



AZ India SOP Engaging Third Parties

KEY PRINCIPLES

- **We do not tolerate bribery even if it means losing business.**
- **We work with third parties we confirm are as committed to ethics and integrity as we are.**
- **We work with third parties when we have a real business need.**
- **We choose third parties based on their expertise, ability, quality, and cost.**
- **We pay fair market value for goods and services.**

WHY IT MATTERS

We rely on everyone in AstraZeneca to follow the law and work ethically in every decision and action. Because we are ethical, we expect the same of third parties we engage.

We protect society and our own reputation by choosing third parties who have a track record of doing business ethically, showing no tolerance for bribery, respecting human rights, and protecting the environment.

When we engage the right third parties the right way and hold ourselves accountable for what they do on our behalf, we show that we can be trusted with the company's reputation and money.

Use this standard, along with our values and behaviours and your own judgment, to help you make the best decisions about choosing and working with third parties to support our business.

WHAT YOU NEED TO KNOW

Third parties. We buy services and supplies from third parties when we have real business needs we cannot meet internally or cannot meet as cost-effectively. We use many types of third parties across our business, such as distributors, construction firms, laboratory supply houses, contract manufacturing organisations (CMOs), healthcare organisations (HCOs), researchers, healthcare professionals (HCPs), and market research agencies.

Our agreements. We need written agreements (a contract or purchase order) with third parties, detailing the responsibilities of AZ and the third party. We take responsibility for making sure we get what we pay for before authorising payment. We use AZ-approved contract templates and purchasing systems.

ENGAGEMENTS

What are they?

An engagement is our relationship with a third party we have chosen to fill a real business need. The engagement ends with payment for the contracted goods or services.

Why and How We Do It

- We make sure that everything we say and do shows that we only engage third parties who are qualified to deliver what we need and whose ethical standards are consistent with ours. We do not engage anyone to do anything on our behalf that we are not allowed to do ourselves.
 - Before we engage anyone, we perform due diligence to confirm their commitment to, and reputation for, doing business ethically and address any risks or gaps we find.
 - We actively oversee third parties through the term of the agreement to make sure they continue to live up to our ethical standards. If we discover that the third party has been involved in illegal or unlawful conduct, we immediately consult management and our local Legal or Compliance partner.



- We make sure our agreements are not, and do not appear to be, a reward or an effort to buy a favour or to buy business, or a cover to build relationships or to gain access to promote our products.
- When we choose a third party, we act in the best interest of AstraZeneca. In any situation where our own self-interest could, or could appear to, get in the way of making the best choice for AstraZeneca, we raise it to a manager and remove ourselves from any decisions about that third party.

Engaging Health care Professionals (HCP) for AZ Organised or AZ Supported Meetings:

- **Travel:** We (or our representatives, or any person acting on our behalf), should not extend travel facilities inside or outside the country, including rail, air, ship, cruise tickets, paid vacations, etc., to healthcare professionals or their family members (both immediate and extended) for attending conferences, seminars, workshops etc., unless the person is a **speaker** for a AZ Organised, AZ supported, CME or a CPD Program.
- **Hospitality:** We (or our representatives, or any person acting on our behalf), should not extend hospitality like hotel stay, expensive cuisine, resort accommodation etc., to healthcare professionals or their family members (both immediate and extended) unless the person is a **speaker** for a AZ Organised, AZ supported, CME or a CPD Program.
- **Monetary Grants:** We or our representatives, should not pay cash or monetary grant to any healthcare professional or their family members (both immediate and extended) under any pretext.

SUPPORT FOR RESEARCH

To provide rational support and encouragement to research and innovation through the industry-academia linkage, interaction between pharmaceutical companies and healthcare professionals may be subject to the following:

- The said study or research should be one that has the requisite approval from the competent authority (such as ICMR, DCGI, Ethics Committee, Institutional Authority etc.) and is conducted, where so applicable, at a recognized site or location. Instructions by relevant bodies like NMC, etc., may be complied with.
- Engagement of healthcare professionals in consultant-advisory capacity shall be for bona-fide research services, under a consultancy agreement involving a consultancy fee or an honorarium-based payment, subject to the relevant provisions of the Income-Tax Act, 1961. Such engagements should ensure the patient interest is not compromised and integrity of the healthcare professional is maintained in line with the NMC regulations.
- Expenditure on research by pharmaceutical companies is an allowable expenditure subject to the provisions of the Income Tax Act 1961 as amended from time to time.
- Before a third party does any work or incurs any expenses, we make sure we have a fully authorised agreement (including all signatures on a contract). We include in the agreement a detailed description of the work to be performed or goods to be provided, along with payment terms, compensation, and expenses or other costs we will pay for or reimburse.
 - We may reimburse third parties for modest expenses directly related to the service based on supporting documentation; we do not reimburse personal expenses.
 - When travel is necessary to perform the service, we arrange and pay for (or reimburse where direct payment is not practical) modest transportation and accommodation based on AstraZeneca's travel and expense standards
- We provide meals and other hospitality as a business courtesy when it makes sense for the location and duration of a meeting. We use modest venues that are appropriate for business discussions and make sure meals are also modest in value based on local limits. We do not



provide entertainment and are careful not to create an impression that a meal is a reward or an effort to buy a favour.

- 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.
- For engagements with external stakeholders, business units must follow the fair market value guidelines defined 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. For clarity, aggregate compensation limits include only fees for services and do not include spend on external stakeholders for items of value or hospitality.
- The maximum limit to engage an external stakeholder for speaker services is **15 per year**, except for the HCPs approved as an exception by the CP. This limit does not apply to services that are delivered without fees. To clarify, the maximum limit is including all Business units and not per Business unit. To further clarify an HCP can be engaged on the same day for more than one event, but only with appropriate review and approval. For e.g. as a Speaker in a AZ organized program and then in an Advisory Board on the same day. Each such engagement will be considered as a separate engagement. The interaction should be within the relevant monetary limits and activity limits. Further, HCPs as speakers or similar engagements, should be engaged for a minimum of 30 mins to avoid risks of being perceived as inducement.
- Before we approve payment, we make sure the agreed goods or services have been provided and only pay for what is actually delivered. When pre-payments are necessary, we list them in the agreement and make sure they are in proportion to the start-up work required (for example, start-up costs for a clinical trial).
 - We make payments through approved AstraZeneca financial payment systems.
 - A third party may make payments on our behalf if (i) we have a real business need for them to do so and (ii) our agreement requires the third party to document, track, and report to us all such payments.
 - We do not pay cash or cash equivalents, except where approved by above market Finance.
 - We do not make donations to charitable organisations in place of direct payments for goods or services.
 - We do not pay for anything a third party should do or provide for free as part of its customary business practice or legal obligation.
- 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. See details of the fair market value for services provided furtherin this SOP.
- We document all aspects of third party engagements.
- 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)



GENERAL RULES

Below is a list of applicable rules for Fees for service in the engagement of HCPs for genuine services.

Categorization:

Category 1 - HCPs of International scientific repute – Maximum limit of Rs 70,000/- per service engagement (Rs 17,500/- per hour and not more than 5 hours including preparation time for each service engagement). *Approval for HCPs of International Repute will be on a case to case basis and expected to be limited in number, which the BU Head will review and has to be approved by the Lead Nominated Signatory.*

Criteria: determination must be made based upon a holistic assessment of many factors, including:

1. Super specialist Qualification with strong peer presence: 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 super specialist.
2. 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)
3. Member of international Advisory board/ Chair at national Advisory board run by AZ
4. Member of National or International editorial board/Reviewer for National or International peer reviewed journal
5. Published in National or International peer-reviewed journal in the last 2 yrs. (at least 3 papers)
6. Member of national/international treatment advisory/guideline committee
7. Member or chair of scientific committee of national/international associations or conferences
8. Chair / speaker at a national/international scientific meeting/conference
9. Has been or is Principal Investigator for a Global study / national coordinator of a Global clinical trial

Not all factors listed above may be relevant to each HCP, and additional factors not listed may be considered. The reviewer and approver must use his/her expertise, professional judgement, and other similar requirements to weigh the factors on a case-by-case basis.

Category 2 – HCPs with strong science knowledge and experience – Maximum limit of Rs 45000/- per service engagement (Rs 12000/- per hour and not more than 5 hours including preparation time for each service engagement). BU head must review the proposal prior to the proposal being submitted to Nominated Signatory for approval.

Criteria: HCPs in this category have to meet at least 4 of the 9 parameters listed for the previous category (refer previous page)

This is Specific HCP based and not an automatic process i.e. all HCPs who meet 4 of the 9 proposed parameters will not be in Category 1. Instead, every HCP has to be proposed individually and approved.

Category 3 – Post Graduates (MD etc) or PG Diplomas with good science knowledge and peer acceptance - Maximum limit of Rs 30000/- per service engagement (Rs 8,000/- per hour and not more than 5 hours including preparation time for each service engagement).

Criteria: HCPs in this category should be Super specialists or Post Graduates or PG Diplomas or equivalent course, by qualification with good science knowledge and peer presence. Proposals for HCPs in this category have to be reviewed by line manager and approved by the Nominated Signatory

NOTE: Fees for service must not be provided to General Practitioner (Graduates such as HCPs with only MBBS qualification)



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.

Category	Description	Revised Rate
Category 1	HCPs of International Repute	Rs. 17,500 per hour; max of Rs. 70,000 per service engagement
Category 2	HCPs with strong science knowledge and experience	Rs. 12,000 per hour; max of Rs. 45,000 per service engagement
Category 3	Post Graduates (MD etc) or PG Diplomas with good science knowledge & peer presence	Rs. 8,000/- per hour; max of Rs. 30,000/- per service engagement
Fees for service is not to be provided to General Practitioner (MBBS)		

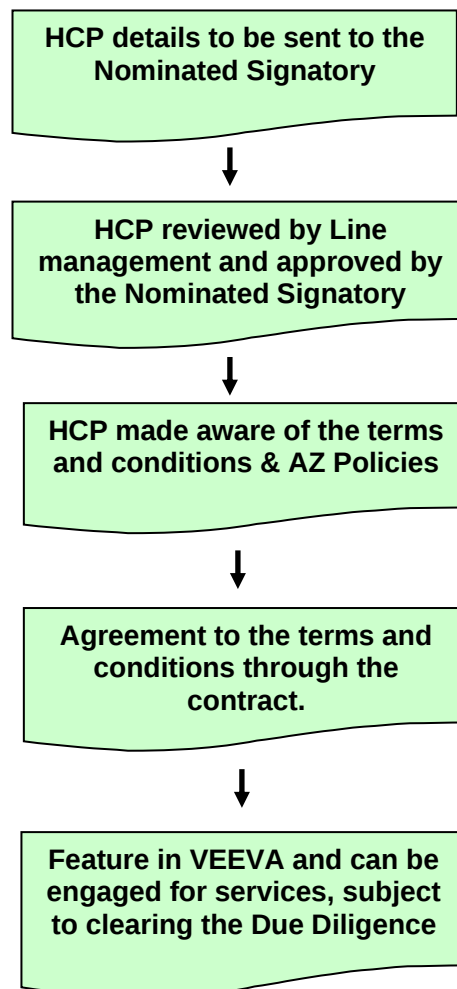
2. Limits are taking into account the amount of time required to provide the services, including preparation time and travel time.
3. When engaging an HCP who is based in another country, the limits of that country have to be applied, and the global process as given in the Nominated Signatory portal has to be followed.
4. 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 Business Travel Policy.
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 required, to validate a legitimate objective





MONETARY AND ACTIVITY LIMITS

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.	The maximum limit to engage an external stakeholder for speaker services is 15 per year (excluding services without fees). Any exception to the limit has to be approved as an exception by the CP. The limit is at Company level and 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: Rs. 17,500/- per hour; max of Rs. 70,000/- per service for Local engagement		
		Category 2: Rs. 12,000/- per hour; max of Rs. 45,000/- per service 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
		Category 3: Rs 8,000/- per hour; max of Rs 30,000 per service for Local engagement		
		Maximum preparation time for an activity: 5 hours for each service		
Maximum amount for a HCP per year (Aggregate compensation)		Rs 7,00,000 per year. For clarity, aggregate compensation limits include only fees for services and do not include spend on external stakeholders for items of value or hospitality Excludes payments for participation in 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 Nominated Signatory.				
MEETINGS AND ASSOCIATED HOSPITALITY				
Activity	Activity Limit	Maximum monetary Limit		
Speaker Discussion Meeting	2 per HCP per year per BU	Rs 3000/- excl tax per person. In sales teams can be carried out only by SLSM(Equivalent Designation) and above. The band requirement is not applicable for non sales teams.		
Modest meals limit in AZ organized meetings	24 times in a year	Rs.3000/- excl. tax, per person as modest meal to avoid perception of expensive cuisines		
SAMPLES				
Samples	Sample packs shall be limited to prescribed dosages for not more than three patients for required course of treatment and not more than twelve such sample packs per drug to a HCP per year. Refer Providing Product samples SOP for further details			



ADVISORY BOARD LIMITS

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

Category	Description	Revised Rate
Category 1	HCPs of International Repute	Rs. 17,500 per hour; max of Rs. 70,000 per service engagement
Category 2	HCPs with strong science knowledge and experience	Rs. 12,000 per hour; max of Rs. 45,000 per service engagement
Category 3	Post Graduates (MD etc) or PG Diplomas with good science knowledge & peer Presence	Rs. 8,000/- per hour; max of Rs. 30,000/- per service engagement
Fees for service is not to be provided to General Practitioner (MBBS)		

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.



Revision History

Version number	Valid from	Modified sections
SOP-0123619	From the date of approval in Veeva ECMS system	- In Page 4,5 & 8 – replace the word from “peer influence” to “peer presence. - Page 7 – In Meeting & Associated Hospitality replaces the word “Local Education Meeting” to “Speaker discussion meeting”. - Page 7- Removed words chairperson, trainer, ad board speaker and retained word as Speaker.
As assigned by ECMS	1 st June 2024	- Page 2 – Added below clauses to align to UCPMP code - Travel, hospitality and grants in engagement with HCP's - Support for research - Page 2 – Changed term “delegate” to “Speaker” to align to UCPMP - Page 3 & 7 - Maximum limit to engage HCP as “Speaker” per year changed from 10 times to 15 times. - Page 7 – removed “Hospitality for Delegates” to align to UCPMP - Page 7 – removed “Contribution to support External Stakeholder Education” to align to UCPMP - Page 7 – Samples section updated to maximum of 12 packs per drug per year per HCP to align to UCPMP - General changes in language, font and formatting to align to Global standards and documents
10	1 st May 2023	- Page 5 – added a statement guiding to the details of the Fair Market value - Page 5 – removed statement that Business Units are responsible for setting the Fair Market Value - Page 9 - Added the Due Diligence requirement for HCPs to feature in Speaker Pool - Page 10 – Amended speaker limit to state that exception should be approved by CP (removing the exeption limit of 20 times) to allow CP to approve based on explanation by requestor. - References to ‘global’ removed to avoid confusion and provide clarity that the principles of this SOP apply
9	15 th April 2022	- Pg. 10 – added 24 times as the annual limit for meals as hospitality for delegates at AZ organized meetings. - Pg. 10 – clarified that Local Education meetings are for Band F and above for sales teams
8	15 th June 2021	- Page 2 – Revision history brought to page 2 for ease of reference - Maximum Preparation time for a HCP engagement as 5 hours at different reference sections - Page 5 – Exceptional approval of HCP maximum number of times engagement changed from 20 to “as approved by CP” and added 30 minutes as minimum time per engagement for HCPs as Speaker or other similar services
7.0	July 2019	Simplification of Language and aligned to Global Standard



6.3	Jan 2019	- Pg. 9 & 15 .The second category of higher engagement of 20 limits added - Pg. 13. The guidance on reduced fees for same presentation removed, to allow for holistic judgement based approvals - Pg. 14. SARAL reference replaced with Veeva
6.2	March 2018	Changes to relevant sections to provide clarification that an HCP can be engaged for more than one event on the same day with appropriate review and approval. Each such engagement will be considered as a separate engagement. The interaction should be within the relevant monetary limits and activity limits.
6.1	May 2017	- Revision of Categorization of fees for services to HCPs and external stakeholders (Pg. 11, 12, 13, 15, 16) - Revision of the Maximum amount for a HCP per year as Aggregate compensation to align to global policy requirement of limit to be only for fees for service and not other logistics (Pg. 15)

Document Approvals

Business Approval	Ramesh Varadarajan Ramesh.varadarajan@astrazeneca.com 30-Jan-2025 05:48:10 GMT+0000
Administrative Approval	Sanjeev Panchal sanjeev.panchal@astrazeneca.com 30-Jan-2025 18:14:59 GMT+0000