


Title of SOP: Engaging Third party for Services

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AstraZeneca – India

Policy Owners: All Functional Heads of Department

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 02/06/2016

**Document discussed by the Compliance Committee*

Supersedes: INDGPEI version 5.0

Valid from: June 06, 2016

Next Review: Not later than May 2018

SOP: Engaging Third party for Services

With Regard to the Global
Policy on Ethical Interactions



Refer to the EI Policy
Principles & other
supporting SOPs for the
specific principles & limits

INDIA

Engaging third party for Services



This Standard includes requirements for AZ employees and business units responsible for engaging third parties for services.

General Rules

- A third party may be engaged (including external stakeholders and patients) for services only if there is a genuine business need, and only in the necessary amount. The Company can engage only those third parties who are qualified and appropriate to provide the services.
- Third party engagements must not be used (or appear to be used) as a way to gain access to the third party, to disguise promotion of AZ products or uses, or to induce or reward any favourable action by the third party towards AZ, such as prescribing or using AZ products.
- Payments must not be given to a third party for voluntary activities or for incidental activities that are not necessary to address a genuine business need.
- The employee engaging the third party is accountable for ensuring that the third party's reputation and conduct are consistent with AZ's high ethical standards. The employee must ensure that appropriate risk assessments and any necessary due diligence are conducted before agreeing to the engagement. Based on this, the employee may be required to take some actions to address any risks identified, such as including relevant clauses in agreement, reserving audit rights or communicating any necessary training. The employee must also ensure that they maintain continued oversight and conduct periodic reassessments throughout the engagement.
- If an employee becomes aware, before or during an engagement, that a third party has been the subject of any allegation, investigation or conviction for bribery or other form of corruption or unlawful conduct, they must work with Legal or Compliance partner (as appropriate) to evaluate the information before continuing with the engagement.
- Compensation for a third party's services must not exceed fair market value, reflecting the type, amount and duration of the services and the third party's qualifications. The third party may be paid or reimbursed modest expenses that are incidental and directly related to the services. To clarify, a HCP providing services such as moderator, chairperson etc can be provided travel and accommodation but shall not be provided fee as compensation.

General Rules

- If an engaged third party does not perform all of the agreed services, the Company must reduce the agreed compensation to reflect only those services actually provided, and may pay or reimburse only those expenses directly related to the services actually provided.
- For engagements with external stakeholders, business units must follow the fair market value guidelines and must also follow the limits on aggregate compensation and engagement frequency for compensation and engagements within their budgetary control. These guidelines and limits are established in order to prevent improper influence or an appearance of improper influence when engaging external stakeholders for services. In situations where multiple local marketing companies are likely to engage a particular external stakeholder, they should share data to ensure that the total compensation and engagements across local marketing companies are not excessive and do not create improper influence or an appearance of improper influence. For clarity, aggregate compensation limits include only fees for services and do not include spend on external stakeholders for items of value or hospitality.
- Business units must also establish relevant procedures to enable AZ to satisfy external transparency and reporting obligations with respect to compensation paid to external stakeholders.

Execution of the Engagement

- Engagement owners (that is, employees responsible for engaging with and managing the services provided by a third party) may only engage third parties for services to address a genuine business need. Engagement owners must ensure that the third party provides the services and that outcomes from the services are utilized to the fullest extent possible.
- As an example, a genuine business need may not exist if the services sought can be provided more cost-effectively within AZ or if the services are known to duplicate services being obtained through other means. Also, a genuine business need may not exist if a third party is engaged to provide paid services that the third party should provide without compensation under local law or customary business practice. In addition, building or maintaining a good relationship with a third party is not a genuine business need.
- **E**ach engagement with an external stakeholder or patient for services must be documented in a signed contract. If the external stakeholder or patient is not accepting compensation or payment/reimbursement of expenses, the requirement for a signed contract may be waived with written line manager approval. If the requirement for a signed contract is waived, other formal documentation should be used to mitigate risks.
- Each engagement with other third parties (other than external stakeholders or patients) for services must be documented in the format required for the particular services to be provided, such as a contract, Terms & Conditions, a purchase order, or other documentation of offer and acceptance of services (“agreements”).
- All engagements and associated agreements with third parties must be approved through AZ’s applicable internal review procedures (including those related to engagements where external stakeholders are providing services outside of their home countries). The reviewer(s) must consider the genuine business need, the proposed compensation and other relevant details.
- When signed contracts are required, they must include signatures from authorised representatives of all parties. If the third party is an individual who is not self-employed, the engagement owner must obtain adequate assurances that the engagement is permissible under the individual’s terms of employment.

Execution of the Engagement

- When signed contracts are required, they must include the key terms and conditions of the engagement included in the AZ-approved contract templates, including, at a minimum, all of the following information:
 - The nature of the engagement, including specific performance criteria and/or deliverables.
 - Agreed total compensation, including an itemization of compensation for each service to be provided.
 - Travel, accommodation, meals & other directly related, incidental expenses to be arranged and paid by AZ, or to be reimbursed to the 3rd party.
 - The term or duration of the engagement.
 - The frequency of performance reviews and contract review dates.
 - Risk mitigation clauses to address the risks identified through the assessment
- A third party must not provide any services related to an engagement until the engagement has been fully approved by all parties, including signatures on contracts where required.
- Engagement for services must not be linked to the purchase or reimbursement of AZ products. Compensation for services must not be paid to reduce a third party's cost of purchasing or reimbursing AZ products.
- Compensation paid for services must match the compensation specified in the agreement with the third party and must be paid either directly to the third party, or, if the third party is an individual who is not-self employed, directly to the third party's employer, as described in previous page.
- Compensation must not be paid to a charitable organisation at the request of a 3rd party, unless the charitable organisation is the third party's primary employer.
- Compensation must not exceed fair market value, which is determined by the home country of the third party. This may result in different compensation for third parties from different home countries, even when engaged for similar services.

Execution of the Engagement

- In determining fair market value, AZ must consider all of the following:
 - The qualifications of the third party.
 - The type of services to be provided.
 - The time required to provide the services, including any preparation time.
 - Travel time (if permitted by procedures in the 3rd party's home country).
- Travel, accommodation, meals & other expenses (e.g. registration fees) must be arranged and paid by AZ or reimbursed to third parties as described below in this SOP. These expenses must meet all of the following requirements:
 - They must be directly related and incidental to the services provided, and must be proportionate to the nature and extent of the services.
 - They must only be for those individuals providing the services.
 - They must be supported by appropriate receipts
 - They must be modest and consistent with the requirements of the Global Business Travel Policy and Standards applicable to employees, except as specifically permitted in paragraph below.
- In the limited circumstances where the 3rd party has a medical or physical impairment, alternative arrangements (not consistent with the Global Business Travel Policy and Standards) may be permitted, with written approval from the engagement owner's line manager. Other exceptions must be approved in writing by the relevant SET member or designee.
- AZ must not arrange or pay for, or reimburse expenses associated with, any of the following:
 - The use of private or charter aircraft.
 - Travel upgrades.
 - Personal travel, accommodation, meals and other personal activities and expenses (for example, personal phone or internet expenses), including any guest expenses.
 - Recreation or other entertainment (including in-room movies).
 - Any other expenses not directly related to the services.
- Whenever practical, travel and accommodation arrangements must be made by AZ and booked through the appropriate AZ-designated agency (for e.g., travel agency or meetings agency) or paid by AZ directly to the travel/accommodation provider (or meeting organiser, as relevant).

Execution of the Engagement

- When it is not practical for AZ to make the travel or accommodation arrangements as described, third parties providing services may make their own travel and/or accommodation arrangements, and AZ may reimburse the third parties for modest and necessary expenses, when reimbursement for such expenses is specified in the agreement with the third party, and with appropriate receipts. AZ must not provide advance payment to the third parties to cover these expenses. When it is reasonable or necessary for the third party to travel by personal car to provide the services, the associated travel expenses (for example, mileage allowance) will be reimbursed at the rate applicable to employees.
- AZ may reimburse third parties for modest meals and other modest, incidental expenses directly related to the services provided (for example, parking), including expenses incurred in preparation for providing services.
- Compensation and incidental expenses may only be paid or reimbursed by AZ where the third party has provided documentation or other evidence clearly demonstrating that the services were actually provided by the third party. If for any reason the third party does not provide some or all of the services, or does not provide sufficient documentation or other evidence, engagement owners must ensure that the agreed payment is reduced accordingly.
- The maximum limit to engage an external stakeholder for speaker services is 10 per year. To clarify, the maximum limit is including all Business units and not per Business unit.
- Business units managing engagements must establish relevant procedures to document, track and report engagements of external stakeholders (and associated compensation), to ensure compliance with applicable engagement frequency and aggregate compensation limits and to satisfy external transparency and reporting obligations

Representative Training and Business Cycle Activities

- Engagement owners may engage external stakeholders and patients to educate or otherwise inform sales representatives and their first line managers during training activities, as well as during routine business cycle activities (collectively “representative training and cycle activities”). Specifically, engagement owners may engage an external stakeholder or patient to transfer his or her skills, knowledge or experience at representative training and cycle activities, to enable the participant(s) to gain a better understanding and insight into a therapeutic area or disease state, including the patient treatment journey.
- Representative training activities, by their nature, cannot accurately or efficiently be developed or delivered by the business unit responsible for representative training. Representative training activities may take place on AZ premises, at an external stakeholder’s place of business, or at another offsite location, as appropriate to the education being delivered. Representative training activities must be based on a documented and approved genuine educational need relating to the participants’ current area of responsibility.
- During the course of a representative training activity involving observation of a healthcare professional (“HCP”) in the practice of medicine, participants may observe HCP-patient examinations and discussions and may learn information relating to patients. The participants must confirm that the HCP has obtained written consent from each patient to be observed during the representative training activity.
- External stakeholders engaged to lead or conduct representative training or cycle activities must be appropriately informed on AZ’s requirements applicable to these activities.

General Rules

Please find below a list of applicable rules covered by the various stages of engagement of HCPs.

Categorization:

Category 1:

Super specialist Qualification with strong peer influence:

HCPs with qualifications such as, but not limited to, DM / DNB/ US Board certified /MRCP/FRCP - Cardiology, Endocrinology, Gastro, Onco, Pulmo, CC, Nephro, Neuro; M.Ch - equivalent surgical qualification, would be classified as Category 1. They have to be super specialist by qualification.

Category 2:

Non DM (non Super specialist) and with strong peer influence: At least MD/MS/post graduate, with high stature/ strong peer influence- practicing Cardios/ Diabetos / Endos etc.

Category 2 HCPs need to meet atleast 4 of the following criteria to be termed 'category 2'.

1. University faculty appointment or similar position in corporate hospital set up (HOD/Professor/Associate Professor / Director or Unit Head or Senior Consultant in a Corporate Hospital set up)
2. Member of international ad board/ Chair at national advisory boards run by AZ
3. Member of National or International editorial board/Reviewer for National or International peer reviewed journal
4. Published in National or International peer-reviewed journal in the last 2 yrs. (at least 3 papers)
5. Member of national or international treatment advisory/guideline committee
6. Member or chair of scientific committee of national/international associations or conferences
7. Chair / speaker at a national or international scientific meetings or conference
8. Has been or is Principal Investigator for a Global study / national coordinator of a Global clinical trial

Compensation

1. Compensation must be at fair market value, taking into account the required time to perform the service, including preparation time. A contract/agreement should be signed with the HCP service provider prior to the services being rendered.

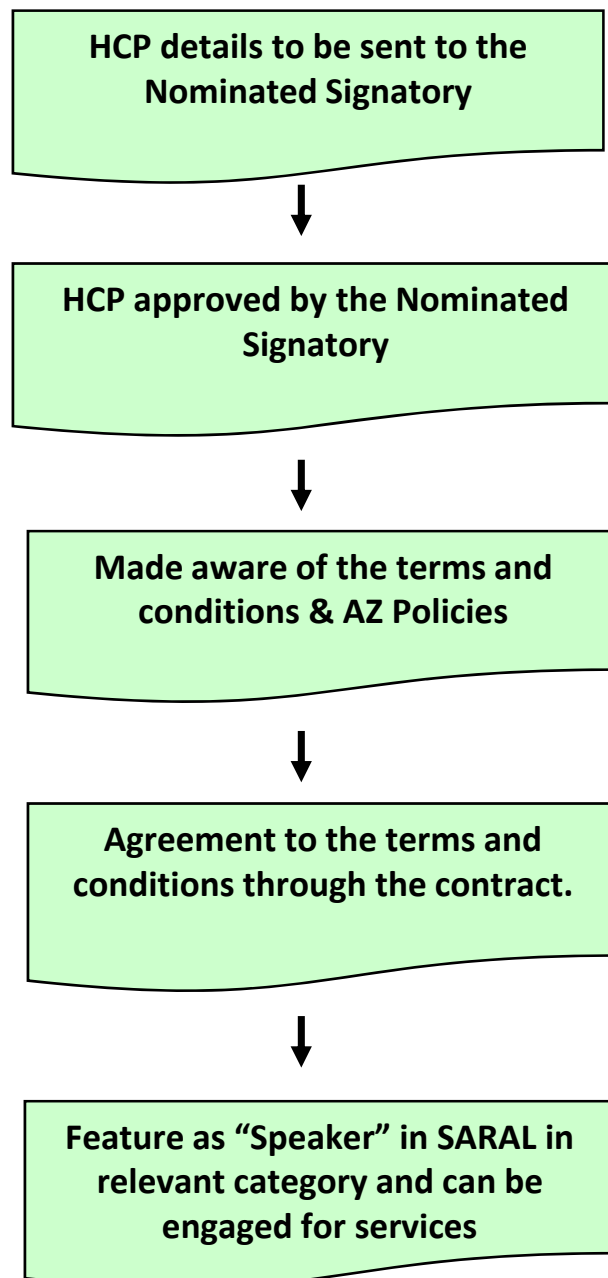
Speaker Category	Description	Revised Rate
Category 1	All DMs with strong peer influence	14k per hour; max of 30 k per day
Category 2	Non DM specialists – PG qualification+ strong peer influence + meeting 4 out of 8 listed criteria	14k per hour; max of 30 k per day
Category 3	MD or PG Diploma by qualification with strong peer influence	8 k per hour; max of 30 k per day
Category 4	General Practitioner (MBBS only)	None

2. Limits are taking into account the amount of time required to provide the services, including preparation time and travel time (if applicable).
3. When engaging an HCP who is based in another country, the limits of that country have to be applied, and the global process as given in the Nominated Signatory portal has to be followed.
4. An HCP should not be paid preparation fee when delivering the same content/topic (of a service) more than once. To clarify, the HCP can be paid for delivering the service.
4. Provided that details are documented in a signed contract, the Company may arrange and pay for modest and reasonable travel, accommodation, meals and other incidental expenses insofar these are consistent with our Global Business Travel Policy and the EI policy regarding hospitality (section 5 of this SOP).
5. Compensation for services must be paid directly to the HCP or its employer. It must not be paid to a charity at the request of the HCP.

Approval of HCP as “Speaker”

Process for review and approval for Speakers

Approval prior to activity by Nominated Signatory is required, who will validate a legitimate objective.



Monetary and Activity Limits for Activities with HCPs

ENGAGING HCPS AND SCIENTIFIC CONSULTANTS				
Activity	Activity limit	Monetary Limit	Hospitality	
“FEE for SERVICE” engagement of HCPs Includes all forms of Fee for service such as Speaker, Advisory Board, Trainer, Chairperson etc	10 Includes engagements by all Therapy Areas	Rs 30,000/hour subject to maximum amount of Rs1,50,000/day for International engagement	Rs 30,000 per night stay incl accommodation and breakfast for International engagement	Rs 8,000 per day for refreshments, meals & beverages for International engagement
		Category 1 and 2: Rs 14,000/Hour subject to maximum amount of Rs 30,000/day for local engagement Category 3: Rs 8,000/Hour subject to a maximum amount of Rs 30,000/day for Local engagement	Rs 18,000 per night incl accommodation and breakfast for local engagement	Rs 6,900 per day for refreshments, meals & beverages for local engagement
		Maximum preparation time for an activity: 4 hours		
Maximum amount for a HCP per year (Aggregate spend)		Rs 20,00,000 per year Includes Fee for service, International engagements, NIS, ERS etc Excludes payments for participation in Global Clinical Trials		
Business class can be provided only for flights above 6 hours In addition, in limited circumstances where the HCP has a medical or physical impairment, business class travel may be permitted, with approval from the Nom Sig.				
Contribution to support External Stakeholder Education		Rs 50,000 per HCP to include travel, modest accommodation, curriculum fees and other related expenses. <i>Contribution only to non-profit organizations and never directly to HCP or individual host institution</i>		
MEETINGS AND ASSOCIATED HOSPITALITY				
Activity	Activity Limit	Monetary Limit		
Local Educational Meeting-Hospitality	2 per HCP per year per BU	Rs 3,000 for RBMs and higher bands		
SAMPLES				
Samples	Sample packs shall be limited to prescribed dosages for three patients and as per the maximum number defined in the Product samples SOP			

Limits for Advisory Boards

The Company has set the following limits that apply to all advisory board meetings.

Participants	Maximum number of HCPS
HCPs	15 HCPs maximum in an Advisory Board

Hospitality	Maximum cost per person
Accommodation	Rs 18,000 per night incl accommodation and breakfast
Meal including drinks	Rs 6,900 per day for refreshments, meals & beverages

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Category 3	MD or PG Diploma by qualification with strong peer influence	8 k per hour; max of 30 k per day
Category 4	General Practitioner (MBBS only)	None

Organizers must satisfy themselves that before engaging HCPs to attend an advisory board meeting that the level of compensation is appropriate and aggregated compensation levels will not be exceeded as a result of the engagement.

