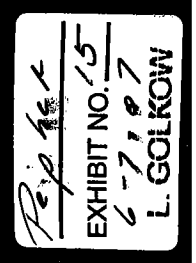

AZ – Business Policies Partners in Policy

#3

AstraZeneca Marketing & Sales Business Policies and Guidelines

AstraZeneca

David R. Brennan
Senior Vice President
Commercial and Portfolio Management

June 26, 2000

Dear AstraZeneca Colleagues,

As AstraZeneca continues to be one of the world's leaders in the pharmaceutical industry, it is important to establish policies and guidelines by which the Company must operate in order to represent an organization driven by high ethical conduct and integrity. Compliance with the Marketing & Sales (M&S) business policies and guidelines will ensure our viability, distinguish us from our competitors and ultimately bring greater value to our customers. These M&S policies and guidelines apply to all personnel who engage in promotional activities, including all Field Personnel, all headquarters-based personnel who interact with customers, and individuals deployed from other skill centers and individuals who support sales and marketing efforts. These M&S policies and guidelines supplement, but do not supersede, corporate policies established by AstraZeneca or its predecessors (the former Astra Pharmaceuticals, Astra USA, Astra Merck and Zeneca) applicable to all employees.

The M&S policies and guidelines are the result of months of work from cross-functional, cross-organizational teams. These teams included members from several different departments, both at headquarters and from the field sales organization. Teams were also populated with members from IRAG, representing all roles within field sales. All M&S policies and guidelines were approved by senior management. The work of these teams and the approval from senior management ensures that these policies and guidelines are appropriate for the new AstraZeneca organization.

It is your responsibility to read, understand and comply with all M&S policies and guidelines. To acknowledge your acceptance of these responsibilities, you must sign and date the enclosed Acknowledgment/Confidentiality Form and return it to the designated person. By accepting your responsibilities, you also understand that any violation of these policies and guidelines may result in disciplinary action up to and including termination of employment. Adherence to the M&S policies and guidelines is necessary, since any violation may have legal implications and consequences for the Company or individual employees. If you have any questions about the policies and guidelines or concerns about compliance with them, you should ask your supervisor for direction.

The M&S policies and guidelines are in effect immediately. Certain activities that were permissible under former Astra and former Zeneca organizations will not be acceptable under our new policies and guidelines. There will be an appropriate washout period to make the transition to the new policies and guidelines. Programs

that are already scheduled will be allowed to stand. However, as new activities and programs are scheduled, the new policies and guidelines will be followed. Placeholder policies have been created when the development of a new policy for AstraZeneca was not possible; usually, this was due to IS issues and being on two separate platforms. The placeholder policies are Adverse Event Reporting (M&S-B-4, B-G-4), Product and Packaging Complaints (M&S-B-5, B-G-5), Product Samples (M&S-B-6) and Patient Assistance Program (M&S-G-1). When a common platform and relevant systems are in place, these policies will be updated.

Remember, as a world leader in the pharmaceutical industry, it is vital that we support a corporate image built on high business ethics, trust, and integrity by cultivating a corporate environment driven by high ethical conduct and integrity and being respected by our customers and competitors.

Sincerely,

David R. Brennan

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www.astrazeneca-us.com

NOTICE

THESE MARKETING AND SALES BUSINESS POLICIES AND GUIDELINES PROVIDE INFORMATION FOR THE CONDUCT OF ASTRAZENECA BUSINESS. THEY ARE THE PROPERTY OF ASTRAZENECA, AND DO NOT CREATE ANY SUBSTANTIVE OR PROCEDURAL RIGHTS. ALL EMPLOYEES ARE EMPLOYEES AT-WILL; THE EMPLOYEE OR ASTRAZENECA MAY TERMINATE THE EMPLOYMENT RELATIONSHIP AT ANY TIME AND FOR ANY REASON OR NO REASON, WITHOUT CAUSE OR NOTICE. ANYONE WHO VIOLATES ANY OF THESE POLICIES OR GUIDELINES IS SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT. FAILURE TO UNDERSTAND THE POLICIES OR GUIDELINES WILL NOT EXCUSE ANY ACTIVITY THAT IS INCONSISTENT WITH THEM.

ASTRAZENECA RESERVES THE RIGHT TO CHANGE OR DELETE ANY POLICY OR GUIDELINE AT ANY TIME, WITH OR WITHOUT NOTICE. EMPLOYEES ARE RESPONSIBLE FOR INSERTING REVISIONS OR ADDITIONS, AND REMOVING ALL SUPERSEDED PAGES, IN ACCORDANCE WITH INSTRUCTIONS ISSUED BY ASTRAZENECA.

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Advisory Program Guidelines	Guideline No.: M&S-F-G-1-d

OTHER

Patient Assistance Program | Policy No.: M&S-G-1

ACKNOWLEDGEMENT

I, the undersigned AstraZeneca employee, acknowledge receipt of the Marketing and Sales Business Policies and Guidelines. I have been informed that I am responsible for reading, understanding and complying with these policies and guidelines, and I agree to do so. I have also been informed that any violation may result in disciplinary action up to and including termination of employment. I am aware that I should ask my supervisor for direction if I have any questions about the policies or guidelines or concerns about compliance with them.

_____ _____

EMPLOYEE'S SIGNATURE DATE

_____

EMPLOYEE'S NAME (PRINTED)

STATEMENT OF POLICY ON CONFIDENTIALITY OF SALES, REPORTING AND PRESCRIBER PROFILING INFORMATION

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 AstraZeneca.

_____ _____

EMPLOYEE'S SIGNATURE DATE

_____

EMPLOYEE'S NAME (PRINTED)

Please return this completed Acknowledgment/Confidentiality form to your District Sales Manager (for PSSs), your Managed Care Director, your Regional Business Director (for BC personnel), your Skill Center Leader, or Dan Witt, Director of Dental Products (for Dental personnel).

White Sheet - Return Original ***Second Sheet - Employees Copy***

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Legal Standards

AstraZeneca

LEGAL STANDARDS

Ethical and Professional Conduct	*Policy No.: M&S-A-1*
Antitrust Laws	*Policy No.: M&S-A-2*
Law Enforcement Inspections and Investigations	*Policy No.: M&S-A-3*
Intellectual Property Claims	*Policy No.: M&S-A-4*
Product Liability Claims	*Policy No.: M&S-A-5*
Patient Privacy	*Policy No.: M&S-A-6*

AstraZeneca

ETHICAL AND PROFESSIONAL CONDUCT Policy No.: M&S-A-1 A-1

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

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

2. Policy

2.1. Responsibilities of Marketing and Sales Personnel

2.1.1. The primary objectives of Marketing and Sales personnel are to conduct business activities resulting in positive long-term professional relationships with healthcare providers and other customers. Field personnel and other Marketing and Sales personnel act as principal contacts for AstraZeneca with identified national and regional customers and, as such, must conduct themselves in a highly ethical and professional manner at all times.

2.1.2. Marketing and Sales personnel must strictly adhere to federal and state law and all corporate policies established by AstraZeneca, as well as all Marketing and Sales business policies specifying in a variety of contexts the roles and responsibilities of field personnel and others who may come into contact with healthcare professionals.

2.2 Status of Marketing and Sales Personnel

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

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2.3 Written Communications, Contracts, and Agreements

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

2.3.2. In order to provide appropriate controls regarding financial commitments of the Company to outside parties, Sales and Marketing employees must adhere strictly to grants of authority established by the Company. 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 grant of authority for review and approval. All written agreements must be in a form approved by the Company's legal department.

2.3.3. Oral agreements with consultants are expressly prohibited. Marketing and Sales 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.

3. Specific Areas of Concentration

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

3.1 Conflicts of Interest

Sales and Marketing employees are required to observe a duty of loyalty to the Company 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 the Company, they should review that situation with their Sales Management.

3.2 Insider Trading

3.2.1. Sales and Marketing 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 Company employment for the employee's own personal profit or the personal profit of another.

3.2.2. 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. A-1

3.3 Standards of Documentation

Sales and Marketing employees are required to maintain and comply with established internal control standards and procedures to ensure that Company 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 Company policy, but also may be in violation of law or government regulations.

3.4 Gifts, Entertainment or Hospitality

3.4.1. No 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 should be reviewed with Sales Management.

3.4.2. No employee should place themselves under an actual or apparent obligation to anyone that is intended, or appears to be intended, to influence his or her business judgment. Gifts or favors should not be accepted if they can be construed as a bribe or a payoff or if they seek to interfere with your business judgment or decision making.

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

4. Personal Responsibilities

4.1 Obligation to be Informed

Marketing and Sales personnel have an obligation to be informed of the principal legal requirements applicable to their activities on behalf of the Company. Marketing 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 the Company's business.

4.2 Duty to Come Forward

Marketing and Sales personnel have the duty to come forward and identify any situation in which he or she believes the Company is in violation, or is in danger of violation, of any law or regulation applicable to the Company, 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 shall bring such issue to the attention of the Legal Department (or, where appropriate, to the Human Resources Department). All such issues shall be reviewed and investigated as necessary.

5. Penalties for Noncompliance

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

Marketing and Sales personnel should recognize that in addition to disciplinary action under this Policy, violation of this Policy may also subject such persons to other penalties which may include fines, imprisonment and loss of professional standing and/or licenses.

AstraZeneca

ANTITRUST LAWS **Policy No.: M&S-A-2** A-2

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To state AstraZeneca's commitment to compliance with all applicable antitrust laws, and to provide guidelines to ensure that AstraZeneca Marketing and Sales personnel conduct their professional activities lawfully. [This policy is intended to supplement AstraZeneca's corporate policy on this subject.]

2. Policy

2.1. General Policy

2.1.1. AstraZeneca 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 the Company. 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.

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

2.1.3. Any questions regarding the propriety of any contemplated action should be referred to the Legal Department for advice and guidance. Antitrust difficulties can best be avoided by following the practice of full and early discussion with 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.

2.2. Failure to Comply

2.2.1. The penalties for failure to comply with the antitrust laws can be severe for the Company, 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 can 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 can 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.

2.2.2. If antitrust difficulties arose, the Company can 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 the Company to a court order limiting its activities and placing it at a serious competitive disadvantage. Other businesses injured by any antitrust violations might be able to recover three times their proven damages, plus attorneys' fees.

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

2.3. 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.

2.4. Employee Responsibilities

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

2.4.1. AstraZeneca 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.

2.4.2. In the event that you are present at a trade association meeting, trade show, medical symposia, or other meeting, or are otherwise participating in a conversation with employees of competitor companies, and one or more competitors reveal or discuss any of the topics outlined above, you should immediately state your objection to that topic and leave the meeting or terminate your participation in that conversation. Promptly inform the Legal Department of any such occurrence. You will receive further directions from the Company's lawyers as to what additional actions, if any, you should take.

2.4.3. 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. AstraZeneca 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 (e.g., pharmacist or specific trade publication). If the information obtained is in the form of an already existing document, the

employee should 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, i.e., 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.

2.4.4. AstraZeneca employees must provide accurate information regarding the nonprofit status of customers and affiliates.

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

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

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.

The 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 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

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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 should 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. The 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.

AstraZeneca

LAW ENFORCEMENT INSPECTIONS AND INVESTIGATIONS **Policy No.: M&S-A-3** A-3

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

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

2. Policy

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

2.1.1. 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 our offices. They may also inspect vehicles used to transport drugs in interstate commerce.

2.1.2. **Request for Inspection of Company Premises by a Government Agent without a Search Warrant** It is AstraZeneca's policy to cooperate reasonably with requests by government authorities for access to Company premises or property. In the event that a government agent, having properly identified himself and displayed his identification credentials, requests access to inspect Company premises or property or to otherwise obtain Company information or property, you are to contact the Legal Department immediately. It will be the responsibility of the Company's lawyers to facilitate an appropriate process for such an inspection. In the alternative, you should request that the investigator direct his inquiry to the Legal Department.

2.1.3. In either event, you should report any such contact with government authorities to the Legal Department.

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2.1.4. **Search Authorized by Warrant** In the event that the government agent presents you with a search warrant authorizing such an inspection, you are to comply with its terms as provided in the warrant. You should obtain a copy of such warrant and contact the Legal Department immediately, transmitting the search warrant by fax as soon as possible. You will receive further instructions from the Company's lawyers. If the government agent removes any Company property, you should seek to memorialize in writing the materials that are removed from the premises.

2.2. Answering Questions

2.2.1. We ask that you advise the Legal Department if you are contacted by any government investigator in connection with any matter involving AstraZeneca.

2.2.2 If you are contacted by any government investigator, you have the right to agree to be interviewed by the investigator or to decline to be interviewed. You are not required to give any statement (unless you receive a subpoena to testify in a formal proceeding).

2.2.3. If you are contacted by a government investigator and decide to speak with the investigator, you have the right to consult an attorney before each conversation. You are also entitled to have an attorney present during any conversation with the investigator.

2.2.4. It may be appropriate for Company counsel to represent you and be present during your interview with the investigator. It also may be appropriate for other counsel to be engaged to represent you at Company expense.

2.2.5. If you decide to be interviewed by a government investigator, you must provide full and truthful information in response to all questions you choose to answer. You should be aware that providing investigators with untruthful or misleading information could subject you to criminal prosecution.

2.2.6. Whether to speak with a government investigator or be represented by counsel is your decision. AstraZeneca does recommend, however, that you consult with counsel before agreeing to speak with an investigator.

AstraZeneca

INTELLECTUAL PROPERTY CLAIMS **Policy No.: M&S-A-4** **A4**

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To guide AstraZeneca Marketing and Sales Personnel in managing situations which potentially could give rise to intellectual property claims against the Company.

2. Policy

2.1. General Policy

In the course of your professional activities on behalf of AstraZeneca, you may encounter situations which involve the intellectual property rights of the Company and/or third parties. To avoid situations which potentially may incur liability for the Company, you should familiarize yourself with and follow this policy.

2.2. Unsolicited Disclosures

2.2.1. This procedure is intended to avoid having any unsolicited disclosure completely revealed to AstraZeneca 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 the Company was actually in the process of adopting an identical or very similar idea. This could lead to disputes about whether the Company misappropriated another's intellectual property for its own use and is obligated to compensate the other financially.

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2.2.2. If a physician, pharmacist, or any other individual or organization outside the Company makes any unsolicited offer to disclose any idea, invention, specific suggestion for a new product (such as different medical uses or combination therapy, etc.), marketing or promotional technique, etc., the following procedure should 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 AstraZeneca Licensing and Business Development, stating in very general, non-confidential terms the nature of the disclosure.

2.2.3. 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 would be between the disclosing party and Licensing. Disclosures pertaining to other matters will be handled by the Legal Department.

2.2.4. A letter acknowledging receipt of the submission and confirming its non-confidential nature will be sent to the disclosing party. If AstraZeneca has any preliminary interest in the disclosure, the disclosing party will be asked to agree in writing to the conditions under which the Company will accept and consider the disclosure.

- ❑ If this agreement is signed, full disclosure will be accepted and will be circulated to appropriate persons at AstraZeneca for consideration.
- ❑ If AstraZeneca is interested in using the disclosure, an effort will be made to enter into an agreement for such use.
- ❑ If AstraZeneca 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 Company files for record purposes.

2.3. Patent, Trademark and Copyright Claims

Persons outside the Company may, rarely, suggest that a communication or material produced by the Company 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 you receive such a communication, you must not comment on the subject. Instead, you should record the information, including the name, telephone number, and the address of the person who communicated with you, and transmit it to the Legal Department.

AstraZeneca

PRODUCT LIABILITY CLAIMS **Policy No.: M&S-A-5** A-5

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To assist AstraZeneca marketing and sales personnel in handling certain situations which may have legal implications for the Company under product liability law.

2. Policy

2.1. General Policy

In the course of your professional activities on behalf of AstraZeneca, you will encounter a variety of situations, which have legal implications for the Company. You are not expected to know about all the ramifications of applicable laws and regulations; however, you 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, you should familiarize yourself with and follow the guidelines provided in this policy. If any of the material is not clear, or if you have questions regarding the legal implications of your activities, seek clarification through your designated supervisor.

2.2. Legal Status of Marketing and Sales Personnel

When you engage in product discussions and other interactions with healthcare professionals, you are **perceived as** acting as the Company's agent. The Company may be responsible for, and bound by, any statements or promises you make.

2.3. Potential Product Liability Claims

2.3.1. You should be aware that your activities could 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 AstraZeneca product and files a claim or lawsuit against the Company under such theories as negligence, breach of warranty or strict liability.

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2.3.2. AstraZeneca 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 oral statements you might make to the claimant's attending physician (or other healthcare professional) which tend to *extend the claims* or to *minimize the risks* could **arguably** nullify the effect of the limitations or warnings in our promotional materials. For example, if a physician used an AstraZeneca product for an unapproved claim on your recommendation and the patient experienced a side effect, the Company could be vulnerable **to claims that we failed** to adequately warn the physician. Therefore, you should not make any oral statements about product claims or risks, which are not consistent with our prescribing information and approved promotional materials. All promotional activities should *always* comply fully with AstraZeneca policy entitled **Product Promotion** (M&S-B-1). In addition, Field Personnel should *never* participate, or create the appearance of participating, in patient treatment.

2.4. Service of Process

If you are ever personally served with a legal document pertaining to one or more of the Company's products or activities, such as a summons or complaint initiating a lawsuit against the Company, you must immediately call the **Litigation Section of the Legal Department** and then notify your 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 can result in a default judgment, which means the Company loses he lawsuit without having an opportunity to defend itself.

2.5. Notice of Potential Claims

If you become aware of a potential legal claim against the Company (for example, if a patient engages an attorney or threatens a lawsuit), you should make no comment on the substance of the claim, but immediately bring the matter to the attention of your designated supervisor.

3. References

3.1 M&S Business Policies

Product Promotion (M&S-B-1).

AstraZeneca

PATIENT PRIVACY **Policy No.: M&S-A-6** A6

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To express AstraZeneca's policy that Marketing and Sales Personnel shall respect the privacy of the relationship between patients and healthcare professionals.

2. Policy

2.1. General Statement

The privacy of the relationship between the patient and the healthcare professional must be respected at all times. AstraZeneca 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. Company 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 other circumstances when consent has been granted.

2.2. General Market Information

General information regarding the extent of usage of specific products by healthcare professionals will be collected by the Company and distributed to Marketing and Sales Personnel. Persons who receive such data are strictly bound by the AstraZeneca policy entitled **Sales and Prescriber Data** (M&S-D-2).

2.3. Product Discussions with Providers

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

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3. *References*

3.1. M&S Business Policies

Sales and Prescriber Data (M&S-D-2).

Promotional and Product Related Policies

AstraZeneca

PRODUCT PROMOTION **Policy No.: M&S-B-1** B-1

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To reinforce AstraZeneca's commitment to comply with all applicable legal and regulatory requirements governing the promotional activities of all Marketing and Sales Personnel.

2. Policy

2.1. General Statement

As representatives of AstraZeneca, all Field Personnel and other Marketing and Sales Personnel must adhere to all applicable laws and regulations, which govern their promotional activities. To that end, and to help ensure that AstraZeneca's products are prescribed and administered in the best interests of the patient by healthcare professionals who are thoroughly knowledgeable about product attributes and characteristics, all Marketing and Sales Personnel must familiarize themselves with the legal and regulatory standards applicable to their promotional activities and must adhere to the practices outlined in this policy.

2.2. Conformance to Full Prescribing Information

2.2.1. Healthcare professionals should receive complete and accurate information about AstraZeneca's products as is appropriate to their role in healthcare delivery. AstraZeneca personnel must not promote a new product or a new indication for an existing product to healthcare professionals until they receive the official communication to do so. 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.

2.2.2. When you engage in a product discussion with a healthcare professional, you are acting as the Company's agent. The Company may be responsible for, and bound by, any statements or promises you make. Any claim which you make orally which does not conform to the Company's full prescribing information may render the product misbranded, which could

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jeopardize the Company's ability to market that particular product. Also, statements extending claims or minimizing risks may expose the Company to product liability claims. Therefore, you must stay strictly within approved claims and never minimize any of the risks associated with the use of any AstraZeneca product.

You must offer a copy of the current full prescribing information for each product discussion you initiate, including discussions in which you reference non-leave promotional materials. If the healthcare professional initiates a discussion about a product which you were not planning to discuss, and for which no current full prescribing information is at hand, you must offer to obtain a copy.

2.2.3. If a healthcare professional mentions a use of a product that is not an approved indication, or mentions using it in ways not recommended in the full prescribing information (such as administering the product in higher-than-recommended dosages), you must clearly state that the product is not indicated for use in that way and leave a copy of the current full prescribing information. If the professional 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)**, M&S-B-3).

2.2.4. If you are drawn into a discussion about product information about which you are not certain, inform the healthcare professional that you do not have that knowledge and offer to assist the professional in obtaining information through a PIR (*see* **Professional Information Requests (PIRs)**, M&S-B-3). This will help you avoid inadvertently making statements beyond the product's approved labeling. Be certain to provide a copy of the current full prescribing information.

2.3. Balanced Presentation

2.3.1. In addition to discussing product information in conformance with the full prescribing information, you 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; you may take into account the scope and frequency of previous communications, the professional'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 healthcare professional must know as much as possible about it. Therefore, you should strive to engage the professional in a complete discussion of the product, including all product characteristics.

2.3.2. In sum, the balanced presentation requirement means that you must make sure that the sum total of your presentations to any health-care professional on a given product adds up to full awareness of the product's benefits and, also, the risks associated with its use. While not exhaustive, the following list sets forth some examples of activities which must be strictly avoided:

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- ❑ Making statements that tend to diminish the warnings in the full prescribing information. Example: *"As you know, Doctor, with almost any drug, hematologic 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 professional 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 you wish to stress could be construed as an attempt to distract attention from or diminish information which the healthcare professional should know.
- ❑ Lifting statements out of context from the full prescribing information or approved promotional materials in a way which 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 healthcare professional.

2.3.3. 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.

2.4. Promotional Materials

2.4.1. The law requires that any promotional materials given to a health-care professional contain "full disclosure": adequate directions for use, including 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 material and reminder items) must have prior approval through the Company's quality review and approval processes. You have access to a variety of currently approved promotional materials via the Menu of Options (MoO) or your designated management support. You must never use homemade materials for promotion (including cutting or pasting approved materials), use or distribute unapproved journal articles or

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reference texts, write notes to healthcare professionals containing product information, use approved material outside of the scope of its intended use, or provide copies of non-leave pieces to professionals.

2.4.2. You are responsible for ensuring that you always use the most current approved promotional materials and related full prescribing information in accordance with the Company guidance or directions accompanying such materials (including directions about dates of use). You must never use outdated materials (typically, the approval period for promotional materials is one year) or materials for which you have received directions to discontinue use. The approval status of promotional materials may be confirmed through consulting the MoO or your designated management support.

2.4.3. Consistent with the policies set forth above in Sections 2.2 and 2.3, you 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.

2.4.4. Consistent with the policies set forth above in Section 2.3.2, approved reprints and printouts that are left behind must not be underlined, highlighted, annotated, or otherwise marked by the Pharmaceuticals Sales Specialists.

2.5. Comparisons with Competitive Products

2.5.1. Comparisons of safety, efficacy and/or tolerability between products and related superiority claims can be made only if supported by head-to-head clinical trials. Such comparisons cannot be made on the basis of prescribing information-to-prescribing information or on the basis of results from two individual studies.

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

2.5.3. In the event of a misunderstanding on the part of a healthcare professional regarding a competitive product that does **not** involve safety, efficacy and/or tolerability (*e.g.*, dosing frequency), you may refer to that product's prescribing information to dispel confusion. Any such reference must offer only a factual accounting of points in the full prescribing information. As a general matter, due to its sensitivity, you ordinarily should avoid discussing the Clinical Pharmacology section of a competitive product's prescribing information. If you must refer to another company's full prescribing information, you must take reasonable precautions to ensure that the prescribing information is current. Full prescribing information in the latest edition of *Physician's Desk Reference* or in the most recent supplements to this publication generally may be assumed to be current. Of course, if you have actual knowledge or reason to believe that the prescribing information is not current, you may not use that source.

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2.5.4. If you are asked a question requiring a product comparison which cannot be answered within the foregoing policy guidelines, offer to assist the professional in obtaining information through a PIR (*see* **Professional Information Requests (PIRs)**, M&S-B-3).

2.6. Medical Information Scientists

2.6.1. 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 healthcare professionals. This includes, but is not limited to, information regarding AstraZeneca's products.

2.6.2. ***All MISs must adhere to the provisions of the Marketing and Sales Product Promotion Policy, as well as all other Marketing and Sales Business Policies to the same extent as all other Field Personnel unless otherwise stipulated in this policy.***

2.6.3. In addition, MISs 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 MIS may perform a computer database search only in response to a specific and unsolicited request by a healthcare professional.
- ❑ Only databases approved by the Company for MIS use 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

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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 must inspect the search and determine if it contains data of an off-label nature relating to an AstraZeneca product. If the search does contain data of an off-label nature, the MIS must specifically document:
  - The name and address of the healthcare professional 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 party.
- Full text copies of one or more of the cited articles may be provided only if:
  - The healthcare professional makes a specific and unsolicited request for such articles after reviewing the citation list;
  - The selection of articles was not influenced by the MIS in any respect; and
  - Copies are made only with the permission of the copyright owner or do not otherwise violate U.S. copyright laws.
- Printouts of requested searches and articles may be delivered by the MIS in person, by the Pharmaceutical Sales Specialist through whom the request was directed (provided that the search did not involve the off-label use of an AstraZeneca 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 WHICH WAS CONDUCTED PURSUANT TO YOUR REQUEST OR OF THE INFORMATION GENERATED BY THE SEARCH.

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- ❑ Printouts must not be underlined, highlighted, annotated, or otherwise marked by the MIS, except with the legend quoted above.
- ❑ MISs must not initiate discussions with healthcare professional of issues raised by information generated through a database search except in strict conformance with this policy.

3. References

3.1 M&S Business Policies

Gaining Access to Healthcare Professionals (M&S-B-2); **Professional Information Requests** (PIRs) (M&S-B-3); **Product Samples** (M&S-B-6).

AstraZeneca

GAINING ACCESS TO HEALTHCARE PROFESSIONALS **Policy No.: M&S-B-2** B-2

Issued by: Marketing and Sales
Date Issued: 03/31/2000

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To establish standards, consistent with all relevant legal obligations, governing the use of meals, entertainment, hospitality, "value-added services" and "solutions" to gain access to a healthcare professional's time and attention in order to appropriately and effectively promote AstraZeneca's products based upon their safety and efficacy characteristics (hereinafter 'the Policy').

2. Definitions/Terms

Access: For purposes of this Policy, the ability of an AstraZeneca Pharmaceutical Sales Specialist (PSS) to gain the adequate time and attention of an healthcare professional (HCP) in order to promote our products is referred to as "access" or "promotional access."

Business Solutions: The term "business solutions" means those goods or services whose primary purpose is to benefit the HCP's business operations, such as billing software, the creation of a physician practice logo, Internet advertising advice, etc.

Fair Market Value: The term "fair market value" means the reasonable cost to a customer, a physician or a physician's practice of obtaining a good or service from a third-party vendor in the open market.

Healthcare Professionals: For purposes of this Policy, the term "healthcare professionals" ("HCPs") shall mean physicians and other individuals who have prescribing authority under the relevant laws of the state in which they are licensed.

Healthcare Providers: The term "healthcare providers" shall include other personnel who do not have independent prescribing authority, but who provide healthcare (i.e., nurses).

Institution: The term "institution" shall include hospitals, surgery centers and residents' clinics.

Medical Solutions: The term "medical solutions" means those goods or services whose primary purpose is to benefit an HCP's practice of medicine, such as a medical textbook.

Patient Solutions: The term "patient solutions" means those goods or services whose primary purpose is to benefit patients, such as an educational brochure regarding a disease state.

Per Year: For purposes of the annual aggregate limits, the Policy will reference the calendar year, beginning January 1, 2001. In the interim, PSS's shall seek to adhere to these annual aggregate limits as closely as is reasonably possible for the duration of the calendar year 2000.

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Selling Team: The term "selling team" shall include all employees of AstraZeneca who support the same therapeutic area by calling on a single HCP.

Staff: The term "staff" shall include personnel who support the provision of healthcare, such as office managers or "back office" support personnel.

3. *Policy - Background and Overview*

3.1. Introduction

AstraZeneca seeks to inform and educate HCP's, through the use of appropriate detailing and other promotional activities, regarding the safety and efficacy of our products.

The Company also recognizes that HCP's are often extremely busy and have a limited ability to provide our specialists with a sufficient amount of time and attention to permit an adequate and effective opportunity for detailing, or otherwise promoting, our products. Such scarce time as HCP's have available for such promotional activities is also sought by sales representatives from other companies who, therefore, compete with AstraZeneca PSS's for this access.

To be successful, the Company must be able to obtain such promotional access so that HCP's may learn about our products.

To help facilitate this access in appropriate ways, AstraZeneca has developed this Policy permitting a number of different activities (or access "tools") which can be used individually, and in the aggregate, to assist PSS's 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, as will be described more fully below, it is essential that PSS's adhere to the letter and spirit of this Policy. AstraZeneca never wants to be in the position where these access activities have been misused, or could be misconstrued to be for the purpose of "buying" a doctor's business or inducing an HCP to use the Company's products.

Each of these access "tools" consists of a specific activity or category of "solution," most, but not all, of which have been assigned specific dollar limits per activity or solution per HCP as well as an annual aggregate limit. Each of these dollar limits are attributable to a specific activity or solution and cannot be transferred from one activity or solution to another.

3.2. Specific Access Tools

For purposes of this Policy, these "access" tools consist of the following seven activities or types of solutions:

1) Providing lunch, or other refreshments, to one or more HCP's, and their staff members, on the HCP's premises while detailing the group ("Lunch and Learn") (described more fully in Exhibit E);

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2) Providing a meal to an HCP outside the HCP's office at a restaurant or as a take-out meal (the "Food for Thought" program) either while, or after, detailing the HCP, or otherwise promoting the Company's products ("Stand-Alone Meals") (Exhibit F);

3) Taking an HCP to an entertainment function, such as a concert, the theater or professional sporting event, in order to facilitate detailing the HCP ("Stand-Alone Entertainment") (Exhibit G);

4) Providing a "patient-related" solution (Exhibit H);

5) Providing a "medical-related" solution (Exhibit I);

6) Providing a "business-related" solution (Exhibit J);

7) Providing a library grant (Exhibit K).

With regard to items 4-7 above, it is anticipated that the PSS will have at least one, or more, opportunities to detail the HCP, or HCPs, for whose benefit the solution or grant is provided.

The dollar limits, and additional policy requirements, for each of these access tools are set forth below in Exhibits E-K. Community Health Fairs are addressed at Exhibit L. The dollar limits for each of these access tools are also summarized, for ease of reference, at Exhibit A. Exhibit B provides a "quick reference" list of key principles and standards of good practice that must be followed by all AstraZeneca employees in using these access tools. Exhibit C also provides a chart graphically portraying the relative degree of potential risk for these various activities.

4. *Exclusions From The Policy*

- This Policy does not govern meals or entertainment that are provided to an HCP in the context of, and incidental to, a continuing medical education program. This activity is covered by a separate policy entitled **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S C-2).

- This Policy also does not govern compensation to an HCP in conjunction with any contract that HCP might have with AstraZeneca for the provision of personal services to the Company, such as consulting agreements, clinical trial agreements, etc. Consulting Agreements are covered by a separate policy entitled **Engaging Healthcare Professionals for Consulting Services** (M&S F-1).

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- This Policy also does not govern the provision of entertainment or hospitality to an HCP that is in the context of, and incidental to, the provision of such consulting services. This is covered by the **Engaging Healthcare Professionals for Consulting Services** policy referenced above.

- This Policy also does *not* govern the provision of charitable donations to charitable causes on behalf of AstraZeneca, or on behalf of physicians or physician practices. This Policy is in development.

- During the course of promotional activities, Pharmaceutical Sales Specialists may provide an HCP, or the HCP's office, with "reminder" items. Reminder items are any item offered to a customer that calls attention to the AstraZeneca name, or the name of any AstraZeneca product, but does not include indications or dosage recommendations for the use of those products. While reminder items are subject to separate policies (**Product Promotion**, M&S B-1 and **Creation and Distribution of Reminder Items**, M&S-B-7), and must comply with all applicable Food and Drug law requirements, they also may constitute materials that are classified as either patient, medical or business solutions for purposes of this Policy and, therefore, may be subject to the dollar and other limits set forth herein. In time, information regarding the appropriate classification of such reminder items will be displayed electronically. Until then, please consult with your Field Promotions Manager.

- Contract sales organizations are subject to separate policies regarding the use of access tools by members of these independent sales forces. Those policies are consistent with, but separate from, the terms of this Policy.

5. *Fundamentals of Federal and State Laws and Regulations*

Any activity by AstraZeneca which provides "value" (including goods or services) to HCP's, healthcare providers or office staff is subject to various federal and state laws prohibiting "kickbacks," bribery, false claims or "fraud" if one purpose of providing the value is, in whole or in part, to induce the purchase, use or recommendation of AstraZeneca products. In this context, "value" also includes paying cash to an HCP, or providing that HCP 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 AstraZeneca provides to HCPs, including meals, entertainment, hospitality, library grants, and patient, medical and business-related solutions in order to gain access to physicians or other HCPs. (These laws also govern our contract services with HCP's for consulting arrangements, clinical trial programs, etc.)

5.1. Federal Law

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The federal fraud and abuse rules (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 or the purchase of our products. The courts have held that the law can be 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 a healthcare professional, healthcare provider or staff member. The OIG takes the position that there need not be a direct "quid pro quo" (i.e., 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 rules. Rather, it will look to all of the facts and circumstances surrounding our relationship with an HCP, etc., 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 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 which exceeds the reasonable (fair market) value of those services provided may be viewed as intended to induce the use of AstraZeneca's products.

Inferences regarding AstraZeneca's intent may be drawn from the structure of the transaction and the interrelationship between the value provided and the volume of prescriptions or sales.

Evidence showing over-utilization of the Company's products or reduced quality of services to patients also is considered evidence regarding 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 VIOLATION.

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5.2. 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. Generally, these laws also prohibit the use of money, gifts, goods or services to bribe a healthcare provider or to induce or influence the purchasing behavior of AstraZeneca's customers.

There are presently two states, Minnesota and Georgia, which have adopted special state rules. Pharmaceutical Sales Specialists in these jurisdictions should consult with their management regarding any special requirements needed to comply with these state laws.

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

5.3. The Law Permits the Use of Access Tools

It is entirely appropriate to provide HCP's with entertainment, "value-added services" or "solutions" so long as the sole and exclusive purpose of that meal, entertainment, service or solution is to gain access to the time and attention of an HCP in order to inform them about the safety and efficacy benefits of our products. It is essential, however, that the purpose of such a service or solution is solely and exclusively to gain access and that there is no other (illegal) purpose to induce the use of our products because of the "value" we are providing to the HCP.

Because the purpose of such access involves a promotional dialogue between the HCP and the AstraZeneca PSS, the term access, as used in this Policy, is not the same as obtaining an HCP's "goodwill" or building a "relationship" with a customer. While developing an excellent relationship with AstraZeneca's customers obviously is important to the effective conduct of business, and may be an incidental benefit resulting from an effective promotional presentation facilitated as the result of using an access tool, building goodwill alone can never justify the use of the access tools permitted pursuant to this Policy. So, for example, it is not appropriate to take an HCP to dinner if the purpose is merely to socialize and, thereby, strengthen the relationship between the HCP and the PSS when the PSS had no intention nor opportunity to promote the Company's products during the course of that dinner.

6. *AMA Guidelines on Gifts to Physicians from Industry*

On December 3, 1990, the AMA's Council on Ethical and Judicial Affairs issued guidelines on gifts to physicians from industry. These guidelines have been incorporated in the AMA's Code of Ethics for the Medical Profession. A summary of the Guidelines is enclosed as part of Exhibit D.

While AstraZeneca does not view these Guidelines as binding on the Company's access policy, they are a useful reference point in providing items of value to an HCP, and employees are encouraged to adhere to the Guidelines whenever possible.

7. *Adherence to Policy and Good Judgment/ Substantial Compliance*

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In order to permit AstraZeneca to employ all of these access tools appropriately, it is important that all PSS's adhere to the letter and spirit of these policies. Additionally, because PSS's 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 the Company, for complying with this Policy.

It is the desire and the intention of the Company that all of the dollar limits set forth below are followed. However, the Company also recognizes that, in the context of meals or entertainment, circumstances may arise where the dollar limits are unintentionally exceeded.

The Company expects substantial, good faith compliance with these rules. For example, a doctor 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, the Company expects that the PSS 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.

In adopting the Policy, the law also requires that AstraZeneca adopt a Compliance Program that ensures adequate training for all relevant employees, appropriate supervision of those activities by all levels of management, and programs for tracking and periodic auditing of our activities. The complete framework for this compliance infrastructure is under development and will be communicated to all relevant employees as soon as possible.

8. *Appropriate Planning*

Prior to employing any of these access tools, a PSS should prepare a plan for using these tools effectively and in a manner that conforms to Company policy.

9. *Call Reports*

Each promotional opportunity arising as a result of employing an access tool must be recorded as a call with a reasonably specific entry accurately describing the promotional efforts actually undertaken.

10. *Expense Reporting*

The PSS must ensure that all expense-related information submitted in support of reimbursement regarding the amounts spent and the identity of the HCP's receiving the goods or services provided are accurately and completely documented when submitting travel expense reports to the DSM for approval.

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11. Spouses

Because the Company's access policy is intended to facilitate meaningful business discussions, spouses and other family members may not be invited to attend any function covered by this Policy.

In the event that an HCP arrives at a function in the company of their spouse, or other family member, PSS's must use good judgment and professional courtesy in managing that circumstance. If such an event occurs, a PSS will need to use good judgment to ensure that the same difficulty is avoided in the future.

Additionally, the Company is cognizant of the fact that there may be occasions when a PSS may feel reluctant to undertake an unescorted entertainment event with an HCP (i.e., at an evening function such as the theater, a concert, etc.). In that event, the Company recommends that an additional (counterpart) PSS also be invited to attend the function, or, alternatively, the District Sales Manager. In the event that these options are not available, a PSS should consult with his or her DSM as to whether the PSS might invite his or her spouse (and, consequently, the HCP's spouse) to join that function. It is anticipated that this will be a rare occasion.

12. Gifts

While the provision of nominally valued gifts (i.e., a flower basket on the occasion of an HCP's birthday) unrelated to any patient, medical or business-related solution, or which do not constitute reminder items is not illegal, the Company has decided that such gift giving is not consistent with the standards of professional integrity the Company wishes to display to HCP's and to the public at large, and, consequently, the provision of such gifts generally is not permitted.

This prohibition does not prevent PSS's from providing an HCP with a holiday or birthday card.

Additionally, on the occasion of a birth or death in an HCP's immediate family, or the immediate family of an HCP's staff, a PSS may provide that HCP or staff member with a reasonably priced floral arrangement to commemorate the event, or, alternatively, may donate money to a designated charity. In either event, the value of the flowers or the donation shall not exceed $50 per occasion.

The purpose of the expenditures, and the identity of either the recipient of the floral arrangement, or the individual on whose behalf the donation was made, shall be expressly noted on the expense report submitted to the DSM for reimbursement.

These requirements are summarized in Exhibit A1.

13. References

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13.1 M&S Business Policies

Product Promotion (M&S-B-1); **Creation and Distribution of Reminder Items** (M&S-B-7); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1).

EXHIBIT A

Activity	Customer	Dollar Total	$ per Customer/Year	Aggregate Total Y or N	Tracking	DSM Approval	RSD Approval
Lunch & Learn	*Multi-Team*	<$25/attendee, $100/HCP + Staff/event	$1,600/HCP + staff	Separate Limit	Audit	Territory Expense Report Approval	NA
	Single Team	<$25/attendee, $100/HCP + Staff/event	$600/HCP + staff	Separate Limit	Audit	Territory Expense Report Approval	NA
	Institutional	<$15/attendee	NA	NA	Audit	Territory Expense Report Approval	NA
Stand Alone Meals	*Multi-Team*	<=$50/HCP/event	<=$150/HCP	Y	$	>$50/event,	NA
	Single Team	as above	as above	Y	$	Territory Expense Report Approval	NA
Entertainment	*Multi-Team*	<=$125/HCP/event	<=$250/HCP	Y	$	Territory Expense Report Approval	NA
	Single Team	<=$125/HCP/event	<=$250/HCP	Y	$	Territory Expense Report Approval	NA
Patient Solutions	*Multi-Team*	Reasonable	Reasonable	N	?	Supervision	NA
	Single Team	Reasonable	Reasonable	N	?	Supervision	NA
Business Solutions	*Multi-Team*	<= $100/HCP, <=$2,000/Gp Practice	<= $100/HCP, <=$2,000/Gp Practice	Y	$	Evaluation Process	>$2,000 for gp practice >20, cost </HCP
	Single Team	<= $100/HCP, <=$2,000/Gp Practice	<= $100/HCP, <=$2,000/Gp Practice	Y	$	For higher value solutions	NA
Medical Solutions	*Multi-Team*	<= $100/HCP/ST	$400/HCP	Y	>$35/item	Supervision	NA
	Single Team	<= $200/HCP, no gp practice limit	$200/HCP	Y	>$35/item	Supervision	NA
Library Grant		Falls under Medical Soln for individual HCP or Practices except for use to purchase pt ed mat'ls		Y	$	Grant Approval Process	NA

HCP = healthcare professional (prescriber)

$ Total: $700-900 per HCP per annum plus Patient Solutions plus "Lunch and Learns"

Exhibit A

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EXHIBIT A1

Institutional Promotion

Activity	Dollar Total	$ per Customer/Year	Aggregate Total Y or N	Tracking	DSM Approval	RSD Approval
In-Service Lunch and Learn	<$15/attendee	Reasonable	N	Audit	Territory Expense Report Approval*	NA
Institutional Personnel**	See Exhibit A					
IV Pumps	<$2,500 per item	<$5,000	Y	Y	Y	>$5,000 (with Legal Dept.)
Milestone Events	<$50 per occasion for flowers or designated charity	Reasonable	N	Audit	Territory Expense Report Approval	NA

*The sign-up list of attendees must be submitted with the expense report.

**Institutional HCP's shall include physicians and other individuals who have prescribing authority under the relevant laws of the state in which they are licensed, staff pharmacists, purchasing agents and executive staff personnel who play any role in contracting with AstraZeneca, or in determining whether the institution shall use AstraZeneca products.

Essential Principles/Standards of Good Practice

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

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

2) Reasonable and modest entertainment, value-added services or solutions as defined by this Policy, may be used by Pharmaceutical Sales Specialists to assist them in gaining access to an HCP's time and attention in order for us to effectively educate that HCP regarding our product's efficacy and/or safety characteristics and, thereby, to promote our product.

3) AstraZeneca employees must familiarize themselves with their obligations under this Policy and the fraud and abuse rules and by directing questions to their designated supervisors or to the Legal Department.

4) Access tools should always be provided in a way that allows AstraZeneca to compete for business based on the quality of our products and the appropriateness of our products.

5) Entertainment, value-added services and/or solutions can never be used to induce, influence, or as consideration for, an HCP's prescribing habits, or the recommendation, purchase or use of our products by any healthcare provider or staff.

6) Access tools should never be used in a way that could be considered lavish or excessive in value. (For example, combining access tools for multiple HCP's in a way that appears extravagant.)

7) Access tools should not be provided on such a regular or routine basis that they act as, or appear to be, an inducement.

8) Access tools must not be provided specifically to HCP's because of their prescribing habits or tied to their volume of purchases in any way.

9) Access tools cannot be used to "reward" an HCP for his or her current or past prescribing habits.

10) The purpose of this Policy is to provide tools to gain access to an HCP. If you already have adequate access to an HCP, these tools should not be used unnecessarily. It is not appropriate to use an access tool merely to socialize with an HCP, even if the opportunity to socialize may help guild goodwill or rapport with your customer. 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 detailing our products.

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11) Any access function must be entirely professional in tone and appropriate to the serious business of healthcare.

12) Entertainment functions generally should not present undue physical risk to participants.

13) When we employ an access tool, a PSS must use that opportunity to educate physicians 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.

14) Pharmaceutical Sales Specialists must always attend stand-alone meals or entertainment functions in order to discuss and promote our products.

15) Whenever possible, use the "lowest risk" access tool possible to achieve the access required. For evaluating the relative degree of risk involved in using a specific access tool, please review the risk chart attached Exhibit C. If you have questions in this regard, please consult your DSM.

16) Whenever possible, use the lowest dollar value tool within any one category possible to achieve the access required.

17) Never, even in jest, suggest or hint at an improper motivation on your behalf, or on behalf of your customer, as to the reason why we are providing a good or service to an HCP.

18) 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.

19) Access tools should be used singularly, and not in combination with multiple access tools, in order to maximize the frequency of achieving promotional access with an HCP.

20) The Company has other policies that govern compensation to HCP's for the provision of consulting services, such as service on advisory boards, etc. These policies are intended to obtain the services identified and are ***not*** to be used for the purpose of gaining access. Likewise, the Company's policy on charitable donations shall also not be used for the purpose of gaining access.

21) Spouses or family members may not be invited to stand-alone entertainment functions or meals. (Spouses may attend other entertainment activities that are incidental to, or associated with, other functions such as a CME conference, or Advisory Boards, etc.)

22) Spouses and family members may not benefit from any "value" provided to an HCP as part of an access tool.

23) Pharmaceutical Sales Specialists should not pay for value-added services with cash or personal checks, but always with an authorized company check or by use of a corporate credit card. B-2

24) Managers are always responsible for the conduct of their subordinates.

25) 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.

26) Examples of Prohibited Activities:

All of the possible activities that might violate the anti-kickback laws cannot be 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 utilization of AstraZeneca products in exchange, or as a quid pro quo, for prescribing an AstraZeneca product, switching a prescription to an AstraZeneca product, or placing an AstraZeneca 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 AstraZeneca 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 healthcare professional in the absence of the performance by the professional of bona fide services.

- When bona fide services are actually performed by healthcare professionals as investigators, speakers or in other consulting capacities, paying, or offering to pay, compensation which 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 AstraZeneca products if the cash, goods or services are valuable enough to affect the person's independent judgment, are likely to cause inappropriate utilization of AstraZeneca products, or are likely to increase costs to Medicaid or other governmental or private insurers.

Exhibit C

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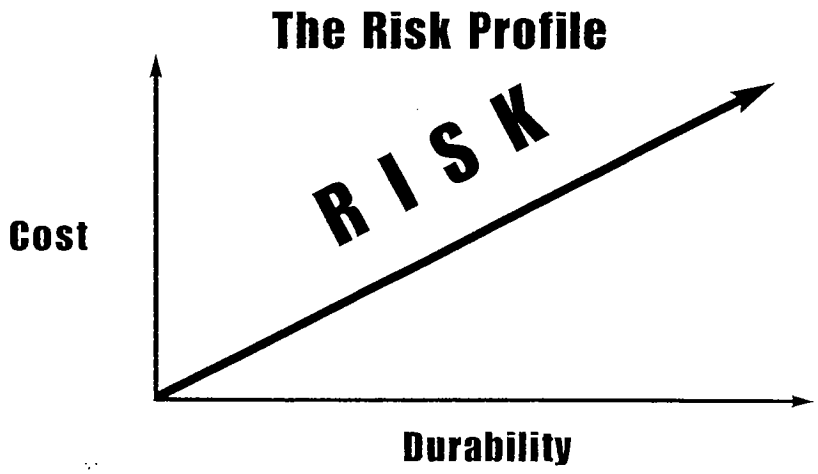
EXHIBIT C



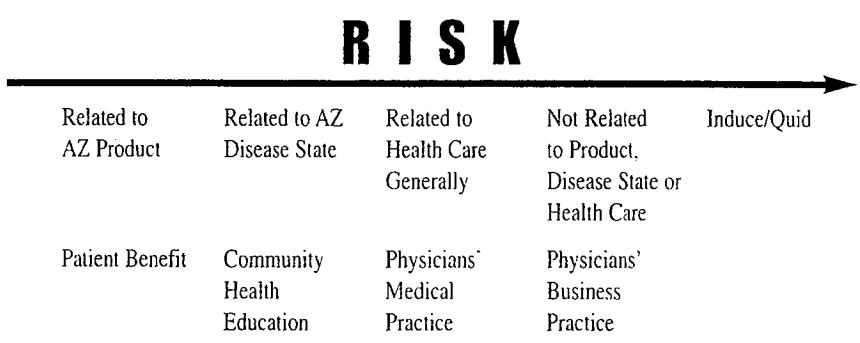


Exhibit D

EXHIBIT D

AMA Guidelines Summary

General: The AMA's Guidelines suggest the following standards in providing items or services of value to physicians:

- ❑ Any items provided to individual physicians should primarily benefit patients and should not be of substantial value.
- ❑ Textbooks and modest meals are appropriate if they serve a genuine educational function.
- ❑ Cash payments are never appropriate.
- ❑ Individual reminder items of minimal value are permissible as long as they are related to the physician's work (e.g., pens and notepads).

- No items of value should ever be provided to an HCP with "strings attached." In accordance with this principle, no employee shall give any item of value to a physician relating to that physician's prescribing habits.

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- When AstraZeneca underwrites medical conferences or lectures organized by third parties, responsibility and control over the selection of content, faculty, educational methods, and materials should 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 can 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. Spouses may participate in such modest meals or social events.

- 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 honoraria and reimbursement for reasonable travel, lodging, and meal expenses. (Such payments must also comply with all applicable AstraZeneca 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 beneficiaries of the funds are selected by the academic or training institution.

- Sponsorship of a professional society's charitable event or other charitable donations may be permissible, but must comply with AstraZeneca corporate policies on charitable contributions. This Policy is under development.

B-2 **EXHIBIT E**

Lunch and Learns

1. Definition

As used herein, the "lunch and learn" activity includes any occasion at which, a PSS provides one or more HCP's, and their staff, with a free lunch, or other refreshments (such as breakfast fare or snacks) while on the HCP's premises during ordinary business hours for the purpose of facilitating a detail or undertaking some other promotional activity.

2. Criteria

- These events are always conducted on premises.
- The lunch and learn must be organized and implemented in such a way as to maximize the PSS's opportunity to promote AstraZeneca's products, and to facilitate a promotional discussion.
- Whenever office or medical staff personnel share in the lunch, etc., the cost of providing their food and drink shall be included in the aggregate total for the HCP for whom they work, or, if they support multiple HCP's, to one of the attending HCP's if the staff member supports an entire practice (i.e., the office manager).
- Alcohol may not be served at a lunch and learn.

3. Dollar Limits (See Exhibit A)

Rule 1: The total dollar value of food and drink provided for any one individual (whether an HCP or staff member) shall not exceed $25 for a single "lunch and learn" event.

Rule 2: The total dollar value of food and drink for any one HCP and his or her associated staff members (i.e., non-prescribers) shall not exceed $100 in the aggregate for a single lunch and learn event.

Examples: If one doctor (or other prescriber) attends a lunch and learn alone, the total maximum value of the lunch is $25. If the HCP attends with three nurses, the value of the lunch, etc., for the individual HCP and the three (3) individual nurses cannot exceed $25 per person, and the aggregate value of the lunch cannot exceed $100 for those four individuals.

If the value of each lunch served is only $20, then one (1) HCP and up to four (4) staff members may attend ($20 X 5 = $100).

If two (2) HCP's attend a lunch and learn costing $25 per person, a total of eight personnel (two (2) HCP's and six (6) support staff) may attend for a total aggregate cost of $200 (8 X $25 = $200).

If the cost of that same lunch is only $20 per person, up to ten people can attend (two (2) HCP's and eight (8) support staff) ($20 X 10 = $200). B-2

Rule 3: If a single AstraZeneca PSS calls on a doctor or other HCP, that PSS may employ "lunch and learns" a minimum of at least six (6) times per year for that doctor, etc., for a maximum aggregate value of $150 for the individual HCP (6 X $25 = $150) and $600 for the HCP and that HCP's associated office staff (i.e., 6 X $100 per event = $600).

If the PSS provides food, etc., that costs less than $100 per event, then he or she can employ lunch and learns as many times a year as the annual aggregate limit of $600 permits (i.e., 12 times per year if the individual event costs were $50, and not $100). (The $25 maximum per person always applies.)

Rule 4: If multiple AstraZeneca PSS's call on a single physician or other HCP, each selling team (i.e., those PSS's that promote products in the same therapeutic area) may employ a minimum of at least four (4) lunch and learns for each therapeutic area, up to a maximum value of $400 per therapeutic area.

Rule 5: If multiple selling teams call on a single HCP, the total annual aggregate shall not exceed $1,600 across all therapeutic areas that call on that physician or other HCP.

Rule 6: It is the responsibility of each selling team to coordinate their activities.

Illustration: If two selling teams call on a single doctor, they can employ at least eight (8) lunch and learns, with a maximum value of $25 per person, $100 per event, or a total of $800 for both selling teams ($400 for each of the two selling teams). Three selling teams could employ at least twelve (12) lunch and learns (3 teams X 4 events = 12 events) for a total aggregate value of $1,200 (12 X $100 per event).

Teams may always utilize more lunch and learns if the value of a single lunch and learn is less than $100 for each HCP and their associated staff members.

4. *Review and Approval*

DSM's shall review "Lunch and Learn" expenditures at the time a PSS submits an expense report for approval.

DSM's shall satisfy themselves that the PSS has complied with this Policy and that the documentation submitted is complete and accurate.

It is anticipated that reports of these activities will become available through the GELCO system.

B-2 **EXHIBIT F**

Stand-Alone Meals

1. Definition

As used herein, "Stand-Alone Meals" includes any activity where an AstraZeneca PSS invites a physician or other HCP to a breakfast, lunch or dinner served at a restaurant so as to gain access to that HCP's time and attention in order to promote our products. The Policy also permits take-out fare from a restaurant if certain criteria are satisfied (the "Food for Thought" program).

2. Criteria

- ❑ At least one PSS must attend the stand-alone meal.
- ❑ The locale and atmosphere of the restaurant must be appropriate in tone and conducive to promotional activities.
- ❑ This Policy does not encompass dinners, etc., which may be provided to HCP's in the context of, and incidental to, a continuing medical education course or a symposium.
- ❑ PSS's may not invite an HCP's spouse or family members to attend stand-alone meals.
- ❑ Alcohol may be an appropriate part of the meal. (See below.)

3. Dollar Limits (See Exhibit A)

Rule 1: The total dollar value of food and drink provided to a single HCP shall not exceed $50 per HCP for any one meal.

This cost does not include the cost of the meal for the PSS.

A PSS may request approval from his or her DSM to increase this per meal limit in those districts where the cost of an appropriate and suitable meal is substantially greater than $50.

Rule 2: The total annual aggregate value for "stand-alone meals" per HCP per year is $150.

Rule 3: Unlike lunch and learns, this annual aggregate limit of $150 shall apply without regard to how many AstraZeneca PSS's call on that HCP.

Rule 4: The Company expects substantial compliance with these rules. See Section 8 above.

4. Guidelines When Alcohol is Served

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In the event that alcohol is consumed during the course of the meal, a PSS should use good common sense in insuring that the function ends safely and appropriately.

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

Reasonable steps should be followed to avoid intoxication, i.e., 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. Food for Thought

In addition to the "stand-alone meal" at a restaurant, it is also appropriate to permit an HCP to take his or her meal home (as take-out) if the following criteria are satisfied:

1. The same individual and aggregate dollar limits apply as if the meal was hosted at the restaurant.

2. The PSS must arrange for a separate room at the restaurant where the PSS will have an opportunity to engage in meaningful and effective promotional activity.

3. AstraZeneca will not pay for food for the HCP's spouse or family members.

4. The restaurant should take the HCP's meal order at the beginning of the promotional dialogue. The PSS should not call the HCP's order into the restaurant beforehand. It also would not be appropriate for the HCP's assistant to pick up the order at the restaurant.

5. The Food for Thought program permits a meaningful promotional opportunity. The term "Dine and Dash" may connote to some people, or the media, a lack of effective access and should not be used to describe this activity.

Example: For example, a program can be conducted where a physician would come to a restaurant in which a private room has been reserved. AstraZeneca personnel staff the room. Upon arrival, the physician can order food to go, and, while waiting for the food to be prepared, will talk to the PSS or any thought leaders who are present regarding the safety and efficacy of the Company's products.

B-2 6. *Review and Approval*

The DSM shall review "Stand-Alone Meal" expenditures at the time a PSS submits an expense report for approval.

DSM's shall satisfy themselves that the PSS has complied with this Policy and that the documentation submitted is complete and accurate.

In those districts where the cost of living necessitates a higher per meal per HCP limit than $50, the DSM may review the issue on an annual basis and approve a higher dollar limit for stand-alone meals within the DSM's district, so long as it is reasonable under all of the circumstances, and does not exceed the reference index for comparative costs of meals in designated urban areas in a Dining Index that will be distributed in the near future.

A decision to adopt a higher dollar limit shall be communicated in writing to the RSD, with a copy to the Legal Department, attention General Counsel.

In the event that a PSS wishes to invite a spouse to a stand-alone meal, the DSM shall ensure that the request complies with Policy Section 11 (Spouses) above.

It is anticipated that reports of these activities will become available through the GELCO system.

Stand-Alone Entertainment

1. Definition

As used herein, "Stand-Alone Entertainment" encompasses all social activities, such as the theater, concerts, sporting events, modest and reasonable games of golf and tennis, etc., where the purpose is to gain an opportunity to detail that HCP as part of the entertainment function. **It also includes the cost of any meals that may be incidental to the entertainment function.**

2. Criteria

- ❑ The function must be of a type that will facilitate discussion between the PSS and HCP. These opportunities can include transportation to and from the event.
- ❑ Meals associated with the entertainment function must be included in the event dollar limits set forth below.
- ❑ The nature and locale of the event must be suitable in tone and appropriate for the important subject of healthcare.
- ❑ Sporting events can be divided into spectator and participatory activities.
- ❑ All participatory sports raise the obvious possibility of physical injury to the PSS or the HCP.
- ❑ Certain participatory sports present acceptable physical risks, such as tennis or golf.
- ❑ Other participatory sports, such as scuba diving, white-water rafting, hang-gliding, etc., present such a risk of physical harm to either the PSS or the HCP that the Company does not choose to permit activities of that nature. Consult with your DSM if you have questions about the appropriateness of the sport.
- ❑ There are two types of participatory sports, hunting and fishing, which, while presenting some degree of physical risk, are such a traditional form of entertainment that the Company will permit them with certain reasonable safeguards. (See below.)

3. Golf Outings

The Company recognizes that a golf outing may offer a substantial opportunity to access an HCP's time and attention, and so recognizes golf as an approved form of entertainment.

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Nevertheless, golf outings have been associated in the past with a high degree of abuse (the golf "junket" at a plush resort in Florida, or Bermuda, etc.), and this type of outing is an area of concern to government regulators and can draw media attention.

Likewise, large scale tournaments, with invitations, entertainment and prizes may attract unwanted attention and criticism.

Consequently, permitted golf outings are to be conducted at modestly priced, local golf courses, in small groups, possibly with a modest and reasonable meal provided as incidental to the outing.

As always, PSS's must be in attendance and must maximize the amount of time reasonably spent on promoting the Company's products.

This Policy does not include support for charitable activities that may include golf outings as part of a charity campaign. These charitable activities will be governed by the Company's charitable contributions policy.

4. *Hunting and Fishing*

With a DSM's prior approval and subject to the safety precautions outlined below, experienced PSS's may take customers on a hunting or fishing trip.

There are a few basic safety considerations that you must apply. These are outlined at Exhibits G1 and G2.

5. *Dollar Limits (See Exhibit A)*

Rule 1: The total dollar value for a stand-alone entertainment function provided to a single HCP shall not exceed $125 (including food and drinks) for any one occasion.

This does not include the cost of the entertainment for the PSS.

Rule 2: The total annual aggregate value for stand-alone entertainment is $250 per HCP per year.

Rule 3: This annual limit shall apply regardless of how many AstraZeneca PSS's call on that HCP.

Rule 4: The Company expects substantial compliance with these dollar limits. See Section 8 above (Appropriate Planning).

6. *Review and Approval*

DSM's shall review "Stand-Alone Entertainment" expenditures at the time a PSS submits an expense report for approval.

DSM's shall satisfy themselves that the PSS has complied with this Policy and that the documentation submitted is complete and accurate. B-2

It is anticipated that reports of these activities will become available through the GELCO system.

In the event that a PSS wishes to take an HCP hunting or fishing as an access tool, the DSM must approve that activity in advance and shall ensure that the appropriate safeguards set forth in Exhibits G1 and G2 are satisfied.

In the event that a PSS wishes to invite a spouse to an entertainment function, the DSM shall ensure that the request complies with Section 11 above (Spouses).

EXHIBIT G1

Safety Guidelines for Fishing and Boating

Although fishing and boating are relatively safe sports, there are some safety guidelines that should be followed to assure an enjoyable outing. Remember, you are the "host" of any outing that you arrange and to which you invite counterparts or HCP's. It is the host's responsibility to use good judgment and make wise decisions concerning you and your guests, not only on a fishing/boating outing, but also on the way home afterwards. This means that as "host" you are responsible to make sure your guests are capable of driving home. Appoint a "designated driver" if others will be drinking.

Fishing with Charter Fishing Captains or Guided Trips

This is the safest, most reliable way to go fishing. Not only do captains and guides know the waters they are operating in, but they also should be licensed and fully insured.

Fishing with a Personal Boat or a Rental Boat

- ❑ The boat should be equipped with all U.S. Coast Guard required equipment, i.e., fire extinguishers, personal flotation devices, etc.
- ❑ Watch alcohol consumption. The drunk driving rules for boaters on the water are the same as they are for automobiles on the roads.
- ❑ Use proper equipment.
- ❑ Have a first-aid kit on board.

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EXHIBIT G2

Safety Guidelines for Hunting

The following rules and guidelines should be reviewed with all participants prior to any and all outings where firearms are involved.

The host should verify that all participants have completed an approved gun safety course and that they hold a current certificate, or the host should have prior knowledge of the experience level of his or her guests.

While it is impossible to identify every precaution that may promote the safe use of firearms, at a minimum, the responsible hunter will always use good common sense and observe the following simple rules:

- ❑ Control the direction of your firearm's muzzle, always keeping the gun pointed in a safe direction. Carry the firearm safely, keeping the safety on until you are ready to shoot. Keep your finger off the trigger until you are ready to shoot.
- ❑ Identify your target and what is behind it. Never fire in a direction in which there are people or any other potential for mishap. Know the identifying features of the game you hunt.
- ❑ Be certain the barrel and action are clear of obstructions and that you have only ammunition of the proper size for the firearm you are using.
- ❑ Unload firearms when not in use. When you pick up a gun, immediately open the action and look into the chamber–it must be clear. (If the gun has a magazine, remove it before opening the action.) Firearms should be carried empty in cases to and from shooting areas. Keep firearms unloaded at all times–including during transport to and from hunting areas or camp.
- ❑ Avoid all horseplay with firearms. Never even point a gun at anything you do not intend to shoot.
- ❑ Never climb a fence or tree, or jump a ditch or log, with a loaded firearm.
- ❑ Never use alcoholic beverages or other mood-altering drugs before or while shooting.
- ❑ Store guns and ammunition separately and beyond the reach of children and careless adults.
- ❑ Always know where your hunting companions are. Whenever possible, wear blaze orange clothing and hats to increase visibility.

Patient Solutions

1. Definition

For this Policy, "patient solutions" means those goods or services whose primary purpose is to benefit patients, such as an educational brochure regarding a disease state.

2. Criteria

The process for employing either standardized or original patient-related solutions can be obtained by consulting your Field Promotions Partner and Standard Operating Procedure Document (SOP) 401.

3. Dollar Limits (See Exhibit A)

There are no explicit dollar limits associated with the distribution of patient-related solutions to HCP's. However, it is anticipated that each PSS, in consultation with their DSM, will provide a reasonable and appropriate amount of patient-related materials to any one practice, relatively proportionate to the specific needs of that practice.

4. Review and Approval

It is anticipated that reports of these activities will become available through the "Compass" system.

B-2 **EXHIBIT I**

Medical Solutions

1. Definition

For this Policy, "medical solutions" means those goods or services whose primary purpose is to benefit an HCP's medical practice, such as a medical textbook.

2. Criteria

The process for employing either standardized or original medical-related solutions can be obtained by consulting your Field Promotions Partner and in SOP 401.

3. Dollar Limits (See Exhibit A)

Rule 1: For a single selling team customer, the total aggregate limit for medical solutions *per* HCP per *year* is a fair market value of $200.

Rule 2: The "fair market" value of authorized medical solutions can be obtained by consulting your Field Promotions Partner.

Rule 3: If more than one selling team is calling on an HCP, each selling team may provide medical solutions to that HCP with a fair market value of not more than $100 *per* HCP *per* year.

Rule 4: If more than one selling team is calling on an HCP, the fair market value of the total annual aggregate per HCP per year shall not exceed $400 for all medical solutions, regardless of the number of selling teams calling on that HCP.

Rule 5: Rules 1-4 apply to each HCP in a medical practice without regard to how many HCP's may be a member of that medical practice.

Rule 6: It is the responsibility of each selling team to coordinate their activities in complying with these dollar limits.

Examples: If one selling team calls on an HCP, the fair market value of the total annual limit for all medical solutions provided to that HCP is $200. If two (2) selling teams call on an HCP, the fair market value of the total annual aggregate for all medical solutions provided to that HCP is $200 (2 X $100). For three (3) selling teams, the limit is $300 (3 X $100); for four (4) selling teams, the annual limit is $400 (4 X $100).

4. Review and Approval

It is anticipated that reports of these activities will become available through the "Compass" system.

Business Solutions

1. Definition

For this Policy, "business solutions" means those goods or services whose primary purpose is to benefit the HCP's business practice, such as billing software, business logos, Internet advertising, etc.

2. Criteria

The process for employing either standardized or original business-related solutions can be obtained by consulting your Field Promotions Partner and SOP 401.

3. Dollar Limits (See Exhibit A)

Rule 1: Any one HCP may not receive business-related solutions with a fair market value of more than $100 per HCP per year.

Rule 2: Rule 1 applies to each HCP within a practice up to an annual aggregate limit of $2,000 for any one physician practice group or hospital, representing twenty (20) HCP's.

Rule 3: For physicians or hospital practices which have more than twenty (20) HCP's, the total annual aggregate may exceed $2,000 if, and only if, (i) the RSD gives his or her prior written approval, (ii) the additional cost of the proposed business solution is related solely to an increased incremental cost based upon the fact that a greater number of HCP's are receiving a benefit, and (iii) that the increase in incremental cost is less than $100 per additional HCP, thus reducing by some factor the net cost of the business solution on a per capita basis.

4. Review and Approval

In the event that a PSS wishes to employ a business-related solution in excess of $2,000, the DSM and RSD must authorize that expenditure in advance and must ensure that the expenditure satisfies the terms of this Policy.

It is anticipated that reports of these activities will become available through the "Compass" system.

B-2

EXHIBIT K

Library Grants

1. *Definition/Criteria*

See **Library Grant Guidelines** (M&S C-G-2-d).

2. *Dollar Limits (See Exhibit A)*

Library grants are subject to the same dollar limits as medical solutions.

Community Health Fairs

1. Definition

The Company recognizes two types of community health fair support:

First, AstraZeneca 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 Corporate Policy (in development) on charitable donations.

Second, AstraZeneca may also sponsor health fairs that AstraZeneca initiates or for which we provide specific Company support in conjunction with a physician group practice or hospital. These local activities shall be administered as a form of patient-related solutions as set forth in Exhibit H above.

2. Criteria

There are several general criteria you should consider in conducting a patient-related health fair:

There are substantial FDA issues involved any time AstraZeneca becomes involved in activities that are targeted to consumers, or potential consumers, and PSS's should consult their Promotional Regulatory Affairs Field Partners for further guidance before engaging in community health fair-related activities.

- ❑ Programs should be oriented towards patient and/or public health issues.
- ❑ Any donation can acknowledge AstraZeneca's support for the program, but should not advertise or promote specific Company products.
- ❑ Contributions/support should not provide any personal benefit to an HCP.
- ❑ Programs should not provide direct billing opportunities for healthcare providers.
- ❑ Community healthcare or awareness programs cannot be used as an inducement for a physician or other customer to use AstraZeneca's products.

B-2 **EXHIBIT M**

Institutional Promotion

1. Definition

As used herein, "Institutions" shall include hospitals, surgery centers, and residents' clinics. While the terms of the Policy generally shall apply to such activities at these designated facilities, there are certain unique features to gaining access to healthcare providers in the institutional context that justify certain special rules.

2. Dollar Limits (See Exhibit A1)

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

This Rule shall substitute for the requirements of Section C in Exhibit E for the Lunch and Learn access tool.

Rule 2: For purposes of this Policy, in the context of institutional promotion only, the term HCP shall be expanded to include institutional staff pharmacists, purchasing agents and executive staff personnel who play any role in contracting with AstraZeneca, or in determining whether the institution shall use AstraZeneca products.

The Policy dollar limits and other terms for each type of access tool shall apply to these HCP's.

The PSS also shall ascertain that the use of such access tools does not violate any applicable institutional policy.

Rule 3: On occasion, it may be appropriate to donate an IV pump to an institution.

A DSM must review and approve such a donation, not to exceed $2,500 per single IV pump and $5,000 in the aggregate per institution, and affiliated institutions, per year.

An RSD must review and approve, with advice of the Legal Department, any donation in excess of $5,000 per institution, and affiliated institutions, per year.

In the event that AstraZeneca provides an institution with the donation of an IV pump, the Company also will provide the institution with a "zero dollar" invoice denoting that the equipment was donated by AstraZeneca to the institution without cost, and noting that the institution must determine whether it has any reporting obligation to the federal, or applicable state, government with regard to the donation of such a pump. B-2

A copy of said invoice shall also be provided to the Legal Department, Attention: General Counsel.

Such durable goods can never be offered in conjunction with, in consideration for, or as an inducement to, any contracting discussions AstraZeneca is undertaking with that institution.

It is anticipated that the provision of such durable goods will be rare and generally will be predicated on a recognized need for such equipment by the institution in order to improve patient care.

3. *Review and Approval*

- ❑ When submitting an expense report pertaining to an on-premises, in-service function, the PSS shall identify the name of the institution where the activity took place and shall attach the sign-in sheet of attendees to the expense report submitted for reimbursement.

- ❑ Except as set forth in Rule 1 above, the review and approval procedures set forth in this Policy with regard to all other access tools shall apply as provided for in Exhibits E through K.

- ❑ Prior to undertaking any commitment to provide capital goods to an institution, the PSS shall review with his or her DSM, and the DSM shall approve any expenditure of $5,000 or less. The DSM also shall ensure that the PSS complies with the terms of Rule 3 above.

- ❑ Any proposed donation of capital goods to an institution whose aggregate value exceeds $5,000 shall be approved by the RSD and the DSM, and shall be reviewed with the Legal Department before approval.

B-2 **EXHIBIT N**

Prospective Policies

1. Managed Care Activities

The Company also is developing a policy for gaining access to managed care organizations (MCO).

This policy will address three separate relationships–(i) the Company's relationship with the MCO as an entity, (ii) the Company's relationship with physicians who provide medical services on behalf of the MCO and (iii) the Company's relationship with non-medical employees or other agents of the MCO who participate in, or contribute to, the decision whether to contract with AstraZeneca, to purchase the Company's products or to enroll those products on the MCO's formulary.

2. Activities by Marketing and Other AstraZeneca Personnel

The Company also is developing a policy providing guidance for the activities of Marketing, headquarters and other Company personnel which provide "value" to HCP's, or to potential customers, and which are not otherwise covered by a recognized safe harbor under the federal fraud and abuse rules.

For example, to the extent that headquarters personnel acting in a marketing capacity call on an HCP and provide that HCP with items or services of value, or entertain that HCP, the Company will need to evaluate whether to apply the same annual aggregate limits as they apply to PSS's and, if so, under what circumstances, or whether to adopt additional or other limits.

For example, the Company may conclude that any activity that fairly can be considered predominantly promotional in nature should be subject to the single annual aggregate set forth in this Policy, while other activities, such as an incidental dinner during a national convention hosted in order to maintain an ongoing association with a national opinion leader, may be subject to separate and additional limits.

AstraZeneca

PROFESSIONAL INFORMATION REQUESTS (PIRS) **Policy No.: M&S-B-3** B-3

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To provide direction for AstraZeneca Field Personnel when handling an inquiry regarding an AstraZeneca product which 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. This policy is intended to support the safe and effective use of AstraZeneca products in the delivery of healthcare through objective scientific exchange, and to ensure our adherence to applicable law.

2. Policy

2.1. PIR Definition

A Professional Information Request (PIR) is an unsolicited request for information about an AstraZeneca product by a healthcare professional which 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 healthcare professional requests further medical information.

2.2. When Appropriate

2.2.1. A PIR should be submitted only in response to an unsolicited question or request for information from a healthcare professional. Field Personnel should never prompt a PIR. The inquiry should be posed in the words used by the healthcare professional.

2.2.2. There are situations in which an answer is needed immediately (for example, an emergency overdosage situation in which a healthcare professional has questions not answered by reference to current product labeling). The healthcare professional may call the Information Center at AstraZeneca directly in these cases.

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2.3. When Not Appropriate

2.3.1. Healthcare professional describes an adverse event (including overdosage) in a patient who received an AstraZeneca drug. Reports should be submitted directly to Drug Safety in accordance with the **Adverse Event Reporting Policy and Guidelines** (M&S-B-4, M&S-B-G-4). (A PIR may be submitted for routine information about adverse events related to an AstraZeneca 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).

2.3.2. Product and packaging complaints. Complaints about product condition or packaging should be handled in accordance with the appropriate **Product and Packaging Complaints Guidelines** (M&S-B-G-5).

2.3.3. Requests for approved reprints. Such requests should be handled via the appropriate marketing and sales mechanism for obtaining approved reprints.

2.3.4. Situations in which the healthcare professional expresses an opinion about some aspect of drug therapy, but does not actually request information about an AstraZeneca product.

2.3.5. Situations in which the healthcare professional wants legal advice concerning his or her obligations.

2.3.6. Request for pricing or contracting issues. Such requests should be directed to Pricing/Contracts Management.

2.3.7. 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.

2.4. Subject Matter

2.4.1. Most PIRs that arise are relatively specific questions about a particular AstraZeneca product. The specific question should be submitted in the healthcare professional's own words. Make sure the question accurately reflects the healthcare professional's intent. Use appropriate medical terms to help avoid ambiguity. Always include the product name in the question.

2.4.2. Very general questions can result in information with little focus. If the healthcare professional initially poses a very general question, you should inquire if there are specific aspects of that subject that are of particular interest.

2.4.3. 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) may be an appropriate subject for a PIR (if the request cannot be answered by reference to the current full prescribing information for the products). B-3

3. References

3.1. M&S Business Policies

Product Promotion (M&S-B-1); **Adverse Event Reporting** (M&S-B-4); **Product and Packaging Complaints** (M&S-B-5).

AstraZeneca

PROFESSIONAL INFORMATION REQUESTS (PIRS) GUIDELINES **Guideline No.: M&S-B-G-3** B-G-3

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Procedure

1.1. Procedure for Submitting PIRs

1.1.1. PIRs may be submitted by computer (Lotus Notes® Mail or MS Outlook 98), facsimile (FAX), or written request via US Mail. Electronic submission is always encouraged, but PIRs will be accepted by FAX or US mail where necessary or appropriate.

1.1.2. Regardless of how the PIR is submitted, the following information is needed to ensure the requester receives a response and you receive a copy of this response:

- ❑ Full name, degree (e.g., MD, DO, RPh.), and title (e.g., Dr., Ms., Mr.) of the requester;
- ❑ Full street address, zip code, and telephone/FAX numbers of the requester;
- ❑ Your name, customer unit, and territory number; and
- ❑ Date of the request.

1.1.3 Lotus Notes Electronic PIR Submission

Complete a Professional Information Request (PIR) via the SubmitPIR database form.

NOTE: Former Zeneca products will appear in the product selection of the PIR request form.

1.1.4. SNAP/MS Outlook 98 Submission

Former Zeneca products medical inquiries should be submitted via the MedTech form in SNAP/Pharma. For former Astra products, complete the Zeneca Pharmaceutical Interim Medical Technical

Inquiry form and e-mail the inquiry through MS Outlook 98 to the Medical Knowledge Skill Center as instructed below.

- For former Astra products - in the "Product" field, select "<OTHER>" and then put the former Astra real product name in the question field
- The form can be accessed in MS WORD as follows:
- Select "File" and "New" from the pull-down menu
- In the Dialog box that appears, click on the "Zeneca Info" tab
- Click on the "Medical-Technical Inquiry" icon
- Click OK
- After completing the information, click on "File" and "Send" from the pull down menu
- In the MS Outlook message box that appears, type "Medical Technical Inquires" in the "To:" field
- Send your message

1.1.5. Submission by FAX

Professional Information Request Forms may be requested from the Medical Knowledge Skill Center. Completed forms should be sent via FAX to (610) 695-1400.

1.2. Immediate Need for Information

1.2.1. There are situations where the HCP needs an immediate answer. The HCP may call the company directly in these cases.

HCPs with questions about the following products should be directed to call 1-800-456-3669 ext. 3838:

ACCOLATE
ARIMIDEX
CASODEX
CEFOTAN
DIPRIVAN
FASLODEX
HIBICLENS/HIBISTAT
IRESSA
MERREM
NOLVADEX
SEROQUEL
SULAR
TENORMIN/TENORMIN IV/TENORETIC
TOMUDEX
ZESTRIL/ZESTORETIC
ZOLADEX
ZOMIG
ZD4522 (Statin)

Questions about other AstraZeneca products should be directed to the Information Center at 800-236-9933.

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At the request of the healthcare professional, you may place the call to the AstraZeneca Medical Information Center, identify yourself and the healthcare professional to the AstraZeneca Medical Information Center, and put the healthcare professional on the line to ask his/her question.

Field Personnel should not request information directly from the Information Center on behalf of healthcare professional.

1.2.2. 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 (M&S-B-4).

1.3. Follow Up

If you do not receive a copy of the response to a PIR within four to six weeks, call 1-800-942-0424, extension 1414, in order to determine whether a response has been sent or should be sent out promptly.

2. References

2.1 M&S Business Policies

Adverse Event Reporting (M&S-B-4).

AstraZeneca

ADVERSE EVENT REPORTING **Policy No.: M&S-B-4** B-4

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To ensure that AstraZeneca complies with Food and Drug Administration regulatory requirements by reporting adverse events. All reports must be made promptly and accurately following the applicable procedures explained in the **Adverse Event Reporting Guidelines** (M&S-B-G-4)

2. Policy

2.1. Definition of Adverse Events

2.1.1. An adverse event is defined as any unfavorable and/or unintended change in the structure (signs), function (symptoms), and/or chemistry (laboratory data) of the body temporally associated with the use of an AstraZeneca Drug, whether or not considered related to the use of the Drug.

2.1.2. These may include, but are not limited to:

- ❑ Unfavorable side effects;
- ❑ Toxicity;
- ❑ Injury;
- ❑ Overdose;
- ❑ Sensitivity reactions; or
- ❑ Failure of the Drug to exhibit its expected pharmacologic/biologic effect.

2.1.3. An exacerbation of any pre-existing condition(s) occurring during the use of an AstraZeneca's Drug is also considered an adverse event.

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2.2. Reporting Obligations

Marketing and Sales Personnel are obligated to report to Drug Safety as soon as they become aware of an adverse event associated with an AstraZeneca Drug. An adverse event must be reported:

- Whether or not the reported effect is described in the full prescribing information or the published literature; and
- Whether or not the reported effect is thought to be caused by the drug.

2.3. What Should Be Reported

2.3.1. As much information as possible should be gathered concerning the details of the adverse event. You must identify, at a minimum:

- The date you were informed of the event
- Your name and phone number
- The name and address of the reporting physician or other healthcare professional
- Patient identifying information (such as age, sex and initials only)
- The adverse event, and
- The AstraZeneca Drug involved.

2.3.2. You should forward any written reports, letters or other documents you may receive that relate to the adverse event to Drug Safety. You should also retain a copy for your records.

2.4. Timeframe for Reporting

It is very important that you report the adverse event to Drug Safety immediately. It is essential that you send your report to Drug Safety on the same day you are informed about the event. If any requested information is not available, please so indicate, but do not delay in reporting all available information.

2.5. 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.

2.6. Enrollment in Clinical Studies

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If the patient involved in the report is enrolled in an AstraZeneca clinical study, indicate this in your report and ask the physician or other health care professional to indicate this in his or her report.

2.7. 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 AstraZeneca 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. *References*

3.1 M&S Business Policies

Product Promotion (M&S-B-1); **Professional Information Requests** (PIRs) (M&S-B-3).

AstraZeneca

ADVERSE EVENT REPORTING GUIDELINES **Guideline No.:M&S-B-G-4** B-G-4

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Procedure

1.1. Methods of reporting

1.1.1. Adverse events may be reported by either of these methods:

By Fax:

- Complete the paper Adverse Event Report Form and fax the completed form directly to Drug Safety at 610-296-5824.
- It is 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 signature on the Adverse Event Report Form.
- If no legacy forms are available, supplies of the Interim Adverse Event Report Form may be obtained by telephoning Drug Safety at (610) 578-8778.

By Telephone:

- Telephone the Information Center at AstraZeneca at either 1-800-236-9933 or 1-800-456-3660 (ext. 2232 or 2237). The Information Center will take down the information and forward the report to Drug Safety.

1.2. Emergencies

If you receive a report of an emergency about which a physician or other healthcare professional wants immediate information:

1. Ask the treating physician or other healthcare professional to telephone the Information Center at AstraZeneca at 1-800-236-9933, or 1- 800-456-3660 (ext. 2232 or 2237), so that communication between the treating physician or other healthcare professional and the Information Center at AstraZeneca is established.

2. Immediately report the adverse event following one of the two methods described above, even though the physician or other healthcare professional may have already telephoned the Information Center at AstraZeneca.

3. If the physician or other healthcare professional indicates he/she will only provide details by phone, indicate this in your report along with the phone number where he/she can be reached.

1.3. Identifying the Treating Physician

If you receive a report of an adverse event from someone other than the treating physician (e.g., nurse, pharmacist, patient, etc.), make every effort to consult with the treating physician. If you cannot consult with the treating physician promptly, make every effort to identify the physician and include the name, address, and telephone number in your report, along with the other information requested.

1.4. General Requests for Information

If healthcare professionals ask for information about adverse events, a Professional Information Request may also be submitted. However, if the reporter indicates that a patient (or patients) has (have) experienced the adverse event, then this must also 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.

1.5. Return of Drug

Do not accept the return of any containers of the Drug involved, except upon specific request from the Company.

1.6. Questions

Any AstraZeneca employee who has any questions or concerns relating to the policy or procedures on Adverse Event Reporting should consult Drug Safety (610-578-8778).

AstraZeneca

PRODUCT AND PACKAGING COMPLAINTS Policy No.: M&S-B-5 B-5

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To state AstraZeneca's commitment to compliance with Food and Drug Administration and Consumer Product Safety Commission reporting requirements, and to establish procedures to ensure compliance with these requirements.

2. Policy

2.1. General Statement

AstraZeneca is dedicated to ensuring that the Company and its employees comply with all applicable reporting requirements relating to AstraZeneca product and packaging complaints. Product and packaging complaints are classified as either manufacturing or packaging emergencies, or non-emergency complaints. Marketing and Sales Personnel must be familiar with the reporting requirements for each type of complaint, and must follow the reporting procedures outlined in the **Product and Packaging Complaints Guidelines** (M&S-B-G-5). All reports must be made promptly and accurately.

2.2. Manufacturing/Packaging Emergencies

A manufacturing or packaging complaint (Product Quality Complaint) is an emergency when:

- **Mislabeling or product mix-up:**
  - A market package contains 2 different products
  - A market package contains 2 different strengths of the same product
  - A blister is overfilled
  - The drug or strength on the label does not agree with the contents of the market pack.
- **Empty or underfilled capsules**
  - **Extraneous material in a parenteral.** Since parenterals are injected into the body, it is critical that our parenterals do not contain extraneous material.

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- ❑ **Possible microbial contamination in a parenteral**
- ❑ **Alleged tampering**
- ❑ **Child-resistant closure has a defect which might cause it not to work**
- ❑ **Inhaler mouthpiece is inhaled**

2.3. Non-Emergency Complaints

A non-emergency Product Quality Complaint involves:

- ❑ Defective packaging, such as short fills, burnt induction seals (except if a child-resistant closure problem is involved)
- ❑ Broken tablets or capsules, extraneous material in non-parenterals, changes in color

2.4. Confidentiality

Do not discuss a complaint with anyone except the complainant, your designated supervisor, the Information Center at AstraZeneca, and 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:

The Information Center at AstraZeneca
1-800-236-9933* (8:00 AM – 7:00 PM ET)
Monday through Friday, excluding holidays.

***Until future notice, customers with requests for information about former Zeneca products and services should call:**

1-800-456-3669, extension 2231 (8:15 AM – 4:30 PM ET)
Monday through Friday, excluding holidays.

After you obtain the information necessary to report the complaint, you should have no further discussions with the complainant, unless the Information Center at AstraZeneca directs you to do so.

2.5. Response Letters

A follow-up letter is sent to the customer regarding the complaint.

3. References

3.1. M&S Business Policies

Professional Information Requests (PIRs) (M&S-B-3); **Adverse Event Reporting** (M&S-B-4).

AstraZeneca

PRODUCT AND PACKAGING COMPLAINTS GUIDELINES **Guideline No.:M&S-B-G-5**

B-G-5

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Manufacturing/Packaging Emergencies

If, in any way, you become aware of a manufacturing emergency or packaging emergency, you should take the following actions, in the order listed:

- ❑ Quickly assemble all available information (lot numbers, dates, names, addresses, telephone numbers, reports of injuries or deaths, if any, etc.)
- ❑ Contact The Information Center at AstraZeneca immediately by calling 1-800-236-9933 * * to provide all of the available details. Do not delay calling based on a lack of complete information; and
- ❑ Call your designated supervisor immediately, and provide him or her with full details of your action.

1.2. Non-Emergency Complaints

If you become aware of a non-emergency complaint, contact The Information Center at AstraZeneca at 1-800-236-9933* to provide all of the available details.

1.3. Questions

If you have questions regarding this procedure, call The Information Center at AstraZeneca at 1-800-236-9933*.

**Until future notice, customers with requests for information about former Zeneca products and services should call: 1-800-456-3669, extension 2231*

AstraZeneca

PRODUCT SAMPLES **Policy No.: M&S-B-6** B-6

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To state AstraZeneca's commitment to compliance with federal standards governing the distribution of samples and to outline the applicable legal standards under the Prescription Drug Marketing Act of 1987, as amended ("PDMA"), and other sections of the Federal Food, Drug, and Cosmetic Act.

2. Policy

2.1. General Statement

AstraZeneca 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 which is not intended to be sold and is intended to promote the sale of the drug. Marketing and Sales Personnel involved in the distribution of samples must familiarize themselves with the provisions of this policy, the PDMA and all applicable Company procedures and training materials relating to samples.

2.2. Samples Distribution

2.2.1. The primary AstraZeneca distribution strategy for samples is "send only". This means that samples can only be sent from a central location.

Currently being developed are new systems for product sampling that will include new methods, policies, and procedures (i.e., Reconciliation process (variances) and Sample Storage). This will be available at a later date. In the interim, legacy policies and procedures for product sampling will be followed until the new systems are available.

AstraZeneca 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.

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AstraZeneca 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 utilized 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.

2.2.2. The PDMA permits the distribution of samples only to "licensed prescribers," defined to mean 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.

2.2.3. Licensed 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 prescriberís name, professional designation, address, state license number 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 licensed prescriber.

2.2.4. The distribution of product samples by AstraZeneca to licensed prescribers is intended to help the licensed prescriber evaluate the product in actual practice, and to enable the licensed prescriber to offer a small supply of medication to a patient who is beginning to take the product for the first time. AstraZeneca samples should be distributed with these objectives in mind.

2.3. Sale, Purchase, or Trade of Samples Prohibited

2.3.1. 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. The law also entitles a "whistle-blower" (someone who provides information leading to the arrest and conviction of a person for violating these provisions) to one-half of the criminal fine collected.

2.3.2. 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. B-6

2.3.3. 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.

2.3.4. There are certain defenses to these civil penalties which, in effect, require a company to diligently implement 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.

2.4. Mishandling of Samples Prohibited

In the course of their professional activities, Marketing and Sales Personnel may come into contact with the samples of both AstraZeneca and other companies. AstraZeneca 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 AstraZeneca samples) from the Company, a health care professional, or any other person in possession of such samples. Theft includes the removal of any samples from a health care professional's samples closet without the professional's express consent. As a general rule, Field Personnel should not receive samples from health care professionals in the course of their promotional activities. All Marketing and Sales Personnel must always be cognizant that:

- ❑ Samples of AstraZeneca products remain the property of the Company until such samples are transferred on the request of a licensed prescriber. Once transferred, the samples become the property of the transferee. At no point do such samples become the property of an AstraZeneca employee or other agent.
- ❑ Samples are strictly regulated under federal law, and may be dispensed for use *only* under the supervision of a licensed prescriber.

2.5. Reporting Violations of Law or Policy

2.5.1. All Marketing and Sales Personnel are obliged to report immediately to the Company every sale, pur-chase 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 AstraZeneca employee by any health care professional.

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2.5.2. The reporting required under Section 2.5.1. 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
- ❑ ***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

2.5.3. Any information (whether first- or second-hand) which an AstraZeneca employee acquires concerning sample diversion or other mishandling or misuse of samples (whether AstraZeneca samples or those of another company) should be reported as soon as possible to the Legal Department.

2.5.4. The Company will, as appropriate, forward information concerning apparent violations of law to proper government authorities.

AstraZeneca

CREATION AND DISTRIBUTION OF REMINDER ITEMS **Policy No.: M&S-B-7** B-7

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To establish standards governing the creation and distribution of reminder items.

2. Definitions

"Fair market value" means the reasonable cost of an item to an individual on the open market.

"Medical relevance" means something that is of use to healthcare professionals in administering patient care. Examples of items with medical relevance include anatomy charts, blood pressure cuffs and caliper pens.

"Patient relevance," means something that directly supports patients in understanding their disease and/or the management of their health. Examples of items with patient relevance include brochures containing disease information, pill boxes and magnets reminding patients to take their medication.

"Professional relevance," means something that is of use to healthcare professionals in improving their professional skills or the management of their professional practice. Examples of items with professional relevance include patient sign-in sheets, pens and pads.

"Reminder item" means any item offered to a customer that calls attention to the AstraZeneca name or the name of any AstraZeneca product, but does not include indications or dosage recommendations for use of the product.

3. Policy

Reminder items play an important role in increasing company and brand awareness. They also play a significant role in AstraZeneca's public image. Consequently, all reminder items bearing the name of AstraZeneca or any of its products, whether distributed in a physicianís office, hospital or pharmacy

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setting, a convention, or a company-sponsored event, must comply with the following requirements:

3.1 Reminder items with a fair market value of $35 or above

Reminder items with a fair market value of $35 or above must exhibit medical, professional or patient relevance.

3.2 Reminder items with a fair market value under $35

Reminder items with a fair market value under $35 need not exhibit medical, professional or patient relevance, but must be consistent with overall product strategy. Reminder items with the AstraZeneca name must support a positive corporate image. Items created under this section 3.2, whether centrally- or field-generated, must be approved by the TA NSD prior to their production.

3.3 Compliance with regulations, policies and branding

All reminder items, irrespective of fair market value, must be approved through the Companyís review and approval processes and must comply with all applicable laws, regulations and business policies, including **Gaining Access to Healthcare Professionals** (M&S-B-2). In addition, all reminder items must follow the applicable corporate identity standards and the branding requirements for the specific product(s) referenced.

4. References

4.1. M&S Business Policies

Gaining Access to Healthcare Professionals (M&S-B-2).

Professional Relations and Educational Programs

AstraZeneca

ASTRAZENECA STANDARDS FOR CME AND OTHER SCIENTIFIC AND EDUCATIONAL ACTIVITIES **Policy No.: M&S-C-2**

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Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To state AstraZeneca's commitment to providing financial support for non-promotional accredited or non-accredited activities involving medical education and to describe the types of medical education grants provided by AstraZeneca 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, these programs will typically not be considered product promotion and will not be regulated as such. Programs of a promotional nature are covered under **Professional Education Programs** (M&S-C-3).

The purpose of Continuing Medical Education (CME) is to enhance the physician's ability to care for patients. The Essentials and Standards of the Accreditation Council for Continuing Education (ACCME) govern activities providing CME credits to physicians. If the program is therapeutically related to AstraZeneca product areas, we must follow both ACCME and FDA guidelines. ACCME guidelines only must be followed if the program is non-therapeutically or product related. Involvement in an ACCME accredited program does not necessarily mean we are in a "safe harbor." FDA can still scrutinize our involvement in the program. The guiding principles need to be recognized that there are different concepts in the FDA and ACCME guidances and we need to consider both sets. AstraZeneca may support accredited activities through designation of an educational 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:

- ❑ The ACCME's Standards for Commercial Support of Continuing Medical Education ("ACCME Standards", see Attachment I)
- ❑ FDA's Guidance: Industry-Supported Scientific and EducationalActivities (the "FDA Guidance", see Attachment II)

2. *Policy*

2.1. Medical Education Grants - General Policy

Medical Education grants may be used to fund only activities or programs with an educational purpose. They may be accredited or non-accredited by institutions or organizations.

2.1.1. Through medical education grants, AstraZeneca financially supports non-promotional medical education activities without influencing the content of these activities. If medical education grants are made in accordance with FDA guidelines on independent education, these programs will typically not be considered product promotion and will not be regulated as such. It is essential that AstraZeneca employees involved in the administration of medical education grants follow all applicable laws, regulations, and Company policies to ensure that medical education grants remain non-promotional in nature.

2.1.2. If the content of a Company-supported educational program is influenced directly or indirectly by the Company, 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 **Professional Education Programs** (M&S-C-3) for additional guidance on programs that are deemed to be promotional.

2.1.3. The FDA considers to evaluate the independence of an educational or scientific program. The FDA has stated that these factors are intended to furnish guidance on the design and conduct of educational activities, and will be considered by the agency as part of an overall evaluation of an activity; no individual factor is likely by itself 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

(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.

2.1.4. Medical education grants may be used to fund only activities or programs with an *educational* purpose.

2.1.5. Medical education grants may only be used to support programs. Grants may not be used to support people's individual interests or expenses.

2.1.6. Activities which ***may*** not be funded by a Medical 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* **Local Conventions and Hospital Display Guidelines,** M&S-C-G-4)
- ❑ Research or Health Economics studies
- ❑ Charitable contributions
- ❑ General/miscellaneous education funds
- ❑ Parties or social events for physicians
- ❑ Testimonial dinners
- ❑ Medical missions to foreign countries
- ❑ Medical school yearbook advertisements
- ❑ Requests for medications
- ❑ Travel for non-faculty physicians or other healthcare providers to attend medical education programs (accredited or non-accredited)
- ❑ Purchase of tickets for physicians (or AstraZeneca employees) to play golf or tennis, to take trips, or to participate in similar activities
- ❑ Private schools/colleges attended by physicians or their families

Medical Education 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 Policy for specific guidelines regarding support for these types of events.

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2.1.7. Medical education grants may be used to support either accredited or non-accredited medical educational programs.

Accredited medical education programs include, but are not limited to, the following:

- ❑ Regional CME symposia
- ❑ Monographs for CME (physician) or ACPE (pharmacist)
- ❑ Educational seminars for physicians
- ❑ Development of CME programs on Internet or CD-ROM
- ❑ Third-party accredited educational programs

Non-accredited medical education programs include, but are not limited to, the following:

- ❑ Community education programs
- ❑ Customer-initiated health fairs
- ❑ Funding for a customer to create, produce, or distribute a patient education newsletter on their own
- ❑ Physician training programs at academic institutions
- ❑ "Doctor to Doctor" preceptorship type programs conducted by academic institutions

These types of funding for non-accredited programs often are provided to increase access to or provide opportunities to access individual physicians or practices. As such, they are subject to the policy, guidelines, and limits that AstraZeneca has established in **Gaining Access to Healthcare Professionals** (M&S-B-2).

2.1.8. Grants for Grand Rounds activities, which are accredited for continuing medical education credit, should follow Medical Education Grant guidelines.

If Grand Rounds activities are non-accredited and the AstraZeneca employee is choosing or arranging for the speaker, the AstraZeneca employee requesting the program should follow the **Professional Education Programs** (M&S-C-3) policy and **Speaker Program Guidelines** (M&S-C-G-3-b).

2.1.9. If a grant is used to fund an accredited medical education program, AstraZeneca must adhere to both the FDA standards for independent medical education programs and the ACCME's Standards for Commercial Support of Continuing Medical Education ("ACCME Standards") or similar standards of another representative accrediting body. These standards generally

prohibit AstraZeneca 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. AstraZeneca 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.

2.1.10. AstraZeneca may not provide grants with "strings attached." Receipt of a grant should never be contingent upon the recipient's activities with respect to AstraZeneca or AstraZeneca products. For example, grants should never be offered or provided in exchange for, as an inducement to, or in any way in consideration of the prescribing, purchasing, use or dispensing of, promoting of AstraZeneca products or based on the customers' existing prescribing practices or formulary status (*see* **Gaining Access to Healthcare Professionals**, M&S-B-2).

2.1.11. Medical education grants cannot be promotional in nature and, therefore, cannot be used to fund an exhibit or display booth. Accredited providers may, however, waive exhibit fees at their discretion (whether or not medical education grants are provided) for related medical education programs.

2.1.12. Medical education grants must be made payable to organizations, societies, or groups consistent with FDA and ACCME standards.

2.2. Post-graduate Grants

Post-graduate Grants provide funds that allow medical students, residents, or fellows to attend carefully selected national conferences. The medical students, residents, or fellows must be chosen by the institution receiving the grant. Post-graduate Grants must be administered in accordance with the AMA Guidelines on Gifts to Physicians from Industry, (*see* **Gaining Access to Healthcare Professionals,** M&S-B-2).

Post-graduate Grants may not be used to provide funding for physicians, pharmacists, nurses, or other healthcare professionals to attend conferences.

2.3. Library Grants

A Library Grant is provided to a recipient institution to support the purchase of library materials. Library Grants may be used, for example, to fund the updating of medical libraries and the purchasing of medical textbooks, medically related computer software, or patient education materials.

Library Grants may not be used to support the purchase of durable goods such as office equipment or medical testing equipment. Since the value of a Library Grant has a direct benefit to individual physicians or practices, the distribution of a Library Grant is subject to and must remain within the acceptable limits as defined in **Gaining Access to Healthcare Professionals** (M&S-B-2).

2.4. Standards for Support of Accredited Activities

Accredited activities may be supported through provision of a medical education grant to an accredited organization. Activities providing Continuing Medical Education (CME) credits to physicians are governed by the Essentials and Standards of the Accreditation Council for Continuing Medical Education (ACCME). Accredited activities providing continuing education credits other than CME credits to healthcare professionals (e.g., ACPE for continuing pharmacy education) should follow the applicable guidelines and standards of the appropriate governing body

2.4.1. The ACCME Standards are intended to ensure that company-supported CME activity is designed primarily "to enhance the physician's ability to care for patients."

2.4.2. The ACCME Standards are also intended to ensure that company-supported CME activities are free from commercial bias for or against any product. If the activities concern commercial products, they must present objective information about those products, based on scientific methods generally accepted in the medical community.

2.4.3. The ACCME Standards provide a series of specific standards that should be adhered to in planning, designing, implementing, and evaluating commercially supported CME activities. These standards address the following general subject matters:

(1) General responsibilities of accredited sponsors

2) Enduring materials

(3) Identifying products, reporting on research, and discussing unlabeled uses of products

(4) Exhibits and other commercial activities

(5) Management of funds from commercial sources

(6) Commercially supported social events

(7) Disclosure of faculty and sponsor relationship

(8) Financial support for participants in medical education activities

2.4.4. Distribution of enduring materials, invitations, or business reply cards for CME programs must be in accordance with **AstraZeneca's CME Material Guidelines** (M&S-C-G-2-e).

2.5. Exhibits at Accredited Programs

2.5.1. Company exhibits may be displayed during symposia or conventions with the consent of the accredited provider or appropriate third party organization (*see* **Exhibits,** M&S-C-4). C-2

2.5.2. FDA regulations must be observed as they relate to the *independence* of the medical education program. In particular, exhibits must not be in the same room as the medical education activity.

2.5.3. When exhibits are displayed in relation to accredited programs, additional consideration must be given to ensure compliance with ACCME Standards or other applicable guidelines of the accrediting organization. ACCME Standards must be observed for exhibits during CME events.

2.6. Payment

2.6.1. Educational grants must be made payable to organizations, societies, or groups consistent with FDA and ACCME standards.

2.6.2. When a third party (eg., medical communications companies) is involved, the accredited provider should be paid - **not** the third party.

2.6.3. Educational grants cannot be used to fund an exhibit or display booth. However, an exhibit space may be provided by the accredited provider complementary when a grant is provided for the educational program.

2.6.4. 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 AstraZeneca Lecture Bureau.

2.6.5. Medical 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 expediently, please notify the AstraZeneca Lecture Bureau of the situation. The Lecture Bureau will then make every reasonable effort to accommodate the request.

2.7. Letter of Agreement

AstraZeneca 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 unless the appropriate letter of agreement has been signed by the grant recipient and received by the AstraZeneca Lecture Bureau.*

2.7.1. An AstraZeneca grant letter must be signed for each Medical Education Grant.

2.7.2. AstraZeneca 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 (via the AstraZeneca Lecture Bureau) for review and an appropriate signature.

ACCME requires that medical education grant recipients have a signed letter of agreement on file for each program. AstraZeneca's grant letter of agreement satisfies ACCME's requirements for a written agreement. Therefore, the recipient should sign the AstraZeneca agreement and keep that same contract for his/her files.

AstraZeneca's agreement also indemnifies AstraZeneca against any misuse of the funds. This clause would not ordinarily be included in another entity's agreement.

2.7.3. AstraZeneca's medical education grant letters of agreement have been developed to support a broad range of the types of medical education programs that AstraZeneca may support. The language of these agreements must never be altered without review and approval of the appropriate authorities within the Professional Relations and Education and Legal departments.

2.8. Grant of Approval

All Medical Education Grants must be first approved by the DSM (or appropriate corresponding member of AstraZeneca management) up to their grant of authority. Grants exceeding the DSM grant of authority limit are subject to approval according to the requirements in the Grants of Authority database.

3. *References*

3.1. M&S Business Policies
Gaining Access to Healthcare Professionals (M&S-B-2); **CME Material Guidelines** (M&S-C-G-2-e); **Professional Education Programs** (M&S-C-3); **Speaker Program Guidelines** (M&S-C-G-3-b); **Exhibits** (M&S-C-4); **Local Conventions and Hospital Display Guidelines** (M&S-C-G-4).

ACCME Standards

The Accreditation Council for Continuing Medical Education (ACCME) has published guidelines governing industry support for CME programs. The ACCME's standards are reprinted below, followed by ACCME's 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 non-accredited 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.

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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*

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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 educational 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 honoraria 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, each commercial supporter should report to the accredited sponsor information concerning their expenditures in support of the activity.

6. Commercially Supported Social Events

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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 shall 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 post-meeting publications.

c. Disclosure for Regularly Scheduled Activities

In the case of regularly scheduled events, such as grand rounds, disclosure shall be made by the moderator of the activity after consultation with the faculty member or a representative of the s upporter. 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, honoraria, 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.

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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? G-2

   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.

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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 verbal or written.

10. ***Question:*** Is there a written statement that discourages (or forbids) the use of third parties to provide speakers (i.e., 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 re-contact 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, e.g., 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.

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*19. **Question:*** If commercial support is provided for an activity relating to a non-clinical topic, e.g., 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 (i.e., 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 non-accredited 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" (e.g., 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? C-2

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 non-accredited 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 non-accredited 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.

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Promotional CME activities, whether sponsored by an accredited or non-accredited 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 (e.g., 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 (e.g., 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.

ATTACHMENT II C-2

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 healthcare 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 healthcare 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 non-promotional 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 non-promotional 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 post-graduate and continuing education for healthcare 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 non-promotional 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 (e.g., 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 post-graduate and continuing professional education and scientific exchange lies with the scientific and healthcare communities and accrediting organizations. Accordingly, FDA will work closely with scientific and professional healthcare 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 non-promotional and those that the agency considers promotional, and to provide 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*

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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 (e.g., 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 non-promotional 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 (e.g., 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 (e.g., 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, non-promotional, 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 non-promotional.

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 non-promotional. The agency also recognizes the importance of avoiding undue Government interference in post-graduate and continuing education for healthcare 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.

AstraZeneca

MEDICAL EDUCATIONAL GRANT GUIDELINES | **Guideline No.: M&S-C-G-2-a** C-G-2A

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Introduction

Through medical education grants, AstraZeneca financially supports *non-promotional* medical education activities without influencing the content of these activities. If educational grants are made in accordance with FDA guidelines on independent education, these programs will typically not be considered product promotion and will not be regulated as such.

Medical Education grants may be used to fund only activities or programs with an *educational* purpose. They may be *accredited* or *non-accredited* by institutions or organizations.

1.2. Accredited Medical Education Programs

1.2.1. AstraZeneca should not direct or influence the content of the educational program or activity supported by the grant and should play no role in the selection of speakers or presenters other than responding to unsolicited independent provider requests for suggestions of presenters, sources of possible presenters or assistance with educational planning, and otherwise in compliance with applicable ACCME and FDA laws and regulations.

1.2.2. AstraZeneca may not provide grants with "strings attached."

- ❑ Receipt of a grant should never be contingent upon the recipient's activities with respect to AstraZeneca or AstraZeneca's products. For example, grants should never be offered or provided, either directly or indirectly, in exchange for prescribing, purchasing, using or dispensing AstraZeneca products.

1.2.3. Distribution of enduring materials, invitations, or business reply cards for CME programs must be in accordance with AstraZeneca's **CME Material Guidelines** (M&S-C-G-2-e).

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1.2.4. Payment

- Educational grants must be made payable to organizations, societies, or groups consistent with FDA and ACCME standards.
- When a third party (eg., medical communications companies) is involved, the accredited provider should be paid not the third party.
- Educational grants cannot be used to fund an exhibit or display booth (*see* **Exhibits,** M&S-C-4 and **Local Conventions and Hospital Display Guidelines,** M&S-C-G-4).

1.2.5. 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 AstraZeneca Lecture Bureau.
- Medical 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 expediently, please notify the AstraZeneca Lecture Bureau of the situation. The Lecture Bureau will then make every reasonable effort to accommodate the request.

1.2.6. Letter of Agreement

AstraZeneca 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 unless the appropriate letter of agreement has been signed by the grant recipient and received by the AstraZeneca Lecture Bureau.*

- An AstraZeneca grant letter must be signed for each Medical Education Grant.
- AstraZeneca 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 (via the AstraZeneca Lecture Bureau) for review and an appropriate signature.

- ❑ Other letters of agreement will **not** substitute for AstraZeneca's letter of agreement.

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1.2.7. Grant of Approval

All Medical Education Grants must be first approved by the District Sales Manager (or appropriate corresponding member of AstraZeneca management) up to their grant of authority. Grants exceeding the DSM grant of authority limit are subject to approval according to the requirements in the Grants of Authority database.

1.2.8. Activities which ***may*** be funded by a Medical Education Grant include, but are not limited to:

Accredited programs, such as

- ❑ Educational seminars for physicians
- ❑ Development of CME programs on Internet or CD-ROM
- ❑ Third-party accredited educational programs
- ❑ Regional Symposia

Non-accredited programs, such as

- ❑ Health Fairs conducted by institutions, clinics, or hospitals
- ❑ Physician training programs at academic institutions
- ❑ "Doctor to Doctor" preceptorship type programs conducted by academic institutions

These types of funding for non-accredited programs often are provided to increase access to or provide opportunities to access individual physicians or practices. If this is the purpose of the grant, the grant is subject to the policy, guidelines, and limits that AstraZeneca has established in the AstraZeneca policy on **Gaining Access to Healthcare Professionals** (M&S-B-2).

1.2.9. Grants for Grand Rounds activities, which are accredited for continuing medical education credit, should follow Medical Education Grant guidelines.

- ❑ If Grand Rounds activities are non-accredited and the AstraZeneca employee is choosing or arranging for the speaker, the AstraZeneca employee requesting the program should follow the **Professional Education Programs** policy (M&S-C-3) and **Speaker Program Guidelines** (M&S-C-G-3b).

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1.2.10. Activities that may ***not*** be funded by a Medical 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* **Local Conventions and Hospital Display Guidelines,** M&S-C-G-4)
- ❑ Research or Health Economics studies
- ❑ Charitable contributions
- ❑ General/miscellaneous education funds
- ❑ Parties or social events for physicians
- ❑ Testimonial dinners
- ❑ Medical missions to foreign countries
- ❑ Medical school yearbook advertisements
- ❑ Requests for medications
- ❑ Travel for non-faculty physicians or other healthcare providers to attend medical education programs (accredited or non-accredited)
- ❑ Purchase of tickets for physicians (or AstraZeneca employees) to play golf or tennis, to take trips, or to participate in similar activities
- ❑ Private schools/colleges attended by physicians or their families

Medical Education 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 Corporate Charitable Contributions Policy for specific guidelines regarding support for these types of events.

1.3. Non-accredited Medical Educational Programs

Non-accredited Medical education programs must follow similar guidelines as accredited programs. However, they do not need to adhere to the ACCME standards for independent educational programs. A letter of agreement is required for non-accredited medical educational programs.

- ❑ Although the ACCME standards do not apply, AstraZeneca will still follow FDA standards to ensure that these programs are independent and non-promotional.
- ❑ If the purpose of giving the grant is to provide access to the customer so that the AstraZeneca employee can discuss AstraZeneca and our products, then the grant is subject to the policy, guidelines, and limits that AstraZeneca has established in the policy on **Gaining Access to Healthcare Professionals** (M&S-B-2).

2. Required Contracts

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- ❑ A Medical Grant Letter of Agreement contract must be completed for each Medical Education Grant (accredited or non-accredited).

3. References

3.1. M&S Business Policies

Product Promotion (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Professional Education Programs** (M&S-C-3); **Speaker Program Guidelines** (M&S-C-G-3b); **Exhibits** (M&S-C-4); **Local Conventions and Hospital Display Guidelines** (M&S-C-G-4).

3.2. Other Sources

- ❑ Corporate Charitable Contributions Policy and Guidelines
- ❑ Grants of Authority Database

AstraZeneca

PHARMACY EDUCATIONAL GRANT GUIDELINES **Guideline No.: M&S-C-G-2-b** C-G-2B

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Introduction

Through educational grants, AstraZeneca financially supports *non-promotional* pharmacy education activities without influencing the content of these activities. If educational grants are made in accordance with FDA guidelines on independent education, these programs will typically 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).

1.2. Accredited Pharmacy Education Programs

1.2.1. AstraZeneca should not direct or influence the content of the educational program or activity supported by the grant and should play no role in the selection of speakers or presenters other than responding to unsolicited independent provider requests for suggestions of presenters, sources of possible presenters or assistance with educational planning, and otherwise in compliance with applicable American Council on Pharmaceutical Education (ACPE) The ACPE guidelines are set forth in the Attachment to these guidelines and FDA laws and regulations.

1.2.2. AstraZeneca may not provide grants with "strings attached."

- ❑ Receipt of a grant should never be contingent upon the recipient's activities with respect to AstraZeneca or AstraZeneca's products. For example, grants should never be offered or provided, either directly or indirectly, in exchange for prescribing, purchasing, using or dispensing AstraZeneca products.

1.2.3. Payment

- Educational grants should be made payable to organizations, societies, or groups consistent with FDA and ACPE standards.
- When a third party (eg, medical communications companies) is involved, the accredited provider should be paid not the third party.
- Educational grants cannot be used to fund an exhibit or display booth (*see* **Exhibits,** M&S-C-4, and **Local Conventions and Hospital Display Guidelines,** M&S-C-G-4).

1.2.4. 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 AstraZeneca Lecture Bureau.
- 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 expediently, please notify the AstraZeneca Lecture Bureau of the situation. The Lecture Bureau will then make every reasonable effort to accommodate the request.

1.2.5. Letter of Agreement

AstraZeneca 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 appropriate letter of agreement has been signed by the grant recipient and received by the AstraZeneca Lecture Bureau.*

- An AstraZeneca grant letter must be signed for each Pharmacy Education Grant.
- AstraZeneca 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 (can be forwarded via the AstraZeneca Lecture Bureau) for review and an appropriate signature.

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- ❑ Other letters of agreement will **not** substitute for AstraZeneca's letter of agreement.

1.2.6. Grant of Approval

All Pharmacy Education Grants must be first approved by the District Sales Manager (or appropriate corresponding member of AstraZeneca management) up to their grant of authority. Grants exceeding the DSM grant of authority limit are subject to approval according to the requirements in the Grants of Authority database.

1.2.7. Activities which ***may*** be funded by a Pharmacy Education Grant include, but are not limited to:

- ❑ Educational seminars for pharmacists
- ❑ APhA Pharmacy Program
- ❑ Patient Centered Asthma Care Education
- ❑ Interactive Workshop for Success Program
- ❑ Regional Pharmacy Educational Symposia

1.2.8. Activities which may ***not*** be funded by a Pharmacy Education Grant include, but are not limited to:

- ❑ Exhibit or display booths at conventions/conferences (*see* **Exhibits,** M&S-C-4)
- ❑ Research or Health Economics studies
- ❑ General/miscellaneous education funds
- ❑ Parties or social events for pharmacists
- ❑ Testimonial dinners
- ❑ Pharmacy missions to foreign countries
- ❑ Pharmacy school yearbook advertisements
- ❑ Purchase of tickets for pharmacists (or AstraZeneca employees) to play golf or tennis, to take trips, or to participate in similar activities
- ❑ Private schools/colleges attended by 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 Corporate Charitable Contributions Policy for specific guidelines regarding support for these types of events.

1.3. Non-accredited Pharmacy Educational Programs

Non-accredited Pharmacy educational programs must follow similar guidelines as accredited programs. However, they do not need to adhere to the ACPE standards for independent educational programs. A letter of agreement is required for non-accredited medical educational programs.

- ❑ Although the ACPE standards do not apply, AstraZeneca will still follow FDA standards to ensure that these programs are independent and non-promotional.

2. *Required Contracts*

- ❑ An AstraZeneca Pharmacy Grant Letter of Agreement contract must be completed for each Pharmacy Education Grant (accredited or non-accredited).

3. *References*

3.1. M&S Business Policies

Product Promotion (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Exhibits** (M&S-C-4).

3.2. Other Sources

- ❑ ACPE Guidelines
- ❑ Corporate Charitable Contributions Policy and Guidelines
- ❑ Grants of Authority Database

AstraZeneca

POST-GRADUATE GRANT GUIDELINES | **Guideline No.: M&S-C-G-2-c**

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Introduction

1.1.1. AstraZeneca may provide subsidies to assist in underwriting the costs of attendees at continuing medical education conferences or professional meetings. They must be given to the academic institution or the accredited sponsor, who can use the money to reduce the conference's registration fees for all conference attendees, but not for any one individual attendee. Such payments to defray the costs of a conference must not be provided directly to the healthcare professionals attending the conference.

1.1.2. Scholarships and other special funds to allow students, residents and fellows (medical, pharmacy, nursing, etc.) in the healthcare area to attend certain educational conferences are permissible if the beneficiaries of the funds are selected by the academic or training institution.

1.2. Post-graduate Grants

1.2.1. Post-graduate Grants provide funds that allow students, residents or fellows to attend educational national conferences.

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 AstraZeneca to meetings.

1.2.2. 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 AMA Guidelines on Gifts to Physicians, as referenced in Attachment I to the policy entitled **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2).

1.2.3. Post-graduate Grants cannot 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 Post-graduate Grants.

1.2.4. Post-graduate Grants will be funded locally by the District/Region responsible for the AstraZeneca employee submitting the request.

1.2.5. All Post-graduate Grants must be first approved by the District Sales Manager (or appropriate corresponding member of AstraZeneca management) up to their grant of authority. Grants exceeding the DSM grant of authority limit are subject to approval according to the requirements in the Grants of Authority database.

1.2.6. 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 AstraZeneca for reimbursement. If expenses are submitted, they should not be processed. Cash payments are not allowed.

1.2.7. Post-graduate Grants may not be used to support healthcare professionals (e.g., practicing physicians, pharmacists, nurse practitioners, managed care administrators, etc.) attending the conference unless the grant is given to the accredited sponsor to support reduction of registration fees for all attendees.

1.2.8. Both parties must agree to and sign a Post-graduate Grant Contract before a Post-graduate Grant may be paid.

1.2.9. Grants should never be used to support charitable events, such as fundraiser golf outings, tennis tournaments for charity, American Heart Ball, etc. Please see Corporate Charitable Contributions Policy for specific guidelines regarding support for these types of events.

2. *Required Contracts*

- ❑ An AstraZeneca Post-graduate Grant Letter of Agreement contract must be completed for each Post-graduate Grant.

3. *References*

3.1. M&S Business Policies

Product Promotion (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2).

3.2. Other Sources

- ❑ Grants of Authority Database
- ❑ Corporate Charitable Contributions Policy and Guidelines

AstraZeneca

LIBRARY GRANT GUIDELINES **Guideline No.: M&S-C-G-2-d** C-G-2D

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Library Grants

1.1.1. A Library Grant is provided to a recipient institution to support the purchase of library materials. Library Grants may be used to fund the updating of medical libraries, which includes:

- ❑ Medical textbooks
- ❑ Trade journal subscriptions
- ❑ Medically-related computer software (e.g., Mosbey's)
- ❑ Patient education materials
- ❑ Internet access fees for medically related web-sites

1.1.2. Library Grants may be given by a grant request; materials should not be purchased and submitted as an expense. The customer must control the selection of materials.

1.1.3. Library Grants must conform to the **Gaining Access to Healthcare Professionals** policy (M&S-B-2) and to the **Medicare and Medicaid Fraud and Abuse laws.**

1.1.4. These types of funding often are provided to increase access to or provide opportunities to access individual physicians or practices. As such, they are subject to the policy, guidelines, and limits established in **Gaining Access to Healthcare Professionals** (M&S-B-2).

1.1.5. Library Grants must not be offered or agreed to, directly or indirectly, as part of the contracting process.

1.1.6. Library Grants are limited to the lesser of (i) $15,000 and (ii) $100 per practicing physician within the institution. Any proposed Library Grants that exceed the foregoing limitation may only be made if approved by the Regional Sales Director, Area Sales Director or National Sales Director according to the requirements in the Grants of Authority database.

1.1.7. Grants will be funded locally by the District/Region responsible for the AstraZeneca employee submitting the request.

1.1.8. All Library Grants must be first approved by the District Sales Manager (or appropriate corresponding member of AstraZeneca management) up to their grant of authority. Grants exceeding the DSM grant of authority limit are subject to approval according to the requirements in the Grants of Authority database.

1.1.9. The cost of purchasing textbooks may also be defrayed by use of a voucher that the customer submits directly to a clearinghouse, when appropriate. For specific instructions on availability and use of a voucher, the Field Promotions Manager should be consulted.

1.1.10. Library Grants may be used to support development or maintenance of 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 Healthcare providers

Funds may not be used for the purpose of directly marketing the organization

1.1.11. 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 non-industry (patients) parties 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.

1.1.12. 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 Corporate Charitable Contributions Policy for specific guidelines regarding support for these types of events.

2. *Required Contracts*

- ❑ Library Grant Contract is required for each Library Grant.

3. References

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3.1. M&S Business Policies

Product Promotion (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2).

3.2. Other Sources

- ❑ Grants of Authority Database
- ❑ Corporate Charitable Contributions Policy and Guidelines

AstraZeneca

CME MATERIAL GUIDELINES **Guideline No.: M&S-C-G-2-e** C-G-2E

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To provide the ability to distribute CME-related materials such as invitations, enduring materials, and Business Reply Cards (BRCs) for CME accredited programs. This same guidance applies uniformly to other accredited types of programs, such as ACPE, AOA, or AAFP accreditation, regardless of the type of accreditation.

2. Guidelines

2.1. Continuing Medical Education - General Guidelines

2.1.1. At the request of the accredited provider, AstraZeneca may suggest ideas for the title, the content of presentations and/or identity of speakers to an "independent program provider" in connection with a continuing medical education seminar program or other symposium, regardless of whether unapproved uses for drugs (approved by FDA for other uses) are to be addressed in that symposium. However, the accredited provider must retain control over the selection for the topic, etc. and should use their own discretion in choosing the topic and faculty. For this purpose, an "independent program provider" is an entity that: (1) has no common ownership or other corporate affiliation with AstraZeneca, (2) engages in the business of creating and producing continuing medical education seminars, programs or their symposia and (3) is accredited by a national accrediting organization pertinent to the topic of the seminars, programs or symposia.

2.1.2. AstraZeneca personnel may attend the CME program, but may not conduct sales activities while in the room where the program takes place.

2.1.3. AstraZeneca personnel must not engage in promotional product discussions or activities in conjunction with delivery of an invitation to a CME event, a BRC for a CME program, or an Enduring Material.

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2.1.4. AstraZeneca can suggest a topic or speakers to the accrediting sponsor, but the sponsor has control over the content. They do not necessarily need to accept our topic or speaker suggestions. This guidance is consistent with the ACCME Essentials and Standards, as long as the accredited provider has the ultimate control over the topic, speakers, and content. It is advisable to have the request for topics and/or speakers in writing from the accredited sponsor of the program.

2.1.5. All materials that will be distributed by AstraZeneca employees to customers, including CME invitations, enduring materials, and BRCs, will be considered by the FDA to be promotional materials and must be reviewed and approved by Promotional Regulatory Affairs prior to dissemination.

2.2. Enduring Materials

2.2.1. CME enduring materials are printed, recorded, or computer-assisted instructional materials which may be used over time at various locations. The CME program should happen only once with one mass distribution of enduring materials. The more often the program is repeated and materials are handed out, the perception that the program is promotional in nature increases and FDA will label the program as such.

2.2.2. Examples of enduring materials are:

- ❑ Programmed texts
- ❑ Cassette tapes
- ❑ Computer-assisted instructional materials (CD-ROMs, web-based programs, etc.)
- ❑ Videotapes
- ❑ Journal Supplements
- ❑ Newsletters (if produced by CME provider and sent to the mailing list only once)

2.2.3. Each request to distribute enduring materials must be evaluated separately using the following key criteria:

- ❑ The accrediting CME provider must request in writing that they require our assistance in the distribution of the enduring materials. This letter must be kept on file at AstraZeneca.
- ❑ If we are going to distribute enduring materials, the accrediting provider must be made aware of the types of customers to which we are providing the enduring materials. The accrediting provider must be in control of the final distribution of the

materials. The best way for AstraZeneca to maintain independence from the program is to not know who is on the final distribution list of all methods of distribution.

- ❑ AstraZeneca must not be the only means of distribution (CME providers may determine which other routes of distribution are appropriate.)
- ❑ The content of the CME program should not be off-label.
- ❑ The program's focus must be on a disease entity or therapeutic area and not product focused.
- ❑ Topics may be non-disease or therapeutic area in nature, such as managed care or other topics of interest.
- ❑ There should be no mention of branded product in the Enduring Materials. The mention of pharmaceutical products is okay as long as it is part of the scientific content of the program and the reference should be (1) using the generic name of the product(s), and (2) be presented in a scientific and objective manner.
- ❑ AstraZeneca support of the program must be disclosed in the program materials.
- ❑ If the materials contain off-label content, we can use a distribution center for warehousing and distribution of the enduring materials. The physician would send a BRC or phone their request into an 800 number. The accredited provider would have access to a list of individuals who received the materials, but AstraZeneca would not. AstraZeneca's involvement in distribution of the materials would be limited to paying for the warehousing and distribution expenses at the request of the accredited provider.

2.2.4. Enduring Materials for a CME program that has been planned or has already been held must be handled in a different fashion:

- ❑ If we know the content and it is not off-label information, the materials may then be submitted into the Promotional Regulatory Affairs Review System. Once the materials are approved, they may be distributed to physicians and other healthcare personnel.
- ❑ If the content is off-label, AstraZeneca cannot have any involvement in the distribution of the Enduring Materials.

2.2.5. Providing that it is acceptable for AstraZeneca to distribute the Enduring Materials based on the above criteria, the following steps must be taken:

- ❑ A letter of agreement must be signed for all CME activities. This should reference sponsorship (financial) support by

AstraZeneca. An appropriate reference would be stated as follows: "Provided by an educational grant from AstraZeneca LP".

- ❑ The letter of agreement must be with the accredited provider. If a third party organization is involved with the CME activity, the accredited provider will be responsible for ensuring that there is an agreement with the third party organization. AstraZeneca may not sign agreements with the third party organization for accredited activities.
- ❑ The AstraZeneca letter of agreement includes all requirements of the ACCME standard agreement and additional language required by AstraZeneca. This agreement should be signed in lieu of the provider's letter of agreement.
- ❑ The letter of agreement should state that we are paying for production and distribution of materials.

2.3. Invitations and Business Reply Cards (BRCs)

2.3.1. AstraZeneca personnel may provide assistance in handing out invitations or BRCs associated with a specific CME program, provided that the following qualifications are met:

- ❑ The accrediting CME provider must request in writing that they require our assistance in the distribution of invitations/BRCs and state there are additional avenues of distribution. This letter should be kept on file at AstraZeneca.
- ❑ If the provider asks AstraZeneca for a mailing list, we can give it to them. They must add our list to their list and determine which names, if any, they want to use from our list. The provider determines the final decision of who gets invitations. We cannot add to the final distribution list for invitations after it is received from the provider.
- ❑ Invitations/BRCs must be disease, not product, oriented and contain no off-label information.
- ❑ Invitations/BRCs may be on non-medical topics, such as managed care issues or other issues of interest to healthcare professionals.
- ❑ Invitations/BRCs cannot be promotional; for example, invitations/BRCs must not make any references to product comparisons.
- ❑ Sales personnel must not engage in promotional product discussions or activities in conjunction with delivery of an invitation to a CME event or a BRC for a CME program.

- AstraZeneca support of the program must be disclosed on the invitation/BRC. C-G-2E
- Products may not be advertised or mentioned in the financial support disclosure by either the company or accrediting provider.

2.4. Vendors or Other Third Party Involvement

Third party vendors, such as medical communications companies, are commonly involved with the creation of large CME programs. It is acceptable to work with these third party vendors as long as the accrediting provider maintains control of the CME program. The following guidance must be used when working with third party vendors to support the creation of a CME program:

- All funding must be provided directly to the accredited provider. The accredited provider will be responsible for paying the third party for their expenses as well as pay all honoraria to the faculty. AstraZeneca may pay a vendor or third party for out of pocket expenses only when directed by the accredited provider. This direction must be supported by a letter from the CME department of the accredited provider and kept on file at AstraZeneca.
- Medical communications companies may also be accredited providers. In this case, it is appropriate to provide funding and sign a letter of agreement directly with the medical communications company, provided that they are providing accreditation for the CME activity.
- If a medical communications company is providing assistance with both CME and non-CME activities for AstraZeneca (whether or not they are the accredited providers), there must be a clear division of labor (separate departments and personnel) for those activities.

3. *References*

3.1. M&S Business Policies

Gaining Access to Healthcare Professionals (M&S-B-2); **Professional Education Programs** (M&S-C-3); **Exhibits** (M&S-C-4).

AstraZeneca

PROFESSIONAL EDUCATION PROGRAMS Policy No.: M&S-C-3 C-3

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To state AstraZeneca's commitment to conducting or underwriting educational programs for its customers in accordance with all applicable laws, guidelines, and regulations and to generally describe AstraZeneca' s professional education programs.

2. Policy

2.1. General Policy

2.1.1. AstraZeneca provides a means for Field Personnel to provide financial support for high quality, ethical and scientifically sound education activities for the health care community. Since AstraZeneca has control, whether it be partial or full control, over certain aspects of such an educational program, the program will typically be regarded as promotional by FDA and is therefore subject to FDA regulation (*see* **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2).

2.1.2. According to the ACCME's Standards for Commercial Support of Continuing Medical Education ("ACCME Standards"), CME credits are not available for speaker programs in which AstraZeneca has control of any aspect of the program. If the Company seeks to maintain control over the content of the program or the selection of the audience or speaker, CME credit cannot be provided. Non-promotional programs, including CME, are discussed in the policy **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2).

2.1.3. The opportunity to be a speaker or otherwise participate in AstraZeneca's professional education programs must never be offered to a provider (i.e., physician, pharmacist or other healthcare professional, including a pharmacy director, PBM executive or other personnel of a managed care organization, hospital, etc.) with "strings attached" (e.g., in exchange for or in consideration of prescribing, promoting or recommending AstraZeneca products; (*see* **Gaining Access to Healthcare Professionals,** M&S-B-2)

2.2. Speaker Programs

2.2.1. Professional education programs are typically programs for which a speaker delivers a lecture or facilitates a discussion on a pre-approved topic to an audience of healthcare professionals. These programs include a variety of formats where a Company employee organizes the speaking event. Only approved talk topics can be used for these professional education programs. Programs must not be conducted using unapproved talk topics disguised as approved titles (i.e., conducting an unapproved talk but using an approved talk title on the program request).

2.2.2. It is not the role of a speaker to draw specific attention to any AstraZeneca product during a presentation. Any references to AstraZeneca products or those manufactured by competitors must be made in an objective and balanced manner and within the approved labeling for the particular product. Any AstraZeneca employee who learns that a speaker has failed to give a balanced presentation and has failed to remain within labeling must report this information to the Company. If a speaker repeatedly fails to give a balanced presentation that remains within labeling, AstraZeneca will no longer use that speaker for Company-sponsored programs. AstraZeneca employees involved in conducting a program must ensure that full prescribing information for any AstraZeneca product discussed by the speaker is offered to each program attendee.

2.3. Honoraria

2.3.1. Standard honoraria ranges have been determined by the Company for speakers at each type of professional education program. An individual honorarium should be determined according to the appropriate AstraZeneca standard for the role of the speaker and type of program being delivered. No commitment should be made to pay any nonstandard honorarium without prior AstraZeneca management approval. Reasons for honoraria outside the standard ranges include, but are not limited to:

- ❑ The program requires more preparation for the speaker than most programs, e.g., 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; or
- ❑ The actual fair market value of that speaker's time is less than or greater than the standard amount.

2.3.2. Honoraria for professional education programs should be paid directly to the speakers/preceptors using their social security numbers or federal tax identification numbers if they are legally incorporated. C-3

- If an honorarium 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.
- According to IRS regulations, a speaker's honorarium cannot be paid directly to a charitable organization on behalf of the speaker. The speaker must claim the honorarium as income and can then donate the money to the organization themselves.
- An educational grant, payable to another organization, society, or group as discussed in the policy **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2), may not be given as a substitute for the honorarium payment to the speaker.

2.3.3. Honoraria can only be paid to the speaker who is providing bona fide services. Attendees to programs cannot receive honoraria, unless they are also participating in the program as a speaker or presenter and are rendering bona fide services.

2.4. Reimbursement of Speaker Expenses

AstraZeneca 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.

2.5. Contracts

2.5.1. AstraZeneca has prepared contractual agreements for use with all types of professional education programs. These contractual agreements must be completed prior to the program being held. AstraZeneca will not pay honoraria or reimburse expenses to speakers unless the designated agreement has been signed by both AstraZeneca and the speaker and has been received by AstraZeneca.

2.5.2. 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 (colloquia, dinner lectures, etc.) conducted during this time period.

2.5.3. For Case Study Programs, one agreement must be signed every time a speaker moderates or participates in a Case Study Program. There are separate agreements for moderators and participants.

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2.5.4. If a speaker is a Federal government employee (full time or part time), they must also complete a Federal Provider Agreement. This agreement is valid for the time period specified in the agreement for all bona fide services provided to AstraZeneca for which they are eligible to receive an honoraria.

2.5.5. Changes or modifications to the AstraZeneca contractual agreements are not allowable unless reviewed and approved by the Professional Education and Legal departments.

3. References

3.1. M&S Business Policies

Patient Privacy (M&S-A-6); **Product Promotion** (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2).

AstraZeneca

CASE STUDY PROGRAM GUIDELINES | **Guideline No.: M&S-C-G-3-a** C-G-3A

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Introduction

The Case Study Program was developed to provide physicians with real life, interactive education 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. Any references made by an employee, moderator, or presenter to AstraZeneca products or those produced by other companies must be done in an objective and balanced manner and within the approved labeling for the particular product. All comments relating to off-label use of any product must be disclosed as being unapproved.

1.2. Responsibilities by Position

1.2.1. Requester

- ❑ Identify need for Case Study Program
- ❑ Work with District Sales Manager (DSM or appropriate level of management) to complete proposal and gain approval at least 8 weeks prior to proposed date of program
- ❑ Establish the date and site
- ❑ Select appropriate physicians to invite
- ❑ Work with Medical Information Scientist (MIS) to invite a physician specialist to serve as moderator
- ❑ Secure moderator
- ❑ Review prospective participants to be invited with moderator
- ❑ Handle the logistics to create invitations, using the Promotional Regulatory Affairs (PRA) approved invitation format
- ❑ Hand deliver approved invitations to prospective participants

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- ❑ Finalize attendee list
- ❑ Communicate the responsibilities to each participant
- ❑ Provide prescribing information for AstraZeneca products to moderator and participants
- ❑ Attend and observe the interactions of the participants
- ❑ Complete the Case Study check request payment spreadsheet for the moderator and participants so they can receive their honoraria
- ❑ Complete summary document
- ❑ Forward completed summary document and disbursement request document to DSM for approval
- ❑ Hand deliver checks to moderator and participants
- ❑ Solicit physician feedback

1.2.2. DSM (or corresponding sales management)

- ❑ Perform a review of the potential case study program
- ❑ Confirm alignment of program with territory and district business plans
- ❑ Confirm available funding
- ❑ Approve the request locally
- ❑ Forward original copy of signed, approved proposal, approved payment spreadsheet, summary document, and original signed completed contracts to Field Professional Education department (requester should keep copies)
- ❑ Assist moderator with facilitation of meeting discussion if the MIS cannot attend

1.2.3. MIS/DSM (or corresponding sales management)

- ❑ Assist moderator with facilitation of meeting discussion
- ❑ Assist in physician participant and moderator selection
- ❑ Work with moderator to review responsibilities and to guide him/her in facilitation and moderator skills prior to the program

1.2.4. Participant

- ❑ Adequately prepare for the Case Study by reviewing patient files and preparing two patient cases related to the topic
- ❑ Give at least one brief oral presentation of a patient case. If time permits, the second case may be presented

- ❑ Provide scientific and clinical opinions based on clinical experience in response to patient cases presented by primary care colleagues

- ❑ Sign participant contract prior to program date

1.2.5. Moderator

- ❑ Moderate oral presentations of a patient case for each physician
- ❑ Provide scientific and clinical opinions based on clinical experience
- ❑ Sign moderator contract prior to program date

1.2.6. Field Professional Education Department

- ❑ Ensure documentation is complete and accurate before payment is made
- ❑ Forward check request payment spreadsheet to Accounts Payable
- ❑ Archive original contracts, Summary Document, and copy of payment spreadsheet

1.2.7. Accounts Payable

- ❑ Cut checks using information provided on the disbursement summary spreadsheet

1.3. Moderator and Participant Criteria

1.3.1. Moderator

- ❑ Specialist in subject matter
- ❑ Peer recognition of expertise of subject matter
- ❑ Teaching ability
- ❑ Ability to moderate discussions within small groups

1.3.2. Participants

- ❑ Healthcare professional treating disorders within AstraZeneca's therapeutic areas
- ❑ Healthcare professionals with patient cases that are relative to the subject matter
- ❑ Ability to prepare patient cases for discussion with other healthcare professionals

1.4. Case Study Format

1.4.1. Participants

- No more than 6 to 8 local physicians, physician assistants, nurse practitioners, or pharmacists
- 1 local practicing physician specialist (moderator)
- MIS or DSM may assist moderator with facilitation of the meeting, if requested

1.4.2. Meeting Location

- Restaurant, office or other suitable location that can ensure privacy

1.4.3. Content

- Educational content is the focus of this program. As such, entertainment or other social activities are not appropriate as part of this program
- Each participant must prepare two patient cases to present to the group and present at least one case
- The cases must be related to the chosen topic
- Patient identities must not be disclosed

1.4.4. Case Study Topics

- All Case Study Programs must be conducted using one of the therapeutic areas currently marketed by AstraZeneca
- The topic of the program must be within the product labeling for AstraZeneca's products

1.4.5. Honorarium

- Moderator receives a $500 honorarium. Since these programs are designed to utilize local moderators, the fair market value of the services being provided have been valued at $500. Increases to this amount are only allowable with prior approval from the Field Professional Education department and the manager approving the program.
- Participating non-moderator physicians will receive a $150 honorarium. Increases to non-moderator honoraria are not allowable.

- ❑ Honoraria for non-physician participants such as physician assistants, nurse practitioners, and pharmacists should be reduced to accurately reflect the fair market value of the services that they are providing

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- ❑ Honoraria will not be disbursed without receipt of appropriate documentation, including original signed contract
- ❑ Honoraria will be funded locally by the District or Region responsible for the AstraZeneca employee requesting the program

2. *Administrative Information*

- ❑ Honoraria payment requests must be made by using the check request payment spreadsheet (copy available through Field Professional Education or Accounts Payable); individual check disbursement requests are not permissible
- ❑ Honoraria will only be disbursed when all supporting documentation and approvals have been received by the Field Professional Education department. Documentation must include completed and approved:
- ❑ Proposal form
- ❑ Moderator and Participant contracts
- ❑ Summary document
- ❑ Check request payment spreadsheet

3. *Required Contracts/Documentation*

- ❑ Case Study Program Proposal
- ❑ Case Study Moderator Contract
- ❑ Case Study Participant Contract
- ❑ Case Study Program Summary Document
- ❑ Case Study Check Request Payment Spreadsheet
- ❑ Support documents such as invitations can be used in the approved formats (See Attachments)

4. *References*

4.1. M&S Business Policies

Ethical and Professional Conduct (M&S-A-1); **Product Promotion** (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Professional Education Programs** (M&S-C-3).

AstraZeneca

SPEAKER PROGRAM GUIDELINES Guideline No.: M&S-C-G-3-b C-G-3B

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Introduction

Speaker programs are presentations given on behalf of AstraZeneca by a National, Regional, or Local healthcare thought leader to an audience of a variety of sizes. Speakers may also be AstraZeneca personnel such as Medical Information Scientists or other company scientists. The following guidelines and related policy (**Professional Education Programs,** M&S-C-3) apply whether or not the speaker is an AstraZeneca employee.

Examples of terminology used to describe speaker programs from the two legacy companies include, but are not limited to:

- ❑ Colloquium
- ❑ Round Table
- ❑ Local Event Lecture (LEL)
- ❑ Forums
- ❑ Visiting Consultant

Although speaker programs provide a form of medical education, these programs are promotional in nature. Because AstraZeneca has influence over these programs, they are subject to the same laws and regulations that govern other forms of promotional activities. These professional education programs allow AstraZeneca to provide the service of medical education to relatively small to medium sized groups of customers.

The speaker must give a balanced presentation that remains within labeling for any AstraZeneca product that is discussed. A question and answer session with the attendees may immediately follow the presentation. All comments related to off-label use of any product discussed must be disclosed as being unapproved.

1.2. Goals/Objectives

- ❑ Provide the service of medical education to customers

- ❑ Provide high quality, ethical and scientifically correct educational programs
- ❑ Support field sales to increase customer contacts and facilitate interactive discussions
- ❑ Support field sales by providing education to customers surrounding our areas of therapeutic interest and related healthcare areas of interest

1.3. Speaker Criteria

Speakers should be selected based on their ability to educate healthcare practitioners. Speakers should not be selected in any way in consideration of, as an inducement to, or in return for the prescribing, purchasing, use or dispensing of our products or based upon their own prescribing practices. 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
- ❑ Participation in Editorial boards

1.4. Titles and Presentation Topics

Only topics approved by Promotional Regulatory Affairs (PRA) should be used.

Any AstraZeneca employee can submit new topics/titles for approval by Promotional Regulatory Affairs.

- ❑ All new topics/titles must include a full outline.
- ❑ When possible, slide kits should be developed for new topics/titles.
- ❑ New topics/titles are not restricted to AstraZeneca products or therapeutic areas of interest but they should be relevant to the Healthcare industry and be relevant to customers' practices in the treatment of patients.

1.5. Collateral Activities

- ❑ Modest and reasonable meals, modest entertainment, and other types of social activities designed to increase attendance to a program may be associated with speaker programs, however, the speaker portion of any program should dominate the agenda and any collateral activities should be incidental to the overall program. The perception of engaging customers in "token" educational activities as a means to provide entertainment 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 entertainment/activity.

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- All types of acceptable hospitality (meals, entertainment, or other types of activities) should be in line with AstraZeneca's policy of **Gaining Access to Healthcare Professionals** (M&S-B-2).
- The maximum annual dollar limit for collateral activities that can be spent on an individual healthcare professional is:
  - — $200 for single team customers
  - — $400 for multi-team customers
- If a speaker program has a meal and entertainment/activity, the cost of the meal and/or entertainment/activity cannot exceed a total of $50 per healthcare professional in attendance at the program. In those districts where the cost of living necessitates a higher per meal per healthcare limit than $50, the District Sales Manager may review the issue on an annual basis and approve a higher dollar limit within the DSM's district, so long as it is reasonable under all of the circumstances, and does not exceed the Dining Index guidance document. The costs involved for collateral activities will have separate and distinct limits which will not count towards the aggregate limits under the **Gaining Access to Healthcare Professionals** (M&S-B-2) policy.
- Spouses and other family members may not be invited to speaker programs or any collateral events. If the healthcare professional chooses to invite them at their own expense, if any, it is appropriate.
- If a spouse/guest is a healthcare professional (nurse, pharmacist, etc.) who may benefit from the content of the speaker program, then they may be invited regardless of whether there is a meal or other collateral activity. The cost of the entertainment/activity would be subject to the limits described above as a healthcare professional.

1.6. Event Related Material

- All materials distributed in association with any AstraZeneca supported speaker programs must have approval from Promotional Regulatory Affairs.
- No gifts beyond company approved promotional items may be distributed.

1.7. Speaker Evaluation

A Speaker Evaluation form should be filled out by the AstraZeneca contact following any paid speaker program. This form is available electronically in Compass. Speaker evaluation forms should also be completed by the attendees and returned to the Lecture Bureau upon completion of the speaker program. In addition, the list of attendees must be documented and submitted by the AstraZeneca program requester with their expense report for the expenses related to the program.

Relevant speaker evaluation criteria should include:

- ❑ Fair and balanced presentation
- ❑ Did speaker stay within the approved topic guidelines
- ❑ Ability of the speaker to maintain attention of audience and facilitate question and answer session
- ❑ Ability of the speaker to field questions from the audience and answer with a professional and educational response
- ❑ Overall presentation quality
- ❑ Knowledge of topic and ability to present the material accurately

1.8. Removing Faculty

Recommendations for the removal of a speaker from the AstraZeneca pool of approved speakers can be made by contacting the Professional Education department and describing the specific reasons for your recommendation. The recommendation will be handled as follows:

- ❑ The Professional Education department will evaluate the recommendation for removal and contact any others in AstraZeneca that need to be involved in the removal decision.
- ❑ Final decision will be made jointly by the Professional Education department and the appropriate member of sales management responsible for that customer.
- ❑ After a decision to remove a speaker from the AstraZeneca 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

1.9. Speaker Expenses

AstraZeneca 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.

- 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 AstraZeneca unless there are extenuating circumstances and prior approval is obtained from the Professional Education department.
- Speaker travel and lodging expenses must never be paid for by any AstraZeneca employee and submitted as a personal expense for reimbursement.

1.10. Honoraria

Honoraria for speakers at speaker programs should fall within the approved range for the type of services that are being provided. Although a single standard honorarium amount is automatically chosen via the electronic request process in Compass. the approving manager with a corresponding grant of authority can adjust the honoraria amount provided that the amount is within the range of fair market value for the qualifications of the speaker and the services being provided.

Ranges:

- Dinner lecture program, audience of 20-30, National faculty speaker – $750-2,000
- Dinner lecture program, audience of 10-15, Regional or Local speaker – $500-1,000
- Roundtable discussion, small group discussion, 5-8 attendees, Local speaker – $200-400
- National Faculty Visiting Professorship - $725-1,250 (They should not be paid per number of appointments that they reach each day. Only the speaking or teaching physician can receive an honorarium for the program.)
- Attendees for a speaker program do not receive an honorarium.
- If multiple programs occur an honorarium will be received for each talk. If adjustments are necessary, prior approval from your manager is required.
- Honoraria should be paid directly to the speaker using their social security number or federal tax identification number if they are legally incorporated.
- Honoraria for speakers must be paid by AstraZeneca's Accounts Payable department, never by a third party organization or an AstraZeneca employee.
- Honoraria will be funded locally by the Region responsible for the AstraZeneca employee requesting funds.

2. Administrative Information

- ❑ Submit request for honoraria through Compass using appropriate type of program under Speaker Programs
- ❑ AstraZeneca will maintain all speaker contracts, dispense as well as maintain speaker expenses

3. Required Contracts

- ❑ AstraZeneca Speaker Contract (one speaker contract per time period valid for all lecture speaker programs)

4. References

4.1. M&S Business Policies

Gaining Access to Healthcare Professionals (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Professional Education Programs** (M&S-C-3).

AstraZeneca

Exhibits **Policy No.: M&S-C-4** C-4

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. 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 free-standing without a related program.

2. Policy

This policy is applicable to conventions, local meetings, and hospital displays held in the US. For US participation in conventions held outside of US, the rules of the specific country would apply. Market Research activity conducted independently by a third party provider independent from commercial or scientific activity is not covered in this policy.

2.1. 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. Booths at conferences held outside the US with US attendees, are expected to follow FDA guidelines and regulations. The Promotional Regulatory Affairs and Legal departments can be consulted on a case-by-case basis for exceptions. AstraZeneca 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 be "separate and distinct"; and that the distinction between the two not be blurred. Commercial exhibits must conform to the regulations listed under 21 CFR ß 202 Prescription Drug Advertising and scientific exhibits must conform to the regulations listed under 21 CFR ß 312.7 (a) Promotion of an Investigational Drug. While only information on products approved in 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.

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2.1.1. National conventions and meetings

For national conventions and meetings, all floor plans, activities, pre-brief training, and information/material/items to be disseminated at all exhibits must be reviewed and approved through Promotional Regulatory Affairs (PRA) review process. It is strongly recommended that all AstraZeneca attendees at national conventions attend a pre-brief before being able to work at the convention. This pre-brief is MANDATORY for all personnel staffing the exhibits. A PRA representative should attend all conventions in which AstraZeneca is participating or be on call at headquarters. However, major conventions displaying AstraZeneca products must have a PRA representative present.

2.1.2. Local conventions and Hospital Displays

See **Local Conventions and Hospital Display Guidelines** (M&S-C-G-4).

3. *Types of Exhibits*

AstraZeneca has identified 2 types of exhibits within each of the two categories and developed guidelines for each. These guidelines will be maintained by the Promotional Regulatory Affairs Department on the Intranet USRA Web Page.

3.1. Scientific:

- **Scientific Exhibits- US and Non-US**
  To exchange scientific information regarding investigational products or marketed products.
- **Institutional Research Exhibits - US and Non-US**
  To promote research being conducted in a specific disease area without providing information on the investigational compounds being researched.

3.2. Commercial:

- **Commercial Exhibits -US**
  To promote products and the uses as approved in US.
- **Commercial Exhibits - Non-US**
  To promote products approved in countries outside of US to Non-US attendees attending US conventions.

4. *References*

4.1. M&S Business Policies

Product Promotion (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Local Conventions and Hospital Display Guidelines** (M&S-C-G-4); **Regulatory Considerations for Information Dissemination at Scientific and Commercial Exhibits at Conventions/Meetings Held in US** (PRA Guidance).

AstraZeneca

Local Conventions and Hospital Display Guidelines	Policy No.: M&S-C-G-4

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Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To provide the ability to fund and staff exhibits at a local and regional level.

2. General Considerations

- ❑ Company 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 organization, regardless of whether there is a specific program event.
- ❑ All convention/symposia and hospital/institution rules for displaying must be observed.
- ❑ ACCME Standards should be observed for exhibits during CME events (*see* **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2)).
- ❑ These displays are considered to be Commercial exhibits and must conform to the PRA Guideline on Commercial exhibits (see USRA Web Site for PRA Guidelines on Exhibits).

3. 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.
- ❑ Regional Exhibits or display fees under $100 can be paid directly to the customer and reimbursed through Gelco. Exhibit fees over $100 must be submitted on a Regional Exhibit Request form in Compass. For expenses over $25, original receipts are required.
- ❑ PREP AC should check to see if a W9 is on file, if not a W9 must be completed.
- ❑ PREP AC should check to see if a vendor is set-up in SAP, if not PREP AC should contact Accounts Payable to have vendor entered.

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- ❑ Requests submitted for exhibits should be initiated at least 4-6 weeks prior to program date.
- ❑ Accounts Payable will cut the check and send it to the Field Professional Education Department, 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 4-6 weeks after being submitted by the author.
- ❑ Circumstances may allow for the waiving of Exhibits fees when Exhibits are included within the Educational Grant request. If Exhibit fees are waived because of an associated Educational Grant, see **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2).

4. Required Contracts

- ❑ No contracts are required for Regional Exhibits or Displays.

5. References

5.1. M&S Business Policies

Product Promotion (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Regulatory Considerations for Information Dissemination at Scientific and Commercial Exhibits at Conventions/Meetings Held in US** (PRA Guidance).

AstraZeneca

GOVERNMENT EMPLOYEES AND AGENCIES **Policy No.: M&S-C-5** G-5

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To state AstraZeneca's commitment to comply with all applicable legal requirements and ethical standards with respect to the participation of government employees in Company-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.

2. Policy

2.1. General Policy

2.1.1. Subject to certain legal and ethical limitations, AstraZeneca may engage government officers, officials or employees (GEs) as speakers, consultants, or participants in connection with preceptorships, tutorials and other training activities. AstraZeneca 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.

2.1.2. AstraZeneca may not pay a 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.

2.1.3. No AstraZeneca employee may offer anything of value to any GE in violation of any law or regulation applicable to that GE.

2.2. Conflicts of Interest

2.2.1. 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.

2.2.2. AstraZeneca may not enter into a consulting arrangement with a GE, or enlist a GE's participation in a Company-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 the Company *if the GE's government activities could have a direct and predictable effect on the Company 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.*

2.3. Consulting Arrangements

Potential consulting agreements with GEs must be evaluated on a case-by-case basis, and must receive the advance approval of the Company's Legal Department. Generally, in addition to the requirements of the **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1) policy, three basic principles must be considered in determining the propriety of a consulting arrangement. The Company 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 that relates to the GE's official duties; and
- ❑ Obtain proof that the consulting arrangement has been approved by the appropriate official from the government agency with which the GE is affiliated.

The AstraZeneca Government Employee/Service Provider Form (see Section 2.5. below) is designed to ensure that the above requirements are met.

2.4. *Teaching, Speaking, and Writing*

AstraZeneca must ensure that any arrangement with a GE does not violate ethic laws or standards such as the federal Office of Government Ethics regulations prohibiting any form of compensation to a government employee for teaching, speaking, or writing that relates to the employee's official duties. 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; or
- ❑ The activity would require disclosure of nonpublic information.

2.5. AstraZeneca Government Employee/Service Provider Form

2.5.1. Before providing consulting services or participating in an AstraZeneca-supported educational program, a GE must complete the AstraZeneca Government Employee/Service 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; and
- ❑ Any compensation given to the GE does not constitute a prohibited gift or otherwise violate the federal ethics regulations.

2.5.2. Before completing the Form, the GE must verify, with the appropriate authorized government personnel, the accuracy of the information submitted. AstraZeneca shall not pay an honorarium to a GE, or compensate or reimburse a GE for consulting services or related expenses, unless the Form has been received by the Company with the appropriate approvals and verification.

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

2.6.1. The Executive Branch of the federal government has adopted 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. AstraZeneca 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 refreshment, such as soft drinks, coffee and donuts, offered other than as part of

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a meal. Similarly, greeting cards, plaques and other items of little intrinsic are not considered gifts under the federal ethic regulations.

2.6.2. Under the general terms of the Standards of Conduct, a healthcare professional or any other employee in the Department of Veterans Affairs (VA), Department of Defense or other Executive Branch agency may not accept 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 or less per occasion, provided that the aggregate market value of individual gifts received must not exceed $50 in a calendar year from any one prohibited source (e.g., contractor or supplier). Gifts from a particular corporate entity, its officers, and employees must be aggregated for purposes of applying the yearly $50 limitation on gifts of $20 or less.

2.6.3. 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, or dispensing of AstraZeneca products.

2.6.4. Any AstraZeneca employee providing a lunch and learn or a reminder item to a healthcare professional or other employee of the VA, DOD, or any other Executive Branch agency must inform the proposed recipient that AstraZeneca policies require that the recipient of any gift comply with the Standards of Conduct and regulations adopted by the recipient's particular agency. In addition, AstraZeneca employees must document the cost, name, title, and organization of the recipient in order to ensure that the calendar year $50 limitation is not exceeded.

2.7. Grants to Government Agencies

2.7.1. AstraZeneca 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 (e.g., the Henry M. Jackson Foundation) authorized to receive such payments and direct them to the appropriate government agency. C-5

2.7.2. 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. AstraZeneca employees must adhere to the specific corporate guidelines governing grants to the Foundation.

3. References

3.1. M&S Business Policies

Engaging Healthcare Professionals for Consulting Services (M&S-F-1).

Customer Information and Competitive Activities

AstraZeneca

REPORTING ACTIVITIES I IN THE MARKETPLACE | **Policy No.: M&S-D-1** | **D-1**

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To ensure that AstraZeneca 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 which must be understood.

2. Policy

2.1. General Policy

Marketing and Sales Personnel are expected to keep AstraZeneca 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 AstraZeneca employees, they also apply to any AstraZeneca third party contractors.

2.2. Applicable Laws

2.2.1. 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 which 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,

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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.

2.2.2. 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.

2.2.3. 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.

2.3. Physicians and Other Healthcare Professionals (Customers)

2.3.1. You should not solicit information about competitive activities from any healthcare professional during a call. If the healthcare professional 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.

2.3.2. Written materials may not be removed from a healthcare professional's premises or copied without the healthcare professional's expressed permission. If such materials are marked confidential, or are materials AstraZeneca 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.

2.3.3. Physicians and other healthcare professionals 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 healthcare professional, your response must stay within the bounds of the AstraZeneca policy entitled Intellectual Property Claims (M&S-A-4).

2.4. Journals

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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.

2.5. Representatives from Other Companies

2.5.1. 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.

2.5.2. 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.

2.5.3. You should regard all confidential or proprietary information to which you gain access at work as the property of the Company. 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.

2.5.4. 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 to 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."

3. *References*

3.1. M&S Business Policies

Antitrust Laws (M&S-A-2); **Intellectual Property Claims** (M&S-A-4); **Product Samples** (M&S-B-6).

AstraZeneca

SALES PRESCRIBER DATA **Policy No.: M&S-D-2** D-2

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. 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.

2. Policy

2.1. Sources of Sales and Prescriber Data

2.1.1. AstraZeneca 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. The Company also internally develops sales and prescriber data.

2.1.2. AstraZeneca distributes sales and prescriber data to Marketing and Sales Personnel for use in strategic assessment of business opportunities and performance evaluations.

2.2. Confidentiality

Any sales and prescription information collected either by or for AstraZeneca is strictly confidential and may be used only within the Company; under no circumstances may it be discussed with or revealed to anyone outside the Company. The meaning is specific: *The information an AstraZeneca employee receives about sales and market share may not be discussed with customers, with competitors, or with anyone else outside the Company, with the exception of co-promotion and other contractual partners with whom AstraZeneca has entered into an agreement to share such information. This restriction applies throughout the employee's active employment with the Company and continues after termination of the employment relationship.*

AstraZeneca 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

D-2 third party vendors. This information must remain highly confidential and cannot be disclosed to or discussed with anyone outside of AstraZeneca."

3. *References*

3.1. M&S Business Policies

Intellectual Property Claims (M&S-A-4); **Patient Privacy** (M&S-A-6); **Safeguarding Company Assets** (M&S-E-1).

Company Interest and Property

AstraZeneca

SAFEGUARDING COMPANY ASSETS **Policy No.: M&S-E-1** E-1

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To state AstraZeneca policy regarding the preservation and use of Company assets by Marketing and Sales Personnel.

2. Policy

2.1. General Policy

All AstraZeneca employees have a responsibility to safeguard and preserve Company assets entrusted to them for their use in conducting Company business. This includes such items as sales equipment (e.g., hospital display units, brochures, electronic devices, computers); computer programs and software; Company cars; corporate credit/charge cards; cellular telephones; telephone charge cards; fleet car service/fuel cards; GELCO authorization cards; funding allocated for various programs (e.g., speaker and lunch programs); videotapes; airline tickets provided for Company-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 Company property and are recorded on the Company books as assets. These items must be returned promptly by the employee upon request by the Company or upon termination of employment.

2.2. Sales Equipment

2.2.1. 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. Company-issued computers and software must be well-maintained and safeguarded against theft or improper use.

2.2.2. Sales equipment placed inside a car must be kept in the trunk of the car at all times when the car is not occupied.

2.3. Company Car

Marketing and Sales Personnel must follow the standards and restrictions for Company automobile use provided in the policy entitled **Fleet** (M&S-E-4) and the Driver Assistance Handbook issued by Fleet Administration.

2.4. Expense Reporting

2.4.1. Marketing and Sales Personnel should 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 the Company. Although not required in all instances, receipts should ordinarily be submitted. Expense reports must be filed no less frequently than once a month.

2.4.2. Marketing and Sales Personnel should familiarize themselves with the Company's **Expense Reimbursement** policy (M&S-E-6).

2.5. Corporate Credit/Charge Cards

2.5.1. Marketing and Sales Personnel are encouraged to use the Company-provided Corporate Card for all travel expenses and local business expenses whenever possible.

2.5.2. The annual membership fee for the Corporate Card and any cash advance fees will be paid directly by the Company. Other fees for this card and fees for other credit or charge cards are not reimbursable.

2.5.3. 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 AstraZeneca employee is permitted to use the Corporate Card for any reason.

2.5.4. All original Corporate Card receipts and those from the selling establishment are to be submitted with the expense report.

2.5.5. 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.

2.5.6. 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 to the employee pursuant to the **Expense Reimbursement** policy (M&S-E-6). Employees will not be reimbursed for any late fees incurred for failure to pay the charges promptly and in full each month.

2.5.7. AstraZeneca management receives monthly account activity reports from the Corporate Card Vendor. Spending is governed by the corporate Expense Reimbursement Policy along with any other Company guidelines or other budgetary considerations.

2.5.8. 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.

2.5.9. The Corporate Card is the property of both the vendor and AstraZeneca. Any abuse of the card (such as delinquencies or personal use of the card) may result in suspension of all privileges and forfeiture of the card.

2.6. Telephone Charge Cards

Marketing and Sales Personnel should use the telephone card provided by the Company for all business-related toll telephone communications to take advantage of favorable Company-negotiated rates.

2.7. Meeting Travel Expense and Airline Tickets

Marketing and Sales Personnel must follow the procedures relating to travel expenses and airline tickets provided in the AstraZeneca policy entitled **Travel** (M&S-E-3) and the **Expense Reimbursement** policy (M&S-E-6).

2.8. Cellular Telephones

The Company-provided cellular telephone is to be used for business purposes only.

2.9. Record-keeping and Reporting Systems

The integrity of the Company's 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 the Company must accurately reflect and fairly represent the Company's activities; therefore, they must be maintained in accordance with Company 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 the Company for any reason.

2.10. Unauthorized Use of Company Funds

Any *unauthorized* use of Company funds by an employee is a violation of Company policy. Criminal charges may be pursued if, in the opinion of the Company, 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 the Company.

2.11. 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.

3. References

3.1. M&S Business Policies

Electronic Communications and Devices (M&S-E-2); **Travel** (M&S-E-3); **Fleet** (M&S-E-4); **Expense Reimbursement** (M&S-E-6).

3.2. Finance Business Policies

Expense Reimbursement Policy

3.3. Other Sources

Driver Assistance Handbook

AstraZeneca

ELECTRONIC COMMUNICATIONS AND DEVICES **Policy No.: M&S-E-2** E-2

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To instruct Marketing and Sales Personnel on the care, security, and use of Company electronic communication systems, including computers, computer-based information, telecommunication systems, and other electronic devices. This policy is intended to supplement corporate policies relating to computers, communication systems and other electronic devices.

2. Policy

2.1. General Policy

Marketing and Sales Personnel are provided with Company-owned hardware and software to assist them with their professional activities. Employees are responsible for the appropriate use, care and security of these valuable Company capabilities and assets, and for the safe return of the assets upon separation from employment.

2.1.1. AstraZeneca hardware and software are intended for work purposes. Notwithstanding the foregoing, personal use of the approved systems and software, of a minimal nature, will not be considered a violation of this policy statement. In no event, however, shall Company electronic communication, internet technologies and voice mail systems be used to communicate language or images which are unlawful, defamatory, offensive, or harassing to co-workers, or which are otherwise inappropriate or violate AstraZeneca policy. Procedures for authorized company internet use will be covered in the Interim Guidelines for Internet Usage.

2.1.2. The Company reserves the right to review, monitor and record the contents of Company electronic communication systems without any notice or permission. Employees should NOT have an expectation of privacy with respect to the contents of any electronic communication. Any party who uses AstraZeneca systems to

transmit or receive communications shall be deemed to have consented to review of such communications by AstraZeneca. The existence of passwords and message delete functions does not restrict the Company's ability or right to access communications.

2.1.3. Employees should keep in mind that all electronic communications, including the most casual note or statement, may be subject to disclosure to the government or private litigants. It is important to consider the potential legal implications of casual language in oral or written communications. The use of such language may raise questions concerning conduct (even conduct that is otherwise proper and lawful) and may undermine Company efforts to comply with applicable laws and regulations.

2.2. Loading, Copying and Use of Software

2.2.1. The installation of software on Company computers is regulated and supported by the Company. Prior approval is necessary for installation of any non-supported software. In order to maintain the integrity of the system, any software not provided or approved by AstraZeneca is considered non-supported software and should not be installed. The Company will not be responsible for the reinstallation of non-supported software in the event of computer failure.

- ❑ Software should never be downloaded from a public source (particularly the Internet).
- ❑ Data files may be downloaded with discretion and require prior approval.

2.2.2. Purchased software comes with a license agreement. It is a violation of the license and AstraZeneca policy to make copies of the software for use by anyone other than the licensee. No copies of any software should be made (even for an employee's own use) unless specifically permitted by the license. Unauthorized reproduction, use and/or distribution of software programs (in whole or in part) may result in severe civil and/or criminal penalties.

2.2.3. Public bulletin boards (e.g., AOL®, Internet) contain programs that may be harmful to computer systems. Software should never be downloaded from such public sources.

2.2.4. Employees must be familiar with and adhere to any guidelines issued by the Company concerning Internet communications.

2.3. Disclosure of Sensitive or Copyrighted Information

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The proprietary and purchased information contained in Company-owned hardware and software is intended for AstraZeneca personnel only. This information should not be copied (electronically or otherwise), printed, shown, discussed with, or provided to anyone outside of AstraZeneca without Company approval. Field Personnel dealing with customers may present Company-approved promotional software or other approved promotional or informational materials in the course of their professional activities.

2.4. Data Security

2.4.1. Data stored on electronic communication systems and sensitive information in any form (memorandum, electronic message, computer file, etc.) must be protected from unauthorized disclosure, loss or alteration — whether deliberate or inadvertent.

2.4.2. Employees must ensure that their activities are in conformance with the appropriate practices, administrative procedures, and protective devices established by AstraZeneca to secure these data.

2.5. Access Controls

Employees will be granted specific authority to access automated data files and facilities to carry out their assigned responsibilities. Each employee is responsible for the use of the associated passwords, security codes, and procedures. User names, passwords & security codes must not be disclosed to any unauthorized personnel. These controls limit personal and corporate liability, and comply with legal, regulatory, and security requirements.

2.6. Equipment

2.6.1. Distribution

All serial numbers of the equipment will be assigned by the IS support team to the receiving employee. Upon receipt of computer equipment, the employee will be required to acknowledge receipt. The receiving employee is responsible for the equipment received. Employees are not permitted to trade or lend personal computers or associated equipment. IS purchasing is responsible for the procurement of all Company-specific hardware and software.

2.6.2. Returning Hardware for Promotions or Transfers

When an employee vacates a position for either a promotion or transfer (including a transfer to corporate headquarters or another field position), all computer equipment (computer, printer, accessories, manuals, etc.) must be sent to the IS support team for redistribution to the employee filling the vacated position. *Employees may not maintain the computer equipment for use in their new assignments.*

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2.6.3. Returning Hardware for Terminations

All returns of electronic communication devices which do not entail a replacement require the direct involvement of the employee's designated supervisor. Therefore, all terminations require a return of all electronic communication devices (computer, printer, accessories, manuals, etc.) to the designated supervisor by the termination date. The supervisor will then arrange for prompt return of the equipment to the IS support team. Incomplete return of computer equipment is subject to replacement charges to the user.

2.6.4. Lost or Stolen Equipment

If computer equipment is lost or stolen, the loss or theft must be reported immediately to the IS support team so that all computer accounts can be disabled. Security must also be notified if equipment is stolen.

2.6.5. Unauthorized Equipment

No equipment other than equipment provided by AstraZeneca or specifically authorized by AstraZeneca for use with the network should be hooked up to the network.

2.6.6. Repair of Hardware

An employee who suspects a hardware malfunction in Company computer equipment should contact the IS support team.

3. References

3.1. M&S Business Policies

Safeguarding Company Assets (M&S-E-1); **Interim Guidelines for Internet Usage.**

AstraZeneca

ELECTRONIC COMMUNICATIONS AND DEVICES GUIDELINES **Guideline No.: M&S-E-G-2** E-G-2

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. IS Support Team

All hardware, software, supply, and other questions arising from use of Company information and telecommunication systems should be directed to the Technology Support Center (TSC) at 1-800-833-2883.

1.2. Loading, Copying and Use of Software

The Technology Support Center has issued a procedure regarding non-supported software. This procedure governs the use of software that has not been rolled out by the Company. AstraZeneca employees must adhere to this procedure in all respects.

1.3. Data Security

All computer data and all computers themselves are considered corporate assets. It is vital that they are protected against unauthorized access. One way to do that is to create passwords that are difficult to guess. AstraZeneca has created the following password formatting standards to help protect its corporate assets. All AstraZeneca personnel and partners should use these standards when creating their network passwords or application passwords.

Password Formatting Standards

- ❑ Passwords should be a minimum of 8 characters in length.
- ❑ Passwords should be a mix of numbers and letters.
- ❑ Passwords should not be recognizable words or words with numbers appended.

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Other Password Guidelines:

- ❑ Change your password every 60 days (the network will prompt you when it is time to change your network password).
- ❑ Do not write your password(s) down.
- ❑ Do not store your password(s) anywhere near your computer, or anywhere that they could be easily obtained.
- ❑ Do not give your password(s) out to others.
- ❑ Change your password immediately if someone else learns what it is.

AstraZeneca

TRAVEL **Policy No.: M&S-E-3** E-3

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

This policy follows the guidelines and established procedures for all US 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.

1.1. 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.

2. Responsibility and Enforcement

Employees are responsible for complying with this travel policy. Each manager is responsible for monitoring compliance with policy when reviewing requests, 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.

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)

3. *Travel Arrangements*

As there are significant dollar savings to be gained by making travel arrangements, all travel arrangements including air, rail, lodging and rental cars must be booked through the designated Travel Management companies.

Carlson Wagonlit Travel
1800 Concord Pike, FOC 1
P.O. Box 15437
Wilmington, DE 19850-5437
Weekdays 7:00 a.m. to 8:00 p.m. (Eastern Time)
(888) 552-7790 / (302) 425-5880

International Business Travel (800) 316-6093 / (302) 425-4470
After hours Emergency Service Center:
(800) 777-7999

Rosenbluth International
7535 Windsor Drive
Suite 104A
Allentown, PA 18195
Weekdays 8:00 a.m. to 5:30 p.m. (Eastern Time)
Reservations (800) 628 5345
After hours Emergency Service Center:
Customer Service (610) 391 8578

Group and Meeting Travel. Any department planning to sponsor group or meeting travel involving 25 or more participants and needing assistance for the event, should call either (302) 886-8459 or (610) 578-8730. This will help maximize discounts and services available through our preferred suppliers.

Traveler Profile Forms. All employees expecting to travel at least once per year should submit a completed travel profile form to the Travel Management Company 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 the Travel Management Company in writing of updates.

4. *Preferred Suppliers*

Preferred suppliers are those with whom AstraZeneca has negotiated advantageous agreements which 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 at http://156.70.231.180/Travel.

5. *Air and Rail Travel*

Air Travel Parameters. Defined as flying time to the first business destination by the most direct route.

Class of Travel Policy:

Domestic/North America

All Staff	Coach

International

<6 Hours	Coach
>6 Hours	Business

Rail

All Staff	Coach

Itinerary Authorizations will be required for all non-corporate charge card transactions. As circumstances allow, the Travel Management Company will take advantage of discounted fares. Frequent flyer programs will not influence carrier selections.

Travel Parameter Exceptions. The booking of flights above entitlement will require 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.

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Parameters for lowest fares. The following parameters have been established to allow for cost savings without a great inconvenience to the individual traveler:

- Employees are expected to make air travel arrangements at the earliest possible time and obtain the lowest fare available. In order to take advantage of discounted fares, determining travel plans at least 7 days in advance is preferred.
- Departure/Arrival Window - If a flight's departure/arrival is within 90 minutes of the requested time (before or after) and does not add more than 90 minutes to overall travel time, the lowest available fare will be considered.
- One stop or connecting flights will be considered if substantial savings can be achieved.
- 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.

Upgrades of Service and Frequent Flyer Programs. It is company policy to allow employees to accept upgrades or use frequent flyer points which 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.

Unused Tickets and Refunds. All wholly or partially unused tickets must be returned to the Travel Management Company which will process a credit for the unused coupon. If for any reason a ticket is exchanged for a lower-priced alternative, the amount refunded or credited by an airline or rail carrier must be returned to the Company.

6. *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 not more than three (3) subordinates, or fifty percent (50%) of the group traveling, whichever is less, should travel with a principal.

7. *Lodging*

Hotel selection. Employees are expected to use the preferred hotel vendors as outlined in the hotel section of the Travel website. Travel Purchasing will negotiate discounted rates with these hotels.

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.

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 to employees.**

Telephone Charges. Calls made through hotel switchboards are usually subject to substantial premiums and should be avoided by using a Company provided phone card.

8. 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

Rentals. All rentals must be booked through the Travel Management Company 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, the Travel Management Company will make arrangements with secondary car rental vendors.

Car rental insurance. When renting a car for company business, use the following as a guideline for insurance:

	LDW	**PAI**	**PEP**	**ALI**
United States	Decline	Decline	Decline*	Decline
United Kingdom	Decline	Decline	Decline*	Decline
Canada	Accept	Decline	Decline*	Decline
All Other Countries	Accept	Decline	Decline*	Decline

LDW = Loss Damage Waiver Coverage
PAI = Personal Accident Insurance
PEP = Personal Effects Protection
ALI = Additional Liability Insurance

*In the event of carrying high value goods in the car, you may want to accept this coverage.

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.

9. Other Transportation

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 at http://156.70.231.180/Travel.

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.

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.

10. 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.

11. 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.

IRS Requirements.

Please refer to the **Expense Reimbursement** policy (M&S-E-6).

12. Other Reimbursable & Non Reimbursable Expenses

Please refer to the **Expense Reimbursement** policy (M&S-E-6).

13. Payment Method - Corporate Card

It is **mandatory** to use the **Corporate Credit 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 pay their corporate card balances upon receipt of statement. Failure to pay the account promptly will result in:

- Notification sent to employee and/or manager;
- Suspension or cancellation of charge privileges; and
- Possible disciplinary action.

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 302-886-3397 or US BankVisa at 800-523-3255 x2452.

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 800-554-2639 in the United States or by calling collect 202-554-2639 from anywhere in the world.

Emergency assistance for US BankVisa can be reached by calling 800-344-5696 in the United States or by calling collect 701-461-2042 from anywhere in the world.

14. Cash Advances

Employees are expected to minimize the use of cash for reimbursement of expenses. Temporary cash advances are available to employees traveling out of town who expect to incur

Out-of-pocket expenses: The Corporate Card cash advance program is available for cash advances to those employees on a pre-approved basis.

15. Settlement of Expenses

Please refer to the **Expense Reimbursement** policy (M&S-E-6).

16. 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.

17. Safety

Employees should always use discretion to maximize personal safety when traveling to their destination. Employees should not use cellular phones while operating a vehicle on Company business. 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.

Travelers should exercise caution when traveling in countries where extra medical safeguards are required or where civil/military/political unrest prevails. Pre-trip medical advice can be obtained from the Company Medical Department.

Travelers needing emergency assistance abroad should refer to the applicable credit card/insurance publications.

18. References

18.1. M&S Business Policies

Safeguarding Company Assets (M&S-E-1); **Expense Reimbursement** (M&S-E-6).

18.2. Finance Business Policies

Expense Reimbursement Policy

18.3. Corporate Business Policies

US Travel Policy

AstraZeneca

FLEET **Policy No.: M&S-E-4** E-4

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To state AstraZeneca's policy regarding use of company owned and company provided automobiles by Marketing and Sales personnel. This policy is a subset of the Corporate Fleet Policy.

2. Policy

2.1. General Policy

Company owned vehicles are supplied so that AstraZeneca employees will have suitable transportation to the places where they must conduct company business. The automobile must be maintained in accordance with the owner's manual so that it may be operated safely and without downtime. The interior and exterior of the automobile should be cleaned regularly so that it reflects the professional nature of the driver and the company.

2.1.1. Vehicle Assignment

Company owned vehicles will remain in their assigned territories through their life cycle. Exceptions can only be made through approval of area business leader and Fleet Services based on business needs.

2.1.2. Registration and Title

Vehicles are registered in the name of the legal owner. The Fleet Management Company is contracted to apply for registration and renewals, license plates and titles except in states where they are unable to do so. In those cases, the driver is provided a limited Power of Attorney to ensure that his/her vehicle is registered before the expiration date.

The drivers are responsible to ensure that their vehicles are legally registered and any fines and penalties incurred will be the responsibility of the driver. The driver is responsible for any emissions or safety inspections that might be required before renewal.

It is the driver's responsibility to ensure that the vehicle has a valid insurance card.

2.2. Eligibility for Company Vehicle

Eligibility for a Company Vehicle will be determined by position within the organization.

Models are determined yearly by Fleet Services and management.

2.3. Driver Training

All employees who have been issued company vehicles must complete training as outlined in the **Motor Vehicle Safety** policy (M&S-E-5).

Permissible Drivers must also complete training. See **Motor Vehicle Safety** policy (M&S-E-5).

2.4. Driver Responsibilities

Drivers must have a current and valid driver's license issued by the state of residence. Offers of employment will be contingent upon possession of a valid driver's license and motor vehicle record check.

Each employee is responsible to insure that all permissible drivers of his or her company vehicle are in possession of a valid driver's license.

2.4.1. Moving Violations

Moving violations and any resulting fees, fines, and/or penalties are the driver's responsibility and must be reported to the immediate supervisor and the Accident Management Company. Moving violations cannot be charged to the company as expense items.

2.4.2. Parking Violations

Parking violations and any resulting fees, fines, and/or penalties are the driver's responsibility and must be reimbursed to the company if paid by the Fleet Management Company. Parking violations cannot be charged to the company as expense items.

2.4.3. Gross Negligence

Employee is responsible for the following conditions if he or she and any permissible driver are operating the vehicle whether or not an accident is involved:

- ❑ Driving while intoxicated or under the influence of drugs in a manner prohibited by law.

- ❑ Driving in a manner disregarding traffic regulations, such as, excessive speed or reckless driving.

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An ad hoc committee will review cases of gross negligence and employee may be subject to disciplinary action up to and including discharge.

2.5. Personal Use of Company Vehicle

Employees will be granted personal use of their company vehicle. The flat per month fee will automatically be deducted from the employee's salary and will include up to 350 personal miles with an employee mileage reimbursement thereafter. Personal use of company car will be calculated and monitored via the business expense reporting system. Employees not using company car for personal use may request a waiver of personal use charge. Employee requests will be evaluated on a case by case basis by senior management and fleet management.

2.5.1. Authorized Drivers/Permissible Drivers

Driving is restricted to the employee, spouse of employee, domestic partner of employee and children 21 years of age or older living in the employee's household. Exceptions will be at the joint discretion of the employee's management and Fleet Services.

Drivers must sign a consent form to authorize company to perform driver's and permissible driver(s) license information checks.

An audit of motor vehicle records of employees and permissible drivers will be completed with frequency in accordance with Vehicle Replacement Policy. A minimum of 10% of the motor vehicle records for authorized drivers will be audited at random, annually.

2.5.2. Leave of Absence

Personal use of Company car is extended to paid leave of absences.

During an unpaid leave of absence it is at the company's discretion to reassign the vehicle or grant permission of personal use. If granted personal use, the personal use fee is paid in advance.

While driving a company car during a leave of absence, expense reporting continues and all miles driven are considered personal.

2.5.3. Accidents During Personal Use

Employees involved in accidents during personal use are responsible for collision damage deductible of $250. The same applies to permissible drivers.

E-4

2.6. Use of Vehicle Outside the U.S.

At least two weeks prior to driving the company car into Mexico and/or Canada, the assigned driver must obtain authorization and insurance information from Fleet Services. Company samples/products should not be in the vehicle when driving out of the country.

2.7. Trailer Towing

Trailer towing is strictly prohibited.

2.8. Miscellaneous

Transportation of firearms, ammunition or controlled substances in the company vehicle as well as towed items is strictly forbidden.

Use of company vehicle in the pursuit of any other income producing activity is strictly prohibited.

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).

Picking up hitchhikers or giving rides to strangers in company vehicle is prohibited.

Any alcoholic beverages transported in a company-provided vehicle shall be carried at all times in the trunk compartment and remain unopened.

Transportation of alcoholic beverages, in a company vehicle, across state lines is prohibited in accordance with state laws.

The carrying and/or use of radar detectors in company-provided vehicles or any vehicle while on company business is strictly prohibited.

Seat belts must be used by drivers and all passengers at all times when the company-provided vehicle is being operated. Small children being transported in a company vehicle shall be in an approved safety seat and appropriately positioned in the back seat of the vehicle as recommended by the National Highway Safety Council and/or the vehicle's Owners Manual.

Deactivation of airbags is prohibited. Exceptions are allowed with appropriate documentation and approval through Fleet Services.

Additional equipment may not be installed in your company vehicle without joint authorization from manager and Fleet Services.

2.9. Maintenance

Maintenance and emergency services are available 24 hours a day, 7 days a week.

A preventive maintenance schedule will be issued to every driver. Drivers will be expected to comply with the schedule.

Fleet Services or the Maintenance Management Company must approve snow tires.

Glass damage not caused by an accident is to be reported for repair and or replacement to the Accident Management Company.

Fuel purchases are limited to unleaded regular gasoline, except in areas where it is unavailable and refueling is necessary.

2.10. Vehicle Replacement

Two to four model years or 65,000 miles with a general minimum of 24 months in service and a maximum of 48 months in service.

Under certain circumstances, vehicles may be replaced at the discretion of Fleet Services.

2.10.1. Employee-Selected Additional Equipment

Employees may add certain specified additional equipment at their own or company expense when ordering a vehicle (in accordance with AZ driver safety and accident control program, section 2.11.1 of this policy).

The company may restrict certain options and or upgrades.

Employee-paid equipment costs cannot be refunded to employee once the new vehicle order has been placed regardless of reason including transfer or termination. Equipment remains with the vehicle and employee receives no allowance before or after resale.

2.11. Purchase of Company Vehicle

Employee may purchase their assigned vehicle or other company vehicles being replaced or not needed. Used vehicle prices are not negotiable.

Once a used vehicle purchase quote is issued, any repairs other than routine maintenance must be approved by Fleet Services.

Insurance on the used vehicle will cease at midnight of the day the new vehicle is delivered.

E-4 Used vehicles not being purchased must be traded in at the dealership delivering the new vehicle.

2.11.1. Driver Safety and Accident Control Program

Employee and permissible drivers will be entitled to a discount on the purchase of the company vehicle after meeting the following criteria for two consecutive years:

- ❑ Driving record clear of preventable accidents
- ❑ Absence of moving violations
- ❑ Properly maintained vehicle

The discount will be as follows: 3% at the third year and an additional percentage for every year up to 10 years or a maximum of 10%.

The proper maintenance of a vehicle is outlined in accordance with the Preventative Maintenance Schedule and AstraZeneca Fleet Policy.

Employees who meet the above criteria will be entitled to company-paid optional equipment on their vehicles when due replacement. Driving records of permissible drivers will impact employee's eligibility.

Vehicle purchase discounts will be regarded as income to the employee and will be reflected in your W2 as gross income.

See the **Motor Vehicle Safety** policy (M&S-E-5) for other safety-related implications.

2.12. Vehicle Expense Reporting

Vehicle expense data is captured by the Fleet Management Company, resulting in an Exception Report that denotes high/low-operating costs. Exception Reports are forwarded to the driver's manager for review and will be used as a performance measurement tool during annual performance reviews.

2.13. *Insurance*

2.13.1. Insurance

AstraZeneca Inc. is self-insured for physical damage, which includes collision, fire, theft and comprehensive damage. For automobile liability insurance, company vehicles are covered under a blanket fleet policy.

2.13.2. Automobile Liability Insurance

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This provides insurance coverage for anyone driving with the permission of AstraZeneca for their legal liability, resulting from bodily injury and/or property damage, to third parties.

Liability insurance also covers substitute or temporarily borrowed vehicles.

2.13.3. Comprehensive (fire, theft, etc.) and Collision

Self-insured by the company and subject to a $250 deductible paid by employee for damage to the company vehicle occurring during personal use (unless damage was caused by an uninsured or hit and run driver).

2.13.4. Personal Effects in Vehicle

Loss of personal items will be reimbursed to employee while on business. Reimbursement will be reduced by any other insurance and subject to a $250 maximum limit. In the case of theft, reimbursement will be available only if the vehicle was properly locked. Excluded from reimbursement is theft, loss or damage to all types of sound reproduction, transmitting or peripheral equipment.

The company has no responsibility to repair or replace any stolen, damaged or destroyed employee-paid optional equipment. Said equipment may be replaced with standard equipment at the company's discretion.

2.13.5. Uninsured Motorists Coverage

Coverage is for bodily injury resulting from an accident with an uninsured, underinsured, or hit and run motorist in accordance with the terms of Company's Automobile Liability Policy. However, the company rejects such coverage, except where minimum statutory limits apply.

2.14. Reporting Incidents

2.14.1. Stolen Vehicle

Theft must be reported immediately to the police in the locality, driver's manager, the Accident Management Company, and to Fleet Services.

2.14.2. Legal Action by Third Parties

Drivers must forward all legal documentation regarding an accident to the Legal Department in Wilmington and inform their managers.

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2.14.3. Reporting Accidents and Convictions/Suspensions

Motor vehicle accidents involving company owned vehicles or accidents that occur in company owned, rented or personal vehicles (during business use), shall be reported as soon as reasonably possible, but no later than 24 hours after the occurrence. The same policy applies to permissible drivers.

The Accident Management Company will investigate all accidents. Determination of preventable will be reported on the accident report and a copy will be forwarded to management.

3. References

3.1. M&S Business Policies

Motor Vehicle Safety (M&S-E-5).

3.2. Corporate Policies

Corporate Fleet Policy, Corporate Expense Reimbursement Policy, Corporate Safety Policy

AstraZeneca

MOTOR VEHICLE SAFETY **Policy No.: M&S-E-5** E-5

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To assure the safety of AstraZeneca Field Sales employees who drive on company business by establishing safe driving requirements and responsibilities. This program has been adopted to fulfill the requirements of AstraZeneca Safety, Health and Environmental (SHE) Standards.

2. Policy

2.1 General Policy

It is the policy of AstraZeneca that all operators of company vehicles and those who drive motor vehicles on company business shall drive in a safe and lawful manner.

This program applies to all AstraZeneca Field Sales employees who drive company owned, leased, rented, or personal vehicles on company business. (Specific approval by your manager is required to operate a personal vehicle on company business.) This program also applies to Permissible Drivers - non-AstraZeneca employees who are permitted to drive a company vehicle (e.g. employee's spouse or child 21 years of age living in the employee's household) while they are operating a company owned, leased or rented vehicle.

2.2. Responsibilities

2.2.1. Management Responsibilities

1. Line Management
   - ❑ Oversight of execution and insurance of compliance with Safety Policy.
2. National/Area Sales Directors
   - ❑ National/Area Sales Directors are responsible for oversight of execution and insurance of compliance with the Policy and for holding Regional Sales Directors and District Sales Managers accountable for implementing the Policy within their sphere of influence.

- National/Area Sales Directors are responsible for ensuring that the requirements of this program are effectively communicated within their organization.

3. Regional Sales Directors/District Sales Managers

   - Driver training and evaluating the driving performance of their employees on an ongoing basis (e.g., motor vehicle accidents, vehicle maintenance, motor vehicle citations, observation of employee driving habits when working with employees, etc.)
   - Ensuring that their employees and permissible drivers have satisfactorily completed appropriate defensive driving courses, as outlined in section 2.5 of this program.
   - Following up on the motor vehicle accident investigations of the employees and permissible drivers under their direct supervision, as outlined in section 2.4 of this program. Investigations will be conducted by Consolidated Services Corporation.
   - Reviewing motor vehicle records to assure that all drivers are driving safely, as outlined in section 2.3 of this program.

2.2.2. Driver Responsibilities

1. All motor vehicle operators shall drive in a safe and lawful manner.

2. Drivers shall not operate motor vehicles when their ability to do so has been impaired by alcohol or drugs.

3. Drivers shall follow the practices of defensive driving and will not drive during extremely bad weather conditions, such as ice storms, until the weather clears and road conditions improve.

4. Drivers will utilize their company vehicle (which is equipped with required safety features, e.g. airbags and ABS) for company business. If the company vehicle is unavailable, the driver should arrange for a rental vehicle that is equipped with the same safety features as company leased vehicles. In special circumstances, a driver's personal vehicle may be utilized but only with specific approval from their manager.

5. All drivers and their passengers must use safety restraints at all times. Passive restraints (such as air bags) alone are not sufficient. Small children being transported in a company vehicle shall be in an approved safety seat and appropriately positioned in the back seat of the vehicle as recommended by the National Safety Council and the vehicle owner's manual.

6. The driver will ensure that the company vehicle assigned is maintained in a clean, professional, and safe operating condition. E-5

7. Drivers are responsible for reporting all motor vehicle accidents as outlined in section 2.4 of this program.

8. Drivers are responsible for reporting moving violations, citations, license suspensions or revocations as outlined in section 2.4 of this program. Moving/parking violations and any resulting fees, fines and/or penalties are the driver's responsibility. These violations cannot be charged to the company as expense items.

9. Drivers are prohibited from using radar detectors in their company vehicle or in any vehicle while on company business.

10. Drivers are prohibited from using cellular phones while driving a company vehicle and while driving any motor vehicle on company business.

11. At all times drivers should exercise caution to reduce their exposure to crime and personal injury, especially when selecting travel routes and parking spots.

2.2.3. Motor Vehicle Coordinator - Regional Office Leader

The Regional Office Leader in each Business Center has the responsibility for acting as a Motor Vehicle Coordinator. The Motor Vehicle Coordinator is responsible for overseeing all clerical activities associated with this policy such as working with Consolidated Services Corporation to acquire driving records as outlined in section 2.3.

2.2.4. Safety, Health and Environmental (SHE) Staff

- SHE Staff is responsible for administration and audit of this program.

- The US SHE Lead is responsible for communicating motor vehicle accident information and performance against goals to upper management and throughout AstraZeneca.

2.3. Minimum Requirements

2.3.1 Valid Driver's License

All drivers covered by this program must have a valid license issued **by the state in which they reside.** Offers of employment will be contingent upon possession of a valid driver's license to be made available to the company for review before employment commences. The Regional Motor Vehicle Coordinators are responsible for ensuring that drivers covered by this program have a valid driver's license.

When relocation occurs, the District Sales Manager is responsible to ensure that company drivers **obtain a valid license in the new state,** within 30 days. Each sales employee is responsible to ensure that all permissible drivers of his or her company car obtain a valid license in the new state within 30 days.

2.3.2 Consent Forms/Permissible Driver Reports

The Motor Vehicle Coordinator is responsible for ensuring that a Consent Form/Permissible Driver Report is maintained on file for all drivers subject to this program (Attachments I and II). The Coordinator is responsible for ensuring that each driver completes a Consent Form/Permissible Driver Report at the time the driver becomes subject to this program.

2.3.3. Motor Vehicle Record (MVR)

- ❑ A third party provider will acquire and review Motor Vehicle Records (MVR) for all new hires and their permissible drivers. An annual random MVR audit will be conducted for all employees assigned company cars.

- ❑ The Regional Sales Directors will review all audited MVRs and take the actions outlined on Attachment III for unacceptable driving performance.

- ❑ When a permissible driver has two moving violations, the Regional Sales Directors will notify the US SHE Lead (302-886-7669) to determine the appropriate course of action, which could include revocation of the permissible driver's privilege to drive the company vehicle.

2.4 Reporting Accidents and Convictions/Suspensions

2.4.1. Motor vehicle accidents involving company owned, leased, rented or personal vehicles shall be reported as soon as reasonably possible, but not later than 24 hours after the occurrence.

(Accidents that occur in company vehicles involving permissible drivers must also be reported in the same time frame.) Representatives should obtain a police report that should then be forwarded to their Regional Sales Director. If an accident occurs during a weekend and is not serious, it can be reported the next working day.

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- ❑ Motor vehicle accidents must always be reported to the District Sales Manager. If unable to contact the District Sales Manager, the employee must contact one of the following individuals (in the order shown):

Title/Name	Work Phone	Home Phone
District Sales Manager	(Each sales employee must maintain a current	
Regional Sales Director	list of appropriate home and business	
Area Sales Director	telephone numbers.)	
National Sales Director		

- ❑ Motor vehicle accidents involving AstraZeneca company owned and leased vehicles must also be reported to Consolidated Services Corporation (800-323-6644).

- ❑ Motor vehicle accidents that occur on company business with rented vehicles must also be reported to the rental car company and the US SHE Leader (302-886-7669).

- ❑ Motor vehicle accidents involving employee injuries must also be reported to the Occupational Health Nurse.

  Occupational Health Nurse
  1-800-456-3669 ext. S-I-C-K (7425)
  Pager #888-957-9316

- ❑ Motor vehicle accidents involving third party injuries and/or property damage must also be reported to Gallagher Bassett Services, Inc. (AstraZeneca's Automobile Liability Administrator (800) 433-0181).

- ❑ Motor vehicle accidents that occur while operating a personal vehicle on company business must also be reported to the AstraZeneca Assistant Manager of Insurance and the employee's personal insurance company.

2.4.2. Consolidated Services Corporation will investigate all moving accidents that involve company owned and leased vehicles and submit an accident report to AstraZeneca. As part of this

investigation report, Consolidated Services will also make an initial determination of preventability using AstraZeneca's guidelines for the preventability of motor vehicle accidents (Attachment IV). However, Regional Sales Directors and District Sales Managers must review accident reports in a timely manner and take appropriate action as outlined in Attachment III.

2.4.3 Regional Sales Directors are responsible for completing an Incident Analysis report when an AstraZeneca employee is injured in a motor vehicle accident (Attachment V).

2.4.4. Company drivers must report moving violations, citations, and convictions (in *any vehicle*) to their immediate supervisor and Consolidated Services Corporation (800-323-6644) by the next working day. Drivers must also report license suspensions or revocations involving themselves and/or permissible drivers by the next working day to their immediate supervisor and Consolidated Services Corporation. The Regional Sales Directors will take appropriate action as outlined in Attachment III. Company drivers and permissible drivers must not operate a company vehicle or drive on company business without a valid driver's license.

2.5. Driver Training

Each Regional Sales Director will ensure that employees who are covered by this program satisfactorily complete a defensive driving course.

2.5.1. All employees who have been issued company vehicles must complete the following training:

- ❑ Smith System safe driving video and corresponding quiz within the first two days of sign-up.
- ❑ Behind-The-Wheel training with their District Sales Manager on their first field day with their manager.
- ❑ District Sales Managers will always consider safe driving as a performance issue when working/riding with sales representatives.

2.5.2. District Sales Managers must be trained as Smith System instructors within the first six months of their appointment.

2.5.3. Permissible drivers must also satisfactorily complete a Smith System Defensive Driving Program which requires a satisfactory MVR check, viewing the Smith System video, and completion of the corresponding quiz (with signature).

2.5.4. All training will be documented within the Regional Business Center.

ATTACHMENT I

Permissible Driver Report

Please contact the Fleet/Safety Department and/or a Regional Business Center to obtain a Permissible Driver Report.

ATTACHMENT II

AstraZeneca Pharmaceuticals Employment History Form Driving Record Supplement

Please contact the Fleet/Safety Department and/or a Regional Business Center to obtain an AstraZeneca Pharmaceuticals Employment History Form Driving Record Supplement.

ATTACHMENT III

Driving Performance

In order to assure a consistent program for all Sales groups, this AstraZeneca incentive program begins new on January 1, 2000. For policy roll-out purposes, the initial eligibility will begin with selectors for model year 2001 for qualified drivers only. Driving records will not be grandfathered. Commencing with policy rollout a motor vehicle report will be ordered for all AstraZeneca Vehicle Drivers. A qualified driver will be defined as an employee who has no moving violations as measured by the MVR and no Preventable Accidents January 1, 2000 (the date Consolidated Services began accident investigation and rating) forward. Incentives will only be paid out in additional vehicle options. No cash or check payment will be given. Awarded additional vehicle options are regarded as income to the employee and will not be grossed up for income tax purposes by the company.

	Incentive/Disincentive
• Authorized driver has no moving violations or preventable accidents for 2 consecutive years. All scheduled and necessary vehicle maintenance has been performed in accordance with AstraZeneca Fleet policy, as certified by driver and immediate supervisor.	– Selected menu of additional vehicle options to be evaluated annually as determined by fleet and sales management. – Discount toward purchase of Company Vehicle.
• Authorized driver has 1 Violation or 1 Preventable Accident.	– Will be addressed in Performance Management System review.
• Authorized driver has 2 Violations during the same calendar year.	– Potential disqualification for the Circle of Excellence Award for that year.
• Authorized driver has 2 Preventable Accidents or one Violation and one Preventable Accident in one year.	– Driving record review committee - sanctions that could include delay or reduction in salary action, ineligibility for promotion for a specific time period, or termination of employment.
• 3 Violations or 3 Preventable Accidents or any combination totaling 3 within 3 years.	– Special driving course attended on personal time.

The following violations are considered flagrant and may lead to suspension or termination on a first offense:

- ❑ Driving under the influence of alcohol or drugs
- ❑ Leaving the scene of an accident
- ❑ A sufficient past violation to put the license in jeopardy of being suspended
- ❑ Driving without a valid driver's license

AstraZeneca
Safe Driving Program
Discount Toward Purchase Of Company Car

If a sales employee has no moving violations and no preventable accidents and permissible drivers have no moving violations or preventable accidents while operating the company vehicle, the employee is eligible for a discount toward the purchase of his or her company car. Vehicle purchase discounts are regarded as income to the employee and will not be grossed up for income tax purposes by the company.

Years of Safe Driving Completed	Percent Discount Earned
Up to 2 years	0%
2 years	2%
3 years	3%
4 years	4%
5 years	5%
6 years	6%
7 years	7%
8 years	8%
9 years	9%
10 + years	10%

The dollar amount discount earned is calculated on the purchase price of the company car. Actual quotes will vary depending on make, model, options, and amount paid for each vehicle. For example, the average resale price for an employee's car is about $6,000. If the employee has been a safe driver for five years, he or she will have earned a $300 discount toward purchase of his or her company car.

ATTACHMENT IV

AstraZeneca Guidelines For Determining The Preventability Of Motor Vehicle Accidents
(Based on the National Safety Council's Guidelines)

A preventable accident is one in which the AstraZeneca driver failed to exercise every reasonable precaution to prevent the accident. The extent of property damage and/or personal injury, to whom the accident occurred, or the location of the accident are not factors in determining preventability.

Accident prevention is based on defensive driving. Defensive driving is driving so as to prevent accidents in spite of the incorrect actions of others, or adverse driving conditions such as weather, traffic, lighting, vehicle, or road conditions, or a driver's physical or mental state.

Each driver involved in an accident usually contributes to it in some degree. If the "other driver" admits he was at fault, it usually only means that he sees how he contributed to the situation. Admission of being at fault by the "other driver," a record of the "other driver" being cited for a traffic violation and witness or police statements of exoneration for the company are not, in themselves, conclusive evidence to adjudge an accident "non-preventable." It is likely that the AstraZeneca driver contributed to the situation in some manner.

Statements of exoneration are generally based on legal responsibility without respect to the definition of preventability used in these guidelines. Consequently, a careful study must be made of all conditions to determine how the employee in question contributed to the situation.

Unless a thorough investigation indicates that the employee in question could not have avoided involvement by reasonable defensive driving practice, the following types of accidents should be regarded as PREVENTABLE.

INTERSECTIONS

Complex traffic movement, blind intersections, or failure of the "other driver" to conform to law or traffic control devices will not automatically discharge an accident as "not preventable." Therefore, AstraZeneca drivers should approach, enter, and cross intersections defensively.

Intersection accidents are preventable even through the driver has not violated traffic regulations. His/her failure to take precautionary measures prior to entering the intersection are factors to be studied in making a decision. When the AstraZeneca driver crosses an intersection and the obvious actions of the "other driver" indicate possible involvement either by reason of his/her excess speed, crossing his/her lane in turning, or coming from behind a blind spot, the accident should be classified as PREVENTABLE.

BACKING

Practically all backing accidents are preventable. A driver is not relieved of responsibility to back safely when a guide is involved in the maneuver. A guide cannot control the movement of the vehicle; therefore, a driver must check all clearances for himself/herself.

FRONT-END COLLISIONS

Regardless of the abrupt or unexpected stop of the vehicle ahead, employees can prevent front-end collisions by maintaining a safe following distance at all times. This includes being prepared for possible obstructions on the highway, either in plain view or hidden by the crest of a hill or the curve of a roadway. Overdriving headlights at night is a common cause of front-end collisions. Night speed should not be greater than that which will permit the vehicle to come to a stop within the forward distance illuminated by the vehicle's headlights.

REAR-END COLLISIONS

Investigation often discloses that drivers risk being struck from behind by failing to maintain a margin of safety in their own following distance. Rear-end collisions preceded by a roll-back, an abrupt stop at a grade crossing, or traffic signal, or when the employee fails to signal a turn at an intersection. should be charged PREVENTABLE. Accidents which result from failure to signal intentions or to slow down gradually should be considered PREVENTABLE.

PASSING

Failure to pass safely indicates faulty judgment and the possible failure to consider one or more of the important factors a driver must observe before attempting the maneuver. Unusual actions of the driver being passed or of oncoming traffic might appear to exonerate a driver involved in a passing accident; however, the entire passing maneuver is voluntary and the driver's responsibility.

BEING PASSED

Sideswipes and cut-off involving an AstraZeneca driver while he/she is being passed are preventable when he/she fails to yield to the passing vehicle by slowing down or moving to the right where possible.

LANE ENCROACHMENT

A safe driver is rarely a victim of entrapment by another driver when changing lanes. Similarly, entrapment in merging traffic is an indication of unwillingness to yield to other vehicles or to wait for a break in traffic.

Blind spots are not valid excuses for lane encroachment accidents. Drivers must make certain there are not vehicles in their blind spots before changing lanes. Also, employees are expected to avoid traveling in other drivers' blind spots and to exercise additional cautions when they must do so.

Squeeze plays causing involvement with parked cars, pillars, and other road structures can be prevented by dropping back when it is apparent that the other driver is forcing the issue or contesting a common portion of the road.

OPPOSING VEHICLES

It is extremely important to check the action of the AstraZeneca driver when involved in a head-on or sideswipe accident with a vehicle approaching from the opposite direction. Exact location of vehicles, prior to and at the point of impact, must be verified. Even though an opposing vehicle enters the employee's traffic lane, it may be possible for the employee to avoid the collision. For example, if the opposing vehicle was in a passing maneuver and the employee failed to slow down, stop, or move to the right to allow the vehicle to reenter his/her own lane, he/she has failed to take action to prevent the occurrence. Failing to signal the opposing driver by flicking the headlights or sounding the horn should also be taken into account.

TURNING

Turning movements, like passing maneuvers, require the most exacting care by an employee. "Squeeze plays" at left or right turns involving other vehicles, scooters, bicycles, or pedestrians are the responsibility of the driver making the turn. Failure to signal, to properly position the vehicle for the turn, to check the rearview mirrors, to check pedestrians lanes, or to take any other defensive action should be considered. Sudden turns by other drivers should be carefully examined. You may find that the employee failed to take precautionary action from tip-offs from the other vehicle immediately preceding the incident. U-turns by the employee that result in a collision are PREVENTABLE.

PASSENGER ACCIDENTS

Passenger accidents in any type of vehicle are preventable when they are caused by faulty operation of the vehicle. Even though the incident did not involve a collision of the vehicle, it must be considered preventable when the driver stops, turns, or accelerates abruptly. Emergency action by the company driver to avoid a collision that results in passenger injury should be checked to determine if proper driving prior to the emergency would have eliminated the need for the evasive maneuver.

PEDESTRIANS

Traffic regulations and court decisions generally favor the pedestrian hit by a moving vehicle. An unusual route of a pedestrian at mid-block or from between parked vehicles does not necessarily relieve a driver from taking precautions to prevent such accidents. Whether speed limits are posted or the area is placarded with warning signs, speed too fast for conditions may be involved. School zones, shopping areas, residential streets, and other areas with special pedestrian traffic must be traveled at reduced speeds equal to the particular situation. Young and inexperienced operators generally operate bicycles, motor scooters, and similar equipment. The driver who fails to reduce his/her speed when this type of equipment is operated within his/her sight-distance has failed to take the necessary precautions to prevent an accident. Keeping within posted speed limits is not taking the proper precaution when **unusual** conditions call for voluntary reduction of speed.

WEATHER

Adverse weather conditions are not a valid excuse for being involved in an accident. Rain, snow, fog, sleet, or icy pavement have never **caused** an accident. These conditions merely increase the hazards of driving. Failure to adjust driving to the prevailing weather conditions should be cause for judging an accident preventable. When driving in poor weather conditions, employees are expected to drive at speeds which will enable them to maintain complete control of their vehicle at all times, and to increase the distance between their vehicles and the vehicle ahead (following distance). If the investigation indicates that the employee was driving too fast for conditions, or if he/she failed to maintain a safe following distance, it should be regarded as preventable.

ALLEYS, DRIVEWAYS, AND PLANT ENTRANCES

Accidents involving traffic originating from alleys, driveways, plant entrances, and other special intersecting locations should be carefully analyzed to determine what measures the AstraZeneca driver might have taken to avoid the occurrence. Failure to slow down, sound a warning, or to yield to the other driver should be considered cause to judge such an accident preventable.

FIXED OBJECTS

Collisions with fixed objects are preventable. They usually involve failure to check or properly judge clearances. New routes, strange delivery points, inclined entrances to docks, marquees projecting over traveled section of road and similar situations are not, in themselves, valid reasons for excusing a driver from being involved. He/she must be constantly on the lookout for such conditions and make the necessary allowances.

PARKING

Unconventional parking locations, including double parking, generally constitute evidence for judging an accident preventable.

MECHANICAL FAILURE

Any accident caused by mechanical failure that reasonably could have been detected by the driver, but went unheeded, should be judged preventable. It is the driver's responsibility to report unsafe vehicle conditions for repairs and to obtain immediate repairs where continued operations might result in an accident.

An accident caused by mechanical failure that results from abusive driving should be considered preventable.

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NON-COLLISION

Many accidents, such as overturning or running off the road, may result from emergency action by the driver to preclude being involved in a collision. Examination of his/her driving procedure prior to the incident may reveal speed too fast for conditions or other factors. The employee's actions prior to involvement should be examined for possible errors or lack of defensive driving practice.

ANIMALS

Accidents in which the AstraZeneca employee strikes an animal should be carefully analyzed to determine what measures the employee might have taken to avoid the collision. Failure to properly scan the driving environment for animals, or traveling at speeds too fast for weather, traffic, road, or lighting conditions should considered cause to judge such accidents as preventable.

ROAD HAZARDS, POTHOLES, AND CONSTRUCTION AREAS

Accidents in which the AstraZeneca employee strikes a large pothole or a road hazard, such as a large rock, tree branch, or other debris, are almost always preventable. They are usually the result of the employee's failure to properly scan the roadway far enough in advance for such hazards and/or driving at speeds too fast for the prevailing weather, traffic, road, or lighting conditions.

CONCLUSION

It is impossible to describe in detail the many ways a driver might prevent an accident without being primarily or legally responsible.

The following definition of Defensive Driving should be applied to all accidents involving AstraZeneca drivers:

> A DEFENSIVE DRIVER is one who commits no driving errors himself/herself and makes allowances for the lack of skill or improper driving practice of the other driver. A DEFENSIVE DRIVER adjusts his/her own driving to compensate for unusual weather, road, and traffic conditions and is not tricked into an accident by the unsafe actions of pedestrians and other drivers. By being alert to accident-inducing situations, he/she recognizes the need for preventive action in advance and takes the necessary precautions to prevent the accident. As a DEFENSIVE DRIVER, he/she knows when it is necessary to slow down, stop, or yield right-of way to avoid involvement.

ATTACHMENT V

Incident Analysis Report

Please contact the Fleet/Safety Department and/or a Regional Business Center to obtain an Incident Analysis Report.

Engaging Healthcare Professionals

AstraZeneca

ENGAGING HEALTHCARE PROFESSIONALS FOR CONSULTING SERVICES **Policy No.: M&S-F-1** F-1

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

To provide a policy to govern AstraZeneca's retention of healthcare professionals for consulting services in exchange for some form of compensation (monetary, gift, perquisite, etc.) in a manner which complies with all applicable laws and relevant company policies. This policy applies to the retention of US healthcare professionals by any AstraZeneca entity including foreign affiliates. This policy is not intended to apply to the retention of healthcare professionals for clinical trial programs. For such activities, please consult company policies on clinical trial programs.

2. Policy

2.1. Types of Consultant Activities

AstraZeneca often retains healthcare professionals for consulting services. Although the types of consulting services for which AstraZeneca retains healthcare professionals can vary, generally, they involve either the healthcare professional providing input and valuable information to the company (for purposes of this policy this will be referred to as "Consultant Advice"), or the healthcare professional educating and training personnel designated by the company or being trained by the company to provide such education (for purposes of this policy this will be referred to as "Speaker/Employee Training"). It is important to understand that regardless of the term used to describe a particular relationship or program, if a healthcare professional is engaged to provide services, the provisions of this policy apply.

2.1.1. Consultant Advice

Examples of activities for which AstraZeneca may utilize a healthcare professional for Consultant Advice include the following:

- ❑ Assessment of Current practice patterns (how healthcare professionals treat certain diseases and why)
- ❑ Assessment of Chain of influence - understanding who is affecting their practice pattern

- Reactions to company promotional materials
- Reactions to company patient education materials
- Discussion of needs in terms of CME or educational topics
- Reactions to company products strategy
- Reactions to company product messages
- Assessment and advice regarding a product's adverse event profile

Terms used to describe types of Consultant Advice in former Astra and former Zeneca include the following:

- Advisory Programs (national, regional (including RAPs), or local)
- Advisory Boards
- Thought Leader Panels
- National and Regional Consultant Meetings
- Advisory Summit Programs

2.1.2. Speaker/Employee Training

Examples of activities for which AstraZeneca may retain a healthcare professional for Speaker/Employee Training include the following:

- A faculty workshop designed to provide an educational platform to enhance the presentation skills, media skills, etc. of healthcare professionals who will serve as AstraZeneca speakers
- A forum designed to educate and/or update company speakers on topics (such as AstraZeneca products) on which they might be consulted by AstraZeneca or on which they might speak on behalf of the company
- A tutorial that consists of an interactive discussion with AstraZeneca employees led by a healthcare professional
- A preceptorship opportunity for an AstraZeneca employee to spend a half or full day with a healthcare professional to learn about disease entities, clinical practices and procedures, and other pertinent information

Terms used to describe types of Speaker/Employee Training in former Astra and former Zeneca include the following:

- Faculty Workshops
- Tutorial Programs
- Preceptorships
- Speakers Update Meetings

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

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2.2.1. A healthcare professional may only be retained for consulting 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 with healthcare professionals are appropriate and conform to applicable legal and company standards include the following:

- ❑ Gaining access to the healthcare professional, in and of itself, no matter how valuable to the company is not a bona fide business need.
- ❑ If more than one consultant is retained to provide the same services, the company must have a genuine business need for the services to be provided by all of the consultants in the aggregate.
- ❑ "Token" consulting 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 consultant must be qualified to perform the services.
- ❑ The services must actually be provided.

2.2.2. It is critical that the intent of any programs involving the retention of consultants is clear both to AstraZeneca employees and to the attendees. Attendees are retained and compensated for the time and the bona fide, necessary services being provided to AstraZeneca. Specifically, everyone must understand what these programs are and are not. These programs are not:

- ❑ Promotional Programs
- ❑ CME
- ❑ An opportunity to entertain customers

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

If AstraZeneca were to characterize a meeting as Consultant Advice or Speaker/Employee Training, or as another bona fide consultant arrangement, but the meeting did not involve bona fide services for which the company has a legitimate business need, or if AstraZeneca properly characterized the meeting but did not follow the requirements for such meetings set forth below 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 of critical importance to determine whether a meeting or other interaction with a healthcare professional is legitimately for necessary consulting services, and if so, to assure that all requirements of this policy are met. Your Legal and Regulatory contacts are available to advise you on these matters.

3. *Requirements for Consultants and Consultant Meetings*

3.1. Selection of Consultants

Consultants should be selected based on their ability to provide the service for which they are being retained. **A healthcare professional should never be selected as a consultant in return for, as an inducement to, or in any way in consideration of, the prescribing, purchasing, use, or dispensing of AstraZeneca products or based upon their prescribing practices.** 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 the consultant. For example, whether a healthcare professional was a prescriber would be relevant in selecting a healthcare professional as a consultant where the purpose of the consultation is to evaluate a proposed advertisement directed to non-prescribers.

3.2. Consultant Agreement

Any time a healthcare professional is retained as a consultant, a written agreement signed by both AstraZeneca and the consultant is required. The agreement must include the following **(any exceptions must be approved by your Legal Representative):**

- ❑ A description of the services to be provided
- ❑ 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
- ❑ The term of the agreement
- ❑ The total compensation to be paid for the services

Your Legal Representative can provide you with an appropriate form agreement meeting these requirements.

3.3. Consultant Meeting Logistics

To the extent it is necessary to convene a meeting of healthcare providers performing consulting services, the provisions of this section, as well as any applicable company Guidelines, apply.

3.3.1. Duration

- ❑ The meeting should be only as long as needed to reasonably perform the service and to accommodate reasonable travel requirements.
- ❑ The overwhelming majority of the time of the meeting must be spent on the services which the consultant is providing.

3.3.2. Venue, Travel, Entertainment, and Meals

- Meetings held outside the continental U. S. and Canada must be reviewed and approved by the Lead or the National Sales Director of the relevant Therapeutic Area except for a regional meeting held within its own region which is located outside of the continental U. S. and Canada.
- Travel by air and rail shall be by coach class. Travel by car shall be reimbursed for mileage traveled at standard rates set by the IRS. Any exceptions must be approved by the Lead or National Sales Director of the relevant Therapeutic Area or designate.
- Meals and any entertainment provided must be reasonable. The overwhelming majority of the time of the meeting must be spent on the services, which the consultant is providing. It is critical to keep in mind that the goal of the meeting is to obtain the benefit of the healthcare professionals' services, not to entertain them.
- Appropriate accommodations would be those with a number 4 rating in the Mobil Guide. This would include properties such as Sheraton, Westin, Hyatt, and Marriott. The company's Meeting Services Group can provide you with a complete list of properties that meet this requirement. Accommodations with a rating above 4 are not permissible without the approval of the Lead or National Sales Director of the relevant Therapeutic Area. 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 such as travel and accommodations.
- 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 as illegal remuneration.

3.3.3. Compensation

- The amount of compensation paid to the consultant must be reasonable, set in advance, and based on the fair market value of the services provided in an arms-length transaction.
- The amount to be paid to the consultant must not be determined in a manner that takes account of the past, present, or future volume or value of business generated by the consultant for the company (e.g., prescriptions written by a physician).
- See Guidelines for particular types of consultant meetings for company-approved compensation rates.
- Compensation should be paid with a company check; cash or personal checks may not be used.

3.3.4. Attendees from AstraZeneca

Attendance by AstraZeneca employees, or particular groups of AstraZeneca employees, may be limited at consultant meetings depending on the activities which are to take place and the topics to be covered (for example, Pharmaceutical Sales Specialists generally would not be permitted to attend sessions where consultants would discuss off- label uses of our products). Please see Guidelines for particular consultant meetings regarding permitted AstraZeneca attendees.

3.3.5. Number of Consultants and Number of Consultant Meetings

The number of healthcare professionals retained for consulting services as well as the number of meetings held with consultants should be determined by legitimate business needs for the services.

4. References

4.1. M&S Business Policies

Gaining Access to Healthcare Professionals (M&S-B-2);
AstraZeneca Standards for CME and Other Scientific and Educational Activities (M&S-C-2).

AstraZeneca

PRECEPTORSHIP GUIDELINES **Guideline No.: M&S-F-G-1-a** F-G-1a

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Introduction

Preceptorships provide an opportunity for AstraZeneca employees to spend a half or full day with a healthcare professional (the Preceptor) to learn about disease entities, clinical practices and procedures, therapeutics issues, and other pertinent information. Since AstraZeneca is retaining preceptors to provide bona fide services to the employees of AstraZeneca, these programs are subject to discretion as employee training programs under the Astra Zeneca policy **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1).

1.2. Overview

1.2.1. Objectives

The goal of the Preceptorship is to expand AstraZeneca employees' understanding of the physician's practice and the disease entities affecting the physician's patients.

1.2.2. Content of the Program

- Preceptors should be prepared to allow AstraZeneca employees to accompany them in the conduct of patient visits, administrative duties, medical consults, and other activities pertaining to their normal daily routine.
- AstraZeneca employees should not initiate product promotional practices during a Preceptorship. If the employee receives a question about an AstraZeneca product during the Preceptorship, the employee must keep all comments within product labeling, in accordance with the policy Product Promotion (M&S-B-1).
- Full prescribing information for any AstraZeneca product discussed during the Preceptorship must be offered to the Preceptor.

1.2.3. Patient Confidentiality

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

- ❑ Prior to participating in the Preceptorship, the Preceptor and the AstraZeneca 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.
- ❑ The physician should be directed to inform the patient that the AstraZeneca representative is not a healthcare practitioner and obtain the consent of the patient(s) for having the representative present for the Preceptorship program
- ❑ 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.

1.3. Preceptorship Selection

Preceptors should be selected based on their ability to educate the AstraZeneca employee. The Preceptor should not be selected in return for, as an inducement to, or in any way in consideration of, the prescribing, purchasing, use or dispensing of our products or based upon their own prescribing practices. These physicians (or other acceptable healthcare professional) should possess the ability to answer questions on a variety of related topics for the AstraZeneca employee. The physician should also be willing to allow the AstraZeneca employee to be present during the normal activities of their day.

- ❑ When a physician has been identified and confirmed for the Preceptorship, have the Preceptor agree to and sign the Preceptorship Agreement. This information should be provided to the AstraZeneca Lecture Bureau.

1.4. Preceptorship Set-Up

Follow the guidelines listed in the *COMPASS & NorthStar Reference Manual* to create, submit, review, and approve Preceptorship requests.

1.5. Honoraria

1.5.1. Honoraria for Preceptorships should be paid directly to the speakers using their social security numbers or federal tax identification numbers if they are legally incorporated.

- ❑ If an honorarium is paid to an organization, it must be paid to the Preceptor's own organization or the organization for which the Preceptor directly works.
- ❑ According to IRS regulations, a Preceptor's honorarium cannot be paid directly to a charitable organization on behalf of the Preceptor. The Preceptor must claim the honorarium as income and then 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 honorarium payment to the Preceptor.

1.5.2. The recommended honoraria range for local Preceptorships is $0-250 for a half day, $0-500 for a full day. A standard honoraria 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 honoraria range.

1.5.3. There are times when training is initiated by the product teams or by sales training and the fair market value of the services that are being purchased from the Preceptor is higher than the local amount. Acceptable honoraria amounts will be determined for these programs on a case-by-case basis.

1.5.4. Honoraria will be funded locally by the Therapeutic Area for the district or region responsible for the AstraZeneca employee participating in the Preceptorship unless the program is initiated by the product team or by sales training.

2. Administrative Information

- ❑ Submit request for honoraria through Compass using Preceptorship Type of Program under Speaker Programs.
- ❑ There should not be expenses associated with the Preceptorship. Any out-of-pocket expenses (e.g., lunch) should be submitted on your expense report to your manager via GELCO/Expense Link.
- ❑ A Preceptorship contract should be on file for each Preceptorship. If not on file, a contract must be signed and received by AstraZeneca prior to the Preceptorship check being disbursed.

F-G-1a

3. *Required Contracts*

- ❑ Preceptorship Agreement

4. *References*

4.1. M&S Business Policies

Patient Privacy (M&S-A-6); **Product Promotion** (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Professional Education Programs** (M&S-C-3); **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1).

AstraZeneca

TUTORIAL PROGRAM GUIDELINES Guideline No.: M&S-F-G-1-b F-G-1b

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Introduction

A Tutorial consists of an interactive discussion with AstraZeneca employees, led by a medical thought leader within the territory engaged by AstraZeneca. Medical thought leaders usually are physicians, but also may be other healthcare professionals (e.g., managed care specialists, consultants, etc.). A Tutorial may be held in a healthcare professional's office, at a company meeting or in a restaurant setting. Since AstraZeneca is retaining these thought leaders to provide bona fide services to the employees of AstraZeneca, these programs are subject to discretion as employee training programs under the AstraZeneca policy **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1).

1.2. Objective

The objective of the Tutorial program is to reinforce and raise AstraZeneca employees' knowledge of disease entities, drug therapies, and local healthcare attitudes and trends.

1.3. Content Of Program

The content of the program should be discussed in advance with the medical thought leader and shared with all AstraZeneca employees who will be in attendance. To ensure success, everyone should have time to make a list of questions or topics in which they are interested so that the 'take away' value of the Tutorial is enhanced for all.

1.4. Tutorial Set-up

Follow the guidelines listed in the *Compass & NorthStar Reference Manual* to create, submit, review, and approve Tutorial requests.

- ❑ All Tutorial program topics must come from the approved talk title list in Compass.

- On occasion, in preparation for the launch of a new product or a new indication for an AstraZeneca product, 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 entity that is new to AstraZeneca and the soon-to-be launched product, or an indication that is not yet approved, in anticipation of approval. These Tutorials are often recommended by the Therapeutic Area and by Sales Training, to assist with the training of field personnel and may be scheduled close to the launch of new product or indication. In this case, Therapeutic Areas and Sales Training must approve of the speakers and materials that are used to provide this training and PRA must approve the training materials and information that will be used to perform this training (*see* **Product Promotion,** M&S-B-1).

1.5. Titles and Presentation Topics

- Only topics approved by PRA should be used.
- Any AstraZeneca employee can submit new topics/titles for approval by PRA (contact your Field Promotion Manager (FPM) for assistance in this process).
- All new topics/titles must include a full outline.
- New topics/titles are not restricted to AstraZeneca products or therapeutic areas of interest but they should be relevant to the Healthcare industry and be relevant to customers' practices in their treatment of patients.

1.6. Speaker Criteria

Speakers should be selected based on their ability to educate healthcare practitioners. Speakers may never be selected in return for, as an inducement to, or in any way in consideration of, the prescribing, purchasing, use or dispensing of our products or based upon their own prescribing practices. 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
- Participation in Editorial boards

1.7. Speaker and Program Evaluation and Follow-Up

F-G-1b

A Speaker Evaluation form must be filled out by the AstraZeneca program requester following any paid speaker program. (The feedback feature in Compass for the PREP speaker request can be utilized for submitting the speaker evaluation). The AstraZeneca employee who scheduled the Tutorial Program is responsible for collecting feedback on the program and entering that information into Compass. The AstraZeneca requester should be responsible for ensuring that any follow up opportunities that arise from the program are communicated to the appropriate persons in AstraZeneca (ex. Mirrored counterparts, sales management, marketing or promotions managers, Medical Information Scientists, etc.).

Relevant speaker evaluation criteria should include:

- ❑ Knowledge of the topic and ability to present the material accurately
- ❑ Fair and balanced presentation
- ❑ Whether speaker stayed within the approved topic guidelines
- ❑ Ability of the speaker to maintain attention of audience and facilitate question and answer session
- ❑ Ability of the speaker to field questions from the audience and answer with a professional and educational response
- ❑ Overall presentation quality

The program evaluation should include:

- ❑ Documenting the Customer Unit members' most important "take aways" from the meeting
- ❑ Best practices for running these programs

1.8. Removing Faculty

Recommendations for the removal of a speaker from the AstraZeneca pool of approved speakers can be made by contacting the Professional Education department and describing the specific reasons for your recommendation. The recommendation will be handled as follows:

- ❑ The Professional Education department will evaluate the recommendation for removal and contact any others in AstraZeneca that need to be involved in the removal decision.
- ❑ Final decision will be made jointly by the Professional Education department and the appropriate member of sales management responsible for that customer.
- ❑ After a decision to remove a speaker from the AstraZeneca pool of approved speakers, the Professional Education department will remove the speaker's name from the database.

Speakers may be removed for any reason, including but not limited to:

- ❑ Not keeping within presentation guidelines (unbalanced/biased presentation)
- ❑ Hostility towards audience
- ❑ Lack of preparation
- ❑ Inappropriate behavior
- ❑ Poor presentation quality

1.9. Speaker Expenses

AstraZeneca 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.

- ❑ 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 exceeding $25.
- ❑ Expenses should not be paid for directly by AstraZeneca unless there are extenuating circumstances and prior approval is obtained from the DSM
- ❑ Speaker travel and lodging expenses must never be paid for by any AstraZeneca employee and submitted as a personal expense for reimbursement.

1.10. Honoraria

- ❑ Standard honorarium for the leader of a Tutorial is in the range of $200-$500; on a case by case basis honoraria may be adjusted when approved by your DSM provided that the amount is within the range of fair market value for the qualifications of the leader and the services being provided.
- ❑ Honoraria should be paid directly to the speaker using their social security number or federal tax identification number if they are legally incorporated.
- ❑ Honoraria for Tutorial speakers must be paid by AstraZeneca's Accounts Payable department, never by a third party organization or an AstraZeneca employee.
- ❑ Honoraria and speaker expenses will be funded locally by the district or region responsible for the AstraZeneca Employees.

2. Administrative Information

- ❑ Submit request for honoraria through Compass using Tutorial Type of Program under Speaker Programs.
- ❑ Speaker expenses and honoraria should be submitted to AstraZeneca Lecture Bureau for processing.
- ❑ A Tutorial contract must be signed prior to the speaker conducting program.

3. *Required Contracts*

F-G-1b

- ❑ AstraZeneca Tutorial Contract (one tutorial contract per event)

4. *References*

4.1. M&S Business Policies

Gaining Access to Healthcare Professionals (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Professional Education Programs** (M&S-C-3); **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1).

AstraZeneca

FACULTY UPDATE GUIDELINES **Guideline No.: M&S-F-G-1-c** F-G-1c

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Guidelines

1.1. Introduction

The objective of the AstraZeneca Faculty Update Program is to provide a platform for AstraZeneca to ensure that National and Regional speakers are properly trained and can adequately and skillfully present information on behalf of AstraZeneca. Through use of the AstraZeneca Faculty Update program, AstraZeneca can ensure that there is an adequate pool of National and Regional speakers prepared to deliver presentations related to AstraZeneca's currently marketed products and therapeutic areas. This program will typically be held when there is new information for one of AstraZeneca's currently marketed products or a new product that needs to be launched (e.g., scientific update or slide kit training).

Faculty updates involve consulting services. Please see **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1) as the provisions of this policy apply to Faculty Updates.

To ensure the successful outcome of this program across all participating Business Centers and Therapeutic Areas, AstraZeneca has designed an interactive and educational program with the goal of promoting consistent and measurable results. These programs must not be used to train more speakers than can reasonably be used for programs within the Therapeutic Area and speakers may not be trained more than once on the same matter.

1.2. Responsibilities/Assignments

1.2.1. Medical Information Scientists

- ❑ Identify speakers for the programs
- ❑ Review approved slides, talk titles, and program details with speakers
- ❑ Attend Workshop
- ❑ Provide speaker scientific support during workshop preparation when appropriate
- ❑ Perform assessment of scientific accuracy of speakers

- ❑ Meet with speakers post program to follow up on scientific topics that need further MIS support

1.2.2. Field Promotions or Regional Sales Management (Regional Programs only)/Professional Relations & Education Managers (National Programs only)

- ❑ Work with MIS (Regional) or TA (National) to identify appropriate individuals as potential speakers for AstraZeneca based on Speaker Criteria
- ❑ Submit PREP speaker requests (1 per speaker) in Compass (Regional)
- ❑ Complete payment request spreadsheet (National)
- ❑ Confirm completion of speaker contract by each speaker
- ❑ Craft invitation from approved template or submit new invitation to PRA for approval
- ❑ Mail sufficient invitations with the goal of confirming desired number of speakers
- ❑ Follow-up to ensure speaker's receipt of invitation
- ❑ Confirm participating speakers
- ❑ Choose presentation skills vendor identified by Field Professional Education Department or an alternate vendor who will develop program with goals outlined in guidelines, if included in agenda (refer to Attachment A for Sample Objectives of Optional Speaking Skills Session)
- ❑ Contact vendor to confirm date of program and local venue
- ❑ Coordinate venue
- ❑ Attend Program
- ❑ Provide support to speakers prior to presentation in venue ready rooms
- ❑ Utilize these trained speakers to speak at professional education programs for AstraZeneca
- ❑ Submit participating speaker information to PREP (Regional) or communicate to Regions to promote speaker utilization (National)
- ❑ Document with MIS or AstraZeneca Lecture Bureau which speakers have participated in programs and identify according to therapeutic area
- ❑ Deliver program opening and closing remarks
- ❑ Assure that no more speakers than necessary attend each program
- ❑ Honoraria, speaker expenses, and program expenses will be funded locally by the Therapeutic Area district or region responsible for the speakers participating in the program if initiated locally or by the TA if initiated centrally

1.3. Size and Frequency

- 10-15 physicians should be trained per Regional Faculty Update program
- No more than one program per Region should be held for each new product or new product information training need
- 30-50 physicians should be trained per National Faculty Update program
- There may not be more speakers trained Nationally or Regionally than reasonably are planned to be used to provide speaking services for AstraZeneca on a routine basis
- If training on speaking skills is included, a physician speaker should only receive this training once
- Physicians that are existing speakers and need to be trained on new product information can be involved in multiple programs to receive updated information, however they should not receive speaking skills training more than once
- The number of Regional Faculty Update programs to be conducted per year should be approved as part of the Region business plan by the TA Regional Sales Director

1.4. Speaker criteria

Speakers should be selected based on their ability to educate healthcare practitioners. Speakers should not be selected in consideration of, as an inducement to, or in return for the prescribing, purchasing, use or dispensing of our products or based upon their own prescribing practices. When selecting a speaker, the speaker must be qualified to speak on the subject matter.

Speakers that are trained during this workshop should be chosen based on the bona fide need for AstraZeneca to retain them for the speaking services to be provided and their ability to meet those needs

Additional 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/health care 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

F-G-1c

1.5. Program Logistics

- ❑ Lodging paid for only if program exceeds one day and/or travel is reasonably required
- ❑ Venue at location suitable for conduct of program that allows adequate room space and privacy for presentations, speaker ready rooms, and one on one consultation with the vendor.
- ❑ Venue should not be more extravagant than is necessary for the conduction of the program content (*see* **Engaging Healthcare Professionals for Consulting Services,** M&S-F-1).

1.6. Vendor Requirements for optional Speaking Skills session
(see Attachment A for additional information)

- ❑ Conducted by the vendor and with participation exclusively by speakers (no employee training)
- ❑ AstraZeneca employees may attend and observe but may not participate in the speaker skills training activities
- ❑ Designated AstraZeneca employees can be available to support speakers in the ready rooms
- ❑ One vendor consultant will moderate speaking skills assessments
- ❑ Each speaker will make their practice presentations required by the workshop including time for Q&A
- ❑ Speakers will utilize slide kits and/or approved talk topic previously given to speaker by MIS
- ❑ Vendor will be required to complete one assessment per speaker

1.7. Assessments

- ❑ Vendor will administer and collect speaking assessments
- ❑ Assessment results will be made available to each respective speaker
- ❑ Assessments will be compiled into a report with vendor narrative remarks
- ❑ Report will be sent to each respective Regional Sales Management and MIS with copy to Field Professional Education Department
- ❑ For Regional meetings, MIS will complete scientific accuracy assessment and schedule follow-up meetings with speakers, if necessary. For National meetings, this assessment should be completed by a designated member of the TA within CDMA, such as the Medical Marketing Manager.

1.8. Honoraria

- ❑ Honoraria for speakers have been determined at the fair market value for the type of services that are being provided.
  - ❑ The acceptable honoraria for a speaker at a Regional Faculty Workshop is $500. Honoraria in excess of this amount must be approved by the NSD for that TA.

- ❑ The acceptable honoraria for a speaker at a National Faculty Update program should be within the range of $1,000-2,000. Honoraria in excess of this amount must be approved by the TA Leader or their designee.
- ❑ Honoraria should be paid directly to the speaker using their social security number or federal tax identification number if they are legally incorporated.
- ❑ Honoraria for speakers must be paid by AstraZeneca's Accounts Payable department, never by a third party organization or an AstraZeneca employee.
- ❑ Honoraria for Regional programs will be funded locally by the Therapeutic Area within the Region responsible for the AstraZeneca employee requesting funds.
- ❑ Honoraria for National programs will be funded centrally by the Therapeutic Area responsible for the program.
- ❑ If a stipend is to be provided in lieu of expense reimbursement for a Regional program, the honoraria amount should be increased by $100 in the Compass request.

1.9. Speaker Expenses

If a stipend is not a reasonable alternative to cover expenses (i.e., expected expenses will exceed $100), AstraZeneca 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.

- ❑ 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 AstraZeneca unless there are extenuating circumstances and prior approval is obtained from the Professional Education department.
- ❑ Speaker travel and lodging expenses must never be paid for by any AstraZeneca employee and submitted as a personal expense for reimbursement.

2. Required Contracts/Documentation

- ❑ AstraZeneca Speaker Contract
- ❑ Vendor Contract
- ❑ Post-Program Assessment

3. *References*

3.1. AstraZeneca Approved Talk Titles (located in Compass)

3.2. PRA approved slide kits

3.3. M&S Business Policies

Engaging Healthcare Professionals for Consulting Services (M&S-F-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Professional Education Programs** (M&S-C-3).

ATTACHMENT I

Sample: Objectives of Optional Speaking Skills Session Conducted by Vendor

1.1. Introduction

- ❑ Instructor charts responses from speakers on impressions and perceptions they want to leave with their audience
- ❑ Speakers discover for themselves, without being told by a consultant, that they are concentrating more on content and data than delivery
- ❑ Speakers discover importance of speaking skills in conveying successful messages

1.2. Baseline

- ❑ Speaker presents a brief set of "Opening Remarks" from the product presentation
- ❑ Each delivers in his/her own style and receives objective feedback (not a critique) from his/her peers
- ❑ Feedback serves as baseline starting point from which to gauge individual and group improvement as the workshop progresses

1.3. Enhancing Speaking Skills

- ❑ Instructor offers options and suggestions in several specific areas (Eyes-Voice-Hands-Posture-Filler words)
- ❑ Every participant practices each new skill or behavior with coaching from the instructor
- ❑ Skills are "layered" upon one another and peer feedback is constantly driven back to support the chart containing the impressions and perceptions each speaker wants to convey

1.4. Facilitation Module

- ❑ Concept of a more interactive presentation versus the classic didactic lecture style most presenters practice is introduced
- ❑ Concept of querying the audience's interests, questions, and objectives prior to moving into the data will be practiced

1.5. Questions and Answers

- ❑ Presenter now needs to field and control questions and answers confidently
- ❑ Instructor will offer a set of skills each speaker will again practice to succinctly field, process, and answer questions with confidence and poise
- ❑ These skills allow the speaker to negotiate and handle questions asked during the presentation, which might otherwise potentially derail the speaker

1.6. Workshop Presentation

- ❑ Instructor/coach now becomes a mentor for the speakers
- ❑ Instructor provides an objective eye by which to measure each speaker's improvement
- ❑ Assessment tool allows Region/TA to confidently compile a roster of physician speakers for future presentations on behalf of AstraZeneca

AstraZeneca

ADVISORY PROGRAM GUIDELINES Guideline No.: M&S-F-G-1-d F-G-1d

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

Advisory Programs have been designed so that AstraZeneca can better understand disease states, treatment regiments, customer needs, differences among customer segments and geographic locations, etc. Such understanding assists the company in developing product claims, effective product messages surrounding those claims and marketing strategies. The purpose of these programs is to gather information from customers to obtain this understanding. Stated differently, the goal is to seek advice from customers on how best to implement strategies and promotional messages. Advisory Programs can be national, regional, or local in nature.

Advisory programs involve consulting services. Please see the policy on **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1) as the provisions of this Policy apply to Advisory Programs.

It is important to understand that Advisory Programs may not be promotional in design or content.

Advisory Programs are designed to obtain input, reactions and feedback from participants on subjects such as the following:

- ❑ Current practice patterns (how healthcare practitioners treat certain diseases and why)
- ❑ Chain of influence - understanding who is effecting their practice pattern
- ❑ Promotional materials
- ❑ Patient education materials
- ❑ Needs in terms of CME or educational topics
- ❑ Our product strategy
- ❑ Our product message - how can we most successfully communicate this message and the impact of any regional demographics and practice patterns
- ❑ Health economic studies or ongoing clinical development programs
- ❑ Obstacle handling surrounding our product messaging

It is critical that the intent of these programs is clear both to AstraZeneca employees and to the attendees. Attendees are consultants to AstraZeneca. Their services are requested for specific input. Specifically, everyone must understand what these programs are and are not. These programs are not:

- ❑ Promotional programs
- ❑ Speaker training programs
- ❑ An opportunity to entertain customers

2. *Process*

2.1. Overview

2.1.1 Develop annual plan/program proposal

2.1.2 Execute program(s)

2.1.3 Report findings

2.2. Annual Plan

Each Therapeutic Area will develop an annual plan setting forth all the national, regional, and local Advisory Programs planned for the year. The plan will include the following information for each program:

- ❑ A description of the purpose
- ❑ Desired number of participants
- ❑ Budget
- ❑ Geographic Location (and venue, if known)
- ❑ Desired geographic focus (national, regional, or local) and number of each type

The Annual Plan must be sent to the Promotional Regulatory Affairs Leader and the Legal Department contact for the Therapeutic Area. If PRA or Legal have any objections to the Plan, they must be resolved by working with the Therapeutic Area team, and, if necessary, Senior Management. All national, regional, and local Advisory Programs must comply with the annual plan. Any changes to the annual plan, and any plans for Advisory Programs inconsistent with or in addition to those set forth in the annual plan require prior approval of the Lead of the US Therapeutic Area or his/her designee, and must be reviewed by the Legal Department contact for the Therapeutic Area. If Legal has any objections to the changes, these objections must be resolved as set forth above.

3. *Program Execution*

3.1. Advisory Program Agreement

A written agreement is required for each participant in an Advisory Program. Please see the policy on **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1) for details.

3.2. Meeting Agenda

The meeting must be designed to provide meaningful opportunity for input and feedback from the participants. It must be conducted in a way which results in the capture of legitimate, useful, information.

3.3. Honoraria

Honoraria should be determined based on fair market value. Typical fair market value ranges are set forth below. Generally, honoraria for local or regional programs should be at the lower end of the ranges, while honoraria for national programs should be at the higher end of the ranges. If honoraria fair market value is in excess of the applicable range, the compensation rate must be approved by the Lead or National Sales Director of the relevant Therapeutic Area.

- Participants should be compensated for consulting services provided to AstraZeneca, typically in the range of $500 to $1,000/day.
- Moderators should be compensated, typically in the range of $1,000 to $1,750/day. This amount can be increased if the moderator has to work in advance of the meeting.
- Similarly, if a chairperson is required, they should be compensated at fair market value which will vary depending on the amount of work required. Typically, chairpersons are to be compensated in the range of $1,250 to $2,000/day.

Honoraria for services provided less than a day in duration shall be pro-rated as appropriate.

Expenses including parking, transportation, and, if required, lodging would be reimbursed or a stipend less than or equal to $100 may be offered if an expense reimbursement is not feasible.

3.4. Who should attend from AstraZeneca?

The purpose of these meetings is to gain insight from participants through in-depth discussions. The meetings are intended to provide face-to-face discussion time.

Since the meeting is not meant to be promotional, and should not be perceived as such, it is not appropriate for Pharmaceutical Sales Specialists to attend the research sessions at the meeting (unless they are participating in a mock detail on which information is being gathered or unless the purpose of the program is to educate the sales representatives via the feedback from the

participants). Pharmaceutical Sales Specialists can attend social activities that are associated with the meeting.

3.5. Number of Participants

Each meeting should have no more participants than reasonably necessary to achieve the desired outcome. The appropriate number of participants could vary due to such factors as the topics covered, as well as whether the program is national, regional or local in scope.

3.6. Report Findings

A person must be designated for each program to capture and communicate findings to the relevant Therapeutic Area Team. These summaries should provide findings and recommendations for each of the subjects covered. A copy of the findings for each program must be sent to the Promotional Regulatory Affairs Leader.

4. *Required Contracts/Documentation*

- ❑ Annual Plan
- ❑ Chairperson Contract (if applicable)
- ❑ Moderator Contract (if applicable)
- ❑ Participant Contract
- ❑ Support documents such as invitations can be used in the approved formats
- ❑ Summary Document

5. *References*

5.1. M&S Business Policies

Ethical and Professional Conduct (M&S-A-1); **Product Promotion** (M&S-B-1); **Gaining Access to Healthcare Professionals** (M&S-B-2); **AstraZeneca Standards for CME and Other Scientific and Educational Activities** (M&S-C-2); **Engaging Healthcare Professionals for Consulting Services** (M&S-F-1).

Other

AstraZeneca

PATIENT ASSISTANCE PROGRAM **Policy No.: M&S-G-1** G-1

Issued by: Marketing and Sales
Date Issued: 03/31/2000

1. Purpose

AstraZeneca is committed to providing product free of charge to patients who would otherwise be unable to benefit from the drug because of cost. Product is provided to the indigent population of the US and Puerto Rico through the Patient Assistance Program (PAP).

Currently being developed is a new process for obtaining free product through the PAP. This new process will be available at a later date in 2000. In the interim, this placeholder will appear in the new sales policy.

Legacy policies and procedures for Patient Assistance Program will be followed until the new process is developed.

2. Accessing the Patient Assistance Programs

2.1 AstraZeneca LP Patient Assistance Program

- **Physician Requests Should be Directed to:**

  AstraZeneca Patient Assistance Program
  Physician's office should call (800) 355-6044.

- **Products Covered by Program**

  ATACAND
  EMLA Anesthetic disc
  EMLA Cream
  LEXXEL
  PLENDIL
  PRILOSEC
  TONOCARD
  TOPROL-XL

- **Eligibility**

  The AstraZeneca LP Patient Assistance Program is available to qualified patients with a demonstrated medical and financial need, who have exhausted third party insurance and/or aid from Medicaid and social agencies, and who do not have other means to pay for their medication.

G-1

❑ **Other Program Information**

The physician's office must apply on behalf of a patient. An application is mailed to the provider for his/her signature. Upon receipt and approval of a completed application, a three-month supply of medication will be shipped to the provider's office to be dispensed to the eligible patient.

A re-enrollment is required every three months.

The program is for the benefit of patients who cannot afford to purchase the medication. It must not be used as a sales/marketing tool to influence sales.

❑ **Contact with questions:**

Linda Dawson - (302) 886-4935

2.2 AstraZeneca Foundation Patient Assistance Program

❑ Physician Requests Should be Directed to:

Patient Assistance Program
AstraZeneca Foundation
PO Box 15197
Wilmington DE 19850-5197

For an application, physician's office or patient should call **(800) 424-3727**.

❑ Products Covered by Program

ACCOLATE
ARIMIDEX
CASODEX
NOLVADEX
SEROQUEL
SORBITRATE
SULAR
TENORETIC
TENORMIN
ZESTORETIC
ZESTRIL
ZOLADEX
ZOMIG

❑ **Eligibility**

Patient applications are evaluated on a case-by-case basis by the AstraZeneca Foundation. Eligibility is based on income level/assets and absence of outpatient private insurance, third-party coverage, or participation in a public program. Income eligibility is based upon multiples of the US poverty level adjusted for household size.

❑ **Other Program Information**

G-1

Reapplication is required every 12 months. A reapplication is automatically sent to enrolled patients. Patient/family members/physician can obtain applications forms from the Foundation by calling the number indicated above. Physicians can also obtain a packet of applications from their sales representative. Enrollment in the program requires a valid Social Security Number. A $5 shipping/handling fee in the form of a money order or credit card is required with each prescription for all products except SEROQUEL. In most cases, the product is sent directly to the patient's address (exception: SEROQUEL and ZOLADEX).

The program is for the benefit of patients who cannot afford to purchase the medication. It must not be used as a sales/marketing tool to influence sales.

❑ **Contact with questions:**

Linda Dawson - (302) 886-4935

2.3 FOSCAVIR Assistance and Information on Reimbursement (F.A.I.R)

❑ **Physician Requests Should be Directed to:**

State and Federal Associates
1101 King Street
Alexandria, VA 22314

Only the physician should call (800) 488-FAIR (3247).

❑ **Products Covered by Program:**

FOSCAVIR

❑ **Eligibility**

If the patient is not covered for outpatient prescription drugs under private insurance or a public program, the patient's income must fall below the level selected by the company. If the patient has insurance coverage for outpatient prescription drugs, he or she may be eligible for assistance with deductibles or maximum benefit limits. Eligibility is determined by the company based on income information provided by the physician.

❑ **Other Program Information**

Referral must be made by the physician.

The program is for the benefit of patients who cannot afford to purchase the medication. It must not be used as a sales/marketing tool to influence sales.

❑ **Contact with questions:**

Linda Dawson - (302) 886-4935

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GLOSSARY OF TERMS

1. ***ACCME:*** Accreditation Council for Continuing Medical Education publishes guidelines governing industry support for CME programs.

2. ***ACPE:*** American Council on Pharmaceutical Education publishes guidelines governing industry support for pharmacy educational programs.

3. ***An Interactive Workshop for Success:*** An interactive workshop for pharmacy administrators that provides a forum for the discussion of strategies to advance the profession of pharmacy.

4. ***APhA Pharmacy Program:*** ACPE program focusing on "hands on" use of devices available for the treatment of asthma, including Pulmicort Turbuhaler.

5. ***Case Study:*** The Case Study Program, which is educational in nature but not a CME program, was developed to enhance AstraZeneca's ability to assist physicians in educating other physicians who manage patients with therapeutic disorders related to AstraZeneca's portfolio.

6. ***Community Seminar Series (CSS):*** Mainly CME accredited dinner programs discussing the appropriate use of beta-blockers in hypertension and coronary artery disease. Dependent on speaker expertise, the topics vary from hypertension/JNC-VI to CHF.

7. ***Consulting Services:*** Retention of healthcare professionals for consulting services in exchange for some form of compensation (monetary, gift, perquisite, etc.) in a manner which complies with all applicable laws and relevant company policies. These include programs such as:

Preceptorships	Tutorials
Faculty Update	Advisory Programs

8. ***Exhibits***: Used for paying the fees associated with a local exhibit or display. These exhibits are typically held at locations such as local society meetings or local hospitals/institutions. The funds are used only to fund the actual booth space.

9. ***Fair Market Value:*** The reasonable cost to a physician or physician practice, for obtaining a good or service from a third party vendor in the open market.

10. ***Grand Rounds:*** Mainly focused on teaching institutions, but some community hospitals are targeted. A series of cardiovascular Grand Round lectures entitled "Reviewing the evidence: New Perspectives on Beta-Blockade and other Appropriate Therapies in Cardiovascular Disease." These programs were not typically CME accredited.

11. ***Grants:*** A means of providing financial support for non-promotional activities involving medical education over which AstraZeneca has no influence.

12. ***Healthcare Professionals (HCP):***, An individual who has prescribing authority under the relevant laws of the state in which they are licensed. For example – physicians, nurse practitioners, physician assistants. In the institutional or managed care setting, a formulary decision maker (ex. Clinical pharmacists) may also be referred to as a HCP.

13. ***Healthcare Provider:*** Personnel who do NOT have prescribing authority, but who provide healthcare services (nurse, pharmacist).

14. ***Library Grant:*** Support used to update medical libraries, acquire medical textbooks, and provide medically relevant software. It is not intended for supporting customer websites.

15. ***Medical Educational Grant:*** Support used for medical education programs that can be CME or non-CME, where the proceeds are used to support a specific educational activity, not a general fund.

16. ***Micromarketing:*** Expenditure of funds for inexpensive meals, gifts, event tickets, etc. for a customer. See Gaining Access to Healthcare Professionals (M&S B-2) and Professional Education Programs (M&S-C-3, C-G-3-a and C-G-3-b).

17. ***PACE (Patient Centered Asthma Care Education):*** CME program developed in conjunction with AAAAI (via grant). Targets managed care plans with an asthma CME program.

18. ***PAP:*** Patient Assistance Program.

19. ***Pharmacy Educational Grant:*** Support used for pharmacy educational programs that can be ACPE or non-ACPE, where the proceeds are used to support a specific educational activity, not a general fund.

20. ***Physician on Line:*** CME accredited educational monographs and on-line discussion groups with author and moderator.

21. ***PIRs:*** Professional Information Requests. A PIR is an unsolicited request for information about an AstraZeneca product by a healthcare professional which 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 healthcare professional requests further medical information.

22. ***Post-graduate Grant:*** Support used for students, residents, and fellows chosen by the institution to attend continuing medical education conferences or professional meetings.

23. ***PREP (Professional Education Programs):*** educational programs that AstraZeneca provides for its customers. Allows Field Personnel to provide financial support for high quality, ethical and scientifically sound education activities for the health care community. Since AstraZeneca has control, whether it be partial or full control, over certain aspects of such an educational program, the program will typically be regarded as promotional by FDA and is therefore subject to FDA regulation.

24. ***Problem Based Learning (PBL):*** Mostly CME accredited case based programs discussing appropriate therapy for asthma and rhinitis. Used for smaller groups (5-15 PCPs per program) and focused on PCPs. The objective is to move PCPs to practice "early intervention" in the treatment of asthma. This program is run by an outside vendor and is accredited through the University of Illinois College of Medicine.

25. ***Regional Symposia:*** Full day CME accredited program on cardiovascular disease underwritten by RUSH (AstraZeneca grant to RUSH) – 6 hours CME.

26. ***Selling Team:*** All selling roles within AstraZeneca who support the same therapeutic area by calling on a single HCP.

27. ***Solutions:*** Promotional programs utilized by sales to gain access to healthcare professionals. Solutions are divided into three categories as follows:

    Patient solutions are those goods or services whose primary purpose is to benefit patients of a HCP, such as an educational brochure regarding a disease state.

    Medical solutions are those goods or services whose primary usage benefits a HCP's in the practice of medicine, such as a medical textbook.

    Business solutions are those goods or services whose primary purpose is to benefit the HCP's business operations, such as billing software, the creation of a physician practice logo, Internet advertising advice, etc.

28. ***Speaker Programs:*** A means for the Sales to provide financial support for promotional activities involving medical education over which AstraZeneca has influence. A local, regional, or national thought leader delivers a presentation or facilitates a discussion on a pre-approved topic. Speaker programs are a subset of Professional Education Programs.

29. ***Stand-Alone Entertainment:*** Event outside the customer's workplace in which there is NOT an educational component. The event is planned to gain access to a customer in order to provide information concerning our products.

30. ***Stand-Alone Meal:*** A meal outside the customer's workplace which does NOT have and educational component. The meal is utilized to gain access to a customer in order to provide information concerning our products.

31. ***Value-Added Program:*** Any money paid or services provided (directly or indirectly) to a customer, by or on behalf of AstraZeneca, which imparts value to a customer.

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ZENECA FIELD INFORMATION AND COMPANY POLICY MANUAL AND COMMERCIAL COMPLIANCE GUIDE CROSS REFERENCE

Field Information and Company Policy Manual
Employment Policies – Section 5

◆ Conflict of Interest	Refer to corporate policy
◆ Antitrust Compliance Policy & Guide	Refer to Antitrust Laws, M&S-A-2
◆ Policy on Ethical Conduct of Business	Refer to Ethical and Professional Conduct, M&S-A-1
◆ Summary of Guidelines for the Administration of Value-Added Programs	Refer to Professional Education Programs and the guidelines M&S-C-3, C-G-3-a & b, Engaging Healthcare Professionals for Consulting Services M&S-F-1, F-G-1-a thru d, Gaining Access to Healthcare Professionals, M&S-B-2
◆ Personal Use of Company Car	Refer to Fleet, M&S-E-4 and Corporate Fleet policy
◆ Zeneca Lobbying Policy	See Corporate Lobbying policy

Computer – Section 6

◆ Equipment Agreement	Refer to Safeguarding Company Assets M&S-E-1, Electronic Communications and Devices M&S-E-2, E-G-2

Safety/Company Car – Section 9	Refer to Safety, M&S-E-5, Corporate Safety policy

PAP & Adverse Experience – Section 10

◆ Patient Assistance Program	Refer to Patient Assistance Program, M&S-G-1
◆ Adverse Experience/Product Complaint	Refer to Adverse Event Reporting, M&S-B-4, B-G-4, Product and Packaging Complaints, M&S-B-5, B-G-5
◆ Handling Product Complaints for Parenteral Products	Refer to Product and Packaging Complaints, M&S-B-5, B-G-5

Miscellaneous – Section 11

◆ Electronic Mail and VoiceMail	Refer to Electronic Communications and Devices, M&S-E-2 & E-G-2
◆ Wholesale Return Goods Policy	See Corporate Policy
◆ Hospital Return Good Policy	See Corporate Policy
◆ Retail Return Good Policy	See Corporate Policy
◆ Managed Care & GPO Accounts Return Good Policy	See Corporate Policy
◆ Travel Guide	Refer to Travel, M&S-E-3 and Corporate Travel Policy

Samples and Repack – Section 12

◆ Sample Requests, Order Confirmation, Sample Distribution, Recording Sample Calls on Laptop, Inventory Reconciliation, Inventory Adjustment, Lost or Stolen Product, Physical Inventory Review, Sample Check Out Procedures, Witnessing Physician Signatures on Sample Signature Cards, Repacking Orders	Refer to Product Samples, M&S-B-6

New Hires Only – Section 13

◆ Confidentiality Statement	Refer to Acknowledgment/ Confidentiality Form

Commercial Compliance Guide – Module One

Tab 1 – Fraud & Abuse	Refer to Corporate Policy on Fraud & Abuse
Exhibit A – Policy on the Ethical Conduct of Business	Refer to Ethical and Professional Conduct, M&S-A-1
Exhibit B – Guidelines on Provision of Gifts, Entertainment, Educational Grants and Durable Free Goods Policy to Customers	Refer to Gaining Access to Healthcare Professionals, M&S-B-2, Professional Education Programs M&S-C-3, C-G-3-a & b
Exhibit C – AMA Guidelines on Gifts to Physicians from the Industry	Not part of M&S Policy though the AMA Guidelines were utilized as a reference in developing the policies. A summary of the AMA Guidelines on Gifts to Physicians is part of Gaining Access to Healthcare Professionals
Exhibit D – Safe Harbors	Not included in M&S Policy binder
Tab 2 – Gifts, Entertainment, Educational Grants and Durable Free Goods Policy	Refer to Gaining Access to Healthcare Professionals, M&S-B-2
Exhibit A – Vendor Gift Disclosure Report and Policy on Minnesota Law Prohibiting Gifts to Physicians	Not included in M&S Policy Binder,
Exhibit B – PhRMA Code of Pharmaceutical Marketing Practices	Not included in M&S Policy Binder

Exhibit C – AMA Guidelines on Gifts to Physicians from the Industry	Not part of M&S Policy though the AMA Guidelines were utilized as a reference in developing the policies. A summary of the AMA Guidelines on Gifts to Physicians is part of Gaining Access to Healthcare Professionals
Exhibit D – Safe Harbors	Not included in M&S Policy binder

Commercial Compliance Guide – Module Two

Tab 1 – Ad Boards	Refer to Exhibits, M&S-C-4, M&S-C-G-4
Tab 2 – Conventions	Refer to Exhibits, M&S-C-4, M&S-C-G-4
Tab 3 – RFA (Review for Approval) Guidelines and Procedures, Exhibits A- H	See Promotional Regulatory Approval intranet site
Tab 4 – Guidelines for the Administration of Value-Added Programs	Refer to Gaining Access to Healthcare Professionals, M&S-B-2, Professional Education Programs M&S-C-3, C-G-3-a & b
Exhibit A – Value-Added Approval Process	Refer to Training manual or see District Sales Manager
Exhibit B – Value-Added Request for Approval Form	Refer to Training manual or see District Sales Manager
Tab 5 – Vendor Relations, Sales and Marketing Procurement	See Corporate Policy
Appendix 1 – 12 Processes and Forms for Vendor Selection	See Corporate Policy
Appendix 13 – Guidelines for Engaging Consultants	Refer to Engaging Healthcare Professionals for Consulting Services, M&S-F-1, F-G-1-a thru d