee in attendance must record the expenditure.

The IRS requires a complete list of attendees, business relationship, and the business purpose in order to demonstrate the business nature of the expense. This documentation supports both the deductibility of the expense for the Company and the non-taxability of the reimbursement to the employee. This information must be included on the expense report form. The original, itemized transaction receipt from the vendor must be included with this expense report. Tear tabs are not to be used as a receipt.

Expenses incurred for program meals or meals that are served at a company-sponsored event, such as a "Lunch and Learn," are reimbursable. These meals are considered business meals, and should be recorded as such.

12. Entertainment

The original, itemized transaction receipt from the vendor must support all entertainment expenses.

The IRS requires the names and business relationship of all individuals entertained, the name of the establishment where the entertainment took place, date, type of entertainment, and business purpose.

If a meal is included at an entertainment event, then the expense should be recorded as entertainment.

The most senior level AstraZeneca staff member in attendance must record the expense.

For specific entertainment guidelines for Marketing and Sales, please see Marketing and Sales policies.

13. Tipping

Tipping expenses are reimbursable if maintained within reasonable limits according to local customary practices.

14. Reimbursable and Non-Reimbursable Personal Expenses

14.1. Reimbursable Personal Expenses

The following types of expenses, if incurred on behalf of the Company, are reimbursable within reasonable limits (contact Line Manager first, then the Expense Reimbursement Department with questions):

- Postage, telephone, fax
- Passports, visas
- Reasonable valet services and baggage checking
- Laundry services when necessary
- Health Club use, up to $15 a day, while on business trips

14.2. Non-Reimbursable Expenses

Non-reimbursable expenses are those that are not necessary in the performance of business under normal circumstances. Certain types of expenses would be considered personal in nature and, pursuant to IRS regulations, cannot meet the strict test of directly benefiting the business.

List of expenses that are not reimbursable include, but are not limited to the following:

- Delinquent fees on the Corporate Card
- Baby sitting fees and pet boarding fees
- Traffic tickets
- In-room movies
- Items which, though related to business, are personal in nature (e.g. attaché cases, luggage)
- Gifts to consultants, vendors, and family members

AstraZeneca Senior Management will make the final determination of a valid expense.

15. Gifts/Awards

Cash awards or Non-Cash awards (certificates) to employees for excellence or recognition are governed by a separate tax policy. These items should not be expensed on an expense report. Gifts to non-employees are governed by Marketing and Sales business policies and the AstraZeneca Business Ethics policy.

16. Telephone

Phone calls (including business calls made from home), if incurred on behalf of the Company, are reimbursable within reasonable limits.

16.1. Field Sales Employees – Cell Phone Reimbursement

This policy applies to all Field Sales Employees. It is up to each line manager's discretion as to whether a specific field position requires enough business travel to warrant cell phone reimbursement.

Company will reimburse for a one-time purchase of a cell phone up to a maximum of $50. Employee pays for all expenses above $50 – including upgrades. Employee owns the phone. Replacement phones and accessories are the responsibility of the employee.

The company will not reimburse for service contract termination fees for an employee to break an existing personal service agreement in order to enter into a service agreement for business purposes. When the personal service agreement expires, the employee can then switch to a new reimbursable service agreement.

The Company will reimburse for cell phone service including all maintenance, insurance, taxes, required fees, and optional features. The maximum monthly reimbursement is:

- District Sales Manager (DSM) $150.00
- All other staff, including Pharmaceutical Sales Specialists $ 75.00

Employee receives and pays for all related invoices and is responsible for all aspects of the phone contract. The employee must include the phone company's original invoice statement with the summary detail with the expense report. Employee will not be reimbursed for any early termination fees other than those related to a geographical relocation of assignment

16.2. Field Sales Employees – Second Telephone Installation

All field employees who work from their home, and are not assigned to an office are entitled to reimbursement for the initial installation of a second phone line in their homes and subsequent basic monthly maintenance fees for that line.

Service fee reimbursement is limited to the basic package offered by the phone company. Additional services such as call waiting, call forwarding, etc. are not reimbursable. The phone company's original invoice statement with the summary detail must be included with the expense report.

The purpose of the second line is to allow field personnel to synchronize without tying up personal phone lines. In addition, toll calls that are not Company-related on the second phone line will not be reimbursed.

16.3. Corporate Calling Card

The summary calling card invoice must be included with the expense report for reimbursement. Reimbursable telephone toll expenses, both personal and business, necessitated by travel will be reimbursed. The Company-provided calling card should be used whenever possible to avoid hotel surcharges.

16.4. Business Calls Made from Personal & Cellular Telephones

The original pages of a telephone bill indicating business calls must be included as a receipt with the Expense Report. Personal telephone bills are not to be submitted to Accounts Payable for payment.

17. Spousal Travel

Expenses incurred as a result of a spouse accompanying an employee on a business trip or convention are reimbursable only if the Company requires accompaniment by the spouse.

Approval of an AstraZeneca Leadership Team (AZLT) member or General Manager of US R&D must be obtained in advance.

AstraZeneca will not reimburse travel and entertainment expenses incurred by a spouse or other individual accompanying an employee on business unless both of the following conditions have been met:

- There is a bona fide business purpose for taking the spouse or individual.
- Such expenses have received prior approval by an AstraZeneca Leadership Team (AZLT) member or the Vice President, Research and Development Site General Manager.
- Requests and approvals must use the "Travel Request for Spouses" authorization form (AM5627).

All reimbursable expenses for spousal travel are taxable to the employee (included as income to the employee) as required by the IRS. Charges for the employee and charges for the spouse must be clearly identified in the expense report.

18. Miscellaneous Expenses

18.1. Memberships

Membership to country clubs is not reimbursable by the Company.

Professional, civic, or trade organization memberships are reimbursable, if approved in advance, by the head of the cost center to which the employee is assigned.

Membership in airline clubs may be reimbursed at the discretion of the AstraZeneca Leadership Team (AZLT) member or General Manager of US R&D who leads the employee area. Reimbursement should be limited to those employees who regularly travel by air and are away from their home locations more than 50% of the time. Under IRS regulations, reimbursement of airline club dues must be included as income to the employee.

18.2. Charitable Contributions-Field Sales Staff Only

Financial contributions that are approved pursuant to the Charitable Contributions Policy may be reimbursed through AZER only if the contribution does not exceed $100.
Refer to Marketing and Sales Business Policies and Guidelines for further information

- Contribution must be charged to the AMEX Card to verify contribution to organization
- A vendor receipt is not required. The AMEX statement is suitable documentation.
- Charitable contributions using a personal check will not be honored.

18.3. Political Contributions

These expenses are not reimbursable under the Expense Reporting Policy.

19. Relocation

Moving and travel expenses related to employee relocation are covered under the Company's Relocation Policy, and as such, employees may not request relocation reimbursement through the AZER expense reporting application.

20. Education Reimbursement Policy

Educational Assistance is covered under the Company's Educational Assistance Policy, and as such, employees may not request tuition reimbursement through the AZER expense reporting application.

21. Related Policies and References

Under the AZ US Policies Site:

- AstraZeneca Code of Conduct
- Delegations of Authority
- Education Reimbursement Policy
- Fleet Policy
- Group Purchasing Policy
- Marketing & Sales Business Policies and Guidelines
- Personal Use of a Company Car Policy
- Relocation Policy
- US Travel & Meetings Policy – Travel Intranet Site

22. Related Help Desk References

- IBM Help Desk – (877) 371-0280

AstraZeneca

MEMO

FROM:
John Goddard
Sr. Vice President and CFO

DATE:
March 1, 2002

TO:
All AstraZeneca Employees

SUBJECT:
Rollout of New **A**stra**Z**eneca **E**xpense **R**eimbursement (AZER) Travel System

Over the past few months, you have received several communications about the upcoming implementation of the new **A**stra**Z**eneca **E**xpense **R**eimbursement (AZER) travel system that will replace the Gelco Travel Expense Reporting system presently in use. AZER will enhance the travel expense reimbursement process and allow AstraZeneca employees to operate more efficiently and effectively.

It is key that every employee and manager understands and complies with the AstraZeneca Travel Expense Reimbursement Policy ('The Policy') to ensure that business travel expenses incurred or approved are within policy guidelines. We recommend that you carefully read the Policy, prior to completing an AZER expense report. The new AZER system provides a link to view the revised Policy for reference while completing an expense report and automated business rules are built into the system to ensure compliance.

AZER will introduce the following significant process enhancements:

- **Offline access to AMEX transactions and creation of expense reports**
  - Employees must use AMEX card for business purposes only.
  - Employees will be required to import all AMEX transactions utilizing the AMEX download feature.
  - Applying AMEX credits to expense reports is much easier than in Gelco.
- **Electronic manager approval BEFORE payment of specified expense reports**
  - Managers will be required to approve expense reports with additional scrutiny for those that contain highlighted exceptions to business rules or Travel Expense Reimbursement Policy.
  - Managers will review and approve expense reports electronically, online or offline, without seeing the paper copy.
  - Managers are no longer responsible for matching or reviewing receipts. A third-party vendor, InterpIX, will perform this service.
- **Expense report escalation to next-level manager will occur in absence of manager approval or authority**
  - If a manager is unable to approve an expense report within eight calendar days of submission, it will automatically be escalated to the next higher level of delegated authority.
  - If an expense report amount is greater than a manager's Delegation of Authority, it will automatically be escalated to the next-level manager.
- **Postage-paid, pre-addressed envelopes are available to submit receipts**
  - Employees are responsible for mailing their expense report and receipts to InterpIX in a timely manner.
  - Managers will not be reviewing receipts, but InterpIX will be carrying out an extensive audit process.
- **Increased enforcement of receipt submission – no appropriate receipts, no money**
  - Automatic suspension of AMEX card privileges will result after 75 days of non-remittance of expense reports and appropriate receipts.

- **E-mails will be sent to employees to inform them of the status of their reimbursement**
    - System-generated e-mails from AZER will be sent to employees when an expense report is paid, rejected, or requires additional information.
    - Audit failure and missing receipt e-mails will be sent to employees and managers from InterplX.

Much effort has gone into creating an application that will facilitate the prompt and compliant execution of the travel expense reimbursement process. The rollout of AZER to current Gelco users will begin on March 11 and continue through the end of April. When you are contacted for your deployment, it is essential that you promptly execute all activities to get started on AZER.

Should you have any questions about the updated Travel Expense Reimbursement Policy or the rollout of AZER, please call your local Help Desk.

Thank you in anticipation for your help and support in implementing this important new system to benefit both users and the overall company control environment.

For you reference, the updated Travel Expense Reimbursement Policy is located below:

Patient Assistance Program:

The current policy has not changed. If changes occur, you will be notified electronically via a Sales Connection Newsflash.

Reminder: all current policy information is on the Policy Intranet Site.

Product and Packaging Complaints:

The current policy has not changed. If changes occur, you will be notified electronically via a Sales Connection Newsflash.

Reminder: all current policy information is on the Policy Intranet Site.

AstraZeneca

Product Samples

Policy No.: VI-7

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **The primary AZ distribution strategy for samples is "sample-send"**
- **Sample-carry approach may be used when a product is in the launch phase or if a product is low on inventory. However, these will be exceptions by product, not by selling team.**
- **The PDMA permits the distribution of samples only to "licensed prescribers"**
- **It is a criminal offense for any person to sell, purchase, or trade or offer to sell, purchase, or trade, samples. An AZ employee who becomes aware of such an offer or transaction is obliged to notify the Legal Department immediately.**
- **Samples must never be offered or provided to HCPs or their agents in exchange for, as an inducement to, or in any way in consideration for, the prescribing, purchasing, use, formulary position, or dispensing of an AZ product.**

2. Purpose

To state AstraZeneca's (AZ) commitment to compliance with federal standards governing the distribution of samples and to outline the applicable legal standards under the Prescription Drug Marketing Act (PDMA) of 1987, as amended, and other sections of the Federal Food, Drug, and Cosmetic Act, and other relevant laws, including anti-kickback laws.

3. Policy

3.1. General Statement

AZ is dedicated to ensuring that the Company and its employees comply with all applicable legal requirements and prohibitions in the distribution of samples. For purposes of this policy, "samples" means a unit of prescription drug that is not intended to be sold and is intended to provide an opportunity for the physician and patient to determine tolerability and effectiveness prior to filling an entire prescription. Marketing and Sales Personnel involved in the distribution of samples must familiarize themselves with the provisions of this policy, the PDMA and all applicable laws and Company procedures and training materials relating to samples.

3.2. Samples Distribution

3.2.1. AZ currently uses multiple sampling methods - sample-carry or sample-send, electronic or paper-based or some variation of methods. As a unified sales force, our objective is to implement the same sampling strategy for everyone. The primary AZ distribution strategy for samples is "sample-send." This means that samples can *only* be sent from a central location.

AZ will use the sample-send model since it allows us to align sampling activities to our Value Propositions:

- Sample-send improves customer focus
- Sample-send boosts professionalism
- Sample-send supports development by requiring less personal administrative time.

There will be some exceptions to this approach. Sample-carry approach may be used when a product is in the launch phase or if a product is low on inventory. However, these will be exceptions by product, not by selling team.

3.2.2. The PDMA permits the distribution of samples only to healthcare prescribers, defined as practitioners licensed to prescribe drugs by the state in which they practice. Under certain conditions, which vary significantly from state to state, some physician assistants and nurse practitioners are licensed to prescribe drugs and are eligible to receive prescription drug samples.

3.2.3. Healthcare prescribers must request and acknowledge receipt of the samples pursuant to all applicable procedures. Samples can be distributed only via mail to licensed prescribers in response to a written request. The request form must contain the licensed prescriber's name, professional designation, address, state license or DEA

number, the proprietary name and strength and quantity of the drug sample(s), the name of the manufacturer and authorized distributor, the date of the request, and the signature of the HCP.

3.2.4. The distribution of product samples by AZ to HCPs is intended to help the HCP evaluate the product in actual practice, and to enable the HRx to offer a small supply of medication to a patient who is beginning to take the product for the first time. AZ samples should be distributed with these objectives in mind.

3.2.5. Samples must never be offered or provided to HCPs or their agents in exchange for, as an inducement to, or in any way in consideration for, the prescribing, purchasing, use, formulary position, or dispensing of an AZ product.

3.3. Sale, Purchase, or Trade of Samples Prohibited

3.3.1. Samples must be distributed without cost. It is *illegal* for any person to sell, purchase, or trade or offer to sell, purchase, or trade, samples. Violation of this provision represents a felony punishable by a prison term of up to 10 years or a fine of up to $250,000, or both. Similar penalties relate to the sale, purchase, or trade (or offer to do so) of prescription drug coupons and/or vouchers or the counterfeiting of such coupons and vouchers.

3.3.2. A company that distributes samples through employees or other agents is required to report to FDA any conviction of any employee or agent for violation of this provision of the PDMA or any similar provision of state law. Failure to make such a report could result in civil fines and criminal liability.

3.3.3. A company that distributes samples through employees or other agents is subject to substantial civil fines if its employee or agent is convicted of violating the PDMA or any state law relating to the sale of samples.

3.3.4. There are certain defenses to these civil penalties, which in effect, require a company to implement diligently an independent audit and security system designed to detect such violations. This system may include periodic, unannounced contact by independent persons with licensed prescribers to verify receipt or return of samples. This system also requires reporting of losses or thefts of samples and knowledge of any offer relating to the sale, purchase, or trade of samples. AZ has these systems in place.

3.4. Advice on Billing for Samples Prohibited

AZ employees are prohibited from advising an HRx or their agent to bill patients and/or third party payors for samples, regardless of whether they are AZ samples or not. As a general rule, AZ employees should advise HRxs and their agents that because samples are provided free of charge, it is illegal to bill patients and/or third-party payors for samples.

3.5. Mishandling of Samples Prohibited

In the course of their professional activities, Marketing and Sales Personnel may come into contact with the samples of both AZ and other companies. AZ employees are prohibited from transferring, dispensing, using, or otherwise handling samples in a manner that exceeds, in any way the employee's professional duties. This prohibition includes, but is not limited to, the theft of *any samples* (whether or not AZ samples) from AZ, an HCP, or any other person in possession of such samples. Theft includes the removal of any samples from a HCP's samples closet without the professional's express consent. As a general rule, Field Personnel should not receive samples from HCPs in the course of their promotional activities. All AZ employees must always be cognizant that

- Samples of AZ products remain the property of AZ until such samples are transferred on the request of a HRx. Once transferred, the samples become the property of the transferee. At no point do such samples become the property of an AZ employee or other agent.
- Samples are strictly regulated under federal law and may be dispensed for use *only* under the supervision of an HRx.

3.6. Reporting Violations of Law or Policy

3.6.1. All AZ employees are obliged to report immediately to AZ every sale, purchase, or trade of drug samples or every offer to sell, purchase, or trade drug samples about which they have knowledge. This requirement applies to any such offer made to an AZ employee by any HCP.

3.6.2. All AZ employees are obliged to report immediately to AZ any knowledge of any HRx or their agent who has billed patients and/or third-party payors for samples, or *any sales representative* who has advised an HRx or their agent to bill patients and/or third-party payors for samples, regardless of whether they are AZ samples or not, and regardless of whether the sales representative is an AZ employee or not.

3.6.3. The reporting required under Section 3.6.1. and 3.6.2 should be accomplished through a memorandum addressed to the Legal Department and should include as much of the following information as possible

- ***Who*** made the sale, purchase, or trade of drug samples or the offer to sell, purchase, or trade drug

samples or who billed patients and/or third-party payors for samples or advised an HRx or their agent to bill patients and/or third-party payors

- ***What*** products, strengths, sizes, and quantities were involved
- ***What*** price, or other form of consideration, was offered
- ***When*** the incident occurred
- ***Where*** the incident occurred

3.6.4. Any information (whether first or second hand) that an AZ employee acquires concerning sample diversion or other mishandling or misuse of samples (whether AZ samples or those of another company) should be reported as soon as possible to the Legal Department.

3.6.5. AZ will, as appropriate, forward information concerning apparent violations of law to proper government authorities.

VI – 8 Professional Information Requests

AstraZeneca

Professional Information Requests (PIRs)

Policy No.: **VI-8**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **A Professional Information Request (PIR) is an *unsolicited* request by an HCP for information regarding an AZ product;**
- **AZ personnel must *never* prompt a PIR;**
- **Adverse event reports should not be handled through a PIR and must be reported immediately according to section 4. of this policy.**

2. Purpose

To provide direction for AstraZeneca (AZ) Field Personnel when handling an inquiry, regarding an AZ product, that warrants a response beyond the understanding of Field Personnel or beyond the scope of the prescribing information, approved reprints, or other approved promotional materials. This policy is intended to support the safe and effective use of AZ products in the delivery of healthcare through objective scientific exchange and to ensure our adherence to applicable law.

3. Policy

3.1. PIR Definition

A Professional Information Request (PIR) is an unsolicited request for information about an AZ product, by a healthcare professional (HCP), that warrants a response beyond the understanding of Field Personnel or beyond the scope of the prescribing information, approved reprints, or other approved promotional materials, or for which the HCP requests further medical information.

3.2. When It's Appropriate To Submit PIRs

3.2.1. A PIR should be submitted only in response to an unsolicited question or request for information from an HCP. Field Personnel must never prompt a PIR. The inquiry should be posed in the words used by the HCP. The inquiry should be submitted as soon as possible after the request to insure accuracy. Do not hold for batch submission.

3.2.2. Examples of when a PIR should be submitted, include: off-label use of a product, formulary decisions, certain "Data on File" packets, published information on safety and tolerability, drug interactions, summaries of clinical studies, data from abstracts presented at major meetings, and comparisons between AZ products and competitive products.

3.3. When It's Not Appropriate To Submit PIRs

3.3.1. An HCP describes an adverse event (including overdosage) in a patient who received an AZ drug. Reports should be submitted directly to Drug Safety in accordance with the **Adverse Event Reporting** (VI-1) policy. A PIR may be submitted for routine information about adverse events related to an AZ product; however, **a report of an adverse event in a patient who received an AstraZeneca drug must be submitted through the Adverse Event Reporting process.**

3.3.2. Product and packaging complaints. Complaints about product condition or packaging should be handled in accordance with the appropriate **Product and Packaging Complaints** policy (VI-6).

3.3.3. Requests for approved reprints. Such requests should be handled via the appropriate marketing and sales mechanism for obtaining approved reprints.

3.3.4. Statements of Opinion. Situations in which the HCP expresses an opinion about some aspect of drug therapy, but does not actually request information about an AstraZeneca product.

3.3.5. Legal Advice. Situations in which the HCP wants Legal advice concerning his or her obligations. AZ does not provide Legal advice to HCPs, institutions or organizations.

3.3.6. Requests for pricing or contracting issues. Such requests should be directed to Pricing/Contracts Management.

3.3.7. Medical Advice. Requests pertaining to the overall clinical management of the patient, reviews of therapeutic alternatives for specific diseases, disease incidence, and discussions about the physiology of disease states.

3.3.8. General Medical Questions. Medical Resources does not respond to questions that are specifically related to diagnosis, pathophysiology, mechanism, or general management of diseases. We can, however, provide information regarding the effects and/or use of AZ products in these areas.

3.3.9. Competitive Product Information. Medical Resources does not answer questions that focus solely on information about a competitor's product. Questions dealing solely with the product(s) of another company are best directed to that company. However, a request for information about our product(s) in comparison to another company's product(s) is an appropriate subject for a PIR (if the request cannot be answered by reference to the current prescribing information for the products).

3.3.10. Product Promotion. Medical Resources does not answer questions about product marketing strategies or promotional programs. Contact your District Sales Manager for information regarding promotional strategies.

3.3.11. Study Proposals. Proposals for clinical or health economics studies should not be sent to Medical Resources. HCP study proposals should be directed to the appropriate Medical Information Scientist.

3.4. Subject Matter

3.4.1. Most PIRs that arise are relatively specific questions about a particular AZ product. The specific question should be submitted in the HCP's own words. Make sure the question accurately reflects the HCP's intent by reconfirming with him/her the question being asked. Use appropriate medical terms to help avoid ambiguity. Always include the product name in the question.

3.4.2. Very general questions can result in information with little focus. If the HCP initially poses a very general question, AZ employees should inquire if there are specific aspects of that subject that are of particularinterest.

3.4.3. The content of a PIR response is a scientifically rigorous, objective, and balanced summary of medical scientific literature that answers questions on AZ-specific product(s). All information/published literature available is evaluated and included in these responses and both favorable and unfavorable data is included. PIR responses are not promotional and do not contain misleading statements.

4. Submission of PIRs

PIRs may be submitted by computer (Sales InSite), facsimile (FAX), or written requests via Standard Mail. Electronic submission is always encouraged and preferred, but PIRs will be accepted by FAX or Standard Mail when necessary.

Regardless of how the PIR is submitted, the following information is needed to ensure the requester receives a response and the AZ employee receives a copy of the response:

- Full name, degree (*eg*, MD, DO, RPh.), and title (*eg*, Dr., Ms., Mr.) of the requester;
- Full street address, zip code, and telephone/FAX numbers of the requester; e-mail address (if delivery requested by e-mail);
- AZ product name for the request;
- AZ employees name, title, customer unit, and business telephone number, and date of the request.

4.1. Sales InSite PIR Submission

According to the instructions provided, complete a PIR as soon as possible after the request to ensure accuracy, via the Sales InSite Submission Database.

4.2. Submission by FAX or Mail

Hardcopy PIR forms may be requested from the Medical Resources Skill Center. Completed forms should be sent via Standard Mail or FAX to (610) 695-1400.

4.3. Immediate Need for Information

4.3.1. There are situations when the HCP needs an immediate answer (these are primarily patient-related cases). The HCP may call the company directly in these cases. Questions about AstraZeneca products should be directed to the Information Center at **(800) 236-9933 (8:00 AM – 7:00 PM ET), Monday through Friday, excluding holidays.**

At the request of the HCP, AZ employees may place the call to the Information Center at AstraZeneca, identify employee name and the HCP, and put the HCP on the line to ask his/her question.

Field Personnel should not request information directly from the Information Center on behalf of the HCP.

4.3.2. Urgent reports of adverse events and related inquiries should be handled in accordance with the emergency procedures under the AstraZeneca policy entitled **Adverse Event Reporting (VI-1)**.

4.4. Follow-Up

When AZ employees submit a PIR for an HCP, you will receive a courtesy copy of the response via e-mail. You will NOT receive the enclosures. Do NOT forward your copy of the response to others. These copies are for your information only and are not to be used promotionally. **It is critical that AZ employees do not discuss this response with anyone as it could violate patients right to privacy.**

If you do not receive an electronic copy of the response to a PIR within two weeks, call 1-800-942-0424, extension 1414.

To check on the status of a submitted PIR, you should contact the Information Center at AstraZeneca at 1-800-236-9933. Please do NOT re-submit.

5. References

5.1. AZ Business Policies

Product Promotion (II-1); **Adverse Event Reporting** (VI-1); **Product and Packaging Complaints** (VI-6).

VI – 9 Reporting Marketplace Activities

AstraZeneca

Reporting Activities in the Marketplace

Policy No.: **VI-9**

Issued by: **AZ Business Policy Group**
Date Issued: **03/31/2000**
Date Issued: **07/01/2001**

Contents

1. Key Learnings

- **You should not solicit information about competitive activities from any healthcare professional during a call.**
- **Written materials may not be removed from an HCP's premises or copied without the HCP's expressed permission. If such materials are marked confidential, or are materials AZ would normally hold confidential, AZ employees may not discuss or accept such materials.**
- **AZ employees must *not* solicit or exchange information about prices, distribution, or marketing strategies from representatives of other pharmaceutical companies, and AZ employees must not offer or provide such information to them.**
- **If representatives from other companies refer to this type of information in the AZ employee's presence, the AZ employee should object immediately, discontinue the conversation, and report the occurrence to the Legal Department.**
- **AZ employees should regard all confidential or proprietary information to which they gain access at work as the property of AZ.**

2. Purpose

To ensure that AstraZeneca (AZ) has access to all appropriate available information regarding activities in the marketplace which may have an impact on the Company's business. The collection of such information, however, can pose both legal and ethical issues that must be understood.

3. Policy

3.1. General Policy

AZ employees are expected to keep their management informed regarding activities in the marketplace that may have an impact on the Company's business. Outlined below are potential sources of pertinent information, and the circumstances under which it is acceptable to use the information.

While these comments, policies, and ethical guidelines deal with AZ employees, they also apply to any AZ third party contractors.

3.2 Applicable Laws

3.2.1. State Laws are broadly based on legislation called the Uniform Trade Secrets Act (UTSA). Under state laws, a business can bring a civil suit for damages that are caused by "misappropriation" of a "trade secret." Under UTSA, and similarly under the common law of states that have not adopted the UTSA, a claim of misappropriation arises when two key events have happened:

Someone obtains, uses, or discloses materials another person has taken clear steps to protect the secrecy of (a "trade secret")

The person against whom the claim of misappropriation is made: (1) acquired the trade secret by improper means (theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage through electronic or other means); (2) knew or should have known that somewhere along the line the trade secret was acquired by improper means; (3) knew or should have known that the trade secret was acquired by accident or mistake; or (4) knew or should have known that somewhere along the line the trade secret was disclosed in violation of a confidentiality provision.

3.2.2. The Economic Espionage Act of 1996 (EEA) is the governing federal law regarding theft of "trade secrets." It was designed to protect US business interests from the activities of foreign national intelligence operations. The EEA is very similar, in some ways, to the UTSA. However, the key thing to remember is that the EEA is a criminal law, which means violators face jail and fines.

3.2.3. Confidentiality obligations relate to "improper means" of obtaining a trade secret through "breach or inducement of a breach of a duty to maintain secrecy." Confidentiality obligations can be contained in formal written agreements, or can be derived from an implied obligation that the person making the disclosure to you has with the owner of the confidential information.

3.3. Physicians and Other Health Care Professionals (Customers)

3.3.1. You should not solicit information about competitive activities from any healthcare professional during a call. If the health care professional (HCP) initiates a discussion regarding competitive activities, you may ask questions and send the information you obtain to the appropriate location. If you engage in questioning, ensure you do not misrepresent yourself or induce a breach of confidentiality in such questioning.

3.3.2. Written materials may not be removed from an HCP's premises or copied without the HCP's expressed permission. If such materials are marked confidential, or are materials AZ would normally hold confidential, do not discuss or accept such materials. If you find yourself in accidental receipt of confidential material, or materials that would normally be held confidential, contact your corporate legal representative for instructions on disposition of the material.

3.3.3. HCPs might also discuss the following with you: (1) their impressions of and reactions to our or competitor's promotional materials; (2) trends in medical practice; and (3) their suggested improvements to and modifications of our products. You should not solicit the latter type of information, but if offered by the HCP, your response must stay within the bounds of the AZ policy entitled **Intellectual Property Claims** (I-4).

3.4. Journals

Submit any relevant articles or provide the name of each article, and the name and date of the journal in which it was published, to the appropriate location as outlined in the guidelines.

3.5. Representatives from Other Companies

3.5.1. You must *not* solicit or exchange information about prices, distribution, or marketing strategies from representatives of other pharmaceutical companies, and you must not offer or provide such information to them. If representatives from other companies refer to this type of information in your presence, object immediately, discontinue the conversation, and report the occurrence to the Legal Department. Obviously, you should not discuss Company business with anyone employed by or associated with our competitors. Do not accept samples from competitors.

3.5.2. Although basic Company policy is that representatives of competitors should not discuss prices with each other, such discussions may become necessary when purchases are made from, or sales are made to, a competitor or company controlled by a competitor. Communications that are not related to those arm's-length transactions, such as discussions concerning a company's marketing plan, are forbidden.

3.5.3. You should regard all confidential or proprietary information to which you gain access at work as the property of AZ. You should guard the confidentiality of this information from all outside persons. Additionally, you should not share this information with other Company employees unless they require it to perform their own jobs.

3.5.4. Never be influenced by what you think your competitors are doing or would approve of doing. One study suggests that people generally view their competitors very negatively. They believe competitors will go too much greater lengths and exhibit less ethical behaviors to collect information than they or their own employer would. This perception is seldom accurate; do not be tempted to cross the ethical line because "they do it."

4. References

4.1. AZ Business Policies

Antitrust Laws (I-2); **Intellectual Property Claims** (I-4); **Product Samples** (VI-7).

VII. Glossary

AstraZeneca

Glossary of Terms

Issued by: **Business Policy Team**
Date Issued: **07/31/2002**
Date Revised:

Alphabetical Listing:

501(c)(3) Organizations: Section 501(c)(3) of the Internal Revenue Code designates an organization as charitable and tax-exempt. Under AstraZeneca policy, charitable donations may be given to 501(c)(3) organizations. Proof of 501(c)(3) status is documented in a letter of determination, stating that the IRS has determined that the organization qualifies as a charitable entity. An organization with 501(c)(3) status can readily provide copies of its letter of determination and often automatically includes copies with requests for contributions or sponsorships.

Access: The ability of an AstraZeneca (AZ) sales employee to gain adequate time and attention of a healthcare prescriber in order to promote our products is referred to as "access" or "promotional access."

- Note: the Managed Care Business Group (MCBG) uses Access Tools with healthcare professionals.

Access Meal: Any meal where AstraZeneca personnel meet with a customer over breakfast, lunch, or dinner served at a restaurant to gain access to that individual's time and attention in order to discuss and promote the safety and efficacy of AstraZeneca products PSSs may only use Access Meals with healthcare prescribers. MISs and members of the Managed Care Business Group may use Access Meals with healthcare professionals

Access Tools: Those activities, programs, or items that aid AstraZeneca employees in gaining the time and attention of healthcare prescribers in order to promote our products by educating the prescriber about the their safety and efficacy. The approved Access Tools for PSSs and MISs are Patient and Medical Solutions, Lunch & Learns, and Access Meals.

ACCME: Accreditation Council for Continuing Medical Education publishes guidelines governing industry support for CME programs for physicians.

ACPE: American Council on Pharmaceutical Education publishes guidelines governing industry support for pharmacy education programs for pharmacists.

Adverse Event: The development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a

pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (e.g. nausea, chest pain), signs (e.g. tachycardia, enlarged liver) or the abnormal results of an investigation (e.g. laboratory findings, electro-cardiogram).

Advisory Board: (Also referred to as Advisory Program, Consultants Panel, etc.) A meeting that engages a small group of healthcare professionals (HCPs) as consultants to provide AstraZeneca with in-depth, expert information and advice on a variety of topics critical to making decisions that impact our business including the development of study protocols, marketing strategies, educational materials or programs and sales tactics. As with any activity involving consultants, there must be a bona fide business need for the information and a signed contract specifying the services to be provided and the payment for those services. PSSs and Account Directors are not involved in the planning or execution of Advisory Boards.

Balanced Presentation: The FDA requires that the sum total of any presentation to any HCP on a given product add up to full awareness not only of the product's benefits but also the risks associated with its use (i.e., "well tolerated" typically is balanced with the incidence of adverse events in clinical trials).

Business Meal: A business meal occurs when it takes place with clients, prospects, associates, or AstraZeneca employee(s) and a specific business discussion takes place. Expenses incurred for access meals or meals that are served at a company-sponsored event, such as a "Lunch & Learn," are reimbursable. These meals are considered business meals, and should be recorded as such. The IRS requires a list of attendees, business relationship, and the business purpose in order to demonstrate the business nature of the expense. This information must be included on the expense report form. (Finance Department AZER Policy)

Capital Campaign: An organized drive to collect and accumulate substantial funds to finance major needs of an organization such as a building or major repair project. Supporting Capital Campaigns is not permitted under AstraZeneca Business Policies. (Also known as "capital development campaign" or "building campaign.")

Case Study Program: A promotional, education program that provides healthcare professionals (HCPs) with real life, interactive discussions on how to treat and manage challenging patient cases in therapeutic areas within AstraZeneca's portfolio. The format of these programs must include presentation and discussion of actual case studies prepared by each participant. The number of participants is limited to 8 HCPs and a moderator. These programs are not CME and are considered promotional for purposes of policies contained herein. They must follow all FDA guidelines and AstraZeneca Business Policies pertaining to promotional programs.

Chairperson: A person who presides over a meeting or heads a committee. In some cases they are recognized leaders or experts in their field but this is not a

requirement. They are responsible for ensuring the meeting achieves its objectives and that all participants are involved in the discussion.

Charitable Contribution: A contribution to a charitable organization that may be unrestricted (for general operating expenses) or may be designated to support a specific project or program, but does not generate significant publicity or marketing benefits to the organization or individual making the contribution. (See **Sponsorship of a Charitable Organization/Event below** for comparison.)

Charitable Fund-Raising Event: An event where the primary purpose is to raise funds for a charitable organization or cause; frequently, a secondary purpose of these events is to increase awareness about the organization or cause with the public or with specifically targeted audiences. These events take many forms including (but not limited to) gala dinners featuring awards programs or entertainment, auctions, charity golf tournaments, walks/runs/marathons/dance-a-thons. Increasingly, non-profit organizations are using these types of events to replace traditional "silent" fund-raising campaigns (such as direct mail or telephone solicitations) and are looking to corporations to sponsor the events.

Charity: In its traditional legal meaning, the word "charity" encompasses religion, education, assistance to the government, promotion of health, relief of poverty or distress and other purposes that benefit the community. Non-profit organizations that are organized and operated to further one of these purposes generally will be recognized as exempt from federal income tax under Section 501(c)(3) of the Internal Revenue Code and will be eligible to receive tax-deductible charitable gifts.

CME: Continuing Medical Education. Continuing medical education programs for physicians are those accredited by the Accreditation Council for Continuing Medical Education (ACCME). Every practicing physician must achieve a certain number of credit hours in a given time period to maintain his/her license to practice medicine. Examples of other accrediting bodies for other healthcare professionals include American Council for Pharmacy Education (ACPE) and ACHE for Healthcare Executives.

COLA: Cost of Living Adjustment

Collateral Meal: A modest meal held in conjunction with Speaker Programs, Case Studies, Tutorials, and Preceptorships. The educational component of the program must dominate the agenda (i.e., the meal must be incidental to and not the focus of the program).

Consultant Board/Panel: See Advisory Board

Consulting Services: Retention of qualified healthcare professionals for consulting services based on a bona fide business need in exchange for some form of compensation (monetary, gift, perquisite, etc.) within fair market value for services rendered. All services must comply with all applicable laws and relevant company policies and be necessary and utilized by AstraZeneca. Examples of these services include Advisory Boards, Faculty Updates, Preceptorships, and Tutorials.

Contract Sales Organization (CSO): An entity that AstraZeneca contracts with to promote AstraZeneca products.

Core Visual Aid (CVA): The promotional piece designed by the product teams and approved for use through the eSTaR process that PSSs use in their product discussions with healthcare professionals. CVAs include the specific product messages which support the product promotional strategy

Corporate Foundation: A corporate (company-sponsored) private foundation that derives its grant making funds primarily from the contributions of a profit-making business. Although the company-sponsored foundation often maintains close ties with the donor company, it is a separate, legal organization, sometimes with its own endowment, and is subject to the same rules and regulations as other private foundations.

Customer Capability Agreements (CCAs): An agreement between a managed care organization and AZ designed to obtain valuable data or information from customer institutions or organizations as part of a program provided by AZ (generally, the data or information is generated as a result of the program). In such circumstances, the value of the data or information received is evaluated to determine its fair market value in exchange for the value of the program provided by AZ. The program provided must meet AZ policy requirements and involve legitimate healthcare subject matter and is used only within the Managed Care Business Group.

DDMAC: Division of Drug Marketing Advertising and Communications. DDMAC is the division of the Food and Drug Administration that regulates the dissemination of pharmaceutical information to the professional and lay public.

Durable Goods: Goods that have a use or value over an extended period of time, such as electrical, video, or computer equipment. Under AstraZeneca policy, the provision of durable goods to HCPs is not permitted unless they are providing a specific contracted service for which the durable good is needed to perform the service.

Enduring Materials: Materials provided in conjunction with continuing education programs that are printed, recorded, or computer assisted instructional materials.

Faculty Update Program: A program that provides a platform for AstraZeneca to ensure that National and Regional Speakers are properly trained to adequately and skillfully present information on behalf of AstraZeneca. The program agenda must include a presentation on a speaker's regulatory responsibilities. PSSs are not involved in the planning or execution of Faculty Updates.

Fair Market Value (FMV): The reasonable cost of obtaining goods or services from a third-party vendor in the open market in that particular geography.

Grand Rounds: Educational programs targeted for HCPs in training (i.e., medical students, residents and fellows) that are conducted by hospitals or institutions. These programs may or may include CME credits.

Grants: Medical education grants, pharmacy education grants, post-graduate grants and library grants are a means of providing financial support for non-promotional medical education and/or medical reference materials. Grants are never provided directly to Healthcare Prescribers

Healthcare Prescriber: An individual with "prescribing " authority pursuant to state laws and regulations.

Healthcare Professional (HCP): Denotes individuals such as physicians, nurses, nurse practitioners, PAs, pharmacists, etc. Also include are any individuals who have the opportunity to influence the use of AstraZeneca products including, but not limited to, formulary committee members, members of managed care organizations, advocacy groups, etc.

Institution: Hospitals, long-term care facilities, surgery centers, correctional facilities and other (non-physician practice) facilities where healthcare is administered.

Investigators Meeting: A meeting held with clinical investigators for a specific AstraZeneca product that they were involved in to discuss aspects of the clinical trial including but not limited to, patient recruitment, side effect profile, data collection, data analysis, trial results, etc. Investigator meetings must comply with all policies on engaging healthcare professionals for services.

Labeling: Any written, printed, or graphic material containing drug information, disseminated by or on behalf of the manufacturer of a drug for use by healthcare professionals. Examples include brochures, detail pieces, literature, reprints, film, videos, CD-ROM disks, PowerPoint presentations, "homemade" sales aids, automated telemarketing and press releases.

Library Grant: Financial support given to a recipient institution or organization for the purchase of healthcare-related library materials and/or medical reference materials. The customer must control the selection of materials. Library grants may not be given to individual physicians or physician group practices.

Lunch & Learn: Any occasion at which an AstraZeneca employee provides one or more HCPs, and their staff, with a modest meal or refreshments while on the HCP's premises during ordinary business hours. The purpose of a Lunch & Learn must be to gain access to the time and attention of the HCP in order to promote t the safety and efficacy of our products. PSSs may only utilize Lunch & Learns with healthcare prescribers. (Within certain parameters, it is permissible to have a limited number of Lunch & Learns with Oncology and Long Term Care Nurses.)

Medical Education Grant: Financial support used for non-promotional medical education programs without influencing any aspect of the program. The activities may be accredited or non-accredited programs.

Medical Information Scientist: A Medical Information Scientist (MIS) is a trained expert (e.g., PharmD or Ph.D.) deployed by Scientific Affairs to geographic regions to support scientific and educational needs of customers and AstraZeneca (AZ) personnel. As an extension of AZ Scientific Affairs, the MIS serves a vital role in the exchange of scientific information regarding AZ products and therapeutic areas.

Medical Solutions: Those goods or services whose primary purpose is to support a healthcare prescribers practice of medicine, such as a medical textbook or an anatomical model.

Medically Relevant: Items of a medical nature used by healthcare professionals (HCP) in administering or improve patient care such as medical text books, stethoscopes, anatomical wall charts, etc.

Milestone Event: A birth or death in the healthcare professional's immediate family or the immediate family of a healthcare professional's staff.

Moderator: An individual who presides over a meeting event and facilitates discussion during an interactive AstraZeneca sponsored program (eg, case study program, advisory boards). This person is responsible for ensuring the meeting achieves its objectives and tries to involve everyone in the discussion.

National/Regional Speaker Program: A promotional, educational program in which a national or regional speaker provides a presentation to HCPs on an approved topic using visual aids.

Patient Assistance Program (PAP): AstraZeneca program designed to provide AstraZeneca products to qualifying indigent patients free of charge. Specific financial criteria must be verified in order for a patient to enroll and remain enrolled in the program. The program is not open to members of physicians' families.

Patient Relevant: Those items provided by an HCP to patients that aid the patient in understanding their medication, disease, treatment, or procedure. Examples include brochures explaining high blood pressure, or tear sheets depicting the GI tract.

Patient Solutions: Those goods or services whose primary purpose is to benefit patients, such as an educational brochure regarding a disease state and information on medical procedures.

PED (Professional Education Department): Formerly Field Prep Department.

Personal Meal: Personal meals are for the employee only and are paid for by the Company when the employee is traveling. The original

American ExpressCorporate Card copy (or vendor transaction receipt in instances where the Corporate Card is not used) must be submitted with the expense report form. Tear tabs are not to be used as a receipt.

Pharmacy Grant: Financial support provided for non-promotional pharmacy programs without influencing any aspect of the program. The programs may be accredited or non-accredited.

Post-graduate Grant: Financial support provided to an institution that allows medical students, residents and/or fellows to attend selected national conferences.

Post-Study Investigators Meeting: An advisory board designed to bring together clinical trial investigators who have participated in trials on a specific drug or in a therapeutic area. These advisory boards are sponsored by marketing teams with the objective of developing the most effective promotional messages based on the trial results.

Preceptorship: A training program in which an AstraZeneca employee spends a half or full day with a physician in the physician's environment in order to learn about disease states, clinical practices and procedures, therapeutic issues, etc.

Prescribing Information (PI): A document that contains the FDA-approved labeling for a drug product. The PI, also called 'package insert" or "professional information brochure," is the basis for the Company's promotion of products.

Product Development Scientist: Individuals who drive marketplace awareness of AstraZeneca and market preparations for new AstraZeneca products in the pre-launch phase. These individuals identify and build relationships with targeted national key opinion leaders and provide support for product teams/therapeutic areas with scientific services.

PREP (Professional Education Programs): Includes both Promotional Programs (e.g. Speaker Programs) and Independent (Non-Promotional) Programs (e.g. Medical and Pharmacy Education).

PIRs (Professional Information Requests): Unsolicited requests for information about an AstraZeneca product by a HCP that warrants a response beyond the understanding of field personnel or beyond the scope of the full prescribing information, approved reprints, or other approved promotional materials, or in which the HCP requests further medical information.

Professionally Relevant: Something that is of use to a HCP in improving their professional skills or the management of their professional practice. (Tom – we feel this definition is too broad.)

PRA: AstraZeneca's Promotional Regulatory Affairs Department provides direction in the interpretation and application of FDA regulations pertaining to Prescription Drug Advertising and Promotions.

Reminder Item: An approved patient, medical or professionally relevant item with a fair market value less than $35 that prominently displays the AstraZeneca or product name and logo.

Roundtable: A speaker program where a local speaker gives an interactive presentation to a small group (usually 5-8 attendees) on an approved talk title subject.

Scientific Exchange of Information: Interactions between AstraZeneca personnel and members of the scientific or medical community. These discussions may be for purposes of recruiting investigators or consultants, training speakers, or in response to an unsolicited request for information. The discussions may focus on scientific or clinical research and/or medical discussions and may fall beyond the scope of product labeling. Scientific Exchanges of Information are conducted in a non-promotional manner and do not contain claims of safety or efficacy by roles such as Medical Information Managers, Field Medical Physicians, Medical Information Scientists, and Product Development Scientists. **Field Sales personnel should never conduct scientific Exchanges of information.**

Slim Jim: A pocket-sized version of the Core Visual Aid also used in having product discussions with healthcare professionals

Speaker Program: A promotional program in which an educational presentation is given by a healthcare thought leader on behalf of AstraZeneca on approved talk topics in order to provide medical education to customers.

Staff: Personnel in a physicians office/clinic or in a pharmacy department who support the provision of healthcare, such as office managers, marketing, nurses, continuing education professionals, or other support personnel.

Tutorial: A training program in which a medical thought leader (healthcare professional) leads an interactive discussion with AstraZeneca employees in an effort to reinforce/increase AstraZeneca employee's knowledge of disease states and/or drug therapies.

Visiting Professorship: A speaker program designed to have a medical expert accompany a PSS for a half or full day in their territory to educate local HCPs on diagnostic procedures, techniques, therapeutic options, and other medically relevant topics.

VIII. Other Information

Note: This tab is being provided in the event you wish to keep any other policy information in this binder, such as HR Policies, Code of Conduct, etc.