

<b>GSKCH India Policy</b>	<b>Title: Policy and Standard Operating Procedures on Interactions with Officials from Governments and Inter Governmental Agencies</b>
<b>Official Short Title: Policy on Interacting with Government Officials</b>	
<b>Key Points</b>	
<ul style="list-style-type: none"> <li>➤ This document regulates interactions with Government Officials.</li> <li>➤ This SOP does not regulate GSK relationships with HCPs who may be considered Government Officials only because they are employees or receive funding of government or state-owned enterprises and are acting <u>solely</u> in their capacity as healthcare professionals. These kinds of relationships and professional activities are dealt with under the GSK Corporate Policy on Interactions with HCPs &amp; Promotional Activities to HCPs POL-GSK-401 (see Related Documents section).</li> <li>➤ All interactions with Government Officials irrespective of their profession will also be subject to the Scientific Engagement Policy (POL-GSK-002) and related standards. (see Related Documents section).</li> </ul>	
<ul style="list-style-type: none"> <li>➤ MEETINGS may be held with Government Officials for the purpose of discussing legitimate GSK business in an open and transparent manner whether initiated by GSK or by the Government Official</li> </ul>	
<ul style="list-style-type: none"> <li>➤ SITE VISITS for government officials are appropriate if there is a clinical, scientific, regulatory or medical rationale for the visit, the site carries out activities which are relevant to their official government work and it is allowed by the relevant laws, regulations and codes of conduct which apply to the Government Officials. Payment by GSK for travel, accommodation and meals of Government Officials who participate in Site Visits is discouraged, and exceptions require that specific requirements are met and approvals obtained</li> </ul>	
<ul style="list-style-type: none"> <li>➤ EDUCATIONAL MEETINGS: Sponsorship or funding of Government Officials attendance at educational meetings or congresses organized or sponsored by GSK or by third parties, is not permitted. GSK may, however, invite Government Officials to such meetings provided that GSK does not fund or pay for registration, travel, accommodation or meals.  <b>Exception:</b> Due to the limitations on some Governments to support ongoing education of Government Officials, and where the criteria set out in this SOP are met including transparency and specific approval processes, GSK may invite and sponsor Government Officials from countries classified as <a href="#">low</a> to <a href="#">lower-middle</a> income economies to attend educational meetings or congresses.</li> </ul>	
<ul style="list-style-type: none"> <li>➤ SERVICES: Engagement of Government Officials on a fee for services basis is not permitted.  <b>Exception:</b> When allowed by local law and when the Government Official is the most appropriate provider of the service to be contracted, such engagement will be subject to specific approval requirements.</li> </ul>	
<ul style="list-style-type: none"> <li>➤ Gifts to Government Officials are not permitted.  <b>Exception:</b> Where it is a matter of respect for local customs, items of <u>minimal/modest</u> value may be provided to Government Officials provided it is done in a fully transparent way.</li> </ul>	
<ul style="list-style-type: none"> <li>➤ It is not acceptable for GSK employees, acting in their capacity as GSK representatives, to attend fund raising functions in support of political parties. It is not acceptable for GSK to sponsor social events at political meetings or conferences.</li> </ul>	
<ul style="list-style-type: none"> <li>➤ A log of interactions with Government Officials must be maintained for events involving any</li> </ul>	



payments by GSK to Government Officials including Site Visits, Educational Meetings and Services, and for all other instances where there are any payments or expenses by GSK.

What do this Policy Imply?		Who in GSK has general obligations under this SOP?
The Basics	1. Purpose 2. Scope	<b>All GSK Staff</b> <input checked="" type="checkbox"/>
Specific Requirements	3. Responsibilities 4. Meetings with Government Officials on GSK Business Matters 5. Site Visits 6. Educational Meetings 7. Services 8. Gifts to and from Government Officials 9. Attendance at and Sponsorship of Political Meetings and Party Political Conferences 10. Responsibilities and Documentation 11. Communication of Issues	<b>What functions in GSK have specific obligations under this SOP?</b> Audit, Compliance, & Quality <input checked="" type="checkbox"/> Communications <input checked="" type="checkbox"/> Govt. & External Affairs <input checked="" type="checkbox"/> Finance <input checked="" type="checkbox"/> Global Procurement <input checked="" type="checkbox"/> HR <input type="checkbox"/> IT <input type="checkbox"/> Legal <input checked="" type="checkbox"/> Manufacturing & Supply <input checked="" type="checkbox"/> Marketing, Sales & Support <input checked="" type="checkbox"/> Medical <input checked="" type="checkbox"/> Research/Development <input checked="" type="checkbox"/> Supervisors & Management <input checked="" type="checkbox"/> Senior Management <input checked="" type="checkbox"/> Other <input checked="" type="checkbox"/>
		<b>Contacts:</b> <b>Corporate Ethics &amp; Compliance</b> <b>1-866-GSK Ethics</b>
Glossary and Administration	Glossary Administration Waivers Appendices Related Documents	

## The Basics

### 1. Purpose

This document describes the rules for interactions with Government Officials, to ensure full compliance with laws, regulations and codes of conduct applicable to Government Officials and to protect GSK’s reputation. It also describes the rules for sponsorship and attendance by GSK and GSK employees at political meetings and conferences.

### 2. Scope

- 2.1. This SOP applies to all GSK employees, complementary workers and relevant third-parties (e.g. outsourcing partners).
- 2.2. This document incorporates the principles set out in, and should be read in conjunction with Corporate Policies POL-GSK-007 ([Preventing Corrupt Practices and Maintaining Standards of Documentation](#)), the [Anti-Corruption Framework](#) –



[Third Parties](#) – Procedures and Guidance, Scientific Engagement Policy (POL-GSK- 002) and POL-GSK-302 ([Political Contributions](#)). See also related documents section for additional supporting control documents.

**2.3.** This document regulates GSK relationships with Government Officials, who are defined as:

- Any officer or employee of a government or any department, agency or instrumentality of a government;
- Any person acting in an official capacity on behalf of a government or any department, agency, or instrumentality of a government;
- Any officer or employee of a state or government-owned company or business;
- Any officer or employee of a Government international organization such as the World Bank or United Nations;
- Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or
- Any candidate for political office.

**2.4.** The scope of this Policy includes GSK interactions with Healthcare Professionals when they act in an official capacity on behalf of a government, including:

- HCPs who also hold an official decision making role;
- HCPs who have responsibility for performing regulatory inspections, government authorizations or licenses; and/or
- HCPs who are temporarily or permanently assigned to work for local, regional or national governments or agencies or supranational bodies.

**2.5.** This SOP does not regulate GSK interactions with HCPs, who may be considered Government Officials only because they are employed by, or receive funding, professional service fees or other remuneration from, a government-owned or funded hospital, clinic, university or other healthcare provider organization where they:

- a) act solely in their capacity as healthcare professionals (e.g. prescribing, administering and supplying medicines or influencing the same, conducting clinical trials or scientific research); or
- b) act as members of advisory boards with no decision making capacity or provide technical, scientific or medical advice to Government Officials in relation to healthcare; AND, for both sections a) and b),
- c) do not have any official role in the government with the capacity to take decisions that affect business of GSK.



These types of interactions are regulated by the GSK Corporate Policy on Interactions with HCPs and Promotional Activities to HCPs and related documents.

- 2.6.** A high degree of risk exists for any Government Officer who in an official role on behalf of the government has the capacity to take decisions with the potential to affect GSK business.

Furthermore, as HCPs can have multiple roles, the exact capacity in which HCPs are acting with respect to a government may not be immediately evident. It is therefore important that GSK employees who interact with HCPs establish whether those HCPs would qualify as a Government Official encompassed within the scope of this SOP. If in doubt GSK employees should seek further guidance from their Compliance and Legal contacts.

## The Specifics

### 3. Responsibilities

All GSK employees and complementary workers who engage with Government Officials, and third parties contracted by GSK who as part of the contracted services and in the course of acting for and on behalf of GSK interact with Government Officials, are responsible for adhering to the requirements contained in this SOP.

### 4. Meetings with Government Officials on GSK Business Matters

Meetings may be held with Government Officials for the purpose of discussing legitimate GSK business. In this context, it is acceptable to discuss matters such as awards for supply of GSK products, marketing authorisations, prices and reimbursements, public health policies, policies impacting scientific approaches and process technology, medical ethics and disease areas, regulatory requirements, provided that the meetings and discussions take place in accordance with applicable laws, including competition laws.

#### 4.1. Hospitality

Inviting Government Officials for breakfast, lunch or dinner in the context of meetings to discuss GSK business is discouraged. Meetings should take place preferably in the offices of the Government Official and/or in the context of Site Visits or Educational Meetings.

**Exception:** there may be instances in which some level of hospitality will be appropriate or required, such as in the context of regulatory inspections. If further detail is required, business units may create their own SOPs as to the procedures for approval of any such hospitality, including the hospitality principles listed in section 4.2 below.



## 4.2. Hospitality Principles

The hospitality in these cases should be:

- a) Lawful and ethical under the laws, regulations and codes of conduct that apply to the Government Official;
- b) Occasional and exceptional;
- c) Secondary and subordinate to the purpose of the meeting;
- d) In support of GSK's business; and

In no event should the venue be excessive or perceived as lavish or extravagant or inappropriate for a business meeting.

## 5. Site Visits

Government Officials may be invited to visit GSK sites if there is a clinical, scientific, technology, regulatory or medical rationale for the visit, the site carries out activities which are relevant to their official government work and it is allowed by the relevant laws, regulations and codes of conduct which apply to the Government Officials.

Government Officials may also be invited to GSK Sites, where the Government Officials will be performing or participating in a specific official function (e.g. formally opening the site or an extension.)

Procedures for planning and documenting site visits are addressed in this section and in section 10 of this SOP.

Site Visits in the context of regulatory procedures established by law (e.g. site inspections or GMP review of manufacturing sites) are subject to the same hospitality rules contained in section 4.1 and 4.2.

### 5.1. Internal Approvals

Invitations to Government Officials for GSK Site Visits require the approval of the head of the India Consumer Healthcare business unit (or its suitable senior delegate) .

### 5.2. External Approvals

GSK is responsible for ensuring that Site Visits are permitted by relevant laws, regulations and codes of practice applicable to the Government Official concerned; and where required by local law, written permissions have been obtained from the Government Official's employer to GSK authorising the official's attendance at the Site Visit.

A copy of this letter or document must be retained by the GSK manager responsible for the invitation for a minimum of five (5) years or any longer period required under GSK's Records Retention Policy.

### **5.3. Selection of Government Officials**

Where an invitation is to be extended to a Government Official for a Site Visit, or funding is to be provided for a Government Official to attend a Site Visit, the invitation or notice of availability of funding shall be sent directly to the head of the appropriate government agency or organization so that the agency or organization may independently select the Government Official(s) who will attend. GSK must not in any way influence or specify the selection of individual Government Officials.

Where due to the nature of the Site Visit this is not possible or appropriate, GSK must make the selection of the Government Official solely on the basis that the Site Visit is relevant to the Government Official's duties.

### **5.4. GSK Information**

Information provided to a Government Official should be limited to information that is relevant for the Government Official in the context of the Site Visit and should not be used for the specific purpose of obtaining more favourable treatment in the grant of marketing authorisations, prices, reimbursement categories, awards for supply of GSK products, or any other undue advantage.

### **5.5. Travel, Accommodation and Meals**

Payment for travel, accommodation and meals of Government Officials for Site Visits are only permitted where the Government Official's costs would not be met by his or her employing body, payment or reimbursement of travel, accommodation and meals may only be made if the relevant laws, regulations and codes of conduct permit this; and any required internal and external permissions have been obtained (see sections 5.1 and 5.2), including written permission from the Government Official's employer.

### **5.6. Recognised/Acceptable Expenses**

Subject to the provisions of this section 5, the following may be pre-paid or reimbursed:

- a) Reasonable and actual travel costs, which in the case of air travel must be economy class and in the case of train travel may be first or business class if this is permitted by local, laws, regulations and codes of conduct.
- b) Actual cost of accommodation at the Site Visit location but only if this is required because it is not practicable for the Government Official to travel there and back in one day. The accommodation provided must be reasonable and not be perceived as lavish, extravagant or inappropriate.
- c) Appropriate meals (i.e. average cost and standard at the location). Provision of meals must not conflict with the laws, regulations and codes of conduct



applicable to the Government Official, including any limitations on cost per person and should not be perceived as excessive.

- d) Hospitality (i.e., the provision of light refreshments such as pastries, mints/sweets, fruit, hot and cold drinks) may be provided, if the hospitality is modest in value, secondary and subordinate to the purpose of the Site Visit and the refreshments can be expected to be consumed on-site.
- e) Other costs that are not explicitly referred above are not pre-payable or reimbursable by GSK.

Such payments or reimbursements should preferably be made to the government bodies employing the Government Official or directly to the vendors (e.g. the travel agency, airline, hotel provider) rather than to the Government Officials themselves.

### **5.7. Documentation for Travel, Accommodation and Meals**

- a) Where actual expenses are reimbursed under section 5.6, original receipts for expenses must be submitted by the Government Official or employing body (as the case may be). GSK shall not make any payment without the corresponding receipt.
- b) GSK personnel are responsible for documenting all expenses paid for or reimbursed by GSK via the appropriate system.

### **5.8. Guests**

Guests of Government Officials (e.g. spouses) are discouraged and will under no circumstances have any costs covered by GSK.

**Exception:** If the country laws, regulations and codes permit this and the Government Official insists on bringing a guest, all guest's costs (including travel, hotels, meals etc.) must be paid for by the Government Official and not by GSK. Guests should not attend any GSK sponsored or organised meetings.

## **6. Educational Meetings**

### **6.1. Sponsorship**

GSK may not sponsor or provide funding directly or indirectly for Government Officials to attend Educational Meetings, whether organised by or sponsored by GSK or by third parties. This provision does not prohibit attendance by Government Officials at meetings where such attendance is funded directly by the governmental office employing the Government Official.

This general prohibition on sponsorship and funding of Government Officials does not prohibit independent sponsorship of Government Officials by organizations such as pharmaceutical associations, bona-fide foundations or educational institutions that may be affiliated with GSK through membership or



funding. To be permissible, the sponsorship by such third-party organization must not be at the direction of or influenced by GSK or any GSK employee.

**Exception:** Only in [low](#) to [lower-middle](#) income economies as defined annually by the World Bank, GSK may sponsor attendance of Government Officials to Educational Meetings and cover associated reasonable costs of travel and accommodations as long as:

- a) it is allowed by the relevant laws, regulations and codes of conduct, which apply to the Government Officials;
- b) each case is reviewed and approved prior to initiating invitations by the most senior Compliance Officer of the GSK business unit offering the sponsorship;
- c) the meetings are relevant to the invitees work as Government Officials;
- d) the meetings have as their primary purpose the education of attendees;
- e) the invitation shall be sent directly to the head of the appropriate government office (see section 6.5)
- f) tracking and reporting of cases are maintained according to GSK reporting requirements for Government Officials
- g) sponsorship is never in the form of direct payments to the Government Official.

## 6.2. Invitation

GSK may issue an invitation to Government Officials to attend Educational Meetings, in accordance with section 6.1, if:

- a) the Educational Meetings are relevant to their work as Government Officials;
- b) the Educational Meetings have as their primary purpose the education of attendees; and
- c) it is allowed by the relevant laws, regulations and codes of conduct, which apply to the Government Officials.

Meeting locations (both the general location and the specific premises at which the meeting will be held) when organised by or sponsored by GSK must be appropriate for a business meeting and selected to minimize the travel time for attendees. Meetings should not be held at locations which could reasonably be perceived as lavish or extravagant or inappropriate for a business meeting or conference.

## 6.3. Internal Approvals

Educational Meetings require the approval of the head of the India CH Business and head of the relevant local business unit or the General Manager of the LOC of country where the Educational Meeting is taking place, only where GSK is sponsoring or providing funding for the attendance of the Government Officials under the exception of section 6.1.



#### **6.4. External Approvals**

GSK is responsible for ensuring that attendance and/or sponsorship at Educational Meetings is permitted by relevant laws, regulations and codes of practice applicable to the Government Official concerned; and where required by local law, written permissions have been obtained from the Government Official's employer to GSK authorising the official's attendance at the Educational Meeting.

A copy of this letter or document must be retained by the GSK manager responsible for the invitation for a minimum of five (5) years or any longer period required under GSK's Records Retention Policy.

#### **6.5. Selection of Government Officials**

Where an invitation is to be extended to a Government Official for attendance to an Educational Meeting, or funding is to be provided for a Government Official in exceptional circumstances contemplated in section 6.1 to attend an Educational Meeting, the invitation or notice of availability of funding shall be sent directly to the head of the appropriate government agency or organization so that the agency or organization may independently select the Government Official(s) who will attend. GSK must not in any way influence or specify the selection of individual Government Officials.

Where due to the nature of the Educational Meeting this is not possible or appropriate, GSK must make the selection of the Government Official solely on the basis that the Educational is relevant to the Government Official's duties.

#### **6.6. GSK Information**

Information provided to a Government Official should be limited to information that is relevant for the Government Official in the context of Educational Meetings and should not be used for the specific purpose of obtaining more favourable treatment in the grant of marketing authorisations, prices, reimbursement categories, awards for supply of GSK products, or any other undue advantage.

#### **6.7. Travel, Accommodation and Meals**

Payment for travel, accommodation and meals of Government Officials is only allowed for Educational Meetings under the terms of the exception of section 6.1.

Payment or reimbursement of travel, accommodation and meals may only be made if the relevant laws, regulations and codes of conduct permit this, and any



required internal and external permissions have been obtained (see sections 6.3 and 6.4), including written permission from the Government Official's employer.

## **6.8. Recognised/Acceptable Expenses**

Subject to the provisions of this section 6, the following may be pre-paid or reimbursed:

- a) Reasonable and actual travel costs, which in the case of air travel must be economy class and in the case of train travel may be first class if this is permitted by local, laws, regulations and codes of conduct.
- b) Actual cost of accommodation at the Educational Meeting location but only if this is required because it is not practicable for the Government Official to travel there and back in one day. The accommodation provided must be reasonable and not be perceived as lavish, extravagant or inappropriate.
- c) Appropriate meals (i.e. average cost and standard at the location). Provision of meals must not conflict with the laws, regulations and codes of conduct applicable to the Government Official, including any limitations on cost per person and should not be perceived as excessive.
- d) Hospitality (i.e., the provision of light refreshments such as pastries, mints/sweets, fruit, hot and cold drinks) may be provided, if the hospitality is modest in value, secondary and subordinate to the purpose of the Educational Meeting and the refreshments can be expected to be consumed on-site.
- e) Other costs that are not explicitly referred above are not pre-payable or reimbursable by GSK.

Such payments or reimbursements should preferably be made to the government bodies employing the Government Officials or directly to the vendors (e.g. the travel agency, airline, hotel provider) rather than to the Government Officials themselves.

## **6.9. Documentation for Travel, Accommodation and Meals**

- a) Where actual expenses are reimbursed under section 6.8, original receipts for expenses must be submitted by the Government Official or employing body (as the case may be). GSK shall not make any payment without the corresponding receipt.
- b) GSK personnel are responsible for documenting all expenses paid for or reimbursed by GSK via the appropriate system.

## **6.10. Guests**

Guests of Government Officials (e.g. spouses) are discouraged and will under no circumstances have any costs covered by GSK.

**Exception:** If Indian govt laws, regulations and codes permit this and the Government Official insists on bringing a guest, all guest's costs (including travel,



hotels, meals etc.) must be paid for by the Government Official and not by GSK. Guests should not attend any GSK sponsored or organised meetings.

## **7. Services**

### **7.1. Paid Services by Government Officials by GSK**

GSK may not contract the Services of Government Officials.

**Exception:** There are instances where a Government Official's knowledge and expertise are considered unique, and such Services are unavailable by any other non-Government Official provider. In these cases, such Services may only be provided to GSK if and to the extent that:

- a) the Services are permitted by relevant laws, regulations and codes of practice applicable to the Government Official;
- b) prior written approval of the Government Official's employer has been obtained as described in section 7.5; and
- c) prior approval from the CET member responsible for the corresponding business unit has been obtained which confirms the legitimate basis for the engagement of the Government Official, and which also establishes that the engagement is for Services and not intended to influence the Government Official in his/her capacity as a Government Official. The CET member can delegate the authority to approve these Services arrangements to a member of his leadership team (but no lower than to one of his direct reports).

### **7.2. Contract**

In advance of any Services to be provided by the Government Official to GSK, a contract for Services must be signed by the GSKCH and the Government Official. The contract must specify the scope of the work to be performed, the remuneration to be paid and the basis for paying expenses, if relevant.

### **7.3. Fair Market Value**

Payments for Services rendered must be set based on the following principles:

- a) The payment must not be driven by any expectation of future awards for supply of any GSK products or of more favourable treatment in the grant of marketing authorisations, prices, reimbursement categories or any undue advantage by the Government Official. The payment may only be for the specific Services provided.
- b) The payments should be determined based on the relevant expertise, licensure and experience of the Government Official within his/her applicable local market or country of origin, and in line with amounts specified by the employer of the Government Official for providing external services or, where these are not specified, should be determined by GSK and the Government



Official through a process consistent with negotiation between independent parties.

- c) The contracted payment must be based on the work anticipated to be performed and for reasonable expenses incurred by the Government Official.
- d) Payments may only be made for work actually performed and for expenses actually incurred. If the Government Official's travel time is substantial in comparison to the duration of the Services to GSK, travel time may be considered in setting the fee to be paid for the work to be performed, or the travel time may be considered to be work performed.
- e) Payment may be calculated by reference to the hours worked, a daily rate or a rate for the task.
- f) Cash payments are prohibited.
- g) Payment of travel, accommodation and meals is acceptable where a Government Official is providing Services to GSK.

#### **7.4. Internal Approval**

Contracting of Government Officials for the Provision of Services requires the approval of the head of the Indian business and the CET member responsible for the business unit. The CET member can delegate the authority to approve these Services arrangements to a member of his leadership team (but no lower than to one of his direct reports).

In addition, where these Services relate to Scientific Engagement activities prior to authorisation (e.g. provision of advice), approval is also required from the relevant Medicine or Vaccine Development Leader. Where the activities are taking place after authorisation approval of the LOC Medical Director is also required (see STD-GSK-002).

#### **7.5. External Approvals**

GSK is responsible for ensuring that provision of Services are permitted by relevant laws, regulations and codes of practice applicable to the Government Official concerned; and written permission has been obtained from the Government Official's employer, regardless of any local laws or Codes of Practice.

A copy of this letter or document must be retained by the GSK manager responsible for the invitation for a minimum of five (5) years or any longer period required under GSK's Records Retention Policy.

#### **7.6. Selection of Government Officials**

In all cases where GSK contracts the Services of a Government Official, GSK must make the selection of the Government Official solely on the basis that the Government Official has the qualifications, expertise and/or experience to provide the Service in question.

## **7.7. GSK Information**

Information provided to a Government Official should be limited to information that is relevant for the Government Official in the context of Services provided and should not be used for the specific purpose of obtaining more favourable treatment in the grant of marketing authorisations, prices, reimbursement categories, awards for supply of GSK products or any other undue advantage.

## **7.8. Travel, Accommodation and Meals**

Payment of travel, accommodation and meals is acceptable where a Government Official is providing Services to GSK.

## **7.9. Recognisable/Acceptable Expenses**

Subject to the provisions of this section 7, the following may be pre-paid or reimbursed:

- a) Reasonable and actual travel costs, which in the case of air travel must be economy class and in the case of train travel may be first class if this is permitted by local, laws, regulations and codes of conduct. Business class air travel may be agreed if this complies with the laws, regulations and codes of conduct applicable to the Government Official concerned.
- b) Actual cost of accommodation at the meeting location but only if this is required because it is not practicable for the Government Official to travel there and back in one day. The accommodation provided must be reasonable and not be perceived as lavish, extravagant or inappropriate.
- c) Appropriate meals (i.e. average cost and standard at the location). Provision of meals must not conflict with the laws, regulations and codes of conduct applicable to the Government Official, including any limitations on cost per person and should not be perceived as excessive.
- d) Hospitality (i.e., the provision of light refreshments such as pastries, mints/sweets, fruit, hot and cold drinks) may be provided, if the hospitality is modest in value, secondary and subordinate to the Services provided and the refreshments can be expected to be consumed on-site.
- e) Other costs that are not explicitly referred above are not pre-payable or reimbursable by GSK.

## **7.10. Documentation for Travel, Accommodation and Meals**

- a) Where actual expenses are reimbursed under section 7.9, original receipts for expenses must be submitted by the Government Official or employing body (as the case may be). GSK shall not make any payment without the corresponding receipt.
- b) GSK personnel are responsible for documenting all expenses paid for or reimbursed by GSK via the appropriate system.

### 7.11. Guests

Guests of Government Officials (e.g. spouses) are discouraged and will under no circumstances have any costs covered by GSK.

**Exception:** If local country laws, regulations and codes permit this and the Government Official insists on bringing a guest, all guest's costs (including travel, hotels, meals etc.) must be paid for by the Government Official and not by GSK. Guests should not attend any GSK sponsored or organised meetings.

## 8. Gifts to and from Government Officials

- 8.1. Gifts to Government Officials are generally not permitted under POL-GSK-007 (Preventing Corrupt Practices and Maintaining Standards of Documentation). “Gift” does not include fair market compensation for Services rendered and the cost of reasonable travel, accommodation and meals which comply with this SOP.
- 8.2. On an exceptional basis and where it would be considered respectful of local customs and compliant with local laws and regulations, items of minimal/modest value may be provided to Government Officials provided it is done in a fully transparent way and their provision is not intended to influence the Government Official in his/her capacity as a Government Official.
- 8.3. Where the Government Official is also an HCP, the exception of section 8.2 shall not apply, and the provisions of POL-GSK-401 (Interactions with Healthcare Professionals and Promotional Activities to HCPs) shall apply.
- 8.4. GSK staff may accept gifts or entertainment from Government Officials that are lawful and ethical, are infrequent, low in value, and are customary in a business relationship (e.g., pens, coffee mugs or calendars). If any GSK staff is uncertain about whether offering or receiving a gift is permitted or not, he or she must seek guidance from his or her supervisor or a Compliance Officer. [See POL-GSK-001 Code of Conduct for further guidance.]

## 9. Attendance at and Sponsorship of Political Meetings and Party Political Conferences

- 9.1. Please refer to [POL-GSK-302 Political Contributions](#) before committing to any payment, contribution, or donation that might possibly be considered to be a political donation under the UK law’s broad definition which covers payments to relevant EU organizations anywhere in the world. This definition includes organisations which would not normally be regarded as political. POL-GSK-302 requires prior approval to be obtained before any such payment can be made and may prohibit certain payments. GSK plc’s Main Board of Directors are personally liable to repay with interest any unapproved EU political contributions.



They are also personally liable for any damages in respect of any loss or damage sustained by the Company as a result of the unlawful payment.

- 9.2. Subject to section 9.1 and 9.3, it is acceptable for GSK employees to attend political meetings and conferences (e.g., party conferences or meetings organised by politicians) in their capacity as representatives of GSK, if the employee has a legitimate business reason for attending such meetings or conferences. In this context, GSK may pay for entry fees for GSK employees required to attend such meetings.
- 9.3. It is not acceptable for GSK employees in their capacity as GSK representatives to attend fund raising functions in support of political parties, apart from the exceptions noted in section 9.6.
- 9.4. It is not acceptable for GSK to sponsor social events at political meetings or conferences. It is acceptable for GSK employees to attend social events at such meetings and for GSK to pay for the cost of their attending the event, so long as the intent of the social event is not to raise funds and the costs are moderate and the employee has a legitimate business reason for attending such event.
- 9.5. It is acceptable for GSK to fund independent bodies running satellite meetings at political meetings or conferences. Any refreshments provided should be incidental to the main purpose of the meeting and comply with section 4.2 of this SOP. GSK's sponsorship must be clearly identified on programme invitations, hand outs and other meeting or conference related materials.
- 9.6. Nothing in this section prevents GSK employees from attending/funding political meetings, events and conferences in a private capacity. Similarly, employees' contributions to and by the GSK Political Action Committee in the US are unaffected by this provision and employees may attend in their capacity as GSK representatives all kinds of events and functions organized, sponsored and/or funded through the GSK PAC.

## **10. Responsibilities and Documentation**

The GSK manager responsible for the interaction with any particular Government Official is responsible for ensuring compliance with this SOP and for maintaining a log and supporting documentation for the interactions listed below. All relevant logs should be stored in such a way as to ensure internal transparency of the interactions and to facilitate monitoring of compliance with this SOP. This could be at LOC, Site, Business Unit or Departmental level.

A log must be maintained in any of the following situations where a payment is offered or made by GSK:

- a) Site Visits
- b) Educational Meetings



- c) Services by Government Officials for GSK
- d) All other instances where there are any payments or expenses by GSK,

The information that must be captured, logged and documented includes:

- a) The date of interaction,
- b) Reason for the interaction,
- c) Name and title of the Government Official,
- d) Branch of the government and government agency name,
- e) Any payment for Services or reimbursement of costs,
- f) Other items of value provided
- g) Name of GSK employees involved in the interaction.

A template interactions log is attached to assist responsible managers in capturing the data needed to comply with this SOP. Managers may continue to use existing alternative documentation formats that meet the requirements of this SOP.

Documentation about other interactions in the normal course of business where there is no payment or expenses by GSK is not mandatory and will be determined by the normal requirements of the business.

Care should be taken to ensure that the frequency of interactions with any particular Government Official is appropriate to their role and to GSK's business requirements.

It is important to note that the information collected in this log is Personally Identifiable Information (PII). As such, you must comply with the requirements of POL-GSK-010, specifically:

- If there is a contract between GSK and the Government Official, regardless of which country, privacy language should be included in the contract,
- If there is no contract between GSK and the Government Official and the country in question does not require notice or consent, then the LOC can decide what to do,
- If there is no contract and the country in question requires notice or consent, the LOC must comply with that requirement.

## **11. Communication of Issues**

For clarification around any element of this SOP or any concerns about violations or potential conflicts of interest associated with this SOP please contact Compliance Officer & Head Regulatory & External Affairs.

## **Glossary & Administration**



## Glossary

**Government Official under this SOP** shall mean:

- A civil servant acting in an official decision making capacity,
- An employee of a statutory body/payer that manages healthcare,
- An officer of a government regulatory agency,
- Any officer or employee of a company or business owned in whole or part by a government
- Any officer or employee of an international Governmental organization such as the World Bank, the United Nations or the World Health Organization;
- Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party;
- Any candidate for political office.

**Educational Meeting:** clinical, scientific or medical meetings, or technical and regulatory meetings related to the understanding of the manufacturing processes of production, organised or sponsored by GSK or a third party, at a GSK Site or elsewhere, with the primary purpose of educating attendees about medicinal products, disease areas and/or technical processes related to the manufacturing of GSK products.

**Healthcare professionals:** members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their employment and delivery of patient care, may prescribe, recommend, purchase, administer, supply (or influence the supply) of medicines.

**Services:** provision of personal services by a Government Official for GSK outside of their official role, for pay. In this context, “Services” shall be lawful work done for GSK that is allowed by local laws where the Government Official is domiciled and is authorized by the institution, agency or office where the Government Official is employed (e.g. chairing or speaking or acting as a panellist at a meeting sponsored or organised by GSK, stakeholder mapping, expert advice on market access or reimbursement, future trends in the management of therapies and clinical trial design, development of evidence, strategy on submission dossiers.)

**Scientific Engagement:** The interaction and exchange of information between GSK and external communities in order to advance scientific and medical understanding including the appropriate development and use of our medicines and vaccines; the management of disease; and patient care.

**Site Visit:** a visit to a GSK site or the site of a third party contractor (e.g. contract manufacturer, CROs) by a Government Official for the purpose of conducting a regulatory inspection or learning more about the activities being conducted on that site.

<b>Administration</b>	
<b>Approval:</b>	GSKCH Board of Directors
<b>Owner:</b>	GSKCH Management Team
<b>Author:</b>	Head – Regulatory & External Affairs
<b>Approval Date:</b>	5 February 2014
<b>Effective Date</b>	5 February 2014
	New GSKCH India Policy

## **Waivers**

Any requirement of this SOP may be waived conditionally on a case-by-case basis in very exceptional circumstances with written indication from the Corporate Compliance Officer as approved by Corporate Legal and Regulatory. Once approved, these exceptions will be recorded by Compliance officer. The approved exception author/sponsor is required to notify all relevant GSK employees, contractors and third parties of the granted exception.

## **Related Documents**

[GSK Code of Conduct \[POL-GSK-001\]](#)

[GSK Standards of Conduct \[STD-GSK-001\]](#)

[Preventing Corrupt Practices & Maintain Standards of Documentation \[POL-GSK-007\]](#)

[Anti-Corruption Framework – Third Parties – Procedures and Guidance](#)

[Political Contributions Policy \[POL-GSK-302\]](#)

[Scientific Engagement Policy \[POL-GSK- 002\]](#)

Global Scientific Engagement Standards [forthcoming STD- GSK-002]

[Privacy of Personably Identifiable Information \[POL-GSK-010\]](#)

[Interactions with Healthcare Professionals & Promotional Activities to HCPs \[POL-GSK-401\]](#)

Pharma Europe Engaging HCPs SOP (SOP-Ph-Eu-04),

Pharma International SOPs Engaging Healthcare Professional Experts and Congresses, Conferences, Professional Meetings Activities

[POL-R&D-0011 Payments to Healthcare Professionals](#)

[POL-R&D-0012 Use of External Experts](#)



[POL-R&D-0116 Provision of Gifts to Healthcare Professionals and Potential GSK Customers](#)

## Appendices

### Appendix 1: Template for Government Interactions Log



Interactions with  
Government Officials