do more
feel better
live longer

Our Code of Practice

for promotion and scientific engagement (prescription medicines)

Who does this Code apply to?

- **Vaccines**
- **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 POL, SOP, STD and other GSK documents

Reference to digital resources including: Connect GSK and Compliance Document Management System (CDMS)

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

See appendix 3: Glossary

Principles of Our Code of Practice

Our intentions and actions are driven by our values:

Patient focus
Integrity
Respect for people
Transparency

- 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 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 are followed when interacting with specific audience groups or undertaking specific activities which are not included in this code.

See appendix 1

Other key GSK written standards relevant for our external interactions are provided in appendix 2.

See appendix 2

STD-CHC-401:
Consumer Healthcare code for promotion and scientific engagement

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 adopted due to:

- Local, regional or business unit specific GSK standards or restrictions.
- Local laws, regulations or applicable industry codes.

Go to Connect GSK
Find: Ways of working
Search for:
IFPMA Code of Practice

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 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-GSK-409:
Medical governance policy

Contents

1 Promotion

External references relating to this section

- POL_132175: Policy for use of digital channels
- SOP-GSKF-414: Copy Approval SOP
- SOP_375788: Conducting promotional webinars
- STD-GSK-512: Travel, meetings and expense standard for GSK employees
- STD-GSKF-415: Standards for external interactions by Medical and R&D staff
- SOP-GSK-007: Interactions with officials from government and inter governmental agencies
- SOP_344448: Engaging with healthcare professionals (HCPs) to provide services
- SOP_54813: Medical Information responses to healthcare professionals and consumers
- STD-CHC-401: Consumer Healthcare Code of Practice

Go to Connect GSK

Find: Ways of working
Search for: **Pipeline presentations**

Find: Ways of working
Search for: **ViiV Healthcare Code of Practice**

Find: International medical
Search for: **IMED ref materials**

Go to CDMS

Find: EDOC compliance
Search for: **Commercial practices policies**

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 where their 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)/other healthcare staff (OHS). The frequency and timing of appointments does not cause inconvenience.

Our promotional information is:

- Consistent with locally approved prescribing information (API) (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.

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

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 electronic) that includes benefit claims for the medicine, includes:

- Abbreviated prescribing information (API) 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 API 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.

1.2 Promotional information
continued

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.

Communication of efficacy and safety data includes the absolute rates, 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%).
- Medicine X reduced the relative five year risk of prostate cancer by 50% compared to placebo (the reduction for medicine X was 25% and for placebo it was 50%).

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 rates are similar.

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 health benefit is permitted only where the type of data are made clear and there is an established link between that data and the 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 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.

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

- Valid.
- Current.
- Verifiable (by citing published references or obtaining 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.

1.2 Promotional information
continued

- 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).

A procedure for reporting adverse events is included in the body of the material or in prescribing information (eg API) that is included 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 produced by above country business units for distribution to LOCs follows this code.

SOP-GSKF-414: Copy approval

ⓘ 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

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

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.

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 bring about 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.

1.4 Promotional meetings

1.4.1 All promotional meetings

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

- Meetings (including third party medical education events) that we 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.

1.4 Promotional meetings
continued

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

SOP_375788: Conducting promotional webinars

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

Go to Connect GSK
Find: Ways of working
Search for: 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 procurement for meetings, refer to STD-GSK-512:

STD-GSK-512: Travel, meetings and expense standard for GSK employees

1.4.2 Material (including content of presentations)

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

See sections 1.1 and 1.2

API or full prescribing information (as required by local regulations or applicable codes) must be available at the meeting. Alternatively, if specifically permitted 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).

STD-GSKF-415: Standards for external interactions by Medical and R&D staff

SOP-GSK-007: Interactions with officials from government and inter governmental agencies

- 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.

1.4.3 GSK speakers and attendees

Appropriately trained Commercial and/or Medical/R&D staff may present on our medicines and/or the associated disease areas at promotional meetings (see **STD-GSKF-415:** Standards for external interactions by Medical and R&D staff).

Our staff who speak, attend or participate in meetings are transparent about their employment by GSK.

1.4.4 External speakers

Government Officials: We do not pay HCPs/OHS who are considered Government Officials 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 **SOP-GSK-007:** Interactions with officials from government and inter governmental agencies).

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.

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.

1.4 Promotional meetings
continued

SOP_344448:
Engaging with healthcare professionals (HCPs) to provide services

Our SOP on engaging HCPs/OHS to provide a service is followed (see **SOP_344448:** Engaging with healthcare professionals (HCPs) to provide services).

- Unpaid speakers may not receive any other quid pro quo arrangements (ie 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/meals for an unpaid HCP/OHS speaker.

- 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.
- No costs may be reimbursed by payment directly to the HCP/OHS speaker.

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 verbal disclosure 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, 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."

1.4.6 GSK sponsored satellite symposia

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

> 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.

1.5 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.

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

1.5 Detailing
continued

SOP_54813: Medical Information responses to healthcare professionals and consumers

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 and 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:

Go to CDMS
Find: EDOC compliance
Search for: Commercial practices policies

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

STD-GSKF-415: Standards for external interactions by Medical and R&D staff

R&D/Medical 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.

R&D/Medical 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 and **STD-GSKF-415:** Standards for external interactions by Medical and R&D staff applies.

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.

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 are not larger than the smallest presentation available within that country).
- 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.

Within Europe, quantities of samples of prescription medicines are limited to four samples per year per HCP for a restricted two year period post-launch. Each LOC within Europe determines the launch date that will trigger the start of this two year sampling 'window' for each new medicine or indication.

Refer to the Codes of Practice for ViiV Healthcare and Consumer Healthcare for requirements regarding samples for those products.

Go to Connect GSK
Find: Ways of working
Search for: 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.

For Japan 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.

For countries in EMAP: Promotional aids are listed on Connect GSK.

Go to Connect GSK
Find: International medical
Search for: IMED ref materials

In the USA and Canada promotional aids are not permitted.

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

1.9 Co-promotion

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 and this code. We seek agreement from the third party to comply with the standards set out in this code.

2 Scientific engagement (non-promotional)

External references relating to this section

- STD-GSKF-415: Standards for external interactions by Medical and R&D staff
- POL_132175: Policy for use of digital channels
- STD_340448: Standard for interacting with patient organisations
- SOP-GSK-301: Procedure on protecting and mitigating risk from internal and external communication activities
- SOP_297780: US Pharma market research: criteria for designing and executing market research conducted in the US
- SOP_54813: Medical Information responses to healthcare professionals and consumers
- SOP-GSKF-416: Scientific engagement of individual and groups of patient caregivers and consumers to seek advice, insights and information
- SOP_344448: Engaging with Healthcare Professionals (HCPs) to provide services
- POL-GSKF-408: Policy on human subject research
- SOP_53431: Public disclosure of human subject research (Pharma)
- SOP_9000026959: Public disclosure of human subject research (Vaccines)
- POL-GSK-016: Policy on grants and donations
- SOP-GSK-016: Grants and donations SOP
- SOP-GSK-007: Interactions with officials from government and inter governmental agencies

Go to Connect GSK

Find: GSK global
Search for: **Scientific engagement**

Find: GSK global
Search for: **Scientific engagement – vendor**

Find: Ways of working
Search for: **Guidance for when a contract is required**

Find: Medicines and vaccines
Search for: **Guidance on the conduct of primary market research in GSK Pharma**

Find: Ways of working
Search for: **GSK Publication Handbook**

Search for: **ABAC requirements**

Search for: **ABAC framework**

Find: Ways of working
Search for: **Moore model**

Find: Ways of working
Search for: **IME agreement contract**

Go to CDMS

Find: EDOC compliance
Search for: **US commercial practices policies**

Go to access.gsk.com

Search for: **Process map for IME**

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.
- Supporting independent 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 medical congresses.

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

See section 1.6

STD-GSKF-415: Standards for external interactions by Medical and R&D staff

ⓘ 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 (eg see appendix 1).

See appendix 1

ⓘ R&D/Medical 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 judgment with consideration of intent, perception, proportionality and timing to ensure that:

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

2.2 Principles for scientific engagement
continued

POL_132175: Policy for use of digital channels

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.

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

SOP-GSK-301: Procedure on protecting and mitigating risk from internal and external communication activities

2.3 Accountability and approval

Go to Connect GSK
Find: GSK global
Search for: Scientific engagement

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.

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

- Prior to the assignment of the MDL/VDL for a medicine, the most appropriate member of the R&D leadership team from within the relevant research unit 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 Global Medical Affairs Leader (GMAL or assigned individual where there is not a GMAL) for a global activity, Area Medical Lead for an area activity, Country Medical Director (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 the signed approval template is completed 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 operational support are those that have organisational firewall protections if they support scientific engagement and promotional activities ('dual purpose' vendors).

- This limitation does not include consultants who are under contract to provide guidance and advice, or vendors who only provide logistical support (eg travel agencies, event management).
- Firewall and training assessment is checked 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**).

Go to Connect GSK
Find: GSK global
Search for: Scientific engagement

2.5 Seeking external advice, insights and information

Go to Connect GSK
Find: Ways of working
Search for: Guidance for when a contract is required

Go to Connect GSK
Find: Medicines and vaccines
Search for: Guidance 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

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).

(b) Pre-planned informal discussions with individuals or groups.

(c) Spontaneous discussions at scientific/medical congresses.

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 pre-planned informal discussions and spontaneous discussions at congresses, care is needed so that the discussion does not evolve into a situation where a contract 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 **Guidance 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

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 agenda is focused on obtaining input.

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

2.5 Seeking external advice, insights and information

continued

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 documented. If more than 12 advisors are required, the rationale is documented.

Only GSK staff who have an active and documented role which is necessary to obtain or record the advice participate in the meeting.

The advisory nature of the interaction 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.

In the USA advice-seeking activities by US Commercial are conducted in compliance with applicable US commercial practices policies:

Go to CDMS
Find: EDOC compliance
Search for: US commercial practices policies

(b) Pre-planned informal discussions with individuals or groups

Medical/R&D staff may interact with HCPs/OHS on a limited basis to gain insights and information. These scientific discussions:

- May be pre-arranged.
- Maintain scientific objectivity, integrity and credibility.

Do not involve proactively providing information about our medicines; information on our medicines may be provided in response to a specific unsolicited question (see **SOP_54813:** Medical Information responses to healthcare professionals and consumers and **STD-GSKF-415:** Standards for external interactions by Medical and R&D staff).

- Are for our staff to listen and learn, and not to provoke discussion of, influence or change opinions about the merits of our medicines. (Medical/R&D staff lead the discussions; senior commercial staff may attend where there is a documented reason for their attendance).

SOP_54813: Medical Information responses to healthcare professionals and consumers

STD-GSKF-415: Standards for external interactions by Medical and R&D staff

Go to Connect GSK
Find: Ways of working
Search for: Guidance for when a contract is required

SOP_54813: Medical Information responses to healthcare professionals and consumers

The extent of informal discussions led by medical is proportionate in length and frequency, and based upon a genuine need to enhance our scientific understanding.

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

Documentation of the outcome of interactions 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:

- Pre-planned informal discussions to understand a disease or general patient management related to a specific disease.
- Contacting an expert HCP to obtain information which is 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.

(c) Spontaneous discussions at scientific/medical congresses

In the context of a scientific forum such as a scientific/medical congress, Medical/R&D staff may interact with HCPs/OHS on a spontaneous basis to gain insights and information.

- These discussions do not involve proactively providing information about our medicines. Limited discussion of publicly available information about our medicines is permitted in order to ask a question or discuss statements made by HCPs/OHS (see examples below). Information on our medicines may also be provided in response to a specific unsolicited question (see **SOP_54813:** Medical Information responses to healthcare professionals and consumers).
- Written agreements or contracts are not required.
- Where important insights and information relevant to our science and/or our medicines is obtained, it is shared with relevant GSK colleagues.

2.5 Seeking external advice, insights and information

continued

Examples of permitted interactions:

- Ad hoc unplanned discussions at a scientific/medical congress between R&D/Medical staff and congress delegates where we are interested in learning more about their science, and there is no promotional intent or purpose.
- New patient management guidelines which may or may not include reference to our medicines are presented at a congress. Our R&D/Medical staff may ask a few HCPs at the congress whether the new guidelines are likely to impact the way they manage their patients.
- Our R&D/Medical staff may ask questions of HCPs/OHS who are presenting data at a congress. The questions are scientific and based on the data described in the presentations, which may or may not relate to our medicines.
- An HCP publishes a paper which includes data based on our medicines or competitor medicines, and R&D/Medical staff may wish to ask the HCP/OHS some questions about the results.

See also

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

STD-GSKF-415: Standards for external interactions by Medical and R&D staff

SOP_344448: Engaging with healthcare professionals (HCPs) to provide services

STD_340448: Standard for interacting with patient organisations

2.6 Scientific communication of our research

POL-GSKF-408: Policy on human subject research

2.6.1 What we can do

(a) We publicly disclose our clinical research according to the principles and requirements of **POL-GSKF-408:** Policy on human subject research. This includes postings on internet registers, congress presentations (oral or posters) as part of core congress programs, and manuscript publications.

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

- Provide medicine related information in response to unsolicited requests from an HCP/OHS.
- Provide information about ongoing clinical trials and/or medical information in response to unsolicited requests at scientific/medical booths.
- On a limited basis, provide a forum at congresses for two-way discussion and debate on the results of our science (scientific workshop).

(c) Support the development of treatment guidelines by medical societies by providing scientific 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.

POL-GSKF-408: Policy on human subject research

2.6.3 Requirements

(a) Scientific public disclosure of our research

For human subject research, public disclosure follows **POL-GSKF-408:** Policy on human subject research and applicable requirements.

Once an investigational medicine enters Phase II, the pre-clinical data that we consider of scientific importance or relevant for patient care is submitted for publication as the data become available.

2.6 Scientific communication of our research
continued

The scientist or physician responsible for the study is accountable for the primary publication and other publications/ presentations that include further data from the study.

For publications and presentations, authors meet International Committee of Medical Journals Editors (ICMJE) guidelines or journal authorship guidelines (where the journal guidelines are more restrictive). We do not pay for authorship of articles or presentations. We may reimburse reasonable expenses associated with authorship or plenary congress presentations of our research (eg travel expenses related to attendance at author meetings or plenary congress presentations).

For congress presentations the target congress is selected according to the scientific/medical significance and the appropriate audience for the data consistent with the Data Disclosure Plan. New data is submitted in a timely manner and is not delayed to increase impact just prior to launch.

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 (eg a therapy area pipeline overview), 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 therapy area pipeline overview to medical audiences in response to an unsolicited request. The information presented is based on information available in the public domain.

See also

Go to Connect GSK
Find: Ways of working
Search for: GSK publication handbook

SOP_53431: Public disclosure of human subject research (Pharma)

SOP_9000026959: Public disclosure of human subject research (Vaccines)

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

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.

Examples of permitted interactions

Ad hoc unplanned discussions at a scientific/medical congress between our R&D/Medical staff and congress delegates who are interested in learning more about our science and instigate the discussion, and there is no promotional intent or purpose.

Our R&D/Medical staff may spontaneously discuss a statement about our medicines made by a congress delegate to provide factual, balanced information that supports or challenges that statement.

Scientific/medical information booths

Scientific/medical booths to provide medical information and/or information on currently recruiting GSK sponsored clinical trials are permitted provided they are physically separate from commercial booths, with at least a tall dividing partition or wall.

Scientific/medical booths are staffed by Medical/R&D staff only. Activities conducted from the scientific booth are non-promotional and there is no pro-active distribution or display of data or information on our medicines.

Scientific workshops

When there is an exceptional and compelling scientific justification, Medical/R&D staff from above country business units may fund and organise a scientific workshop within the infrastructure of a global/regional congress where there is a scientific justification for further bona fide scientific discussion and debate on our research (we do not fund of travel or accommodation for individuals to attend).

2.6 Scientific communication of our research
continued

- The workshop focus is on research which is presented at the congress; presentation of data is limited to enabling the discussion and debate.
- Such workshops are for a limited number of delegates (no more than 30 via prior registration) and may include data related to an unauthorised medicine or indication. The documented justification, approach and plan require approval from all the following: the CMD in the country where the workshop is planned, the MDL/VDL and Chief Medical Officer (CMO) or delegate.

(c) Support for the development of treatment guidelines by medical societies

If we do not have an authorised medicine in a given therapy 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. 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 therapy area and there is no treatment guideline endorsed by a medical society, 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 participation is clearly disclosed.

- 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.

See section 2.8

Our staff declare conflicts of interest if they are involved in the decision-making of the medical society.

2.7 Supporting independent medical education

Independent Medical Education (IME) comprises activities that are delivered or implemented for HCPs/OHS without GSK influence on content, speaker faculty or audience selection.

- Activities where CME or other Continuing Professional Development (CPD) points are given to participants does 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.

> 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. These activities can be independent or non-independent; only independent medical education is considered scientific engagement under this code.

POL-GSK-016: Policy on grants and donations

SOP-GSK-016: Grants and donations SOP

2.7.1 What we can do

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

Grant funding for independent medical education is only permitted in disease areas where we have an authorised medicine.

- Exception: Funding independent medical education in a disease area where we only have a pre-authorisation medicine or indication is permitted when it is related to a significant global public health concern and approved by the GSK CMO or delegate.

2.7.2 Where care is needed

Where we have any influence on the education activity it is not independent medical education and in such cases the activity is conducted in accordance with section 1 of this code.

See section 1

2.7 Supporting independent medical education

continued

2.7.3 Requirements

Grant funding is in response to a proposal. This may be a proposal which is not prompted by us. It may also be a proposal where we publicly 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.

SOP-GSK-016: Grants and donations SOP

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-GSK-016:** Grants and donations SOP).

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

Go to Connect GSK
Search for:
ABAC requirements

Go to Connect GSK
Search for:
ABAC framework

That the applicant:

- Meets our Anti-bribery and corruption (**ABAC**) requirements.
- 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 our **ABAC framework**) non-accredited education providers who meet our requirements can receive grant funding.
- Where relevant (eg for medical education companies), meets our scientific engagement requirements for vendors where they also support promotional activities (see section 2.4). It is preferred that these companies are accredited education providers or work with an accredited provider.

  See section 2.4
- That the budget and expenses 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.

Go to Connect GSK
Find: Ways of working
Search for: Moore model

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 assess 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.

2.7 Supporting independent medical education

continued

Go to Connect GSK
Find: Ways of working
Search for:
IME agreement contract

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.

The process map for IME can be found here:

Go to access.gsk.com
Search for: Process map for IME

2.8 Scientific interactions with payers, governments and public health organisations

SOP-GSK-007:
Interactions with officials from government and inter governmental agencies

Go to Connect GSK
Search for:
ABAC requirements

Interactions with government officials comply with **SOP-GSK-007:** Interactions with officials from government and inter governmental agencies. These stakeholders may also be HCPs/OHS. In these circumstances the strictest requirements apply.

2.8.1 What we can do

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

2.8.2 Where care is needed

Particular care is taken to adhere to our **ABAC requirements** and local rules when interacting with government officials.

2.8.3 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 (see section 4.8) 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.

2.8 Scientific interactions with payers, governments and public health organisations

continued

2.8.4 Requirements

Scientific engagement with employees of governments, 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.

2.8.5 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 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

External references relating to this section

- STD_340448: Standard for interacting with patient organisations
- SOP-CGA-100: Global product and pipeline media materials development and approval procedure
- POL_132175: Policy for use of digital channels
- SOP-GSKF-400: Procedure for identification and tracking of adverse events through PSP (MR and IDM activities that may generate human safety information for GSK products)

- **ABPI Code of Practice for the Pharmaceutical Industry, Section 20**
  www.pmcpa.org.uk/thecode/InteractiveCode2015/Pages/clause20.aspx
- **ABPI guide and case studies on Joint Working with the Pharmaceutical Industry**
  www.abpi.org.uk/our-work/library/guidelines/Documents/joint_working_with_the_pharmaceutical_industry.pdf

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-CGA-100: Global product and pipeline media materials development and approval procedure

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 or via an HCP/OHS. 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 or therapy 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 treatments.

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

POL_132175: Policy for use of digital channels

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 or Commercial.

3.3 Healthcare support services
continued

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 guidance see

ABPI Code of Practice for the Pharmaceutical Industry, Section 20
www.pmcpa.org.uk/thecode/InteractiveCode2015/Pages/clause20.aspx

ABPI guide and case studies on Joint Working with the Pharmaceutical Industry
www.abpi.org.uk/our-work/library/guidelines/Documents/joint_working_with_the_pharmaceutical_industry.pdf

SOP-GSKF-400: Procedure for identification and tracking of adverse events through PSP (MR and IDM activities that may generate human safety information for GSK products)

3.3.1 Patient programmes following prescription

Compliance (or adherence) programmes for patients prescribed our medicines are only administered following initial involvement and endorsement of an HCP involved in the treatment of relevant patients.

Accesses to Medicines Programmes for our authorised medicines (ie those to support affordability) are reviewed by Medical and Legal. They are not an improper inducement for HCPs to prescribe our medicines, or for the patient to request our medicines. They do not constitute advertising of medicines to the patient except where expressly permitted by local laws.

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.

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 onto 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.

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.

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

4 General requirements

External references relating to this section

	Go to Connect GSK
▪ SOP_344448: Engaging with healthcare professionals (HCPs)	Search for: **Corporate security**
▪ POL-GSK-016: Grants and donations policy	Find: Ways of working Search for: **Process map**
▪ SOP-GSK-016: Grants and donations SOP	Search for: **ABAC requirements**
	Find: Ways of working Search for: **IME grant agreement contract**
	Find: Code of Conduct and Our values and standards resource centre Search for: **Pricing risk governance framework**

4.1 Engagement of HCPs and OHS to provide services

SOP_344448: Engaging with Healthcare Professionals (HCPs)

SOP_344448: Engaging with healthcare professionals (HCPs) 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 fair market value (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)). Any exception to the fee schedule is reviewed and approved by the Regional 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.

We do not pay HCPs/OHS to speak about our medicines or associated diseases to other HCPs/OHS. 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

We do not pay for authorship of peer reviewed articles or plenary congress presentations. We may reimburse reasonable expenses associated with these activities.

See section 2.6.3

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).

4.1.1 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 subsistence, travel costs (eg airfare) and accommodation. Payments for clinical trials or activities related to clinical trials are excluded. Exceptions can be approved by the Regional Head of Medical Affairs in consultation with the CMD.

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

Outside the USA, the maximum cap that an LOC can set is the upper limit of fair market value hourly fee x 20 days x 8 hours per day.

4.1 Engagement of HCPs and OHS to provide services
continued

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.

Go to Connect GSK
Find: Corporate security

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 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.

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

4.3 Hospitality

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.

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

For support of independent medical education:

See section 2.7

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

- The scientific content is reputable 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

Congress funding and activities are reviewed by the LOC in the country in which the congress takes place to ensure compliance with local laws, regulations and applicable industry codes.

Funding in response to an unsolicited request from a congress or other third party meeting organiser where the value of any service, privilege or benefit provided in return for the payment is:

- Incidental and substantially less than the funding being sought follows our grants and donations policy and SOP (see **POL-GSK-016** and **SOP-GSK-016**).
- Equivalent to the funding being sought follows processes for sponsorship or fee for service funding. (Note: We may proactively seek a presence at medical/scientific congresses by making payments (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 of a medicine, sponsorship or fee for service 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.
- Before marketing authorisation, we do not fund medical congresses to enable promotional activities (eg commercial booth space, GSK sponsored satellite symposia).

POL-GSK-016: Grants and Donations Policy

SOP-GSK-016: Grants and donations SOP

4.5 Funding HCPs and OHS to attend scientific/medical congresses

Go to Connect GSK
Find: Ways of working
Search for: Process map

Go to Connect GSK
Search for:
ABAC requirements

Go to Connect GSK
Find: Ways of working
Search for: IME grant agreement contract

We do not provide direct financial support to HCPs/OHS to attend medical congresses.

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 (see **process map**). 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.
- Meets our **ABAC requirements**.
- 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.
- 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.

4.5 Funding HCPs and OHS to attend scientific/ medical congresses

continued

Go to Connect GSK
Find: Ways of working
Search for: Process map

- 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 (see **process map**).

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 our ABAC framework). 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(s) 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 guidance 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.

4.5.3 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 may provide non-mandatory guidance 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 HCP/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.

See section 1.4.5

Note: a contract is not required.

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 below

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 in EMAP and Japan where it is considered respectful of local customs and permitted under local laws and regulations and 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

Go to Connect GSK
Find: Code of Conduct and Our values and standards resource centre
Search for: Pricing risk governance framework

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.

This section comes under Commercial accountability.

5 Further information and appendices

External references relating to this section

- POL-GSK-409: Medical governance framework

www.gsk.com/integrity

Go to Connect GSK

Find: Who we are
Search for: **Business Unit Compliance Officer**

5.1 Monitoring

Management monitoring

Local management is responsible for ensuring effective change and embedding plans are in place. A review of this procedure occurs every two years for improvement.

Independent business monitoring

Risk owners are accountable for ensuring that independent business monitoring expectations are clear for this standard.

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-GSK-409**). 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**.

POL-GSK-409: Medical governance framework

www.gsk.com/integrity

Go to Connect GSK
Find: Who we are
Search for: Business Unit Compliance Officer

5.3 Appendix 1: GSK written standards for activities and interactions with audience groups not covered by this code

Activity/audience group	GSK written standard
Approving promotional materials	▪ **SOP-GSKF-414:** Copy approval process for materials under the GSK Code of Practice for promotion and customer interactions
Medical Information	▪ **SOP_54813:** Medical Information responses to healthcare professionals and consumers
Providing grants and donations	▪ **POL-GSK-016:** Policy on grants and donations ▪ **SOP-GSK-016:** Grants and donations SOP
Clinical research	▪ **POL-GSKF-408:** Human subject research
Compassionate use	▪ **POL-GSK-406:** Compassionate use of GSK investigational medicines
Market research	▪ Guidance 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	▪ **POL_132175:** Policy for use of digital channels
Engaging healthcare professionals and other healthcare staff to provide a service	▪ **SOP_344448:** Engaging with healthcare professionals (HCPs) to provide services ▪ **SOP-GSKF-417:** Disclosure of transfers of value to HCPs and HCOs domiciled in Europe/Russia/Ukraine/Turkey
Humanitarian product donations	▪ **POL-GSK-303:** Humanitarian product donations policy ▪ **SOP-GSK-303:** Humanitarian product donations standard operating procedure and emergency response
Interacting with government officials	▪ **SOP-GSK-007:** Interactions with officials from government and inter governmental agencies
Interacting with the media	▪ **POL-GSK-301:** Policy on protecting and mitigating risk from internal and external communication activities ▪ **SOP-GSK-301:** Procedure on protecting and mitigating risk from internal and external communication activities ▪ **SOP-CGA-100:** Global product and pipeline media materials development and approval procedure
Interacting with patient groups	▪ **STD_340448:** Standard for interacting with patient organisations
Procurement for meetings	▪ **STD-GSK-512:** Travel, meetings and expense standard for GSK employees

5.4 Appendix 2: Key written standards for external interactions

Topic area	Written standard
ABAC framework for engaging third parties	▪ ABAC
Safety reporting	▪ **POL-GSK-400:** Management of human safety information for GSK products ▪ **SOP-GSKF-400:** Procedure for identification and tracking of patient support programmes, market research, and interactive digital media that may generate human safety information for GSK products
Engagement of third parties	▪ **POL-GSK-007:** Anti-bribery and corruption policy ▪ Anti-bribery and corruption framework. Third party procedures and guidance
Disclosure of transfers of value	▪ **SOP-GSKF-417:** Disclosure of transfers of value to HCPs and HCOs domiciled in Europe/Russia/Ukraine/Turkey ▪ **POL-TDOR-001:** Transparency data operations and reporting (TDOR) policy
Sanctions and export control	▪ **POL-GSK-014:** Policy on sanctions and export control ▪ **SOP-GSK-014:** Procedure on sanctions and export control
Maintaining privacy and confidentiality	▪ **POL-GSK-010:** Privacy of personally identifiable information
Interactions with US healthcare professional (HCPs) and a US government reimbursed product	▪ **SOP-GSKF-420:** Planning, tracking and execution of US HCP/HCI engagements

5.5 Appendix 3: Glossary

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

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

Grant refers to a financial award.

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 or therapy areas.

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

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.

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.

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.

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

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

5.5
Appendix 3: Glossary
continued

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.

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.

5.6
Appendix 4: Abbreviations

Abbreviation	
ABAC	Anti-bribery and corruption
API	Abbreviated prescribing information
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
ICMJE	International Committee of Medical Journals Editors
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IDM	Interactive digital media
IME	Independent Medical Education
LOC	Local Operating Companies
MDL	Medicine Development Leader
MR	Market research
NICE	National Institute for Clinical Excellence
NIH	National Institutes of Health
PI	Prescribing information
PSP	Patient support programmes
RMCB	Risk Management and Compliance Board
TDOR	Transparency data operations and reporting
VDL	Vaccine Development Leader
WHO	World Health Organization

www.gsk.com

Head Office and Registered Office
GlaxoSmithKline plc
980 Great West Road
Brentford, Middlesex TW8 9GS
United Kingdom
Tel: +44 (0)20 8047 5000
Registered number: 3888792

GSK Cross-Business
STD_344428 (2.0)

Previously
STD-GSK-401/002

V2 (January 2016)