AstraZeneca

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Procedure	INDGPEI	Effective	6.0	1 to 11

Title of SOP: General Principles governing External Interactions

EI Policy – General Principles governing External Interactions

AstraZeneca – India

Policy Owners: All Functional Heads of Department

Approved By: Sanjay Murdeshwar

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**Document discussed by the Compliance Committee*

Supersedes: INDGPEI version 5.0

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EI Policy - General Principles

With Regard to the Global Policy on Ethical Interactions

AstraZeneca

Refer to the supporting SOPs for the specific principles and limits

INDIA

Introduction

This Standard Operating Procedure (SOP) has been issued based on the risk and thereby risk mitigation actions and aligned to the relevant Global policies including the EI Policy and the local laws. Employees can read about all the applicable rules and processes governing a particular commercial activity.

1. The SOP is for guidance purposes only. It contains rules which do not cover every situation.
   Under all circumstances the GPEI and its Global Standards supersede this SOP.

2. This SOP is drafted to help sales representatives & brand teams do their job. CLT members, Brand Leaders or subject matter experts like Nominated Signatory, Legal and Compliance staff are referred to the GPEI or its Global Standards and other such relevant global policies.

3. You must follow the spirit of the GPEI and this SOP and not just its letter. The absence of a specific rule relating to a particular activity does not mean that something is permitted.

Purpose & Audience for the SOP

Purpose

This Policy describes what is required to meet AstraZeneca's ("AZ's") commitment to operate ethically in our business and personal interactions with third parties, including:

- **Patients** – members of the general public who use or may use AZ products.
- **External stakeholders** – AZ's key stakeholders (other than patients). Examples include: healthcare professionals ("HCPs") (including members of the medical, dental, pharmacy and nursing professions, and relevant administrative staff), healthcare organisations ("HCOs"), payors, scientists, medical societies, patient groups and public officials.
- **Other third parties** – third parties (other than external stakeholders or patients). Examples include: the media, vendors, suppliers, distributors, agents and partners.

If a third party could be considered to fall under more than one of the above categories, the more strict requirements apply.

Audience

This Policy applies to all employees of AZ and its consolidated legal entities, including all full-time and part-time directors, officers, employees and temporary staff worldwide (collectively referred to as "employees" in this Policy). This Policy also describes specific requirements for AZ business units.

Although third parties are not directly bound by the requirements of this Policy, AZ is committed to engaging only those third parties who embrace standards of ethical behaviour that are consistent with our own. When adherence to this Policy is required (for example, with respect to a contract sales organisation), this will be detailed in the signed contract or other written agreement with the third party

Principles to Apply

AstraZeneca Values

Each individual employee has the responsibility to comply with all AZ codes, policies, Global Standards and local SOPs that are in place

Following General principles apply to all activities described within this policy

You must consider all applicable requirements from this Policy, its supporting global documents and relevant procedures (collectively, “AZ’s requirements”) to ensure compliance. You must follow the spirit of AZ’s requirements, even if a particular topic is not fully addressed. Talk to your line manager or your Compliance partner if you are ever unclear about any of AZ’s requirements.

You must not attempt to avoid AZ’s requirements by asking, allowing or enabling third parties (including relatives, friends or other associates) to engage in prohibited conduct on your (or AZ’s) behalf.

You must use reasonable business judgment to document your business decisions and supporting rationales in a way that sufficiently demonstrates compliance with AZ’s requirements.

You must obtain all reviews and approvals mandated by AZ’s requirements in advance of any activity.

The term “AZ products and uses” refers to both approved and unapproved products and uses, unless otherwise specified.

Anti-Bribery & Anti-Corruption

The term “something of value” refers to any financial or non-financial benefit, such as cash, compensation for services, a gift or other item of value, a meal or other hospitality, a contribution, or even providing access to resources or information. You may give or receive something of value in appropriate circumstances, according to AZ’s requirements.

Bribery is giving or receiving something of value that is intended or could be seen as improper influence – in other words, as an inducement or reward for behaviour that is dishonest, illegal or a breach of a duty of impartiality, trust or good faith. AZ has zero tolerance for bribery or any other form of corruption, even if AZ loses business as a result.

You must not directly or indirectly give, offer or promise a bribe, or authorise anyone else to do so. You must not directly or indirectly receive, solicit or agree to accept a bribe, or authorise anyone else to do so. This also applies to third parties engaged by AZ for services. For example, you must not give or receive something of value:

- To influence, expedite or reward an official action or decision by a public official.
- To induce or reward an action favorable to AZ, such as prescribing AZ products.
- To compromise or influence an individual’s independence or judgment.
- To secure an improper business or personal advantage.

If you are in a situation where there is any suggestion of bribery, you must promptly seek the support of your line manager or your Legal or Compliance partner to take any necessary actions.

All payments to third parties must be made via an approved AZ financial payment system by bank transfer, cheque or company credit card, and must be appropriately recorded in AZ’s books and records. Specifically-authorised third parties may make payments on AZ’s behalf if there is a genuine business need, as long as the third party is required by signed contract or other written agreement to document, track and report the payments to AZ.

Payments must not be made to any third party in cash or cash equivalent (such as a gift card), except in the limited circumstances approved by Finance.

Ask Yourself

In your every day business activities, ask yourself

- Is the decision or action I am going to take in line with our values and the Code of Conduct ?
- Have I understood the risk and the possible implications of what I am doing ?
- If necessary, have I sought advice to help me make an informed decision ?
- Am I leading by example ?
- Have I considered any potential impact on AstraZeneca's reputation ?
- How will I feel if the action I take today is featured in the newspapers or on television tomorrow ?

If you are seeking clarification or have a question about interactions with external parties

1. Consult your line manager
2. When still in doubt, consult your line manager
3. Consult the 'How to ask a question' section at the end of this document

Abbreviations

Please find below an overview of all abbreviations used in this SOP:

Abbreviation	Description	Abbreviation	Description
GPEI	Global Policy on Ethical Interactions	**MED**	Medical
HCP	Healthcare Professional	**MKT**	Marketing
HCO	Healthcare Organisation	**REP**	Sales representatives
LCO	Local Compliance Officer	**SmPC**	Summary of Product Characteristics
		SOP	Standard Operating Procedure

References

This document has been prepared in accordance with the following codes and policies that apply to AstraZeneca activities and with relevant local laws, codes and regulations:

- AstraZeneca Code of Conduct;
- AstraZeneca Policy on Ethical Interactions and supporting Global Standards and SOPs
- AstraZeneca Global Policies
- The IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Pharmaceutical Marketing Practices
- The OPPI Guidelines,
- UCPMP notification in December 2014 and subsequent extensions
- Drugs and Cosmetics Act 1940 and its subsequent amendments

Valid from:

June 06, 2016

Standard Operating Procedures in this document effective as on respective dates given in the said SOPs governing the various sections of this Principal Policy

Revision History

Version number	Valid from	Modified sections
6.0	June 2016	• Change from One SOP to 1 Principle Guiding Policy and 7 SOPs. Due to this page numbers mentioned in this section refer to Version 5.0. Further, the references stating “in this SOP” to be read as relevant individual SOPs. References to “you” changed to Company employee or Company or AZ . Pages refer to previous SOP • Simplified context of the SOP removing the reference of 2015 and changing it to Company launching the GPEI (Pg. 4) • Added reference to SOP on meetings and hospitality to further explain modest and incidental (Pg. 11) • Clarification that medical abstracts can be provided (Pg. 13) • Added “external stakeholder” to “hosted by AZ” for clarification (Pg. 16) • Added Independent Congress support for media with conditions (Pg. 19) • Added “as per the maximum number defined” to “limited to prescribed dosages for three patients” to provide the numeric limit for samples (Pg. 24) • Added “VEEVA or hard copy” for signature for Samples by HCP (Pg. 24) • Added reference of Interpretation of Drugs & Cosmetics Act for PI (Pg. 24) • Inserted process for samples despatch (Pg. 25) • Added maximum units relation to pack size and therefore changes in limits as a function of the pack size will not lead to change in SOP (Pg. 25) • Replaced TBM/PSR to Sales team to include any changes in designation • Added due diligence process for addition in SARAL, requirement of break up of funds sought by recipient, added the limit of INR 50,000 for sole sponsorship (including clarification on hybrid sponsorship expense) and INR 30,000 as professional fees to HCO and added the need to mention any non utilization of opportunities provided by recipient (Pg. 32) • Changed “manager” to “employee must attend” (Pg. 32/59) • Added clarification on Hybrid sponsorship (Pg. 40) • Added new sheet for the Flow chart “Sponsorship Guidance” (Pg.41) • Clarified that the SOP does not mention “window period” and controls such as non assign of activities due to pendency of documents etc (Pg.55) • Changed Compliance approval to Line manager approval for venues (Pg.56/57/60) • Added requirements of “Photographs” for external promotional meetings (Pg.58) • Joined the point of Geographic location featuring as a separate bullet point to the first point (pg. 60) • Page 63 removed as duplicated in Page 64 (Pg.63) • Clarification on relevant BU being local or global removed (Pg.65) • Changed the approval guidance from “AZ internal review to “Nom Sig approval” (Pg.68) and Added limit of Maximum 15 HCP’s in an Advisory Board (Pg.68) • Added Speaker Bureau process on speaker approval process (Pg.69) • Incorporated “MME” in process flowchart of HOPM (Pg.73) • Removed reference of Sales team initiating meetings and also clarified that both International or Indian HCPs can be engaged for genuine services (Pg. 73) • Removed page on “Local Promo Meeting” (Pg.74) • Added that Medical Assistant raises an Medical activity in SARAL (Pg. 75) • Added two further steps to the flow chart (Pg.75) • Incorporated MME to the process flowchart (Pg.76) • Added a limit of 2 per HCP for a Local Education meeting (Pg. 77 / 79) • Clarified that HCP as chairperson/moderator etc can be provided travel and accommodation but shall not be provided Fees as compensation (Pg. 82) • A further mention as “Relevant category” added in flow chart (Pg. 91) • LEM added “as per BU” and accurate reflection of Sample limit added (Pg. 92) • Moved the last bullet point on Page 95 to next page (Pg. 95) • Corrected reference to Advisory Board to Market Research (Pg. 104) • Overall Simplification of content and language

Revision History

Version number	Valid from	Modified sections
V 5.0	March 2016	• Sample limit table added Pg 25 • Acknowledgment note/manager attendance requirement added in Contribution section (under Sponsorship) Pg 32 • The expense in SARAL added in sponsorship Pg 40 • Addition of Manager attendance at Sponsorship Pg 59 • Added “approved list of venues” in Pg 56, 57, 60 • Added Professional Fees for engagements with HCO Pg 61 • Added maximum limit for sole sponsorship Pg 61 • Photograph requirement added in Pg 69 • Added source as Nom sig portal Pg 90 • Added no fees for preparation when delivering the same topic more than once, Pg 90 • Fees for service capped at Rs 30000 and 10 times Pg 92 • Maximum fees of Rs 30000 in Ad Board Pg 93 • Changed the sequence of pages bringing Market Research guidelines and format in one sequence Pg 97 and Pg 98 moved down and bringing 99, 100 and 101 up • Simplification of content
V 4.0	September, 2015	Simplification of content and alignment with new Global Policy templates and UCPMP requirements. Creation of new guidance on Pre-Approval Activities by Commercial Employees.
V 3.0	September, 2014	TTT guidelines added Clarification provided on Local Education Meeting Adverse Event guidelines
V 2.0	April 2013	All sections
V 1.2	August 01, 2012	All sections