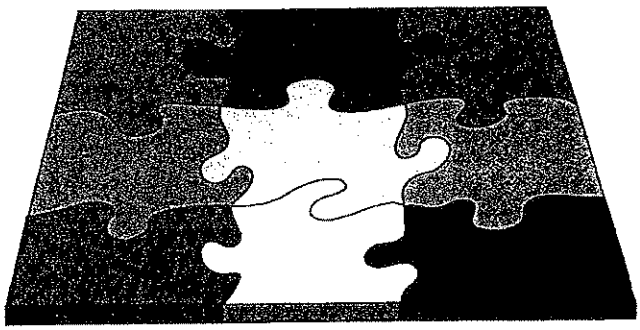
AZ – Marketing & Sales Business Policies and Guidelines #2

AstraZeneca Business Policies

Partners in Policy



Confidential

AstraZeneca

March 2003

Dear AstraZeneca Colleagues:

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

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

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

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

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

Sincerely,

David R. Brennan
President and CEO

Glenn Engelmann
Vice President, General Counsel and Secretary

AstraZeneca

Ethical and Professional Conduct

Policy No.: **I-1**

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

Contents

1. Key Learnings

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

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Product Liability Claims

Policy No.: **I-5**

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

Contents

1. Key Learnings

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

2. Purpose

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

3. Policy

3.1. General Policy

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

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Product Promotion

Policy No.: **II-1**

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

Contents:

1. Key Learnings

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

2. Purpose

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

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Development of Promotional Materials & Related Items

Policy No.: **II-2**

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

Contents

1. Key Learnings

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

2. Purpose

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

3. Policy

3.1 Promotional Regulatory Affairs Policy

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

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Adverse Event Reporting

Policy No.: **VI-1**

Issued by: **AZ Business Policy Group**
Date Issued: **02/08/2000**
Date Revised: **07/01/2002**

Contents

1. Key Learnings

- **All AZ employees are required to report adverse events to Drug Safety as soon as they become aware of an event associated with an AZ product.**
- **An adverse event must be reported whether or not the reported adverse event is described in the full prescribing information or the published literature and whether or not the reported adverse event is thought to be caused by the product.**
- **The HCP's assessment regarding the adverse event relationship to the AZ product does not determine the need to report that event. All adverse events (serious and non-serious) are to be reported to Drug Safety.**

2. Purpose

To ensure that AstraZeneca (AZ) complies with Food and Drug Administration regulatory requirements, all adverse event reports must be forwarded to Drug