

Our Code of Practice

for promotion of
prescription medicines and
for scientific engagement

Who does this Code apply to?



- Vaccines (including Vaccines R&D)
- Pharma (including Pharma R&D)



- ViiV Healthcare
- Consumer Healthcare

These business units have separate codes

Icons used throughout this Code



More information elsewhere in this Code



Further information



Reference to documents which can be located online

Definitions of terms in this document can be found in the glossary



See appendix 2: Glossary

Principles of Our Code of Practice

Our intentions and actions are driven by our values:

Transparency

Respect for people

Integrity

Patient focus

- Activities are intended to enhance healthcare and benefit those who use our medicines.
- Materials and activities that we initiate, arrange or fund, disclose GSK's specific involvement. This declaration of involvement is clearly visible.
- Activities never discredit or reduce confidence in GSK or our industry.
- Activities are carried out in a responsible, ethical and professional manner in compliance with applicable regulatory and legal requirements.



Where activities or interactions are organised or arranged from a business unit or LOC and aimed at individuals from a number of countries or from another country, the relevant Country Medical Directors (CMDs) are consulted to ensure applicable requirements are followed.

Why do we have this standard?

What does this standard (Code) address?

Our external interactions follow high ethical and professional standards and reflect GSK values. This ensures these interactions benefit patients and enhance the practice of medicine.

This Code provides our global standards for promoting prescription medicines and vaccines (referred to as medicines in this Code) and engaging about our science and our prescription medicines in a non-promotional manner. It applies to Vaccines (including Vaccines R&D) and Pharma (including Pharma R&D). It excludes ViiV Healthcare and Consumer Healthcare, who have separate codes.

For non-prescription medicines and other products refer to **STD-CHC-401**: Consumer Healthcare code for promotion and scientific engagement.

Other written standards relevant for our external interactions are provided in appendix 1.

See appendix 1

Local requirements

Local laws, regulations and applicable industry codes are followed (where local or regional industry codes do not exist, the **IFPMA Code of Practice** is applicable).

In addition to these local standards, the global requirements provided in this Code are followed unless a stricter approach is required by the local requirements or where there are additional local, regional or business unit specific GSK standards or restrictions.

Who needs to follow it?

See section 2.3 for accountabilities for scientific engagement



Our staff follow this Code and relevant requirements when undertaking the activities described. This Code does not cover every situation. Our staff apply GSK values, their judgement and/or seek guidance from relevant staff (eg line managers, Legal, Medical and Compliance) when needed.



Managers of staff involved in activities covered by this Code are responsible for ensuring staff are adequately trained on the relevant requirements.

Managers are accountable for breaches of this Code (and other relevant requirements) by their staff when the manager knew, or should have reasonably known, that such breaches were taking place.



Business owners who select and engage third parties including agencies, suppliers (such as contract sales forces, consultants, market research agencies, advertising agencies, medical communication agencies and public relations agencies) and distributors are accountable for ensuring these parties are trained and comply with this Code and other relevant requirements.



Business Development is responsible for ensuring alliance transactions include contractual language that implements this Code and relevant requirements where applicable.



Heads of our business units and **General Managers of Local Operating Companies (LOCs)** are accountable for ensuring this Code and relevant requirements are met.



GSK Chief Medical Officer is accountable for the content of this Code and Medical are responsible for governance frameworks to support implementation of this Code.

POL_87166: Medical governance policy (POL-GSK-409)

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Promotion

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References relating to this section



Written standards

POL_132175: Policy for use of digital channels

SOP_285774: Approval process for promotional and non-promotional materials created by LOCs and Above Country Business Units

SOP_375788: Conducting promotional webinars & Webcasts

STD_404715: Standard on meetings and catering

STD_455141: Anti-Bribery and Corruption Standard

STD_243431: Gifts, Hospitality and Entertainment Standard

SOP_344448: Engaging with external experts (HCPs) to provide services

POL_288892: Commercial practices policies (CPPs)

SOP_54813: Medical information responses to Healthcare Professionals, Other Healthcare staff and Patients/Consumers

STD_544132: Emerging markets & Asia Pacific Pharma Samples Standard

ViiV Code of Practice

STD-CHC-401: Consumer Healthcare Code of Practice

Other links

Pipeline presentations

IMED ref materials

1.1 Principles for promotion

We only promote medicines in a country after marketing authorisations have been granted in that country.

Our medicines are promoted only for approved indication(s), consistent with locally approved prescribing information.

Promotion is only directed at those whose need or interest in the particular information can be reasonably expected based on the locally approved prescribing information.

Nothing is offered or provided in a way that has an inappropriate influence on the recommendation, prescription, purchase, supply, dispensing or administration of our medicines.

Our employees do not use any inducement or deception to gain access or obtain an appointment with Healthcare Professionals (HCPs) and Other Healthcare Staff (OHS). The frequency and timing of appointments does not cause inconvenience.

Our promotional information is:

- Consistent with locally approved prescribing information where it includes benefit claims for the medicine.
 - Promotional materials may not necessarily be limited to using only the verbatim of the approved product information ('the label'). Promotional information respects the context and intent of information in the approved label, and statements from the label may not be reproduced out of context.
- Clear, legible, up to date, accurate, fair, objective and balanced.
- Capable of substantiation (verifiable).
- Based on relevant evidence and sufficiently complete to enable the recipient to form their own opinion of the medicine.

Our promotional information is not:

- Misleading – by distortion, exaggeration, misrepresentation, undue emphasis, omission or in any other way.
- Knowingly offensive or disparaging.
- Disguised in any way.

i Disease information proactively provided for HCPs/OHS meets the requirements of this section unless it is non-promotional disease awareness information to be passed on to patients.

> See section 3
or a scientific engagement activity

> See section 2

i The use of digital channels for promotion follows the requirements of this section and **POL_132175**:

📄 **POL_132175**: Policy for use of digital channels

1.2 Promotional information

Promotional material (printed and digital) that includes benefit claims for the medicine, includes:

- Abbreviated prescribing information or full prescribing information (or direction to this information if this is specifically permitted by legal and regulatory requirements).
- The date of preparation/approval and a unique tracking code. For space-constrained items where no claims are made (eg reminder advertisements) an alternative mechanism for tracking/recall is required.
- For digital channels targeted to audiences from more than one country, users from a single country are able to access the abbreviated or full prescribing information for their country.

The material itself (without reference to included prescribing information) must not give a misleading impression of the medicine and its uses. It must reflect the balance of risks and benefits. Any significant limitations or qualifications of claims are disclosed and included clearly in the body of the material.

Relevant information on the type of evidence available (eg double blind or open label clinical trial), side effects, contraindications, precautions, indications, relevant doses and/or methods of administration is included.

There is a sound statistical basis for information, claims and comparisons in promotional material. Differences which do not reach statistical significance must not be presented in a way which is misleading.

Patient numbers are included when expressing data as percentages.

Where a clinical or scientific issue exists which has not been resolved in favour of one generally accepted view, the issue is treated in a balanced manner.

Where published studies are referred to, clear references are included in the material.

Comparisons between different medicines that provide information relative to a comparator (including a placebo) are based on relevant and comparable aspects of the medicines.

Endorsements, quotations, testimonials and the like (including treatment guidelines) attributed to individuals or organisations such as government agencies, professional bodies or independent agencies are:

- Valid.
- Current.
- Verifiable (by citing published references or obtaining written approval of the promotional material from the individual or organisation).
- Consistent with the approved prescribing information and approved by the same criteria as any promotional claim.
- Follow requirements set by the organisation (for example written approval in advance of the final promotional material that contains or implies an endorsement by the organisation may be required).

Communication of relative risk with respect to efficacy or safety data includes the absolute rates to put the outcome in context, for example:

- Medicine X reduced the relative risk of myocardial infarction by 50% compared to placebo (the risk of myocardial infarction for medicine X was 5% and for placebo it was 10%).
- The study demonstrated a vaccine efficacy (1 minus relative risk) of 95%, reducing the risk of contracting the disease Y. The disease Y was confirmed in 10 participants among 20,000 in the vaccine group and in 200 participants among 20,000 in the placebo group.

Claims for superior potency of a medicine (ie the medicine has a lower effective dose) are avoided unless they can be linked to a practical advantage such as a reduction in adverse reactions or cost of effective dosage.

Price comparisons are made on the basis of equivalent dosage requirements for the same indications. For example, to compare the cost per mL for topical preparations is likely to mislead unless it can be shown that their usage amounts in mL are similar.

1.2 Promotional information

continued

Any claim involving the economic evaluation of a medicine reflects the data available and does not exaggerate its significance. Assumptions made in an economic evaluation are clinically relevant and consistent with the prescribing information.

Medicines must not be stated as being 'better' or 'superior' without reference to the comparator.

Medicines must not be stated as being the best, greatest, strongest (or other superlative words that indicate the highest quality or degree) unless it can be substantiated as a statement of fact.

Claims must not imply that a medicine, or an active ingredient, has some special merit quality or property unless this can be substantiated.

The use of 'in vitro' laboratory or animal data to support claims of a human health benefit is permitted only where the type of data are made clear and there is an established link between that data and the human health benefit (eg a publicly available consensus by the scientific community and/or regulatory authorities).

It must not be stated that a GSK medicine has no side effects, toxic hazards or risks of addiction or dependency. The word 'safe' must never be used to describe effects on patients, and the words 'safely' or 'safer' must never be used to describe our medicines without qualification.




The word 'new' and equivalent terms are only used to describe our medicines (or uses, indications, presentations or formulations) that have been generally available in the relevant country for less than 12 months.

Artwork, including graphs, illustrations, photographs and tables which are taken from publications and included in promotional material:

- Clearly indicate the precise source(s) of the artwork.
- Are faithfully reproduced; except where adaptation or modification is required and permitted in order to comply with local laws, regulations or applicable industry codes, in which case it is clearly stated that the artwork has been adapted and/or modified.
- Are authorised for use in accordance with relevant copyright law.

A procedure for reporting adverse events is included in the body of the material or in prescribing information that is provided together with promotional material that makes a benefit claim.

Information to support promotional claims is readily available and is provided in response to any reasonable requests.

-  Promotional material co-created by Above Country Business Units and selected LOCs for distribution to LOCs follows this Code.
-  **SOP_285774: Approval Process for promotional and non-promotional materials created by LOCs and Above Country Business Units Gifts, hospitality and entertainment (SOP-GSKF-414).**
-  In all countries except the USA and Canada the address of the pharmaceutical company or the agent responsible for marketing the product is included on promotional material.


1.3 Direct to consumer advertising

Prescription medicines are not advertised to the general public unless it is expressly permitted by local laws, regulations or applicable industry codes. This prohibition does not apply to public health activities such as vaccination campaigns approved by relevant licensing authorities.

Where permitted, advertising and promotion of our medicines to the general public:

- Does not encourage unnecessary or inappropriate use.
- Indicates, where applicable, appropriate limitations to the use of medicines.
- Avoids language or imagery which may cause fear or distress.

The introduction of a new medicine is not made known to the general public until reasonable steps have been taken to inform the appropriate HCPs of its availability.

 **See section 3.2** for disease awareness for patients or the general public.

1.4 Promotional meetings

1.4.1 All promotional meetings

Promotional meetings include GSK stand-alone meetings, speaker programmes, promotional webinars and most GSK sponsored satellite symposia at scientific/medical congresses.

➤ See section 2.6.3(b) for scientific satellite symposia

The purpose of our promotional meetings is to proactively provide scientific or medical information about our authorised medicines and/or the associated diseases.

Where hospitality is provided at a promotional meeting, it is incidental and the scientific or medical content of the meeting accounts for at least two thirds of the total duration.

- Meetings which are not scientific engagement that we own, organise or influence (eg by suggesting or providing content or by selecting/recommending speakers) are GSK promotional meetings. They are promotional meetings whether or not they are awarded continuing medical education (CME) points or other continuous professional development credits.

Promotional meetings only occur when we are able to ensure that the meeting adheres to the requirements of this section and other relevant requirements of this Code, including that the data presented and materials provided do not promote off-label use of our medicines.

For any promotional meeting, it is the scientific content of the programme that attracts a delegate to attend.

Promotional meetings are only permitted in disease areas where we have an authorised medicine.

For information regarding promotional webinars, refer to:
SOP_375788: Conducting promotional webinars & Webcasts

A high level non-promotional overview of the R&D pipeline at promotional meetings is permitted following specific requirements provided:
Pipeline presentations

Presentations in the core programme of medical congresses or meetings for Independent Medical Education are not promotional.
 ➤ See section 2

For information regarding meeting logistics and hospitality, refer to **STD_404715**:
STD_404715: Standard on meetings and catering.

1.4.2 Material (including content of presentations)

Materials for promotional meetings follow the requirements of sections 1.1 and 1.2.

Abbreviated or full prescribing information (as required by local regulations or applicable codes) must be available at the meeting. Alternatively, if specifically allowed by local laws, regulations or applicable industry codes, reference or direction to prescribing information is permitted.

Our involvement is disclosed in communications relating to the meeting and in any published proceedings. The declaration of GSK's role is clearly visible.

Materials are reviewed and approved for compliance with local requirements of the country in which the meeting is held. Where specific HCPs/OHS are directly invited from outside the country where the meeting is held (or the meeting, or a recording of the meeting, is targeted to them), the material meets the relevant requirements of the HCPs/OHS home country (eg the material is approved as consistent with the prescribing information of HCPs/OHS home country).

- Promotional information on a medicine may be presented at an international congress held in a country where the relevant medicine or use is not authorised and the following applies:
 - The majority of expected attendees are from outside the venue country and from countries where the medicine or use is authorised.
 - Materials include a statement that the medicine or use is not authorised in the country where the meeting is held.
 - It is permitted by the local laws, regulations, applicable industry codes and local GSK standards for the country where the congress takes place.

1.4 Promotional meetings

continued

1.4.3 GSK speakers and attendees

Appropriately trained Commercial and/or Medical/R&D staff who have relevant content knowledge may present on our medicines and/or the associated disease areas at promotional meetings, where:

- Presentations and associated materials are consistent with the local label and the audience is informed of this.
- Presentations are distinct and separate from non-promotional interactions.
- Our staff are trained on how to handle misrepresentation of information or data by a member of the audience.
- Our staff are trained on how to respond to unsolicited questions on unlicensed GSK medicines or indications.
- Our staff are trained on how to identify and report human safety information reported by attendees.
- Our staff who speak, attend or participate in meetings are transparent about their employment by GSK.

Medical/R&D staff may present data provided:

- There is an identified medical need and patient benefit (eg explaining complex data, providing broader context or strengthening understanding of appropriate patient populations for treatment, dose selection and adherence) above and beyond that which can be provided by a commercial speaker.
- The frequency and type of presentations are appropriate for the medical need.
- There is an audience of at least three HCPs/OHS.
- Targets are never set for Medical/R&D staff based on number of HCPs/OHS reached by the presentations.
- Their work at GSK is their primary employment (ie >50% of their total working hours) and they are employed by GSK in a recognised and defined medical capacity. Medical staff cannot be employed by GSK purely for speaking purposes.

Medical leaders locally and above country are accountable for ensuring the above requirements are met.

1.4.4 External speakers

Government Officials: We do not pay external experts who are government officials and who have an actual or perceived influence on government that could impact GSK business to speak on any topic unless there is an approved exception by a CET member or delegate. We also do not pay for travel, accommodation or meals (see **STD_455141**: Anti-Bribery and Corruption Standard and **STD_243431**: Gifts, Hospitality and Entertainment Standard).

HCPs/OHS: We do not pay HCPs/OHS to speak on our behalf to other HCPs/OHS about our medicines and/or the associated disease areas in promotional meetings.

Patients: Patients may receive payment at fair market value to speak at promotional meetings to HCPs/OHS about their personal experience of a disease/disease area.

1.4.5 HCPs/OHS who agree to speak without payment

We may engage HCPs/OHS to speak about our medicines and/or the associated disease areas without a fee for that service.

Our SOP on engaging external experts to provide a service is followed (see **SOP_344448**: Engaging with external experts to provide services).

- Unpaid speakers do not receive any other 'quid pro quo' arrangements (eg we do not consider unpaid speaking as a factor in selecting the HCPs/OHS to provide other services or to participate in our research).

We may arrange and pay reasonable transportation, accommodation and meals via a GSK approved vendor. We may reimburse additional approved expenses incurred during or related to the contracted activity for an unpaid HCP/OHS speaker, eg taxi fares may be reimbursed directly to the HCP/OHS:

See section 4.1

- This is approved in advance by the General Manager or designee of the country in which the unpaid HCP/OHS speaker resides.
 - Additional prior CET member or designee approval is required for any air travel or overnight accommodation.
-

1.4 Promotional meetings

continued

Contracts are required to define our obligations and those of the speaker. In addition to standard contract requirements, the following is included in contracts with unpaid speakers:

- We require the speaker to make an appropriate and clear disclosure (verbal or written on a slide) at the beginning of each speaking engagement to highlight any payment for travel or other costs (covering the last 12 month period) that they may have received from GSK – for example:

“I am a paid consultant/investigator for GSK Pharmaceuticals/ Vaccines, and GSK has reimbursed my travel costs for this engagement but I have not been paid and will not be paid for this speaking engagement.”

i When HCPs/OHS provide content support to promotional materials they may be paid on a fee for service basis provided they are not acknowledged in the final material, they do not present any slides generated in a GSK promotional meeting and the materials are owned by GSK.

1.4.6 GSK satellite symposia

Satellite symposia may be under Commercial or Medical budget. Medical has accountability for the content of GSK funded satellite symposia.

- The scientific and medical content of a satellite symposium and the appropriateness of the speaker faculty are approved by the relevant CMD or designee for the country in which the event occurs (see above for additional approvals for HCPs/OHS who agree to speak without a payment). Logistical arrangements may be implemented by non-medical teams or a contracted vendor.

1.4.7 Commercial booths at meetings

Commercial booths are permitted at meetings if the topic of the meeting is related to a disease for which GSK has an approved medicine, or where it can be reasonably expected that the audience will have a need or interest in the information presented.

Commercial booths are staffed by those who are trained to discuss our medicines with delegates consistent with the prescribing information and in accordance with relevant promotional rules.

Competitions (including raffles and lotteries), gifts, recreation and entertainment are not permitted (basic refreshments such as tea and coffee are permitted). Non-competitive quizzes that relate to scientific/medical knowledge or skill in the relevant disease area are permitted.

i If an HCP asks an off-label question or asks a question that requires a written response, the question is captured and submitted to Medical Information. Alternatively the HCP may be referred to the GSK Medical Information booth if there is one at the meeting.

1.4.8 Collaborative promotional meetings

There must be a clear reason for working with a Medical society/HCO to deliver medical education on GSK medicines and associated diseases via a promotional meeting. For example the Medical society/HCO may bring clinical experience to the development of the medical education which GSK does not have, or the Medical society/HCO endorsement provides assurance of the quality of the programme.

Such collaborative meetings are:

- Organised by a LOC or an above country unit and approved by the appropriate Medical Governance Board.
- An above country led meeting is reviewed by the LOC in the country in which the meeting takes place to ensure compliance with local laws, regulations and applicable industry codes.

1.5 Detailing

See sections 1.1 and 1.2

The following applies to sales representatives and others who detail our medicines.

Sales representatives are given adequate training and have sufficient scientific knowledge to enable them to provide relevant and accurate information about the medicines they detail.

Sales representatives ensure they do not mislead as to their identity, role or the company they represent.

The use of unapproved materials is not permitted, including unapproved medical papers or extracts of any articles, even if these are published in peer reviewed journals. Materials relating to medicines or indications that do not have marketing authorisation are not referred to or distributed by sales representatives.

– Reprints of journal articles distributed by sales representatives are regarded as promotional material and are approved for such distribution through the copy approval process.

Sales representatives must not solicit any requests for off-label information on our medicines.

Sales representatives receiving unsolicited requests for off-label medical information, or those requiring a written response, forward such requests to the Medical Information function (see **SOP_54813**: Medical information responses to Healthcare Professionals, Other Healthcare staff and Patients/Consumers). Responses to medical information requests are sent directly to the HCP/OHS requesting the information.

Sales representatives must not:

- Deliver Medical Information written responses to HCPs/OHS.
- Receive a copy of the Medical Information responses sent to HCPs/OHS; they can receive notification that their request has been answered.
- Request Medical Information responses for their own use.

Sales representatives supply current, approved prescribing information if requested by an HCP/OHS.

In the USA, journal reprints and clinical practice guidelines may be distributed following the commercial practices policies:

POL_288892: Commercial practices policies (CPPs)

For certain unsolicited questions regarding the availability of data, where permitted by local laws, regulations or applicable codes, Medical may approve that it is appropriate for field personnel to respond “Yes, there is data available” in the course of referring the question to Medical Information.

1.6 Medical/R&D involvement in promotional meetings

Medical/R&D staff do not accompany sales representatives in the field to meet in 1:1 type interactions with HCPs/OHS unless there is an exception approved by the CMD or designee.

Medical/R&D staff do not discuss clinical research or scientific engagement activities with HCPs/OHS in the presence of a sales representative.

When proactively presenting data or information on our medicines and/or the associated disease areas at promotional meetings, Medical/R&D staff are acting in a promotional capacity.

1.7 Samples

Samples are small supplies of medicines given to HCPs free of charge. The purpose of samples is to familiarise HCPs with a particular medicine and its use in patients, and/or to facilitate patient experience with the medicine.

– Samples are not provided for clinical studies or compassionate use or to address issues of patient access to our medicines.

Samples of vaccines are not permitted. Samples of other medicines can be given to HCPs/OHS authorised to prescribe or supply that medicine provided this meets local laws, regulations, applicable industry codes and any global, regional or local GSK requirements for specific medicines.

Respiratory inhaler devices and associated devices (eg spacers) and vaccine reconstitution devices with no active ingredient are not samples but are items of medical utility.

See section 3.4

1.7 Samples

continued

Local requirements, accountabilities, processes and governance of samples are documented in a local SOP which includes:

- The rationale for providing samples.
- An approved list of medicines and presentations which can be offered as samples (pack size is not larger than the smallest presentation available within that country except for antibiotics where a complete course of therapy must be provided on receipt of an unsolicited request from an HCP).
- Acceptable volumes.
- Duration of sample distribution.
- Distribution requirements including storage requirements where needed (eg appropriate refrigeration if required, security of samples, inventory management).
- Labelling (each sample is to be marked 'free product sample – not for resale' or words to that effect and accompanied by prescribing information or other approved product information).
- Processes to monitor and track sample distributions, enable recall and audit.

i Within Europe, quantities of samples of prescription medicines are limited to four samples per year per HCP for a restricted two year period from when the HCP first requests samples of each particular new medicine. In this context, a new medicine is one for which a new marketing authorisation has been granted, either following an initial marketing authorisation application or following an extension application for new strengths/dosage forms that include a new indication.

i Within Emerging Markets and Asia Pacific, an annual limit of samples is agreed and documented by the RMCB:
STD_544132: Emerging markets & Asia Pacific Pharma Samples Standard

i Refer to the Codes of Practice for ViiV Healthcare and Consumer Healthcare for specific requirements regarding samples for those products:
ViiV Healthcare Code of Practice
STD-CHC-401: Consumer Healthcare Code of Practice

1.8 Promotional aids

Promotional aids (sometimes called brand reminder items) can be given to HCPs/OHS provided they are of minimal value (to be defined and documented locally), relevant to the professional activities of the recipient and provided on an infrequent basis.

Promotional aids may carry product branding and company branding.

i In the USA, Canada and China promotional aids are not permitted.

i For Japan, Chile and countries in Europe: No promotional aids are permitted other than pens and pads at GSK meetings or meetings funded by GSK. They do not carry product branding.

i For countries in Emerging Markets and Asia Pacific: Promotional aids are listed **here**.

i Medical/R&D staff are not permitted to provide branded promotional aids to HCPs/OHS.

1.9 Co-promotion with third parties

Subject to applicable competition law and guidance issued for particular types of deal, where a third party is co-promoting or promoting a GSK medicine (ie we own the marketing authorisation), the third party complies with the standards set out in local laws, regulations and applicable industry codes and this Code. Promotional materials and activities carried out by the third party are approved by GSK in accordance with relevant approval processes.

Where we co-promote or promote a third party's medicine (ie where they own the marketing authorisation) we comply with local laws, regulations and applicable industry codes. We also seek agreement from the third party to comply with the standards set out in this Code.

Standard provisions for inclusion in contracts with third parties are found via the **Third Party Oversight intranet site**.

2

Scientific engagement (non-promotional)

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2.9	Scientific interactions with payers, governments and public health organisations	p46

References relating to this section



Written standards

POL_132175: Policy for use of digital channels

STD_340448: Standard for interacting with patient organisations

POL_87160: External and internal communication activities on behalf of GSK (POL-GSK-301)

SOP_191843: External and internal communication activities on behalf of GSK (SOP-GSK-301)

SOP_285774: Approval Process for promotional and non-promotional materials created by LOCs and Above Country Business Units Gifts, hospitality and entertainment (SOP-GSKF-414)

GUI_333516: GSK Guideline on the conduct of primary market research in GSK Pharma

SOP_297780: US Pharma market research: criteria for designing and executing market research conducted in the US

SOP_344448: Engaging with external experts (HCPs) to provide services

POL_288892: Commercial practices policies (CPPs)

SOP_54813: Medical information responses to Healthcare Professionals, Other Healthcare staff and Patients/Consumers

SOP_293924: Scientific engagement of individual and groups of Patients, patient caregivers and consumers to seek advice, insights and information (SOP-GSKF-416)

POL_87187 Policy on Human Subject Research (POL-GSKF-408)

SOP_53431: Publication of Human Subject Research in the Scientific Literature

SOP_9000026959: Public disclosure of human subject research (Vaccines)

SOP_54809: Dear Investigator and Dear Healthcare Provider Letters

POL_251355: Policy on grants and donations (POL-GSK-016)

SOP_264719: Grants and donations Procedure (SOP-GSK-016)

SOP_462904: SOP for Managing Third Party Risk

STD_455141: Anti-Bribery and Corruption Standard

Other links

Scientific engagement

Guidance for when a contract is required

GSK Publication Handbook

ABAC

Moore model

IME agreement contract

access.gsk.com





2.1 Introduction

Scientific engagement is the non-promotional interaction and exchange of information between GSK and external communities in order to advance scientific and medical understanding. This includes the appropriate development and use of our medicines, understanding the management of disease and improving patient care.

The activities and materials associated with scientific engagement are non-promotional in nature and intent, and proportional to the scientific need. There is a clear distinction between scientific engagement and promotional activities.

Scientific engagement activities covered by this Code are:

- Seeking external advice, insights and information.
- Scientific communication of our research.
- Scientific interactions and discussions.
- Supporting medical education.
- Scientific interactions with payers, governments and public health organisations.

	Under scientific engagement, the scientific communication of our research includes papers in peer reviewed journals and presentations in the core programme of scientific/medical congresses.
	There are other activities that involve the non-promotional interaction and exchange of scientific or medical information such as in the conduct of research, engaging regulatory authorities (including preparation for meetings), providing medical information responses and enabling compassionate use of investigational medicines. For these activities please refer to the relevant written standards.
	See appendix 1
	Medical/R&D staff do not discuss clinical research or a scientific engagement activity with HCPs/OHS in the presence of a sales representative.

2.2 Principles for scientific engagement

Scientific engagement with external communities is fundamental to the progress of medical science and to meeting the needs of patients and public health.

Our physicians and scientists engage in the highest standards of peer-to-peer scientific dialogue to increase understanding of diseases and develop effective prevention and treatment therapies.

Scientific engagement is driven by legitimate scientific need. It is balanced, appropriate and proportionate to the scientific need and intent.

Scientific engagement activities or behaviours are not promotional and do not have the appearance of being promotional or being designed to influence the prescription, supply, sale or use of our medicines.

Scientific engagement starts in the early stages of development and continues throughout the life cycle of the medicine.

Whether a proposed activity or material meets the principles for scientific engagement requires medical judgement with consideration of timing, intent, proportionality and perception to ensure that:

- There is a legitimate need for the activity at the time it occurs.
- The intent is clear, transparent and non-promotional.
- The timing and scale are proportionate to the scientific need.
- The activity would not be perceived as being promotional.

Following this TIPP (Timing, Intent, Proportionality and Perception) in conjunction with our values of Transparency, Respect, Integrity and Patient focus (TRIP) helps us to apply judgement when the situation is unclear or not specified in this Code.

The context of any activity is considered in deciding what is appropriate, particularly just before launch when a significant increase in scientific engagement activities could be perceived as being promotional in intent.

2.2 Principles for scientific engagement continued

The use of digital channels for scientific engagement follows the requirements of this section and follows **POL_132175**: Policy for use of digital channels.

- 📘 Scientific engagement with patient advocacy groups and the media follow these principles:
 - 📄 **STD_340448**: Standard for interacting with patient organisations
 - 📄 **POL_87160**: External and internal communication activities on behalf of GSK (POL-GSK-301)
 - 📄 **SOP_191843**: External and internal communications activities on behalf of GSK (SOP-GSK-301)

2.3 Accountability and approval

Accountability and approval for scientific engagement activities resides within our Medical Governance Framework to ensure that the content, frequency and other aspects of scientific engagement are appropriate and proportionate to genuine scientific and public health need.

Scientific engagement materials are reviewed and approved for accuracy and to ensure that they are not promotional in tone or content.

- 📘 See **SOP_285774**: Approval Process for promotional and non-promotional materials created by LOCs and Above Country Business Units Gifts, hospitality and entertainment (SOP-GSKF-414).

Budgets for scientific engagement activities are under Medical/R&D accountability.

The relevant Medicine or Vaccine Development Leader (MDL/VDL) is accountable for scientific engagement and approval of scientific engagement activities from Commit to Medicine Development to marketing authorisation.

- Where there is no MDL/VDL/Global Medical Affairs Leader (GMAL) assigned, the most appropriate member of the relevant therapy or functional area head within the business unit that is initiating the activity is accountable for ensuring that the principles of scientific engagement are appropriately applied.

Once a medicine (or new indication) receives marketing authorisation in at least one key market (eg USA, EU or a franchise market), approval for post-authorisation activities is in line with the level in the organisation where the activity is organised, eg relevant GMAL (or assigned individual where there is not a GMAL) for a global activity, Area Medical Lead for an area activity, CMD for a LOC activity (in countries where a CMD role does not exist, the Area Medical Director is accountable).

Approval templates are available from the **scientific engagement website**. The business owner ensures that where relevant, approval is documented and stored following instructions on the **scientific engagement website** within two weeks of the approval being granted.

- 📘 Where activities or interactions are organised or arranged from a Business Unit or LOC and aimed at individuals from a number of countries or from another country, the relevant CMDs are consulted to ensure applicable requirements are followed.

2.4 Use and selection of vendors

External vendors do not develop scientific engagement plans or content (eg selection and interpretation of scientific data). Vendors can be used for operational support (eg formatting, layout, design, artwork, copy editing, researching references, printing, logistics and overall project management) when the required capabilities or capacity are not available within GSK.

Vendors engaged to provide operational support for the development of content (eg copy editing, researching references) are trained and understand that GSK is responsible for reviewing and approving content.

Vendors engaged for promotional activities and for the operational support of scientific engagement ('dual purpose' vendors) are required to maintain an appropriate level of separation between these activities which may involve organisational firewalls.

- This limitation does not include consultants who are under contract to provide guidance and advice, Clinical Research Organisations (CROs) or vendors who only provide logistical support (eg travel agencies, event management).
- Training assessment is checked by the business owner for each vendor prior to each new engagement. It is recommended that an approved procurement process is used. If Procurement is not involved in the contracting process, the local business owner assumes responsibility for maintaining contracts, organisational firewall declarations and annual training certifications (see **scientific engagement website** for SE vendor contract clauses).

2.5 Seeking external advice, insights and information

2.5.1 What we can do

Seek advice (on pre-determined questions), insights and information related to scientific research, diseases, medicine development, disease management, market access, commercialisation or other medicine related matters through:

- (a) Advisory boards and 1:1 type consultancy (advice-seeking from individuals on a consultancy basis) under contract.
- (b) Scheduled discussions with individuals or groups without a contract/written agreement.

2.5.2 Where care is needed

Interactions described in this section are not used as a vehicle to publicise data. Care is needed to ensure scientific discussions do not become promotional in tone/intent.

For discussions not requiring a contract/written agreement, care is needed so that the discussion does not evolve into a situation where a contract/written agreement is needed (see **Guidance for when a contract is required**).

2.5.3 What is not included

The requirements below do not apply to:

- Advisory boards that are not related to disease areas, medicines or the development or use of medicines.
- Market research/focus groups (eg see **GUI_333516**: GSK Guideline on the conduct of primary market research in GSK Pharma and **SOP_297780**: US Pharma market research: criteria for designing and executing market research conducted in the US).

2.5.4 Requirements

- (a) **Advisory boards and 1:1 type consultancy under contract**
Advice may be sought during the lifecycle of a medicine if there is a legitimate, documented need and the information is not already available through literature, databases or other internal sources including previous advice-seeking activities.

The scale and timing of the advice-seeking activity is appropriate to the scientific need.

The proposed objectives and agenda are focused on obtaining input.

Only data relevant to the specific advice being sought is shared with participants.

Advisors are appropriately contracted and paid a fee for service in alignment with the requirements of **SOP_344448**: Engaging with external experts to provide services.

Medical/R&D is accountable and holds the budget for these activities. Other functions can be involved if relevant to the need.

Advice is sought from as few people as necessary. They are appropriately qualified to provide the advice and their qualifications are documented. If more than 12 advisors are required, the rationale is documented and approved.

Only GSK staff who have an active and documented role which is necessary to meet the objectives may participate in the meeting.

The advisory nature of the engagement is made clear in documentation (including internal plans) and materials, and the specific advice being sought is made clear.

The output and the way we will use the advice is documented.

i In the USA advice-seeking activities by US Commercial are conducted in compliance with applicable US commercial practices policies:
☞ POL_288892: Commercial practices policies (CPPs)

i See also
☞ SOP_293924: Scientific engagement of individual and groups of Patients, patient caregivers and consumers to seek advice, insights and information (SOP-GSKF-416)
☞ SOP_344448: Engaging with external experts to provide services
☞ STD_340448: Standard for interacting with patient organisations

2.5 Seeking external advice, insights and information

continued

(b) Scheduled discussions with individuals or groups without a contract/written agreement

Medical/R&D staff may interact with HCPs/OHS on a limited basis to gain insights and information. The extent of these discussions led by Medical is proportionate in length and frequency, and based upon a genuine need to enhance our scientific understanding. The HCPs/OHS contacted have the relevant expertise to provide the information required. These scientific discussions:

- May be conducted via a brief scheduled visit to the HCP/OHS, by phone or via permitted digital communication channels.
 - May include seeking insights on disease and on post-authorisation medicine-related questions.
 - May be based on a local need for rapid insights or information to support planning or help resolve a medical issue.
 - May be based on an above country written request to LOCs to gain local insights on specified questions from selected HCPs/OHS to help inform Global or Area strategy.
 - Maintain scientific objectivity, integrity and credibility.
 - Must have documented rationale and outcomes.
 - Do not involve proactively providing information about our medicines. However information on our medicines may be provided in response to a specific unsolicited question (see **SOP_54813**: Medical information responses to Healthcare Professionals, Other Healthcare staff and Patients/Consumers) or within the scope of a current documented standing information request. Misunderstandings about our medicines can be corrected as they arise.
- See section 2.6.3 (c)
- Are led by Medical/R&D staff though senior commercial staff may attend where there is a documented reason for their attendance based on TRIP and TIPP.

CMDs are accountable for ensuring that the above requirements are followed for interactions with HCPs/OHS in their market.

Gaining insights and information through scheduled discussions does not usually require written agreements or contracts (see **Guidance for when a contract is required**).

Documentation of the rationale for and outcome of interactions, eg in the local CRM system (eg Veeva) or via a contact report (stored in a business unit or LOC defined system), is required to ensure learning across relevant parts of the organisation.

Examples of permitted interactions:

- Discussions to understand a disease or general patient management related to a specific disease.
- Contacting an expert HCP to obtain information or insights which are not readily available through the scientific literature or other publicly available sources. Examples may include local prevalence of a specified disease, or typical presentation characteristics of a particular patient type in the clinic. Product related questions may be asked to seek insights on evidence gaps, or experience with a new medicine post-authorisation.

2.6 Scientific communication of our research

2.6.1 What we can do

- (a) Scientific public disclosure of our research.
- (b) Other congress activities to communicate or discuss our science:

- Scientific/medical information booths.
- Scientific satellite symposia.

- (c) Provide medicine related information in response to unsolicited requests from an HCP/OHS.
- (d) Present data in response to unsolicited requests.
- (e) Support the development of treatment guidelines by medical societies by providing scientific information.
- (f) Communicate important safety information.

2.6.2 Where care is needed

To ensure:

- The number of publications and congress abstracts (oral or poster presentations) is driven by legitimate medical/scientific need and not a desire to increase citations or publicity. Publications and congress presentations (oral or poster) are included in Data Dissemination Plans.
- There is clear separation of scientific and promotional activities at medical/scientific congresses.

2.6 Scientific communication of our research

continued

2.6.3 Requirements

(a) Scientific public disclosure of our research

We publicly disclose our research according to the principles and requirements of **POL_87187: Policy on Human Subject Research (POL-GSKF-408)**. This includes postings on internet registers, congress presentations (oral or posters) as part of core congress programmes, and manuscript publications.

 See also

 **GSK Publication Handbook**

 **SOP_53431: Publication of Human Subject Research in Scientific Literature**

 **SOP_9000026959: Public disclosure of human subject research (Vaccines)**

(b) Other congress activities to communicate or discuss our science

Scientific/medical information booths

Scientific/medical booths at medical congresses are permitted. These booths may:

- Provide Medical Information support in accordance with **SOP_54813: Medical information responses to Healthcare Professionals, Other Healthcare staff and Patients/Consumers**.
- Display balanced information on all ongoing GSK sponsored clinical studies and GSK supported studies which are relevant to the congress.
- Display areas of GSK scientific interest including areas of focus for GSK discovery research (eg selected immunological pathways) which are relevant to the congress. This must not include specific details on a medicine's mechanism of action.

Activities conducted from the scientific booth are non-promotional and there is no proactive distribution or display of data on our medicines. Scientific information supporting approved medicines is managed from the commercial booth.

Scientific booths are physically separate from commercial booths, with at least a dividing partition or wall in between if sharing a single allocated floor space, or at least a walkway between if separate floor space is used. Scientific/medical booths are staffed by Medical/R&D staff only.

Scientific satellite symposia

Centrally based above country units (eg Franchise Units) may arrange occasional medically led scientific satellite symposia at international congresses. The content may include information that is not strictly on-label. The intent and general content require approval from all the following:

- The CMD in the country where the symposium is planned.
- The MDL/VDL/GMAL.
- The CMO or delegate.

(c) Provide medicine related information in response to unsolicited requests from an HCP/OHS

Responses to unsolicited requests and statements

Medical/R&D staff may provide information in response to an unsolicited request from an HCP/OHS or to respond to a statement made by a congress delegate. Any verbal response is consistent with the medical information response (where relevant). The response is tailored to only respond to the specific question asked or the statement made. Specific unsolicited requests for written medical information are handled via WISDOM (or equivalent) and standard response letters are sent directly to the HCP/OHS by Medical Information (see **SOP_54813: Medical information responses to Healthcare Professionals, Other Healthcare staff and Patients/Consumers**).

Standing Information Requests

This is a request made by an HCP/OHS for externally facing Medical Affairs staff to provide specific medical or scientific information at an agreed frequency. Such requests:

- Are implemented in a market if the CMD decides to based on local regulations and the likely perception of HCPs/OHS.
- Have a degree of specificity as determined by the CMD in conjunction with legal in each LOC.
- Are documented via a CRM system (eg Veeva), to specify the scope and content that the HCP/OHS wishes to receive.
- Are reassessed with the HCP/OHS at least once every 12 months.
- Standing Information Requests received via sales representatives or other staff require documentation to show that the request is unsolicited.

2.6 Scientific communication of our research

continued

(d) **Present data in response to unsolicited requests**
Scientific and medical presentations made by our staff in the core part of medical congresses in response to unsolicited requests from legitimate medical/scientific societies are based on information available in the public domain; are of scientific or medical significance to the intended audience; are factual, balanced, non-promotional and in accordance with local laws, regulations and applicable industry codes.

Medical/R&D staff may present a disease area pipeline overview to medical audiences in response to an unsolicited request, typically from a congress organiser. The information presented is based on information available in the public domain.

External-facing Medical and R&D personnel may participate in 1:1 or group meetings to present information in response to specific, documented, unsolicited enquiries about licensed or unlicensed products or indications where a presentation or discussion has been specifically requested.

When presenting to a group of HCPs/OHS in response to an unsolicited request that was made on behalf of the group, GSK does not solicit attendance of individual HCPs/OHS from within the group.

 See also
 Pipeline slides

(e) **Support the development of treatment guidelines by medical societies by providing scientific information**
If we do not have an authorised medicine in a given disease area, Medical/R&D staff can provide medical and scientific information for the development of a treatment guideline in response to an unsolicited request from a medical society/other appropriate bodies. In these circumstances and upon invitation, we can contribute information to meetings and answer questions in discussions.

When we have an authorised medicine in a given disease area and there is no treatment guideline endorsed by a medical society/other appropriate body, or when existing guidelines need updating, Medical/R&D staff can proactively contribute our data and perspectives.

In either of the above situations, support provided for the generation or revision of guidelines is only considered when our participation brings scientific or medical value for the benefit of patients. GSK support is clearly disclosed. GSK should not be the only healthcare company providing funding or technical support for the development of medical society/other appropriate body treatment guidelines. Exceptions can occur in the case of requests to help support guidelines associated with rare diseases and/or significant public health concerns. In such cases the Medical/R&D staff may participate in discussions but must not be involved in the decision-making of the medical society/other appropriate body. Our staff declare actual or potential conflicts of interest including their affiliation with GSK if they are involved in discussions on the development of treatment guidelines.

– Official bodies (eg agencies and committees) of governments and regulatory authorities may have clearly defined and regulated procedures for the industry submission of information packages to support the development of official recommendations, and these procedures are followed.

 See section 2.9

(f) **Communicate important safety information**
When there is a need to communicate an important safety issue to supplement the Dear Healthcare Provider Letter (DHPL) process (see **SOP_54809**) or in circumstances approved by the CMO or delegate then the following applies:

- Medical leaders are accountable for ensuring that the safety information is communicated by external facing Medical/R&D personnel in a non-promotional manner.
- It is preferable to present the information to groups of three or more HCPs/OHS, but 1:1 interactions may occur with those HCPs/OHS who are in positions that are likely to aid the broader dissemination of safety information.
- Materials used may include details of the safety information which are not in the approved label.

2.7 Scientific interactions and discussions

2.7.1 What we can do

Medical/R&D may have two way interactions with HCPs/OHS to advance scientific understanding. Such interactions may include:

- (a) Understanding HCP/OHS interests and requirements.
- (b) Spontaneous discussions.
- (c) Scientific workshops including “hot topics” and clinical practice.
- (d) Collaborative scientific programmes.

2.7.2 Where care is needed

- Interactions described in this section are not used as a vehicle to publicise data. Medical/R&D ensure that scientific discussions do not become promotional in tone or intent.
- We ensure that the scientific independence of any third-party scientific partners is preserved.

2.7.3 Requirements

(a) Understanding HCP/OHS interests and requirements

At a first meeting with an HCP/OHS, Medical staff may ask questions to understand the scientific interests and needs of the HCP/OHS, and agree on how we may provide appropriate support. This is confirmed and documented (eg in the local CRM system (eg Veeva)).

(b) Spontaneous discussions

Ad hoc unplanned discussions at a scientific/medical congress, or other similar professional or scientific environment, between our Medical/R&D staff and HCPs/OHS or other experts may occur provided there is no promotional intent or purpose.

- These discussions do not involve proactively providing information about our medicines. Limited reference to publicly available information about our medicines is permitted in order to ask a question or discuss statements made by HCPs/OHS.
- When an incomplete or inaccurate statement about our medicines is made by an HCP/OHS, our Medical/R&D staff may provide factual, balanced context that clarifies or challenges that statement.
- Where important insights and information relevant to our science and/or our medicines is obtained, it is shared with relevant GSK colleagues and recorded in the local CRM system (eg Veeva).

(c) Scientific workshops

When there is a compelling scientific justification and HCP/OHS need for genuine scientific discussion, we may conduct a GSK scientific workshop within the infrastructure of a medical congress, as a standalone meeting or in collaboration with a Medical Society or other third party. The purpose is to discuss or debate disease related scientific topics as identified by HCPs/OHS. For a congress based workshop the focus is either on research which is presented at the congress or on a current scientific debate which is relevant to the congress.

The following points apply:

- The topics for a workshop are driven by HCP/OHS needs/ interests identified by a Medical Society, or by review of Medical Information enquiries, Standing Information Requests and discussions recorded in the local CRM system (eg Veeva), or by market research conducted by a third party.
- The workshop may include publicly available information related to an unauthorised medicine or indication.
- GSK initiates and coordinates the meeting including agreeing with the facilitator and/or Medical Society the main topics to be discussed.
- Participants are HCPs/OHS or other experts who can be shown to have relevant expertise and recent or current interest in the proposed topic. There may be up to 30 participants per workshop, and GSK staff with a defined role to play may also participate. For a congress based workshop the participants are already registered as delegates for the congress.
- We may arrange and pay for reasonable travel and accommodation for participants of a standalone workshop but not for a congress based workshop.
- Any materials used (eg slides, invitations etc) are approved as non-promotional in the market in which the activity occurs, in accordance with **SOP 285774**: Approval Process for promotional and non-promotional materials created by LOCs and Above Country Business Units Gifts, hospitality and entertainment (SOP-GSKF-414). Presentation of data is limited to that necessary to enable the discussion.
- Above country medical business owner co-creates the proposal and content for the workshop with the CMD of the country where the event will occur. The relevant Franchise/BU Medical Head is accountable for oversight and proportionality for all workshops. The CMD must gain local legal input and endorsement in advance of the proposal.
- Payments for external speakers are approved by the CMO who reviews lack of in-house expertise/credibility.

i In the US, scientific workshops which refer to our medicines are conducted under promotional rules, with content consistent with label.

2.7 Scientific interactions and discussions

continued

(d) Collaborative scientific programmes
Scientific collaboration between GSK and diverse groups of experts (Academia, Industry, Regulators, Public Health authorities, etc) is necessary to advance key medical/scientific discussions and to contribute and share our broad scientific knowledge and experience in various settings. Examples of collaborative scientific programmes include forward-looking science “think-tanks”, and meetings to address public health priorities and evolving research fields/technology.

These collaborative activities:

- Are not product specific (unless related to a public emergency).
- Can be organised by a LOC or an above country unit and are approved by the appropriate Medical Governance Board.
- Preferably involve two or more pharmaceutical companies to avoid the perception that GSK has organised the event.
- Where sponsorship from multiple companies or institutions is not possible, the reason why GSK is to be the sole sponsor is justified by the business owner and the activity is approved as described in section 1.4.8.

i See also **Collaborative Scientific Programmes on the Ways of Working Portal**.

2.8 Supporting medical education

2.8.1 What we can do

We can support medical education through the following routes:

- Independent Medical Education (IME) comprises activities that are delivered or implemented for HCPs/OHS without GSK influence on content, speaker faculty or audience selection.
 - Grant funding for IME is permitted in disease areas where we have an authorised medicine.
 - Prior to product approval IME is only permitted for general broad based disease topics which are not product pointing, or when it is related to a significant global public health concern and approved by the CMO or delegate.
- Non-independent Medical Education (Non-IME) comprises activities where GSK has influence on content, speakers, faculty or audience selection:
 - Prior to product approval Non-IME is only permitted for disease education which is not directly or indirectly pointing to a product in development.
 - After product approval Non-IME is governed by promotional rules unless the activity meets the criteria for scientific collaborative medical education.

> See section 2.7.3 (d)

2.8.2 Where care is needed

- Where we have any influence on the education activity it is not IME and in such cases the activity is conducted in accordance with Non-IME requirements in this Code. The preferred approach to medical education prior to medicine/indication approval is via IME.
- CME or other Continuing Professional Development (CPD) points given to participants do not necessarily mean that the activity is independent. Similarly, the absence of these points does not necessarily mean that the activity is Non-independent Medical Education.

Preceptorships have the objective of enhancing HCP/OHS medical expertise in a particular speciality and are usually led and organised by credible, renowned expert centres. As an independent activity that develops or increases the knowledge and skills that HCPs/OHS use to provide services for their patients, preceptorships meet the definition of IME and hence may be funded by a grant and fall under medical accountability.

i Medical education comprises activities that maintain, develop or increase the knowledge, skills and professional performance and relationships that HCPs/OHS use to provide services for patients, the public or the profession.

2.8 Supporting medical education

continued

2.8.3 Requirements

(a) Independent Medical Education (IME)

We can provide grant funding for IME that adheres to the requirements of this section and our policies and SOPs on providing grants and donations (see **POL_251355**: Policy on grants and donations (POL-GSK-016) and **SOP_264719**: Grants and donations Procedure (SOP-GSK-016)). Other types of funding such as 'fee for service' for IME are not permitted.

Grant funding is in response to a proposal. This may be a proposal which is not prompted by us. It may also be based on a GSK public call for proposals in our areas of funding interest (eg through GSK public websites, journal or newspaper advertisements). This call for proposals may include application processes, timelines and other details and is made publicly available at least one month prior to the application process closing.

– We may make a minimum of three specific potential applicants aware of the call for proposals by contacting them directly. This can only be done after the call for proposals is made publicly available. Contacting fewer than three third parties requires approval in line with the level in the organisation where the activity is organised eg GMAL for a global activity, Area Medical Lead for an area activity, CMD for LOC activity.

Grant proposals are reviewed under Medical accountability (Commercial functions are not involved). Proposals that are endorsed by Medical are then considered by the relevant Grants and Donations Committee (see **SOP_264719**: Grants and donations Procedure (SOP-GSK-016)).

The Medical review considers grant proposals against pre-defined criteria including: That the applicant:

- Meets our third party management requirements (see **SOP_462904**: SOP for Managing Third Party Risk).
- Is credible and independent. Education programmes that are delivered or implemented by accredited education providers are preferred. Where such education providers do not exist within a country or if they exist but do not meet our requirements (eg compliance with our third party management frameworks) non-accredited education providers who meet our requirements can receive grant funding.
- Where relevant (eg medical education companies), meets our scientific engagement requirements for vendors where they also support promotional activities. It is preferred that these companies are accredited education providers or work with an accredited provider.

➤ See section 2.4

- Proposes budget and expenses that are reasonable, appropriate and directly related to the development and conduct of the proposed educational activity.

Mandatory requirements that the proposed education programme:

- Is in an area aligned with our interests.
- Is non-promotional, high-quality, scientific or clinical education in a disease area where we have an authorised medicine or there is a CMO approved exception.
- Addresses an evidence based educational need (eg identified by the applicant citing external experts or a medical society, literature reviews, clinical audit or evidence from patient record review).
- Has the objective of improving the diagnosis, prevention or treatment of disease; enhancing the management/care of patients, which may include the appropriate use of our medicines; or benefiting public health. Repetition of similar activities/programmes requires justification (eg a different target audience).
- Where applicable, the programme design enables the proposed level of education assessment.

While not mandatory, the preference is that the education programme:

- Includes the provision of education through a number of initiatives or a variety of formats.
- Includes plans to assess HCPs/OHS knowledge change in order to assess the quality, effectiveness and educational impact of the funded activity. It is recommended that the programme assesses knowledge transfer as a minimum of Level 3 of the **Moore model**. This assessment is developed and performed by the IME provider, not GSK.
- Includes plans to make public the outcomes or results of the activity.

2.8 Supporting medical education

continued



[IME agreement contract For Pharma For Vaccines: Travelgrant page IME page](#)

Where grant requests are endorsed by Medical and approved by the relevant Grants and Donations Committee, the applicant signs a contract with GSK which includes the following provisions in addition to standard contract requirements:

- GSK does not in any way influence the content. GSK does not review, edit or otherwise offer comments on the content, potential speakers/faculty or delivery of the programme.
 - Data related to medicines (including non-GSK medicines) is in line with the approved label.
 - The IME provider makes clear to programme participants that it is supported by GSK funding. For example, "this educational activity was supported by an educational grant from GlaxoSmithKline".
 - The IME provider agrees that we may publicly disclose the funding we provide as part of our voluntary or regulatory disclosure requirements.
 - The financial interests in GSK of the faculty and those in a position to control content are declared as part of the programme's disclosure of conflicts of interest.
 - The educational programme meets relevant legal and regulatory requirements.
 - Our relevant requirements with regard to venues and hospitality for HCPs/OHS are met.
- **See sections 4.2 and 4.3**
- If required by relevant laws, regulations or applicable industry codes, IME providers provide us with information on payments and other transfers of value made to HCPs/OHS using our funding, obtaining consent to do so from the HCP/OHS, to enable us to fulfil any transparency policy or disclosure obligation. IME providers provide this information after the activity has been undertaken to ensure we do not influence HCP/OHS selection.

 More information about the IME process and supporting documents can be found [here](#).

(b) Non-independent Medical Education (non-IME) pre approval

We may support disease education to HCPs/OHS through a collaborative approach with a Medical Society

➤ **See section 2.7.3(d)**

or more directly via a GSK selected third party medical education provider. For the direct approach the following apply:

- Documented recognition by a Medical Society or other appropriate third party of an educational gap or need is required.
 - The third party provider is contracted via Third Party Oversight (TPO)/Third Party Resourcing (TPR) processes to provide a programme proposal based on a GSK briefing followed by development and delivery of the programme.
 - Multichannel approaches are preferred, but face-to-face meetings or other formats are permitted.
 - GSK values, ABAC, due diligence, disclosure and transparency of funding, data privacy and data protection all apply.
 - There must be documented justification for the selection of external experts to develop or deliver the programme. If the selection is made by the third party without influence from GSK then the experts may be paid a fair market value (FMV) fee for service. If selection of experts is influenced by GSK or made directly by GSK then a FMV fee is only appropriate for advice, input or content generation.
 - Payment of travel for delegates to attend is not permitted if it is a local programme where participants are from within the same city, but travel costs/accommodation may be covered (in accordance with the rules that apply for promotional meetings) if a national level meeting is required. See section 4.6. Any hospitality complies with section 4.3.
- **See sections 4.3 and 4.6**
- Any materials developed by GSK or by a third party GSK selected medical education provider (eg slides, invitations etc) are approved as non-promotional in the market in which the event occurs, in accordance with **SOP_285774**: Approval Process for promotional and non-promotional materials created by LOCs and Above Country Business Units Gifts, hospitality and entertainment (SOP-GSKF-414).
 - The Medical/R&D business owner gets endorsement from MDL/VDL and submits a plan to the CMO/delegate. Approval of the activity is required from the CMO/delegate and the CMD of the market where the event will occur (following consultation with local legal).

2.9 Scientific interactions with payers, governments and public health organisations

Interactions with government officials comply with **STD_455141**: Anti-Bribery and Corruption Standard. These stakeholders may also be HCPs/OHS. In these circumstances the strictest requirements apply.

2.9.1 What we can do

Engage on our science while respecting the principles of scientific engagement with payers, governments and public health organisations.

2.9.2 Where care is needed

Particular care is taken to adhere to our **ABAC** standards (**POL_150091** and **STD_455141**) and controls and local rules when interacting with government officials.

2.9.3 What is not included

The requirements below do not apply to:

- Non-medicine related interactions to provide industry perspectives on public policy, science related policy and health management activities including disease management, care delivery, evidence-based medicine, health information technology and payment/benefit structures.
- Providing business information related to product-price contracts interactions with regulatory authorities, requests from executives/legislative government organisations (eg US Congress, UK Parliament).

➤ See section 4.8

- Clinical research and partnership agreements between GSK and governments and commercial negotiations on business terms with specialty distributors initiated before marketing authorisation.

2.9.4 Requirements

Scientific engagement with government officials, reimbursement agencies or their advising agents (eg National Institute for Clinical Excellence (NICE), Centre for Effectiveness Research), and public health organisations (eg WHO, CDC, NIH) is permitted following the requirements of this section.

- This can include discussions related to disease areas of mutual interest, our medicines in development, or new indications for authorised medicines.
- Discussions with these stakeholders allow us to contribute to public health preparedness (including budgetary planning), to understand their needs regarding our medicines, and to respond to specific requests for information which may include pre-authorisation data. Data which is not in the public domain may be shared under a confidentiality agreement or where there is approval from the relevant Business Unit Head or designee.

Requirements set by organisations/governments on pathways for interactions are followed and specific objectives for interactions are defined and documented prior to the interaction eg in meeting agendas. When pathways for interaction do not exist, we validate that the proposed interaction meets the organisation's expectations by explicitly communicating our plans for the interaction and asking for their validation (eg by providing an agenda and/or requesting written agreement).

If advice is being sought and individuals are engaged to provide that advice then section 2.5 on seeking external advice, insights and information is followed.

➤ See section 2.5

- Selection and number of people approached and timing/frequency of the interactions is proportionate to the need.

Accountability for pre-authorisation interactions with these stakeholders may be with a range of staff (Public Affairs, LOC General Managers, Market Access functions, Medical). Staff from commercial functions are not prohibited from participating in these interactions; however discussion of medical and scientific data are under Medical accountability.

Unplanned spontaneous discussions between our staff and employees of governmental, payer and public health organisations are permitted and do not require prior approval where there is no pre-determined intent to gain advice or to proactively disseminate information.

2.9.5 Examples of permitted activities

- Proactive contacts with governments, payers, purchasers and public health organisations to understand needs and discuss our progress/developments, including matters of public health (eg public health programmes, vaccination programmes/calendars, budgetary impact of new therapies).
- Responding to specific requests (eg provision of medical/economic data, or pipeline information which is already in the public domain).
- In response to tender specifications, we may share data requested which may not be reflected in the relevant product label (eg data regarding herd immunity, effectiveness, alternative schedules, health economic assessments) or not published (recent clinical data, health economic assessments or assumptions).
- Proactive contact with government personnel eg US Centres for Disease Control and Prevention (CDC) personnel, including the CDC liaisons to Advisory Committee on Immunisation Practices (ACIP) Working Groups for the purpose of sharing scientific information, where expected by these stakeholders according to CDC established procedures for interaction.

3

Other non-promotional activities

3.1	Information about our medicines for the general public	p50
3.2	Disease awareness for patients or the general public	p51
3.3	Healthcare support services	p52
3.4	Items of medical/educational utility	p55

References relating to this section

 Written standards	Other links
STD_340448: Standard for interacting with patient organisations	ABPI Code of Practice for the Pharmaceutical Industry, Section 20
SOP_341206: Global product and pipeline media materials approval procedure (SOP-CGA-100)	ABPI guide and case studies on Joint Working with the Pharmaceutical Industry
POL_132175: Policy for use of digital channels	
SOP_285774: Approval Process for promotional and non-promotional materials created by LOCs and Above Country Business Units Gifts, hospitality and entertainment (SOP-GSKF-414)	

3.1 Information about our medicines for the general public

For direct to consumer advertising:

See section 1.3

For disease awareness for patients or the general public:

See section 3.2

Non-promotional information about our medicines which is made available to the public either directly or indirectly:

- Is factual, balanced and consistent with the locally approved product information.
- Does not raise unfounded hopes of successful treatment.
- Is not misleading about the safety of the medicine.
- Is not intended or designed to encourage the patient to ask their HCP to prescribe a specific GSK medicine.

This includes for example, information provided in response to enquiries from journalists and patient advisory groups, information provided through proactive media activities (eg press releases) and reference information on public websites.

STD_340448: Standard for interacting with patient organisations

SOP_341206: Global product and pipeline media materials approval procedure (SOP-CGA-100)

3.2 Disease awareness for patients or the general public

Non-promotional disease awareness information directed to patients/the general public may be provided directly. When there is no capability or capacity in GSK, we can engage an HCP/OHS to deliver a disease awareness activity on a fee for service basis. This information is not intended or designed to encourage patients to ask their HCP to prescribe a specific GSK medicine. A statement is included that the individual must consult an HCP for personal medical advice.

Disease awareness campaigns do not contain any product branding. It is not permitted to associate HCP/OHS-directed promotional materials with public disease awareness campaign materials (eg via use of brand imagery/colours).

Where there is a medicine in development and we do not have an authorised medicine for a particular disease, disease awareness activity for patients/the general public is not conducted until after marketing authorisation.

Disease awareness information is not provided to patients/the general public where we have the only prescription medicine within that disease area, unless this is approved in line with the level in the organisation where the activity is organised (eg GMAL for a global activity, CMD for a local activity).

Disease awareness material includes an acknowledgement of GSK involvement and/or funding where applicable.

Disease awareness includes information about the characteristics of disease, methods of prevention, screening and available management options.

Disease awareness information may be provided through digital channels subject to this section and POL_132175:

POL_132175: Policy for use of digital channels

Medical is accountable for approving the disease awareness activity.

Disease awareness to HCPs/OHS is promotional and complies with section 1 of this Code.

3.3 Healthcare support services

Healthcare support services are services provided, directly or indirectly, to healthcare organisations (HCO) and/or patients.

These services are non-promotional and have the objective of achieving better healthcare outcomes for patients, enhancing patient care or benefitting a healthcare system while maintaining patient care (eg funding a nurse to identify high risk patients for assessment and health management, analysis of economic data for budget planning). Where permitted by local laws, regulations and/or applicable industry codes we can provide these services.

Eligibility of medical practices to receive the service is based upon objective criteria linked to the defined purpose. It is not linked to the prescription or use of our medicines.

Clinical decisions, which include the selection of appropriate medicines or the development of treatment management plans, are the responsibility of the prescriber.

Patient confidentiality is maintained.

Measures are established for monitoring and processing any adverse event reports that may be received in the course of any healthcare support service.

Any proposal to provide healthcare support services is reviewed and approved in advance by Medical and Legal to ensure compliance with applicable laws and regulations. Accountability can be with Medical, Commercial or Governmental Affairs/Market Access.

The recipient signs a contract with GSK which sets out the details of the service, including activities to be performed by the service provider, the responsibilities of the recipient and the defined duration of the service.


Involvement of GSK in the provision of healthcare support services is made clear to HCPs/OHS involved and recipients of the service.



Healthcare support services are kept separate from promotional activities.

- Healthcare support services can be company branded – they do not include the brand or name of our medicines.
- Materials related to the healthcare support service are non-promotional.
- Sales representatives may introduce, but do not provide, deliver, demonstrate or have other involvement in healthcare support services.
- Information collected in the course of providing a healthcare support service is not used for promotion or to plan promotional activity. This information is not shared with sales representatives.

The success of the healthcare support service is monitored regularly and measured only by reference to criteria directly related to the improved health outcomes that the service is designed to achieve.

The remuneration of those involved in the provision of the healthcare support service is not linked to sales of our medicines.

 For further information see

-  [ABPI Code of Practice for the Pharmaceutical Industry, Section 20](#)
-  [ABPI guide and case studies on Joint Working with the Pharmaceutical Industry](#)

3.3.1 Patient support programmes following prescription

Patient support programmes (PSPs) are a subset of healthcare support services. A GSK-initiated PSP is an organised programme implemented by or on behalf of GSK that involves direct or indirect (via a third party) contact with the patient or carer with the aim of helping them to access and/or manage the patient's medication and positively impact their disease outcomes. Examples include the provision of disease or product specific training or education, guidance on drug administration and/or delivery, post-authorisation patient support and disease management programmes, surveys of patients and healthcare providers, information on patient compliance, or patient Access to Medicines programmes.

3.3 Healthcare support services continued

Compliance (or adherence) support programmes for patients prescribed our medicines are administered following initial involvement and endorsement of the HCP involved in the treatment of relevant patients. Delivery of compliance (or adherence) support programmes for patients must not be via Commercial. Sales representatives may introduce, but do not provide, deliver, demonstrate or have other involvement in healthcare support services. They may provide information about the existence of the programme, where more information can be found and where to enrol into the programme.

The budget may sit with Medical, Commercial, or Governmental Affairs/Market Access. Materials for patient support programmes are approved following the copy approval process. See **SOP_285774**: Approval Process for promotional and non-promotional materials created by LOCs and Above Country Business Units Gifts, hospitality and entertainment (SOP-GSKF-414).

Access to Medicines programmes (ie those to support affordability) are for our authorised medicines for registered indications and doses. GSK employees must ensure that these programmes are never used as an improper inducement for HCPs to prescribe our medicines, or as a way for the patient to request our medicines, or as a means to advertise our medicines to patients.

Following local review by Compliance, Medical and Legal, the final proposals for PSP and Access to Medicines programmes are reviewed and approved by the Medical Governance Board at plus one level above above-country unit. (The approval may be granted as a chairman's action based on a Medical Governance Board sub-team review and recommendation. The sub-team must include Medical, Legal and Compliance.)

i To ensure that patient support programmes are implemented correctly, refer to the checklist on the **Ways of Working Portal**.
In the US, PSPs are implemented according to local governance and processes.

3.4 Items of medical/ educational utility

Items of medical/educational utility which enhance patient care, the responsible use of medicines or are beneficial to the provision of medical services, can be provided to HCPs/OHS.

Such items may be offered or provided free of charge if they are infrequent and of modest value (to be defined and documented locally). These items can be company branded but are not product branded (see exception below for patient support items).

Items we provide do not subsidise the routine operations of any medical practice and may not be provided on long term loan to an HCP/OHS or practice other than in the context of conducting a clinical study.

Items of medical/educational utility are not provided for sales representatives or other GSK representatives to gain access to a medical facility.

i Items of medical/educational utility include so-called 'patient support items' which enable patients to gain instruction and experience using their medicines while under the supervision of an HCP/OHS. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject, which are not passed on to patients to keep. These items may bear the name of a medicine and/or information about medicines only if such detail is essential for the proper use of the item by patients.

i Items of medical/educational utility are not provided by R&D staff to clinical investigators where the items are unrelated to the conduct of the study.

i Items of medical utility are not considered samples. Items of medical utility include dummy inhalers/devices (eg respiratory devices with no active ingredient) and associated devices to support appropriate usage (eg spacers).

i This section does not apply to in vitro diagnostic tests provided for clinical testing.

4

General requirements

4.1	Engagement of HCPs and OHS to provide services	p58
4.2	Meeting venues	p60
4.3	Hospitality	p62
4.4	Funding of scientific/medical congresses and other third party meetings	p62
4.5	Funding of HCPs and OHS to attend scientific/medical congresses	p64
4.6	Funding of HCPs and OHS to attend stand-alone promotional meetings	p67
4.7	Gifts	p68
4.8	Discounts, rebates and other commercial terms	p69

References relating to this section



Written standards

SOP_344448: Engaging with external experts to provide services

POL_251355: Grants and donations policy (POL-GSK-016)

SOP_264719: Grants and donations Procedure (SOP-GSK-016)

Other links

Corporate security

Pricing risk governance framework

4.1 Engagement of HCPs and OHS to provide services

SOP_344448: Engaging with external experts to provide services is followed.

Information provided to an HCP/OHS is limited to the information that is necessary to provide the services.

Payments follow the principle of FMV. FMV rates are based on applicable documented rates/fee schedules set by the CMD in the LOC in the country where the HCP/OHS is domiciled. The following factors are considered:

- Local industry regulator guidelines.
- Local medical association or similar, or industry guidelines.
- Categorisation of the HCP/OHS (eg Doctor – Professor, lecturer, GP, nurse, pharmacist).
- The justification for the local fee schedule is documented and locally approved by the appropriate governance body (eg Risk Management and Compliance Board (RMCB)) and reviewed annually. Any exception to the fee schedule is reviewed and approved by the Area Medical Director or designee.

Business class or premium economy air travel may be provided for HCPs/OHS engaged to provide a service, where the total flying time one way is more than five hours. Travel by train may be business or first class. We may also reimburse reasonable expenses incurred by the HCP/OHS in the provision of the services, subject to submission of receipts.

It is appropriate to compensate an HCP/OHS for travel time only where the travel is long distance (more than five hours), when the travel is required to complete the service and if the HCP/OHS is not already travelling for another purpose.

If compensation for travel time is offered, a clear methodology for the calculation is documented and applied consistently.

i We do not pay HCPs/OHS to speak on our behalf about our medicines or associated diseases to other HCPs/OHS in promotional meetings. Where HCPs/OHS agree to speak without payment for this service there are specific requirements for the exceptional arrangement and payment of transportation/accommodation/meals.

> See section 1.4.5

i We do not pay for authorship of peer reviewed articles or plenary congress presentations. We may reimburse reasonable expenses associated with these activities, see: **GSK Publication Handbook**

i We pay HCPs/OHS a fair market value fee for service to provide advice during an advisory board or under a 1:1 consultancy contract.

i We may occasionally pay HCPs/OHS an FMV fee for service for facilitation or speaking at a scientific symposium held during selected international congresses, or during scientific workshops held in certain specified countries. Such payments are CMO approved and limited to occasions where we lack the relevant expertise internally. The list of selected countries can be found **here**.

i In countries where compensation for travel time is permitted, it is not automatically offered as part of the engagement. Compensation for travel time is calculated as a separate component on an hourly basis, and added to the hours engaged for the actual activity. If there is no set fee schedule involving compensation for travel time the fee is not more than 50% of the fair market value hourly rate multiplied by the number of hours capped at one day (8 hours) per journey (outbound and return count as two journeys).

4.1 Engagement of HCPs and OHS to provide services

continued

4.1.1 Annual cap

Each LOC sets an annual maximum financial limit (cap) for the fees for service that can be paid directly to an individual HCP/OHS within their country. This cap applies whether the HCP/OHS is engaged by the LOC or any other part of GSK.

- The cap covers payments made to the HCP/OHS such as the fee for service and compensation for travel time. Unless required by local laws or regulations, the cap excludes meals, travel costs (eg airfare) and accommodation. Payments for clinical trials or activities related to clinical trials are excluded. Exceptions are approved by the Area Medical Director in consultation with the CMD.

i In the US, please refer to the annual cap that has been set. For all US HCP engagements, please refer to the existing process.

i Outside the US, the maximum cap that an LOC can set is the upper limit of:
FMV hourly fee x 20 days x 8 hours per day.

4.1.2 Records and disclosures

Each LOC keeps detailed records of the fees paid, expenses reimbursed and transfers of value, in respect of services provided by the HCP/OHS in their country. These records are available for disclosure if required.

4.2 Meeting venues

GSK meetings and meetings where we provide financial support:

> See section 4.4

- Are not held at locations which could reasonably be perceived as lavish or extravagant for a business meeting or conference, or at venues which are recognised for their entertainment, sports or leisure facilities. A venue, such as a sports stadium, with conference facilities may be a justifiable venue where the meeting does not coincide with a sporting event.
- Provide safe accommodation where the risks to the security of attendees can be minimised. **Corporate Security and Investigations** are consulted when necessary.
- Take place in approved venues; each LOC maintains an approved list of venues in their country suitable for our meetings.

Our meeting venues are selected to minimise travel time for delegates.

LOC meetings are attended only by HCPs/OHS from that country and are held in the country where the LOC is based unless the meeting:

- Is held during a third party international meeting (eg medical/scientific congress), but outside the specific times of the meeting programme; or
- The meeting has been approved in writing by the Regional President or designee.

We may organise international meetings for attendees from different countries, where the logistics, efficiencies and economies of scale can be demonstrated to justify an international meeting.

- Where an international meeting is organised by LOCs, this is approved by the relevant Area Medical Director. International meetings organised by market clusters or Above Country Business Units are approved by the MDL/VDL or GMAL (or equivalent) depending on who is accountable for the event.

Payments may not be made to individual HCPs or groups of HCPs either directly or indirectly, to rent meeting rooms.

i In Europe the use of hotels of more than a 4 star rating is not permitted.

i For information regarding meeting logistics and hospitality, refer to:
STD_404715: Standard on meetings and catering

4.3 Hospitality

STD_243431: Gifts, hospitality and entertainment (STD-GSK-004) is followed.

Any meals (food and beverages) provided incidentally to invited attendees of scientific, promotional or business meetings do not exceed the local GSK monetary threshold where the event takes place.

We do not invite guests or spouses of those we invite and we do not provide or pay for any hospitality or make arrangements for guests or spouses to attend.

We do not organise or fund meetings for HCPs/OHS that are of a social or sporting nature.

➤ See section 4.4

No entertainment or other leisure or social activities are paid for or organised by us at any time including in connection with our funded or stand-alone meetings. This includes activities for individual HCPs/OHS.

i Hospitality may be provided on an exceptional basis in the context of a 1:1 meeting between field staff (eg sales, MSL) and an HCP/OHS, subject to local regulations and local restrictions. Information on the limits set in Europe and Canada can be found [here](#).

i For information regarding meeting logistics and hospitality, refer to:
[STD_404715: Standard on meetings and catering](#)

4.4 Funding of scientific/medical congresses and other third party meetings

We only provide financial support for medical/scientific congresses (or other third party meetings) when:

- The programme content is developed independently, of good scientific standing and aligned to our scientific or medical interests.
- The venue meets our requirements and has appropriate facilities which are clearly separated from any entertainment, sports, tourist or leisure facilities that may be present.

➤ See section 4.2

- The meeting is supported by two or more sponsors. Sponsorship from multiple companies or institutions is the preferred option to avoid the perception that GSK has organised the event and provided payments to HCP speakers.
- Where sponsorship from multiple companies or institutions is not possible, the reason why GSK is to be the sole sponsor must be justified by the business owner and approved and the contract with the meeting organiser states that funds must not be used to provide payments to HCP/OHS speakers.
- Congress funding and activities are reviewed by the LOC in the country in which the meeting takes place to ensure compliance with local laws, regulations and applicable industry codes.
- We may fund a congress or other third party meeting in response to an unsolicited request from the relevant organiser.

If the value of the service, privilege or benefit provided in return for the payment is:

- Incidental and substantially less than the funding being sought, we follow our grants and donations policy and SOP (see [POL_251355](#) and [SOP_264719](#)).
- Equivalent to the funding being provided, we follow processes for sponsorship or fee for service funding.

We may also proactively seek a presence at medical/scientific congresses by providing funding (eg sponsorship or fee for service) to enable promotional activities (eg commercial booth space) or scientific engagement activities (eg scientific booth space) to take place.

- Before marketing authorisation, we do not fund medical congresses to enable promotional activities (eg commercial booth space, GSK sponsored satellite symposia).
- Before marketing authorisation of a medicine, funding of medical/scientific congresses in that disease area is under Medical accountability.
- Following marketing authorisation the budget may be held by Medical or Commercial.

i For support of independent medical education
➤ See section 2.8

4.5 Funding of HCPs and OHS to attend scientific/medical congresses

We do not provide direct financial support to HCPs/OHS to attend medical congresses or associated satellite symposia.

We may only provide financial support for HCPs/OHS to travel and attend medical congresses by providing funds to the congress organiser or other independent third party to whom the HCP/OHS can apply. The selection of HCPs/OHS to receive funding is made independently by the third party.

4.5.1 Selection of medical congresses

We may provide financial support for HCPs/OHS to attend medical congresses (via an independent third party) that are:

- In disease areas where we have an authorised medicine.
- Scientific, medical and/or educational and meet the requirements of this Code in respect of the venue and hospitality offered.

Medical approve the selection of congresses as part of business plans.

4.5.2 Selection of independent third parties (including congress organisers)

The independent third party:

- Is credible and independent of GSK and our affiliated organisations.
- Meets our third party management requirements (see **SOP_462904: SOP for Managing Third Party Risk**).
- Has infrastructure and resources in place to advertise the available award, review and evaluate applications, communicate decisions, manage the provision of the awards and maintain audit-ready documentation.
- Has processes for management, tracking and disbursement of funds.
- Has independent governance controls.



IME agreement contract
For Pharma
For Vaccines:
Travelgrant page
IME page

- Signs a **contract** with GSK which includes agreements:
 - Not to provide cash payments directly to HCPs/OHS or their affiliated organisation eg university. Payments are made directly to the conference organiser, or travel/accommodation agencies.
 - Not to provide the names of HCPs/OHS to GSK unless required by local laws and/or to meet local disclosure requirements. In such case this information is provided after the activity has been undertaken to ensure we do not influence HCP/OHS selection.
 - To ensure recipients are made aware that GSK has provided grant funding for the programme.
 - To allow independent audit by GSK or a third party we employ.
- Where the medical congress does not (or will not) operate a scheme through which we can provide funding for HCPs/OHS to attend or the scheme does not meet the requirements above, another independent third party may be sought and selected.

The General Manager in the country where the HCP/OHS for whom funding has been made available resides, is accountable for following our controls for engaging third parties (eg SOP_462904: SOP for Managing Third Party Risk). The General Manager is accountable for approving the third party and for approving associated budget and expenses provided to the third party. The Franchise Medical Heads, CMOs of Business Units, or Area Medical Directors as appropriate are accountable for congresses and third parties managed at an above country level.

We monitor the third party chosen to provide funding to ensure compliance with the agreed contracts. Monitoring focuses on appropriate financial management and disbursement to applicants that align with the suggested/proposed criteria for HCP/OHS selection we provide (see below), or to the selection criteria created by the independent third party to which we provided funds.

- The monitoring does not identify or reveal the names of HCPs/OHS selected, unless there is reason to suspect mismanagement of our funds.

4.5 Funding of HCPs and OHS to attend scientific/medical congresses

continued

4.5.3 Selection of HCPs/OHS

The selection of HCPs/OHS to receive funding is made without influence from us. These decisions are made independently by the third party based on merit and need.

We do not specify precise inclusion or exclusion criteria for HCP/OHS selection (eg HCPs/OHS that may also be government officials) but may suggest non-mandatory selection criteria for HCPs/OHS to the independent third party on selection criteria for HCPs/OHS such as:

- HCPs/OHS who can show scientific interest in the conference, or can show benefits to their patients from attending.
- HCPs/OHS who are participating in the conference as presenters or have other active participation in original research or scientific work that is being presented.
- HCPs/OHS who can share learning with a larger community after the conference because they teach in colleges or postgraduate units, or are part of a larger network of HCPs/OHS anticipating feedback from the conference.

HCPs/OHS enquiring about the possibility of financial support are referred to the independent third party (ie we do not select HCPs/OHS that are referred). We do not assist HCPs/OHS in making applications.

4.6 Funding of HCPs and OHS to attend stand-alone promotional meetings

We do not pay for or arrange travel or accommodation for HCPs/OHS to attend our stand-alone promotional meetings.

An exception can only be obtained if the rationale for the arrangement of travel or accommodation for each individual HCP/OHS to attend is documented and approved based on the country where the HCP/OHS resides. These approvals are required before any contact with HCPs/OHS and/or travel or accommodation arrangements are planned.

- The General Manager of the LOC in the country of the HCP/OHS and the relevant CET member or designee approve exceptions.
- Exceptions are not permitted for local in-country meetings where HCPs/OHS are from the same hospital, practice or town/city where travel time or distance is not an issue. Such meetings are typically arranged by sales representatives.
- Exceptions may be considered for national meetings for HCPs/OHS who would need to travel from across the country where the travel distance, time and cost may be more significant. Such meetings are not to be organised by the sales representatives.

Where exceptions are approved, the same travel and accommodation arrangement restrictions and governance for unpaid HCPs/OHS speakers applies with the exception that no contract is required.

➤ See section 1.4.5

4.7 Gifts

Gifts are anything of value, given as a mark of friendship or appreciation or to express the hope of future business success and without expectation of consideration or value in return.

Gifts for the personal benefit of HCPs/OHS are not permitted. Provision of cash or cash equivalents as gifts is prohibited. Except for the items expressly permitted in this Code (see below and sections 1.8 and 3.4) no gift, benefit in kind or financial advantage may be offered or given to HCPs/OHS.

➤ See section 1.8 on promotional aids

➤ See section 3.4 on items of medical/educational utility

4.7.1 Cultural courtesy items

Cultural courtesy items for HCPs/OHS (ie items given to acknowledge significant national, cultural or religious holidays) are not permitted, other than by exception in some countries where it is considered respectful of local customs and permitted under local laws and regulations, provided it is done in a fully transparent way.

– Wherever such an exception applies, it is documented and approved by the local or area RMCB with the rationale for respecting the relevant holiday(s), together with the permitted frequency and cost limits (minimal/modest and proportionate within the country) for the items. The limits for cultural courtesy items in any country are consistent across business units in that country.

4.8 Discounts, rebates and other commercial terms

Discounts, rebates, free of charge goods and other commercial terms relating to price or margin are assessed using the **pricing risk governance framework** and applicable laws and regulations.

Particular care is taken when the purchasing customer is also an HCP/OHS, to ensure that the commercial terms would not unduly influence them to prescribe, dispense or recommend a medicine inappropriately or to act in a way that is not in the best interests of patients or the relevant healthcare system.

Business units and LOCs ensure that their supply arrangements comply with the following requirements:

- A pricing risk assessment must be performed and there must be a documented framework that governs the levels of pricing, discounts, rebates, free goods and other commercial terms. This framework contains the rationale for commercial terms and is reviewed by Legal.
- Commercial terms offered are documented in writing to ensure transparency. The framework specifies the documents required.
- Any discount, rebate or other payment is made via an approved financial method (eg invoice, bank transfer or cheque) and does not take the form of cash or other cash equivalent. Discounts, rebates and other payments are accurately and appropriately recorded in our books and records.
- Any schemes which enable HCPs/OHS to obtain personal benefits in relation to the purchase of medicines are unacceptable even if they are presented as alternatives to commercial terms.

i This section comes under Commercial accountability.

5

Further information and appendices

5.1	Monitoring	p72
5.2	If you have concerns	p72
5.3	Appendix 1: GSK written standards for activities and interactions with other audience groups	p73
5.4	Appendix 2: Glossary	p75
5.5	Appendix 3: Abbreviations	p77

References relating to this section

 Written standards	Other links
POL_87166: Medical governance policy (POL-GSK-409)	www.gsk.com/integrity Business Unit Compliance Officer

5.1 Monitoring

Management is required to assess and monitor controls to ensure they are in place, in use and effective. Management Monitoring (MM) should be appropriate, proportionate, solution focused and documented. Managers are required to record MM activities and retain results to evidence key controls in this written standard are in place.

5.2 If you have concerns

If you have concerns about how to apply this written standard, bring them to the attention of your manager and/or raise them through the Medical governance framework (see **POL_87166**). If you are aware of violations of this written standard, please report them to Compliance or through speak up channels.

To find your local speak up integrity line number or to report online, please visit: www.gsk.com/integrity

If you are out of compliance or feel you are unable to comply with the procedure, please contact your **Business Unit Compliance Officer**.

5.3 Appendix 1: GSK written standards for activities and interactions with other audience groups

Activity/audience group	GSK written standard
Approving materials	<ul style="list-style-type: none"> ▪ SOP_285774: Approval Process for promotional and non-promotional materials created by LOCs and Above Country Business Units Gifts, hospitality and entertainment (SOP-GSKF-414)
Gifts, hospitality and entertainment	<ul style="list-style-type: none"> ▪ STD_243431: Gifts, Hospitality and Entertainment Standard (STD-GSK-004)
Medical Information	<ul style="list-style-type: none"> ▪ SOP_54813: Medical information responses to Healthcare Professionals, Other Healthcare staff and Patients/Consumers
Clinical research	<ul style="list-style-type: none"> ▪ POL_87187: Policy on human subject research (POL-GSKF-408)
Compassionate use	<ul style="list-style-type: none"> ▪ POL_87186: Policy on Compassionate Use (POL-GSK-406) ▪ SOP_454971: Procedure for compassionate use
Market research	<ul style="list-style-type: none"> ▪ GUI_333516: GSK Guideline on the conduct of primary market research in GSK Pharma ▪ SOP_297780: US Pharma market research: criteria for designing and executing market research conducted in the US
Using digital channels for external engagement	<ul style="list-style-type: none"> ▪ POL_132175: Policy for use of digital channels
Engaging with external experts to provide a service	<ul style="list-style-type: none"> ▪ SOP_344448: Engaging with external experts to provide services ▪ SOP_291506: Disclosure of transfers of value to HCPs and HCOs domiciled in Europe/Russia/Ukraine/Turkey (SOP-GSKF-417)
Humanitarian product donations	<ul style="list-style-type: none"> ▪ POL_87162: Humanitarian product donations policy (POL-GSK-303) ▪ SOP_257308: Humanitarian product donations and emergency response procedure (SOP-GSK-303)
Interacting with government officials and anti-bribery and corruption	<ul style="list-style-type: none"> ▪ POL_150091: Anti-bribery and corruption policy (POL-GSK-007) ▪ STD_455141: Anti-Bribery and Corruption Standard
Interacting with the media	<ul style="list-style-type: none"> ▪ POL_87160: External and internal communication activities on behalf of GSK (POL-GSK-301) ▪ SOP_191843: External and internal communication activities on behalf of GSK (SOP-GSK-301) ▪ SOP_341206: Global product and pipeline media materials approval procedure (SOP-CGA-100)
Interacting with patient organisations	<ul style="list-style-type: none"> ▪ STD_340448: Standard for interacting with patient organisations

5.3 Appendix 1: GSK written standards for activities and interactions with other audience groups

continued

Activity/audience group	GSK written standard
Procurement for meetings	▪ STD_404715: Standard on meetings and catering
Grants and donations	▪ POL_251355: Policy on grants and donations (POL-GSK-016) ▪ SOP_264719: Grants and donations Procedure (SOP-GSK-016)
Safety reporting	▪ POL_87163: Management of human safety information for GSK products (POL-GSK-400)
Engagement of third parties	▪ POL_150091: Anti-bribery and corruption policy (POL-GSK-007) ▪ STD_455141: Anti-bribery and corruption Standard ▪ SOP_462904: SOP for Managing Third Party Risk (TPO) ▪ Anti-bribery and corruption framework. Third party procedures and guidance
Disclosure of transfers of value	▪ SOP_291506: Disclosure of transfers of value to HCPs and HCOs domiciled in Europe/Russia/Ukraine/Turkey (SOP-GSKF-417) ▪ POL-TDOR-001: Transparency data operations and reporting (TDOR) policy
Sanctions and export control	▪ POL_201051: Policy on sanctions and export control (POL-GSK-014) ▪ SOP_201078: Procedure on sanctions and export control (SOP-GSK-014)
Maintaining privacy and confidentiality	▪ POL_87130: Privacy of personally identifiable information (POL-GSK-010)

5.4 Appendix 2: Glossary

Abbreviated prescribing information refers to a shortened, ie 'abbreviated', version of the full prescribing information (eg the product label/summary of product characteristics).

Digital Channels refers to externally facing technologies used for communication and collaboration, including but not limited to: websites, banner ads, SMS, web applications, internet forums, social networking sites, blogs, microblogs, wikis, podcasts and instant messaging tools. Digital Channels may be owned and controlled by GSK, owned and controlled by a third party or owned by a third party but controlled by GSK.

Donation refers to a non-monetary award, such as products, services, equipment, subsidies, employee's time or other assets.

Entertainment refers to any extracurricular event or activity the main purpose or value of which is for the entertainment and enjoyment of those who attend the event or activity. This includes sports, musical or art events and/or leisure activities.

External Expert refers to a collective term for HCPs (including Other Healthcare Staff) and any non-HCPs (eg Health Economists, Health Policy Researchers, Health Outcomes Experts) who are recognised by their peers and colleagues as having expertise in their field of science/medical care/research as demonstrated by their research, publications or professional role. Patients who may be occasionally engaged for Advisory Boards or consultancy engagements can also be considered as EEs.

Government Officials (where 'government' means all levels and subdivisions of governments, ie local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) are defined broadly as:

- Any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state);
- Any officer or employee of a public international organisation (for example, the World Bank or United Nations);
- Any officer or employee of a political party, or any candidate for public office;
- Any person defined as a government or public official under applicable local laws (including anti-bribery and corruption laws) and not already covered by any of the above; and/or
- Any person acting in an official capacity for or on behalf of any of the above.

Grant refers to a financial award.

Healthcare organisation (HCO) means any private or public sector organisation, institution or association that is comprised of HCPs and/or that provides healthcare services, and also includes a clinic or medical practice consisting of one or more HCPs.

Healthcare professional (HCP) refers to an individual who in the course of their professional activities is authorised to prescribe, purchase, supply, administer or dispense medicines or medical devices.

5.4 Appendix 2: Glossary

continued

Hospitality includes friendly reception and treatment by GSK staff or third parties with provision of refreshments, meals and/or background music at hotels, restaurants, GSK or third party premises, public arenas, sport or cultural events, product launches and meetings.

Medicine refers, for the purposes of this Code, to prescription and non-prescription medicines and vaccines.

Medical education comprises programmes or activities which have the intent to provide education to HCPs which is across the range of scientific information and therapeutic/prophylactic options relevant to a disease state, balanced, comprehensive and up-to-date, and which may or may not result in the award of continuing medical education (CME) points to participants. These activities are intended to improve and enhance the HCP's skill to engage their patients and deliver care.

Medical society means a body of HCPs that specialise in a particular aspect of medicinal practice and who meet to discuss data/policies/guidelines and other matters of mutual interest to advance patient care within that discipline.

On label means that promotional material must be consistent with the approved conditions of use (eg local product label).

Other healthcare staff (OHS) means any person who, in the course of their employment, may recommend, purchase, supply or use, or influence the purchase, supply or use, of medicines. Other healthcare staff includes but is not limited to pharmacy assistants, hospital management, primary care managers, members of formulary committees, and payer bodies such as staff in health appraisal agencies, reimbursement bodies, pricing bodies and sick funds.

Preceptorships are a period of postgraduate practical experience and training for medical staff, that is supervised by an expert or a specialist in a particular field.

Promotion refers to any activity undertaken by GSK or on its behalf that advertises or promotes the prescription, supply, sale, distribution or use of GSK products.

Promotional activity/material is any activity/branded material that advertises or promotes the prescription, supply, sale, distribution or use of GSK products.

Sponsored satellite symposia are symposia which we fund and organise within the infrastructure of, and officially recognised by, a medical congress.

Stand-alone promotional meetings are meetings we initiate, intended for HCPs/OHS, hosted independently of a congress or other third party meeting, which relate to our medicines and uses, and/or related disease areas.

Transfer of value means any transfer of value, whether of money, in kind or otherwise, made directly or indirectly to or for the benefit of a recipient.

– **Direct transfers of value** are those made directly by GSK to or for the benefit of a recipient.

– **Indirect transfers of value** are those made on behalf of GSK to or for the benefit of a recipient, or transfers of value made through an intermediate and where GSK knows or can identify the recipient.

5.5 Appendix 3: Abbreviations

ABAC	Anti-bribery and corruption
ACIP	Advisory Committee on Immunization Practices
CDC	The Centers for Disease Control and Prevention
CET	Corporate Executive Team
CMD	Country Medical Director
CME	Continuing Medical Education
CPD	Continuing Professional Development
FMV	Fair market value
GMAL	Global Medical Affairs Leader
HCO	Healthcare organisations
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IME	Independent Medical Education
LOC	Local Operating Companies
MDL	Medicine Development Leader
NICE	National Institute for Clinical Excellence
NIH	National Institutes of Health
PSP	Patient support programmes
RMCB	Risk Management and Compliance Board
TDOR	Transparency data operations and reporting
VDL	Vaccine Development Leader
WHO	World Health Organization

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