GSK Code of Practice for promotion and customer interactions

Effective 21 July 2014

GSK Code of Practice

GSK's interaction with external communities and the marketing of our products to ensure their appropriate use and availability is fundamentally important to patients, our customers and GSK. Like all our activities, our objectives and actions in these areas are driven by our values of respect for people, patient focused, transparency and integrity.

All GSK employees are expected to engage with external communities according to our values, adhering to relevant laws, regulations, GSK policies and industry Codes of Practice.

I cannot overstress the importance of adhering to this global Code of Practice. It will ensure that Healthcare Professionals and the general public can be confident that our interactions with them and the marketing of our products is based on the merits of each product and the patient's particular healthcare needs.

By following this Code, each and every one of us will be able to take great pride in the way that we do business, working openly with others to help improve the health and wellbeing of people, whoever they are and wherever they may be.

Our values ensure that doing what is right for the patient is at the heart of every decision and interaction. It is critical that we build trust with doctors, patients and society and this Code and our values will help us to do just that.

Andrew Witty
Chief Executive Officer

Contents

1 Purpose

The purpose of this Code is to ensure that, following any necessary authorisations, GSK's activities and interactions with Healthcare Professionals (HCPs), other healthcare staff, Government Officials, patient groups, media and the general public are carried out in a responsible, ethical, professional and legal manner. The requirements set forth in the Code are not all encompassing and do not establish criteria for every particular situation. In such cases GSK employees should be guided by the GSK Values and seek guidance from the appropriate person, eg line managers, Legal, Medical and Compliance.

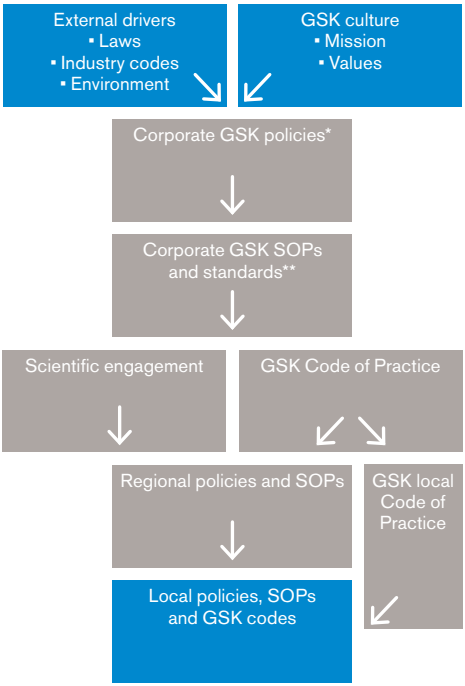
GSK is committed to ensuring a clear distinction between scientific engagement and product promotion.

The activities listed below must comply with the relevant Scientific engagement operating practices:

- Seeking external advice, insights and information.
- Scientific communications of our research.
- Scientific interactions with non medical or scientific audiences.
- Supporting third party medical education.

This Code incorporates the key principles from international external codes. Reference should also be made to **POL-GSK-002** (Scientific engagement policy), **STD-GSK-002** (Scientific engagement global standards) and **SOP-GSK-007** (Interactions with officials from government and inter-governmental agencies).

Hierarchy of control frameworks



* Including:
- Scientific engagement (**POL-GSK-002**)
- Preventing corrupt practices (**POL-GSK-007**)
- Protecting and mitigating risk from internal and external communication activities (**POL-GSK-301**)

**Including:
- Interactions with Government Officials (**SOP-GSK-007**)

2 Scope

This Code applies to all GSK business units across the globe, and covers the promotion of all GSK products and interactions with customers.

- This Code sets the minimum GSK standard. Where local laws, regulations, industry codes of practice and policies set higher standards, they must take precedence over this Code.
- This Code provides core and supplementary information for each clause. The supplementary information provides additional information for example regionally specific requirements. Compliance with all requirements contained in the Code, whether contained in the core or supplementary information, is subject to internal audit.
- This Code applies to the promotion of GSK products to the general public, where permitted. In addition to complying with this Code, in particular clauses 5, 6 and 13, direct to consumer advertising must comply with applicable codes, laws and regulations.

3 General principles

Our intentions and actions are driven by our values of patient focus, transparency, respect for people and integrity. In addition the Anti-Bribery and Anti-Corruption (ABAC) Foundation Principles of legitimacy of intent, no undue influence or conflict of interest, transparency and proportionality must be followed.

- Interactions with HCPs, other healthcare staff, the general public, media and Government Officials must be carried out in a responsible, ethical and professional manner in compliance with regulatory and legal requirements.
- Promotional practices and activities must never bring discredit upon, or reduce confidence in, GSK or our industry.
- Relationships or interactions with HCPs, other healthcare staff, the general public, media and Government Officials must be intended to enhance healthcare and benefit individuals who use our products.
- GSK must only promote products in a country after any necessary authorisations have been granted in that country (see clause 7 for permitted activities at international congresses).
- GSK medicines must be promoted only for approved indication(s), consistent with locally approved product information. Other GSK products must be promoted only for approved uses in the relevant country.
- Promotion should only be directed at those whose need for, or interest in, the particular information can be reasonably assumed.
- Nothing must be offered or provided in a way that has an inappropriate influence on the recommendation, prescription, purchase, supply, dispensing or administration of GSK products.
- Transfers of value (including grants, donations, subsidies, consulting contracts, educational items, practice-related items or other financial benefits or benefits in kind) must not be provided or offered with the intent of improperly rewarding or influencing the recommendation, prescription, purchase, supply, dispensing or administration of GSK products or for a commitment to continue to do so. GSK employees must not use any inducement or deception to gain an appointment with HCPs, other healthcare staff, the general public, media or Government Officials, and the frequency and timing of appointments must not cause inconvenience.
- All materials and activities initiated, arranged or funded by GSK must disclose GSK's specific involvement. This declaration of involvement must be clearly visible.

Supplementary information
ABAC Foundation Principles

Foundation principles	Questions to ask yourself
Legitimacy of intent	▪ Why am I doing this activity and is it consistent with GSK's Values and ABAC Foundation Principles? ▪ Do I have a hidden objective? ▪ Is it legal? ▪ Is it compliant with GSK policies and Standard Operating Procedure (SOP)? ▪ Could any of the activities or engagements (looked at individually or in aggregate) be perceived as an attempt to improperly influence an award of business, product registration or any other decision? ▪ Do we need to seek this information or do we already have it? ▪ Is the frequency or volume appropriate? ▪ Have I taken adequate steps to ensure that any actual or perceived conflicts of interest are effectively managed?* (see footnote) ▪ Would my or the company's reputation be affected if it was reported in the news? ▪ If asked, will there be sufficient documentation to demonstrate why my actions were appropriate? ▪ Could this negatively impact patients, research subjects, shareholders, customers or colleagues?
Transparency	
Proportionality	
No conflict of interest or undue influence	

* For examples of conflict of interest, refer to SOP-GSK-006: Managing and addressing conflicts of interest procedure.

4 Responsibilities

4.1 Accountabilities

The heads of GSK business units are accountable for ensuring that the requirements of this Code and all other applicable laws, codes, policies and SOPs are met. Governance oversight of this Code resides under the medical governance framework (see **POL-GSK-409**: Medical governance policy).

Each manager of staff involved in activities covered by this Code is responsible for ensuring that their staff are adequately trained on the requirements of this Code and other relevant laws, codes, policies and SOPs that apply to their role.

Each manager is accountable for Code breaches committed by their staff when the manager knew, or should have reasonably known, that such activities were taking place in contravention of the Code.

Each GSK business owner who selects and engages with agencies, suppliers (such as contract sales forces, consultants, market research agencies, advertising agencies, medical communication agencies, and public relations agencies) and distributors is accountable for ensuring these parties are aware of and comply with this Code where necessary.

All GSK staff concerned with activities covered by this Code must follow this Code. All such personnel must have access to a copy of the most up to date version of the Code and any supplements.

Supplementary information

Subject to applicable competition law and subject to guidance issued for particular types of deal, where a third party is co-promoting or promoting a GSK product (ie GSK owns the necessary authorisation), the third party must comply with the standards set out in this Code. All promotional materials used, and promotional activities carried out, by the third party must be approved by GSK in accordance with local approval processes.

Where GSK is co-promoting or promoting a third party's product, GSK must comply with this Code. GSK should endeavour to gain agreement from the third party to comply with the standards set out in this Code. Where the third party does not agree to comply with GSK's Code (or the more restrictive approach of the third party) this must be approved by the Medical Governance Executive Committee (MGEC).

4.2 Adverse events

Employees must report any human safety information (information relating to human health and/or wellbeing arising following exposure of humans to GSK products). This information must be reported to the relevant Central Safety Department or Local Operating Company (LOC) Medical department, within 24 hours of initial awareness, in compliance with **POL-GSK-400** (Management of human safety information for GSK products).

4.3 Local policies and procedures

Each GSK business unit must have appropriate written procedures and guidelines where required by this Code and where necessary to ensure compliance with this Code. Such procedures and guidelines must be consistent with the ABAC Foundation Principles, and must describe appropriate governance and control processes.

All materials and activities covered by this Code for external audiences must be appropriately reviewed and approved. Each business unit must have a documented process that describes:

- The development, review, approval and release of such materials and activities;
- The period during which such materials may be used and the retention periods for such materials;
- The role of functions including Medical, Regulatory, Commercial and Legal as appropriate.

4.4 Applicable codes

All promotional materials and activities undertaken, organised or sponsored by or on behalf of GSK must comply with this Code and with the laws, codes and policies of the country in which the promotion or interaction takes place.

Where the promotional material, activity or interaction is aimed at an HCP from a particular country, the laws, codes and policies of the HCP's country must be respected.

Non-promotional activities governed by **STD-GSK-002** (Scientific engagement global standards) must comply with relevant clauses of this Code that extend to all HCP interactions, eg hospitality, venues, fee caps, transfer of value etc.

Supplementary information

In order to comply with the EFPIA Code, any promotion of a medicine for prescription or interaction with HCPs undertaken, organised or sponsored in one European country by or on behalf of a GSK business unit based in another European country must comply with both (i) the local code in the country in which the business unit is based and (ii) the local code in the country in which the promotion or other interaction takes place.

Where materials are provided by an above-country business unit to LOCs for adaptation and use, such materials must meet the requirements of this Code but do not have to be approved under the local code of the country in which the above-country business unit is based before distribution to LOCs. The materials must be approved before use by the relevant LOC as compliant with local requirements before use.

4.5 Monitoring and reporting

4.5.1 Monitoring

Each GSK business unit must monitor compliance with the Code by means of management and independent monitoring and reviews.

4.5.2 Breaches of this Code and reporting

Non-compliance with this Code is a serious disciplinary matter.

GSK staff have a duty to report, without fear of repercussion, breaches of this Code, laws or ethical principles that come to their attention. Concerns must be reported in accordance with the GSK reporting of misconduct procedure (**SOP-GSK-003**).

Any genuine misconduct concerns raised in good faith will be thoroughly investigated with appropriate actions taken based on outcome in accordance with the internal investigations procedure (**SOP-GSKF-522**) and with appropriate protection for the individual who raises the concern in accordance with safeguarding people who report unethical and illegal conduct (**SOP-GSK-015**).

4.6 Corporate Integrity Agreement (CIA)

GSK staff (including contract workers and contingency staff) who perform certain covered functions (promotional, product-related or payer-related) are required to complete annual CIA mandatory training. Individuals who feel they may perform covered functions (listed below) or may be contracting with individuals conducting covered functions must identify themselves to their Compliance personnel to determine whether they are 'covered persons' and complete training within 30 days of identification and then annually thereafter.

All vendors contracted by GSK for covered function work relating to a US authorised product are required to complete the training requirement. In addition, consultants (HCPs and others) contracted by GSK for more than 160 hours per year for covered function work relating to a US authorised product and a US HCP or Healthcare Organisation (HCO) are also required to complete the training requirement.

For CIA purposes, covered functions are described as follows:

- Promotional – selling, detailing, marketing, advertising, or promoting prescription drugs in the US, or direct preparation, review or dissemination of promotional materials to US recipients (preparation of global template promotional materials would not make an individual covered since it is subject to US adaptation and copy approval).
- Payer-related – interacting with entities that provide a drug health benefit programme for US prescription medicines (eg formulary placement, supplemental rebate agreements, and other types of rebate agreements).
- Product-related – activities relating to US prescription medicines including (a) preparing or disseminating non-promotional materials governed by a US federal healthcare program or the US Food and Drug Administration (FDA), (b) contracting with HCPs or healthcare institutions in the US to conduct post-marketing clinical trials or investigator sponsored studies, (c) authorship, publication, and disclosure of articles or study results relating to post-marketing studies, or (d) activities related to the submission of information to compendia.

4.7 Transfers of value

GSK may be required publicly to disclose transfers of value to HCPs, HCOs and patient advocacy groups, whether under this Code, other GSK policies or SOPs, or under applicable local laws or industry codes.

Where disclosure requirements apply, each LOC must keep records of the transfers of value made to HCPs or HCOs in the LOC's country.

Where an above-country business unit makes a transfer of value to an HCP or HCO, or where an LOC makes a transfer of value to an HCP or HCO from another country, these must be reported to the home country of the HCP or HCO, so that these can be recorded and, if required, disclosed.

5 Standards of promotional information

Promotion is only permitted after any necessary authorisations have been granted.

GSK medicines must be promoted only for the approved indication(s) and other GSK products must be promoted only for approved uses, in the relevant country. Promotion of any product must be consistent with locally approved product information.

Supplementary information

In this Code, 'on-label' means that promotional material must be consistent with the approved conditions of use (eg local product label). Promotional materials must be consistent with the approved indications and conditions of use and must be fair, balanced, non-misleading and adhere to local laws and regulations.

This does not limit promotional materials to using only the verbatim of the approved product information ('the label'). Promotional materials must respect the context and intent of information in the approved label, and statements from the label may not be reproduced out of context.

Disease information may be provided to HCPs. For the purposes of this Code, disease information provided to HCPs is classified as promotional information and the requirements of this clause apply.

5.1 Balanced, accurate and non-misleading promotion

Promotional information must be clear, up to date, accurate, balanced, fair, objective, verifiable and sufficiently complete to enable the recipient to form their own opinion of the value of the GSK product concerned. The information must be legible and be based on an evaluation of the relevant evidence and reflect that evidence clearly, accurately and objectively.

Promotional information must present, in a balanced way, information about the claimed benefits of the GSK product. Relevant safety information must be presented as clearly as information about claimed benefits.

All commercial activities and materials must fairly represent the products or services of third parties and not knowingly incorporate any material that could be judged offensive to interested minorities or to persons in general.

Supplementary information

Inclusion of Abbreviated or Full Prescribing Information (see clause 6) alone does not meet the requirements of this clause for the promotional material to be fair, balanced, accurate and not misleading. The material itself must not give a misleading impression of the medicine and its uses eg any significant limitations or qualifications of the claim must be disclosed and included in the body of the material, as well as information on relevant side-effects, contraindications, precautions, indications, relevant doses and/or methods of administration.

5.2 Distortion

Promotional information must not mislead by distortion, exaggeration, undue emphasis, omission, or in any other way. Promotion must encourage the appropriate use of GSK products by presenting them objectively and without exaggerating their properties. Claims must not imply that a GSK product, or an active ingredient, has some special merit, quality or property unless this can be substantiated. Every effort should be made to avoid ambiguity.

5.3 Substantiation

Promotional claims must be capable of substantiation. Information to support promotional claims must always be readily available and must be promptly provided in response to any reasonable requests.

The use of in-vitro laboratory or animal data to support claims of a health benefit, a cosmetic benefit or a physical effect is permitted only where the type of data is made clear and there is a direct causal link between that data and the health benefit or cosmetic/physical effects in humans; or there is a consensus by the scientific community and regulatory authorities to consider these data as surrogate markers of a clinical benefit.

5.4 Comparisons

Any comparison made between different products must be fair, based on relevant and comparable aspects of the products, and must not be misleading or disparaging. The comparison must be capable of substantiation.

5.5 Product safety

Safety statements must respect the principle of fair balance and reflect available evidence.

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 consumers or patients, and the words ‘safely’ or ‘safer’ must never be used to describe a GSK medicine without qualification in promotional materials.

5 Standards of promotional information
continued

5.6 Reproduction of quotations and artwork from publications
All quotations and artwork, including graphs, illustrations, photographs and tables which are taken from publications and included in promotional material must:

a) Clearly indicate the precise source(s) of the artwork;

b) Be faithfully reproduced; except where adaptation or modification is required in order to comply with any applicable local code, in which case it must be clearly stated that the artwork has been adapted and/or modified;

c) Where applicable, be authorised for use in accordance with local copyright law.

Particular care must be taken to ensure that artwork included in promotional material does not mislead about the nature of a GSK product (eg whether it is appropriate for use in children) or mislead about a claim or comparison (eg by using incomplete or statistically irrelevant information or unusual scales).

5.7 References to 'new' products or uses
The word 'new' and equivalent terms may only be used to describe GSK products (or uses, indications, presentations or formulations) that have been commercially available in the relevant country for less than 12 months.

5.8 Disguised promotion
Promotion must not be disguised. All promotional materials and activities must be clearly identified as produced or supported by GSK and not disguised or misrepresented in any way.

5.9 Testimonials and quotations
Advertisements and promotional materials must not claim or imply endorsement by any government agency, professional body, individual, or independent agency unless the endorsement is verifiable and the agency, individual or body is named and has given their written approval in advance to the final promotional material that contains the endorsement.

Testimonials must be valid, true, current, verifiable, consistent with the product labelling and documented, and approved by the same criteria as any promotional claim.

The names, photographs or testimonials of individuals must not be used in any way that is inappropriate or contrary to ethical standards or local laws. If the identity, photograph or testimonial of an individual is used in promotional material, other than by citing published references, their written approval of the final promotional material must be obtained.

The approval of any endorsement or testimonial must include a statement that the organisation or individual is aware of and approves of the use of their name, logo, testimonial or photograph, as applicable, in the context of the promotional material as a whole.

6 Use of prescribing information in promotional material for medicines for prescription

Any branded promotional material (eg detail aids, promotional material left behind with HCPs, advertisements, commercial booth panels), which makes a benefit claim for a medicine, in a printed or in an electronic format, must comply with legal and regulatory requirements and, unless prohibited by local requirements, must include the abbreviated prescribing information or full prescribing information (or direction to it if this is specifically allowed by legal and regulatory requirements). The abbreviated prescribing information must include at least the following information, consistent with the marketing authorisation, clearly and legibly:

- The name of the medicine (usually the brand name).
- The generic (international non-proprietary) name or the name of the active ingredients, using approved names where they exist.
- The approved indication or indications for use.
- The dosage and method of administration.
- A succinct statement of the most relevant contraindications, precautions and/or side effects (see clause 5.1 regarding fair balance).
- A procedure for the reporting of adverse events.
- The name of the pharmaceutical company or the agent responsible for marketing the product.

Supplementary information

Clause 6 applies to promotion of medicines for prescription only. For all other GSK products, all promotional materials (branded and non-branded), both printed and in other formats including electronic media, must comply with all relevant local legal and regulatory requirements.

Slides presented at a meeting do not require the abbreviated prescribing information to be included; but the prescribing information must be available at the meeting.

All new promotional material (printed and electronic) that includes product claims will include the date of preparation/approval and a unique tracking code. For space-constrained items where no product claims are made (eg reminder advertisements) an alternative mechanism for tracking/recall is required.

In the USA, all new and newly revised prescribing information will contain a procedure for the reporting of adverse events.

In all countries globally, except the USA and Canada, the address of the pharmaceutical company or the agent responsible for marketing the product must be included on all promotional material.

6.1 Abbreviated/reminder advertisement

A ‘reminder’ advertisement is a short advertisement in a printed or in an electronic format, that contains a very limited amount of information, and is intended only as a reminder.

Where local guidance or regulations about reminder advertisements exist they must be followed.

Where such local guidance or regulations do not exist, the advertisement must include no more than the name of the product or its international non-proprietary name or the trademark and for these ‘reminder’ advertisements, abbreviated prescribing information and full prescribing information may be omitted.

7 Meetings sponsored or organised by GSK

This clause applies to:

- Sponsorship of, and promotional activities at, third party meetings (eg medical congresses) including commercial booths and satellite symposia.
- GSK organised stand-alone meetings that relate to authorised products and their approved uses, and/or related disease or therapy areas.

GSK funding of independent medical education, where GSK does not influence the content or speaker selection, is governed by the Scientific engagement operating practice on "Support for third party medical education". All other meetings that GSK funds or participates in, or influences the content or speaker selection, are regarded as GSK stand-alone meetings and the requirements of this clause apply – whether or not CME/CPD points are awarded.

Where GSK sponsors or organises a meeting, this must be disclosed in all the communications relating to the meeting and in any published proceedings, and must be sufficiently prominent. All GSK staff attending or participating in the meeting must be transparent about their employment by GSK.

Supplementary information

In specific circumstances, appropriately trained GSK Medical/R&D staff may present at a GSK-organised event ie a GSK stand-alone meeting or satellite symposium (see 8.4.1 of this Code). The contribution of GSK staff must comply with clause 5 of this Code.

GSK may fund independent medical education in countries where such programmes are available (see Scientific engagement operating practice on 'Support for third party medical education' (**STD-GSK-002**)).

Meetings held with external audiences about GSK products and disease areas must be conducted in accordance with this Code, unless for the conduct of research (eg **POL-GSKF-408**) or an activity specified in the Scientific engagement standards (**STD-GSK-002**):

- The Scientific engagement operating practice on 'Scientific communication of our research' must be followed for all medical/scientific activities undertaken or sponsored at congresses.
- If the intent of a meeting is to seek advice on scientific or clinical matters, then the Operating practice on 'Seeking external advice, insights and information' must be followed.

7.1 Sponsorship of congresses and other third party meetings

Sponsorship of independently organised congresses may occur. Following product authorisation the budget may be held by either Medical or Commercial.

All congress funding and activities should be reviewed by the LOC in the country in which the congress takes place to ensure compliance with local rules and regulations (see clause 4.4).

Supplementary information

All GSK employees worldwide must comply with existing US processes and policies when participating in congress activity involving a US based HCO or association taking place anywhere in the world. US Conventions Management must be contacted at **Ww.USConventions@gsk.com** to review any proposed US congress activity to determine if it meets US guidelines. Requirements of the CIA and Sunshine Act must also be met.

Where the organiser of the third party meeting is an HCO or Medical Society, and GSK receives no substantial service, privileges or benefits in return for the payment, it must be considered as a grant and clause 9.1 (Grants and donations) must be applied.

GSK must only sponsor congresses or other third party meetings when the scientific content is reputable and aligned to GSK scientific or medical interests, and when the venue has appropriate conference facilities which are clearly separated from any entertainment, sports, tourist or leisure facilities that may be present. See also clause 8.5.2 (Venues).

Sponsorship of third party meetings may need to be disclosed under local laws or industry codes. (See clause 4.7).

7 Meetings sponsored or organised by GSK

continued

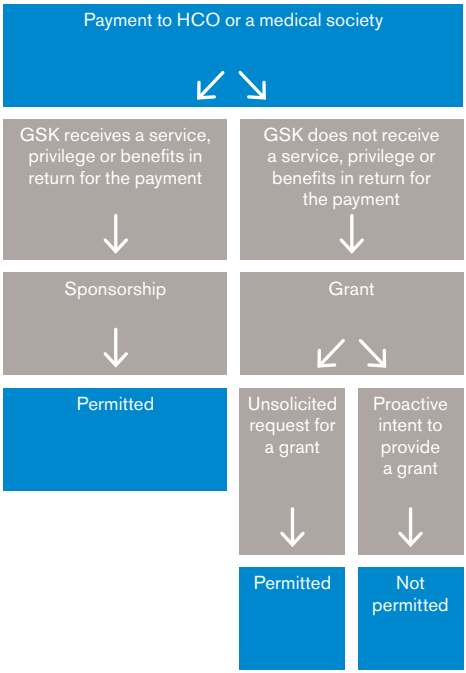
Supplementary information

At an international congress held in a country where GSK does not have the relevant product or use authorised, where the majority of expected attendees are from outside the venue country and from countries where the product is authorised, then a commercial booth and a satellite symposium are permitted, provided it is legally acceptable in the venue country and does not contravene the rules of the congress. Materials must clearly indicate that the product is not locally authorised. It is the accountability of the LOC Medical Director, in the country where the congress is taking place, to ensure compliance with this requirement.

Disclosure of certain transfers of value to HCOs in Europe, including sponsorship of HCO meetings and grants and donations, will be required with effect from 2015 to conform to EFPIA requirements.

The figure to the right provides guidance for determining whether a payment is sponsorship or should be considered as a grant.

Sponsorships and grants



Please also refer to clause 9.1 of this Code

Supplementary information

Please consult with your business unit specific policies and process owners when providing grants or sponsorships to US-based organisations. Due to CIA specific requirements for US-based organisations, three specific processes have been developed based upon the reporting line of the specific business unit:

Business unit	Grant process contact information
US Pharma (includes Stiefel and Puerto Rico)	**www.gskgivesback.com**
Pharma R&D (includes Oncology and Stiefel)	**https://team.gsk.com/sites/grants**
Vaccines (Global)	**https://connect.gsk.com/sites/bio_VaccineDevelopmentProjects/Pages/GovTeam-Summary.aspx?Team=GDSC**

7.1.1 GSK sponsored satellite symposia at scientific or medical congresses

Satellite symposia are those which are funded and organised by GSK within the infrastructure of, and officially recognised by, a medical congress. They are not permitted in disease areas where GSK does not already have an authorised product.

Satellite symposia sponsored by GSK must comply with the requirements of this Code, including clause 5, and all data presented and materials provided must be on-label.

Satellite symposia may be under Commercial or Medical budget. Medical has accountability for the content to be presented.

Supplementary information

The scientific and medical content of a satellite symposium, and appropriateness of the speaker faculty and logistical arrangements (ie travel, venue, accommodation) must be formally approved by the relevant Country Medical Director or designee for the country in which the event occurs. Logistical arrangements may be implemented by non-medical teams or a contracted vendor.

7 Meetings sponsored or organised by GSK
continued

7.1.2 Commercial booths at meetings

The purpose of a commercial booth is to promote authorised products and indications through the provision of approved promotional materials and through dialogue between congress delegates and GSK staff. These booths must be staffed by GSK employees who are trained and competent to discuss products with delegates consistent with the product labelling and in accordance with relevant promotional rules.

All materials and activities at the booth must be appropriately approved, must fairly represent GSK products, and must not knowingly incorporate anything that could be reasonably judged lavish, offensive or in any other way inappropriate in the local environment in which the congress is held.

Any testers of permitted GSK products made available to delegates during a congress must be limited in size and quantity per delegate and must be attached to a suitable product information leaflet where required (see clause 11.1).

Competitions (including raffles and lotteries), gifts, recreation and entertainment are not permitted. Any quizzes must relate to scientific/medical knowledge or skill in the relevant disease area.

Supplementary information

Scientific/medical booths must be implemented according to the Scientific engagement operating practice 'Scientific communication of our research' (**STD-GSK-002**).

7.2 GSK stand-alone promotional meetings

GSK stand-alone promotional meetings are those initiated by GSK, intended for HCPs, which are hosted independently of a congress or other third party meeting, which relate to GSK products and uses, and/or related disease or therapy areas.

GSK stand-alone promotional meetings are only permitted in disease areas where GSK already has an authorised product.

All GSK stand-alone promotional meetings must comply with this Code (including clauses 5 and 8, and the requirement that all data and materials presented be on-label).

For any GSK stand-alone meeting, it must be the strength of the programme content that attracts a delegate to attend.

The purpose and focus of the GSK stand-alone promotional meeting must be to provide scientific, medical or educational information, which may include information about GSK products. Medical education events that are influenced by GSK fit this category (whether or not they are awarded CME/CPD points). A GSK-standalone promotional meeting may focus entirely on a GSK product eg a launch meeting.

Supplementary information

GSK must not initiate a stand-alone meeting, set the agenda, select or brief speakers, or provide materials for use during the meeting unless GSK is able to ensure that the meeting meets the requirements of this Code including that all data presented and materials provided are on label.

The programme content must account for at least two thirds of the total duration of the meeting.

For any meeting involving more than 60 delegates or where the spend is expected to exceed £100,000, reference should be made to the procurement guidance at: **https://connect.gsk.com/sites/gskglobal/mmcoe/Pages/Standards-and-policies.aspx**

8 Interactions with Healthcare Professionals and other healthcare staff

Appropriate relationships with HCPs are intended to enhance the practice of medicine and ultimately benefit patients. Interactions must focus on informing HCPs about products, providing scientific, medical and educational information and support, gaining insights, and/or supporting medical research.

This Clause addresses all interactions with HCPs regarding GSK products or related disease or therapy areas. All promotional interactions must comply with this Code. Non-promotional activities governed by **STD-GSK-002** (Scientific engagement global standards) must also ensure compliance with sections of this clause that extend to interactions with all HCP, eg hospitality, venues, fee caps, transfer of value etc.

The requirements of this clause also apply to GSK interactions which involve or are directed to other healthcare staff. References in this clause to HCPs must be read as referring to HCPs and other healthcare staff.

The requirements of **SOP-GSK-007** (Interactions with officials from government and inter governmental agencies) must be followed in respect of interactions with HCPs who are also Government Officials as defined in **SOP-GSK-007**.

Interactions with individual HCPs include:

- Interactions with HCPs for detailing purposes.
- Activities where an HCP is paid a fee for services (honorarium) for expertise provided to GSK.
- Where permitted, funding for HCPs to attend congresses or GSK meetings.
- All other discussions and interactions with HCPs.

Supplementary information

HCPs will be considered Government Officials subject to the requirements of **SOP-GSK-007** when they act in an official capacity on behalf of a government, including:

- HCPs who have an official decision making role;
- HCPs who have responsibility for performing regulatory inspections;
- HCPs who have responsibility for granting government authorisations or licences;
- HCPs who are temporarily or permanently assigned to work for local, regional or national governments or agencies or supranational bodies.

SOP-GSK-007 does not regulate GSK interactions with HCPs, who may be considered Government Officials only because they are employed by, or receive funding, professional service fees or other remuneration from, a government-owned or funded hospital, clinic, university or other healthcare provider organisation where they:

a) act solely in their capacity as HCPs (eg prescribing, administering and supplying medicines or influencing the same, conducting clinical trials or scientific research); or

b) act as members of advisory boards with no decision making capacity or provide technical, scientific or medical advice to Government Officials in relation to healthcare; AND, for both sections a) and b);

c) do not have any official role in the government with the capacity to take decisions that affect business of GSK.

When engaging with an HCP to provide services or inviting or funding an HCP to attend a meeting, the business owner must establish if the HCP would qualify as a Government Official within the scope of **SOP-GSK-007** as defined above by performing a conflicts of interest check as described in the ABAC Third Party Framework, part A, section V.B.

http://connect.gsk.com/sites/cec/ABAC/ABACTPF/Pages?Selection.aspx

NB: A conflict of interest check may identify additional red flags that need to be resolved.

Where local laws permit, information about GSK authorised products may be provided by commercial staff to other healthcare staff and Government Officials. This information must meet the standards set out in clause 5 (Standards of promotional information). The information provided must take account of the expertise, level of qualification and professional standing of the recipient, and must be factual and presented in a balanced way. The information must not raise unfounded hopes of successful treatment or prevention or be misleading with respect to the safety or efficacy of the product.

8 Interactions with Healthcare Professionals and other healthcare staff

continued

8.1 Interactions with HCPs for detailing purposes

The requirements of this clause apply to sales representatives and others who detail GSK products.

Sales representatives have an important role in the supply of information to HCPs and must comply at all times with this Code.

Sales representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the products which they detail. In a meeting, or when seeking an appointment, sales representatives must at the outset ensure that they do not mislead as to their identity or that of the company they represent.

Sales representatives must only provide information to HCPs that is consistent with the locally approved product information, and that has been approved in accordance with local approval processes. 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 products or indications that do not have the necessary authorisation must not be referred to or distributed by sales representatives.

Both complaints and requests for information must be responded to within a reasonable timeframe, and sales representatives must seek advice from other GSK staff as appropriate in dealing with enquiries. Sales representatives must not solicit any requests for off-label information on any GSK product.

Any unsolicited requests for off-label medical information, or those requiring a written response regarding a GSK product must be handled in accordance with medical information requirements (clause 15 of this Code).

For medicines, sales representatives must supply current, approved prescribing information if requested by an HCP.

Materials provided to sales representatives or other GSK staff must not advocate either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

8.2 Engagement of HCPs to provide services

This clause specifies the requirements for the engagement of HCPs to provide services to GSK whenever the HCP is selected by or on behalf of GSK, including the provision of consultancy services and acting as a speaker on GSK's behalf.

The GSK employee seeking to engage the HCP must ensure that the requirements of this clause, including the requirements on addressing potential conflicts of interest and documentation, have been met.

The engagement of HCPs must be in accordance with applicable SOPs.

8.2.1 Rationale

Any HCP engaged by, or on behalf of, GSK must only be engaged to provide the services for which a legitimate GSK need has been identified. Information provided to an HCP in this context must be limited to the information that is necessary for the HCP to provide the services.

Supplementary information

Any local (within country) engagement of an HCP to provide services must be approved by the relevant manager for the GSK employee who initiates the activity.

Any international (between countries) engagement of an HCP to provide services must be approved by the relevant medical manager for the GSK employee who initiates the activity and by the medical manager in the country where the HCP resides (or, in the case of the USA only, by such other GSK employee as may be specified in local SOPs).

8.2.2 Selection of an HCP to provide services

An HCP must be selected solely on the basis that the HCP has the qualifications, expertise and experience to provide the relevant services. Engagement of an HCP to provide services must not be made or offered in exchange, or as a reward, for the prescription, purchase, supply, dispensing or administration of any GSK products.

Where an HCP is to be engaged to provide services, the requirements of GSK's ABAC framework must be followed. In particular, GSK must understand any potential conflicts of interest that the HCP might have as a result of providing services to GSK, and ensure that any potential conflicts of interest are considered and addressed before the HCP is engaged to provide the relevant service.

8.2.3 Written contracts

When an HCP is engaged to provide a service to GSK, there must be a written contract to specify the obligations on the HCP and the rights for GSK. The contract must be signed by both GSK and the HCP prior to the HCP providing the service and prior to any confidential information being shared with the HCP. The contract must be in a format approved by GSK Legal and must include the relevant ABAC clauses, disclosure provisions and require the expert to declare that he/she is providing a service to GSK whenever he/she writes or speaks in public about a matter that is the subject of the agreement, or any other issue relating to GSK.

8 Interactions with Healthcare Professionals and other healthcare staff

continued

8.2.4 Engagement of HCPs by business units other than the LOC in the HCP's country of residence

The local Medical Director or their designee must be consulted on any proposal to engage an HCP from their country and must review any proposed meeting programme, logistic arrangements (ie class of travel, accommodation, and meals) and proposed fee schedule based on the Fair Market Value (FMV) for the country in which the HCP resides prior to the HCP being engaged. This is to ensure compliance with any local requirements and to ensure that the total of all payments made by GSK to the HCP are within the maximum limit (cap) set by the LOC (see annual cap below). The HCP must not be engaged (ie a contract must not be signed) until the local Medical Director or their designee has confirmed that the proposed arrangements are appropriate.

All fees (honoraria), sponsorships, travel and subsistence payments, made to the HCP must be reported to the HCP's country LOC so that these can be recorded and disclosed according to the LOC's policy. (See clause 4.7).

Supplementary information

The 'External expert engagement process' for cross border engagements must be followed for all above country franchises, business units and LOCs.

In addition, any intended engagement with a US HCP must also use the US website for engaging HCPs to ensure appropriate checks are made:

https://www.gsk-ushcprequests.com/Login.aspx?ReturnUrl=%2fDefault.aspx

More information relating to engaging external experts can be located via the OCMO ways of working portal: **https://connect.gsk.com/sites/ocmo/WaysOfWorking/Pages/Engaging-HCPs.aspx**

Other business units must follow their equivalent processes when engaging HCPs from another country to provide services.

8.2.5 Fair Market Value fees and reimbursement of expenses

The fees for services provided by HCPs must reflect the Fair Market Value for the work performed by the HCP, based on applicable documented rates/fee schedules set by the LOC in the country where the HCP is domiciled. The justification for the local fee schedule must be documented and locally approved by the appropriate governance body (eg Risk Management and Compliance Board (RMCB)). Any exception to the fee schedule must be reviewed and approved by the Regional Medical Director or designee following LOC process. It is appropriate to compensate an HCP for travel time only where the travel is long distance (>5 hours), when the travel is required to complete the service and if the HCP is not already travelling for another purpose. GSK may also reimburse reasonable expenses incurred by the HCP in the provision of the services, subject to submission of receipts.

Supplementary information

If compensation for travel time >5 hours is offered, a clear methodology for the calculation should be documented and applied consistently.

For the USA and Canada, a flat fee compensation has been calculated relevant to travel to specific parts of the world eg Europe, Asia.

In countries where compensation for travel time is permitted, it should not automatically be offered as part of the engagement. Compensation for travel time must be calculated as a separate component on an hourly basis, and added to the hours engaged for the actual activity. The fee is not more than 50% of the Fair Market Value hourly rate multiplied by the number of hours capped at one day (eight hours) per journey (outbound and return count as two journeys).

8.2.6 Annual cap

Each country must adhere to an annual maximum financial limit (cap) for the fees for service that can be paid directly to an individual HCP within their country.

Supplementary information

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

Elsewhere, for HCPs from a given country, a payment cap will be set based on the following calculation: The upper limit of the hourly FMV fee for local speaker engagements set per category of HCP multiplied by 20 days by eight hours per day. The resulting amount is the financial cap. Whilst 20 days worked is part of the methodology to set this cap, in operation this is not intended to apply as a cap on days or hours of work, but only on the amount paid to an HCP. Therefore cap = upper limit FMV hourly fee x 20 x 8.

The cap covers payments made directly to the HCP 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 also excluded. Exceptions can only be approved by the Regional Head of Medical Affairs in consultation with the Country Medical Director.

LOCs must be notified of all planned and actual engagements (local and international for all HCPs domiciled in their country).

Franchise units should have visibility of all planned and actual international engagements and all engagements by above country units for the most engaged experts per product or therapy area.

8.2.7 Records and disclosures

Each LOC must keep detailed records of the fees paid, expenses reimbursed and all transfers of value, in respect of services provided by the HCP in their country to GSK. These records must be available for disclosure if required.

Supplementary information

The LOC (accountability between LOC Finance and the Country Medical Director) must have a means of reviewing the status of payments made to an individual HCP as well as the cap by retaining the records of communications on HCP payments made from outside the LOC and consolidating these with payments made from within the LOC.

Disclosure of fees for service and for transfers of value to HCPs is required for individual US HCPs to comply with the Sunshine Act, and will be required for payments to individual HCPs domiciled in Europe with effect from 2015 to conform to EFPIA requirements.

8 Interactions with Healthcare Professionals and other healthcare staff

continued

8.3 Financial support for HCPs to attend meetings

In countries where it is permitted, GSK may provide financial support to an HCP to enable their attendance as a delegate at national or international meetings, including local or international medical education meetings and congresses organised by third parties (eg scientific or medical congresses), GSK sponsored satellite symposia and GSK (stand-alone) meetings. Such financial support must comply with the following requirements:

- The meeting must be scientific, medical and/or educational in nature and must meet the requirements of this Code in respect of the venue and hospitality offered.
- Where GSK has an authorised product in the HCP's country, GSK may reactively or proactively offer to financially support an HCP who can reasonably be expected to receive educational or clinical practice benefit in the relevant medical or scientific therapeutic area relating to that product.
- Where GSK does not have an authorised product in the relevant medical or scientific disease area in the HCP's country:
  - **Reactively:** GSK may provide financial support in response to an unsolicited request from an HCP who has a legitimate and particular reason to gain from or add to the scientific dialogue at the meeting – for example an HCP who has an abstract or presentation at the meeting (not necessarily on a GSK study) or who has been an investigator in a research study in that field (again, not limited to GSK studies) or has published in that field.
  - **Proactively:** only in circumstances where the HCPs are contracted to provide services to GSK (eg clinical trial investigators, consulting on a research programme) and where the HCP can reasonably be expected to receive educational or clinical practice benefit which can be applied to the contracted service.

There must be clear documented rationale for the selection and number of HCPs supported to attend any given meeting. Final rationale, HCP selection, invitations and the number of delegates funded to attend any meeting must be reviewed and approved by the Country Medical Director (or by the Medicine Development Leader (MDL)/ Vaccine Development Leader (VDL) or equivalent if GSK does not have an authorised product in the therapeutic area).

Approvals for funding support are subject to appropriate checks on the HCP's credentials, and potential conflicts of interest. Any identified potential conflicts of interest must be considered and addressed before financial support is given. An HCP who has been invited by GSK to attend a meeting, but who does not receive any financial support from GSK is not required to complete a conflict of interest check. An HCP who has not received any financial support is permitted to receive refreshments at the meeting provided this is in line with clause 8.5.3 of this Code, and subject to any disclosure requirements (eg for French or US HCPs). (See clause 4.7).

An HCP must not receive funding to attend more than two international congresses (including international congresses in the HCP's home country) in a 12 month period. Exceptions may only be granted in areas of cutting edge or innovative medicine and must be approved by the relevant Regional Medical Governance Board.

An annual financial limit on the level of funding provided to any one HCP must be set by local and area RMCBs.

Above country business units must not directly fund HCPs to attend a meeting. The LOC in the HCP's country must be consulted to ensure that local rules are followed and that the LOC will fund HCPs to attend a meeting, ensuring that caps are respected, and that information for disclosure is compiled. (See clause 4.7). The exception to this would be when an above-country business unit funds an HCP to present data at a congress (oral or poster), in which case, the above country business unit may fund the HCP and must ensure LOC approval is obtained and there is appropriate follow-up for LOC financial disclosure.

In all cases, financial support must be limited to the payment of registration fees, reasonable travel, and accommodation for no longer than the duration of the meeting. Payments must not be made to the HCP, but must be either managed directly from GSK or made to the congress organiser, logistics agency or hotel. Funding must not be given to support HCPs in their normal business operations or to pay their normal business expenses.

Travel and accommodation time must be minimised. Account must be taken of the geographic proximity of the HCP to the meeting, and the possibility of their attendance at equivalent meetings in or closer to the HCP's country.

GSK must never invite or pay for a guest to accompany an HCP to a meeting venue or associated hospitality. GSK must not pay any costs associated with individuals accompanying an invited HCP and must not be involved in any separate arrangements for the guests of HCPs (eg travel plans).

Supplementary information

GSK may make publicly available on an aggregate basis the financial details of financial support of HCPs in relation to attendance at meetings (including registration fees, costs of accommodation and travel). In Europe, disclosure of this type of financial support to HCPs will be required with effect from 2015 to conform to EFPIA requirements.

8.4 Other interactions with HCPs

GSK staff who meet HCPs must always be knowledgeable and trained to participate in appropriate dialogue with the HCPs.

8.4.1 Medical and R&D staff

Engagement and interaction with external audiences about GSK products and their disease areas should be conducted according to this Code unless it is for the conduct of research (eg **POL-GSKF-408**), the treatment use of investigational medicines (**POL-GSK-406**) or a specified scientific engagement activity (**STD-GSK-002**).

Under this Code, GSK Medical/R&D staff may proactively offer or distribute information on GSK products, when necessary to respond to a particular safety issue or for an HCP to provide services to GSK. In addition, appropriately trained GSK Medical/R&D staff may proactively present, offer or distribute information on GSK products to provide information about the safe and effective use of our medicines only as described in role specific guidelines approved by MGEC, or as authorised by the Chief Medical Officer or designee.

As a general rule, R&D/Medical staff should not accompany sales representatives in the field to meet one to one with HCPs, and should not discuss clinical research or scientific engagement activities with HCPs in the presence of a GSK sales representative.

Where appropriate, GSK Medical and R&D staff may respond verbally to requests for information about GSK products. Where available, the responses given must be consistent with the response approved by Medical Information. Written responses should be fulfilled through Medical Information.

8 Interactions with Healthcare Professionals and other healthcare staff

continued

8.5 Travel, venues and hospitality

The following requirements apply to all activities organised or supported by GSK, including scientific engagement activities.

8.5.1 Travel

Funding for HCPs to attend meetings

For those countries where such funding is permitted and GSK provides funding (see clause 8.3), this must be for economy or tourist class travel. GSK can pay for HCP visas as part of the funding for them to attend meetings. The visa payment can be considered as part of the financial support for reasonable travel. If an LOC can, under local regulations, assist an HCP with acquiring the visa then the LOC may do so.

HCPs engaged to provide a service to GSK

Business class or premium economy air travel may be provided for HCPs engaged to provide a service to GSK, where the total flying time one way is more than five hours. Sponsored travel by train may be by business or first class. See also clause 8.2.5 of this Code.

Supplementary information

Funding for HCPs to attend meetings:
Sponsorship of premium economy or business class travel is not allowed unless there are exceptional circumstances (eg for medical reasons or exceptionally long travel times) and in such a case the travel must be approved by the Medical Director or General Manager of the LOC in the HCP's country.

HCPs engaged to provide a service:
A business class ticket may not be exchanged for multiple tickets of a cheaper class or for a single cheaper ticket unless the balance is refunded to GSK. The Medical Director or General Manager of the LOC in the HCP's country must be informed of the class of travel.

8.5.2 Venues

For any GSK meeting or third party meeting sponsored by GSK, or to which GSK financially supports delegates to attend, it must be the strength of the scientific programme content that attracts a delegate to attend and not the associated venue, location or hospitality provided.

A venue for a GSK meeting must be of a size and standard with the necessary business/technical facilities to comfortably accommodate the delegates and facilitate the meeting. Meetings must not be 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. Each LOC must maintain an approved list of venues suitable for meetings.

All venues must provide safe accommodation where the risks to the security of attendees can be minimised. Corporate Security and Investigations must be consulted when necessary.

For GSK meetings, the venue of the relevant meeting must be designed to minimise travel time for delegates invited or sponsored to attend by GSK.

Supplementary information

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 four star rating is not permitted.

Location of GSK meetings

While an LOC may organise its own product meetings, such meetings must be held in the country where the LOC is based and attended only by delegates from that country, unless:

a) the meeting is held during a third party international or multinational meeting, but outside the times of the third party meeting programme; or

b) the meeting has been approved in writing by the Regional President.

GSK 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 must be approved by the relevant Area Medical Director. International meetings organised by above country business units must be approved by the MDL/VDL or Global Medical Affairs Leader (GMAL) depending on who is accountable for the event.

When the largest representative group of HCPs invited to attend an international GSK meeting are from one country, then the meeting must be held in that country. When HCPs invited to attend a GSK meeting are from several different countries, a key consideration for country selection is minimising travel time and overall cost.

In all cases, the speaker or faculty for a GSK meeting may come from another country.

In accordance with clause 4.4 for any international GSK meeting, all materials must be reviewed and approved for compliance with local requirements in the host country, in accordance with the local approval process in the host country LOC and also for compliance with this Code (and the Code of the home country of the above-country business unit) by the above-country medical function which is organising the meeting. Where, in accordance with this clause, GSK invites HCPs from outside the host country to attend, the GSK meeting must also comply with the local requirements of the invited HCPs' country.

8.5.3 Hospitality

Hospitality can only be provided by GSK if it is legally permitted, aligned with GSK's values, related to GSK's business, is infrequent, low in value and customary in a business relationship.

GSK must not provide or pay for hospitality for HCPs other than as a part of a scientific, educational, promotional or business meeting permitted under this Code. In all instances where provision of hospitality is appropriate, it must be incidental and secondary to the meeting itself and only provided to the invited meeting attendee(s). It must be appropriate to the occasion and must not be seen as extravagant. GSK must not organise or sponsor meetings for HCPs which are of a social or sporting nature.

No entertainment or other leisure or social activities should be provided or paid for by GSK in connection with GSK sponsored or standalone meetings.

Supplementary information

No individual entertainment for HCPs is allowed at any time. It is not appropriate to fund attendance at a concert or sports event, purchase tickets, or pay for entertainment in any form. It is acknowledged that organisers of third party meetings, which are sponsored in part by GSK, may themselves organise certain 'entertainment' activities at no additional cost as part of the overall registration fee. GSK should not pay or reimburse any additional fee for such activities, and should ensure that we do not support any activities which may be deemed to be extravagant or inappropriate. GSK must not sponsor HCPs to attend gala dinners at congresses.

GSK will not provide or offer any meals (food and beverages) to HCPs, unless, in each case, the value of such meals (food and beverages) does not exceed the monetary threshold set in the national code or local SOP of the country in which the event takes place.

8.6 Items of medical/educational utility, promotional aids and cultural courtesy items for HCPs

Gifts for the personal benefit of HCPs are not permitted. Provision of cash or cash equivalents as gifts is prohibited. Except for the items expressly permitted in this Code, no gift, benefit in kind, or pecuniary advantage may be offered or given to HCPs. Where there is a local exception or limit permitted or described by this Code, this must be fully documented. Any items that are offered to HCPs must be of minimal or modest value, infrequent and must be monitored for compliance with this Code. Items provided by GSK must not subsidise the routine operations of any medical practice and may not be provided on long term loan, to an HCP or practice other than in the context of conducting a clinical study (see **POL-GSKF-408**: Conduct and public disclosure of human subject research policy).

Different geographical regions and business units within GSK have different requirements regarding items of medical/educational utility, promotional aids and cultural courtesy items.

The provision of items of medical/educational utility, promotional aids and cultural courtesy items for HCPs may need to be disclosed under local laws or industry codes. (See clause 4.7).

Supplementary information

Gifts are anything of value, given ostensibly 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.

8.6.1 Items of medical/educational utility

Where permitted, 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.

Such items of medical/educational utility may be offered or provided free of charge provided that they are infrequent and of modest value (to be defined and documented locally). These items can be company branded but must not be product branded.

The provision of items of medical/educational utility must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicines or for the purpose of a sales representative or other GSK representative gaining access to a medical facility.

Supplementary information

Items of medical utility include so-called 'Patient support items' which enable patients to gain instruction and experience in using their medicines whilst under the supervision of an HCP. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

Provided they have been approved in advance, in limited circumstances, patient support items may be made available to HCPs even though they are not to be passed on to patients to keep.

Exceptions to clause 8.6.1 apply to in vitro diagnostic tests provided for clinical testing; for these products relevant industry codes and local laws must be followed.

8.6.2 Promotional aids

Where permitted, promotional aids (sometimes called brand reminder items) must be of minimal value (to be defined and documented locally), must be relevant to the professional activities of the recipient and may only be provided to HCPs on an infrequent basis.

Promotional items may carry product branding and company branding.

Supplementary information

In Europe:
No promotional aids are allowed apart from pens and pads at GSK sponsored meetings or in congress delegate bags. In Europe, these must not carry product branding.

In EMAP:
Where permitted, only promotional aids covered by the guidance list available on the International Medical web site: **https://connect.gsk.com/sites/ocmo/International%20Medical/Pages/default.aspx** can be used.

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

8.6.3 Cultural courtesy items

Cultural courtesy items for HCPs (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 it is allowed under the local laws and regulations and provided it is done in a fully transparent way. Wherever such exception applies, this must be documented and approved by 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 must be consistent across all business units in that country.

8.7 Sale of medicines to HCPs – discounts, rebates and other commercial terms

Discounts, rebates, free of charge goods and other commercial terms relating to price or margin are permissible business activities and should be assessed using the Foundation Principles (see clause 3). Particular care must be taken when the purchasing customer is also an HCP, to ensure that the commercial terms would not unduly influence them to prescribe, dispense or recommend a product inappropriately by virtue of any personal benefit or otherwise to act in a way that is not in the best interests of the patient or the relevant healthcare system.

All business units must ensure that their supply arrangements with HCPs comply with the following requirements.

- There must be a documented framework that governs the levels of pricing, discounts, rebates, free goods and other commercial terms offered to HCPs. This framework must contain the rationale for commercial terms offered to HCPs. This rationale must be based on objective criteria and reviewed by Legal.
- Commercial terms offered to HCPs must be documented in writing to ensure transparency. The framework must specify the documents required.
- Any discount, rebate or other payment must be made via an approved financial method (eg invoice, bank transfer or cheque) and must not take the form of cash or other cash equivalent. All discounts, rebates and other payments must be accurately and appropriately recorded in GSK's books and records.
- Any schemes which enable HCPs to obtain personal benefits in relation to the purchase of medicines are unacceptable even if they are presented as alternatives to commercial terms.

9 Interactions with Healthcare Organisations and medical societies

9.1 Grants and donations

All requests for grants and donations must comply with **SOP-GSK-016** on 'Grants and donations'.

Grants and donations must never be given to individual HCPs or to a charity nominated by an HCP. Clinical trial registries can not be funded by a grant.

GSK must only provide a grant or donation to an HCO or medical society in response to an unsolicited written request, when the grant or donation has a valid and legitimate purpose.

All requests for grants and donations must be made in writing. Before making any grant to an HCO or medical society, GSK must understand the purposes for which the grant will be applied. The purpose must be sufficiently described for GSK to be able to determine if it complies with this Code, and if the amount of money requested is appropriate (and not excessive) for that purpose. The rationale for the amount of support must be documented and approved in accordance with the local approval procedure.

Where the grant or donation is provided to a recipient in another country, this must be communicated to, and there must be consultation with, the LOC of the country of the recipient to ensure proper coordination of disclosure requirements and application of any specific LOC legal or policy requirements.

The budget for grants and donations to HCOs or medical societies must sit within a non-commercial function (except for grants and donations made in the context of GSK's public policy and advocacy programs in the United States, in which case the budget may sit within the commercial organisation). Grants and donations to HCOs and medical societies must be tracked and, when required, made available for public disclosure. (See also clause 4.7).

GSK must not provide a grant to an HCO or medical society for any project that relates to medical education or disease awareness in disease areas where GSK has no authorised products. Where GSK supports a third party meeting by way of a grant, and influences the content of part of that meeting, then that part must be conducted as a GSK (stand-alone) meeting and therefore subject to this Code. (See clause 7.2 Supplementary information).

Research grants, practice improvement grants and funding to purchase equipment or services (or donations of such equipment or services) are allowed if permissible under local laws and policies and provided that these do not subsidise routine activities or operations of any medical practice. Equipment or services can be donated only where they would be of clear and obvious benefit to a public institution or its patients. Such items or services must be appropriate and fit for purpose, required by the institution, must not carry product branding and must clearly state that they have been provided as a healthcare service to the institution by GSK.

All requests for product donations must follow **POL-GSK-303** and **SOP-GSK-303** on 'Humanitarian product donation'.

GSK must not create a medical society.

Supplementary information

In the USA, GSK can provide grants for medical education after inviting grant applications from a limited number of medical education providers with a documented track record of developing and delivering high quality independent medical education programmes that have a measurable impact on improved patient health.

9.2 Support for the development of treatment guidelines by medical societies

If GSK does not have an authorised product in a given therapy area, then GSK medical 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, GSK can contribute information to the meetings and answer questions in discussions.

When GSK has an authorised product in a given therapy area and there is no treatment guideline endorsed by a medical society, or when existing guidelines need updating, then GSK medical staff can proactively enter into appropriate scientific dialogue with members of the relevant medical society to contribute GSK data and perspectives for the benefit of patients.

In either of the above situations, support provided for the generation or revision of guidelines must only be considered when GSK participation will bring scientific or medical value for the benefit of patients. Support from GSK must be clearly disclosed. It is preferable that GSK is not the only healthcare company providing funding or technical support for the development of a medical society treatment guideline. Exceptions can occur in the case of requests to help support guidelines associated with rare diseases and/or significant public health concerns. In such cases the country Medical Director or MDL/VDL or Global Medical Affairs Leader (GMAL) or designee can make an exception.

In all cases GSK staff must not be involved in the decision-making processes of the medical society.

Supplementary information

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. These must meet the requirements of the official body and are not governed specifically under this Code.

Funding provided by GSK to a medical society or other HCO in connection with the development of treatment guidelines is likely to be a grant, and so subject to the requirements of clause 9.2.

Any transfer of value to medical societies or other HCOs must be tracked and, when required, made available for public disclosure. (See also clause 4.7).

9.3 Healthcare support services

Healthcare support services are services which GSK provides, directly or indirectly, to HCOs and/or patients. These services must have the purpose of achieving better healthcare outcomes for patients, enhance patient care or benefit healthcare and comply with the requirements of this clause.

Adverse Event Reporting

Appropriate measures must be established for the monitoring and processing of any adverse event reports that may be received in the course of any healthcare support service, whether a service provided to an HCO, or a patient programme following prescription. The requirements of **SOP-GSKF-400** (Procedure for identification and tracking of patient support programmes (PSP, market research (MR) and interactive digital media (IDM) activities that may generate human safety information for GSK products) must be followed where applicable.

9.3.1 Services provided to Healthcare Organisations

Any proposal to provide healthcare support services must be reviewed and approved in advance by Medical and Legal, to ensure compliance with all applicable laws and regulations with appropriate contracts in place. Accountability can be with Medical or Commercial depending on the nature of the service.

The healthcare support service must have a defined purpose to achieve better health outcomes for patients, and be designed in all respects to enhance patient care, or benefit a healthcare system while maintaining patient care.

Healthcare support services can bear company branding but must not bear the name of any medicine or product.

The involvement of GSK in the provision of the healthcare support services must be made clear to all recipients of the service.

The healthcare support service must not be designed to promote any medicines. The provision of a healthcare support service must be kept clearly separate from activities for the promotion of medicines. Sales representatives may introduce, but must not provide, deliver, demonstrate or otherwise be involved in healthcare support services.

Patient confidentiality must be maintained at all times.

The provision of healthcare support services must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicines or for the purpose of a sales representative or other GSK representative gaining access to a medical facility. Healthcare support services must not be provided to individual HCPs for their personal benefit or for their own financial advantage. Healthcare support services must not be provided to underwrite a commercial business or generate income for an HCP, practice, administrative staff or other HCO. GSK must not engage, nor provide funding for the engagement of HCPs to perform an activity that includes recommending or prescribing a particular medicine.

Supplementary information

The requirements of this clause 9.3.1 apply where GSK provides services of value to an HCO. The provision of items of medical utility (eg materials and digital apps), the arranging of meetings for HCPs or other healthcare staff and general interactions with HCPs are governed by other provisions of this Code (see clauses 7 and 8) and are not subject to this clause 9.3.1.

Services that enhance patient care may include therapy review services. For example, GSK might fund a nurse to identify high risk patients for assessment and health management purposes. The nurse may assess patients on the HCP's premises, transfer expertise to and educate the practice staff and provide the HCP with information to help them develop an appropriate plan of action for the patient.

Services that benefit a healthcare system may include the analyses of economic data for budget planning and to analyse practice for budget management.

The eligibility of medical practices to receive the service must be based upon objective criteria linked to the defined purpose and must not be linked to prescription or use of GSK products.

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

Materials relating to the healthcare support service must not be promotional. The information collected in the course of providing a healthcare support service must not be used for promotion or to plan promotional activity. This information must not be shared with sales representatives.

Service providers, whether GSK staff or third parties, must operate in accordance with detailed written instructions provided by GSK which must set out the role of the service provider and cover patient confidentiality issues. The written instructions must be designed to ensure compliance with this Code.

Before the service is provided, the recipient HCO must sign a written 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 HCO and a defined duration for the service. It must be made clear that all clinical decisions, which include the selection of appropriate medicines or the development of treatment management plans, are the responsibility of the prescriber. The contract must include the contact name of the individual representative of GSK responsible for providing the service.

Where required by local laws or industry codes to disclose transfers of value made to HCOs, GSK may need to disclose the value of the healthcare support services provided. In this case, the written contract entered with the HCO should specify the value of the services that will be disclosed.

In Europe, disclosure of certain transfers of value to HCOs, including fees for services and grants and donations, will be required with effect from 2015 to conform with EFPIA requirements.

The remuneration of those involved in the provision of healthcare support services must not be linked to sales of any GSK product. The involvement of GSK must be communicated to all relevant HCPs and/or other healthcare staff, and, where relevant, patients.

All materials relating to the healthcare support service must clearly indicate GSK's involvement. GSK and its staff must not have access to data or records that could identify or be linked to particular patients. Any patient level data that is accessible to GSK must be anonymised. GSK must ensure that the service provision complies with data protection law and applicable guidance on the use of patient information. If the service involves review or assessment with individual patients, it is recommended that the service be outsourced to an appropriate provider to ensure that GSK does not have access to data that could identify particular patients.

9.3.2 Patient programmes following prescription

- Compliance (or adherence) programmes for patients prescribed GSK products must only be administered following initial involvement and endorsement of an HCP involved in the treatment of relevant patients, and must be structured in such a way that they are consistent with the requirements of this Code and local regulations.
- Access to medicines programmes for GSK authorised products (ie those to support affordability) need to be carefully considered and reviewed by Medical and Legal. They must not be an improper inducement for the HCP to prescribe a GSK medicine, nor for the patient to request a GSK medicine, nor constitute advertising of the medicines to the patient except where expressly permitted by local laws.

10 Interactions with Government Officials

GSK employees must ensure that dealings with Government Officials are carried out according to the highest standards of integrity required for all GSK business and in compliance with all relevant laws and regulations.

All interactions with Government Officials must comply with **SOP-GSK-007** on 'Interactions with officials from government and inter governmental agencies', where applicable. This SOP describes the rules for meetings, site visits, sponsorship or funding Government Officials at educational meetings, provision of services, gifts and attendance by GSK employees at political meetings and conferences. In addition, scientific interactions with Government Officials must follow the Scientific engagement operating practice 'Scientific interactions with non-medical or scientific audiences' **STD-GSK-002**.

11 Product samples

11.1 Definitions

For medicines, a sample is a small supply of medicine provided, free of charge, to HCPs to familiarise themselves with a particular medicine and its use in patients, and/or to facilitate patient experience with the medicine. Sampling practices vary by geography and individual country practices must be clearly documented (See clause 11.6 Accountability).

For consumer healthcare products not regulated as medicines, testers and samples are small packs of a product (eg emollient or toothpaste) that are given either to the HCP for them to pass on to the patient/consumer, or, where permitted, to the patient/consumer directly, for them to try different products to find out which suits them best.

Supplementary information

Titration packs (packs containing different strengths of a medicine for prescription to establish a patient on an effective dose), and starter packs (small packs designed to provide a sufficient amount of a medicine for prescription to initiate treatment in circumstances where a delay in dispensing medication could be detrimental to patient wellbeing eg analgesics or antibiotics) are not regarded as samples. However, provision of titration packs or starter packs must be reasonable and proportionate with no intent to improperly influence any HCPs.

Titration packs and starter packs differ from samples because they are not intended for familiarisation. Appropriate controls that reflect the intent of titration packs and starter packs must be documented and implemented locally, including describing which products starter packs and titration packs can be used for.

In the USA, titration packs are regarded as samples and are properly used for familiarisation.

11.2 Provision

Samples of medicines for prescription must only be provided to HCPs authorised to prescribe or supply that medicine and pack sizes must not be larger than the smallest presentation available within that country.

Samples of non-prescription medicines may be provided to HCPs subject to local regulatory or other requirements.

Samples of any GSK product must not be provided as an improper inducement to recommend, prescribe, purchase, supply, sell or administer any product, or to gain access to an HCP.

Quantities of samples must be consistent with regional/national codes or regulations or local SOPs. Where these codes, regulations or SOPs also define a time limit for sampling, then this must be followed (eg within Europe, quantities of samples of medicines for prescription are limited to four samples per year per HCP for a restricted two year period post-launch. Each LOC within Europe must determine the launch date that will trigger the start of this two year sampling 'window' for each new product or indication).

Samples may only be provided to HCPs by employees whose role it is to detail to HCPs or by the LOC headquarters.

Provision and transport of product samples to HCPs that require refrigeration or strict temperature control are only permitted if the required environmental controls can be strictly maintained. Samples of vaccines are not permitted.

11.3 Misuse

Samples must not be resold or otherwise misused. Each sample must be marked 'free product sample – not for resale' or words to that effect (or as mandated by local laws/regulations) and must be accompanied by a copy of the prescribing information or other approved product information.

11.4 Samples and clinical studies
Samples must not be used for clinical studies.

11.5 Compliance
Samples must only be supplied in compliance with local legislation, including the need for written requests and HCP signatures where required.

11.6 Accountability
It is the responsibility of the General Manager or designee (eg 'Responsible Pharmacist') working together with the local (or Area) RMCB with input from Legal, to have in place an SOP and an adequate system of accountability in each country or business unit that ensure:

- Compliance with local legislation and relevant codes of practice.
- Appropriate distribution in compliance with the storage recommendations for the product sample.
- Traceability in case of product or batch recall, to safeguard patients (including tracking lot numbers where required).
- Sufficient managerial oversight to prevent abuse of the sampling system.
- Any local activities that do not reflect the intent of familiarisation (eg access to medicine) must be separated from sampling and administered and controlled in a way that reflects their underlying intent (eg under an access to medicines programme or as a humanitarian product donation). Any such activities must be reviewed and approved by Legal to ensure that they are permitted under local law.
- Appropriate processes are in place to monitor and track sample distributions to ensure adherence to the business unit's established policy.

Supplementary information

The local SOP must be based on the ABAC Foundation Principles and describe the rationale for provision, the acceptable volumes of samples, duration of sample distribution and recall provisions. Limits must reflect the intent of familiarisation and must take into account what is acceptable and legal in the country in which they are given.

Exceptions to clause 11 apply to in vitro diagnostic tests provided for clinical testing; for these products relevant industry codes and local laws must be followed.

12 Research activities

12.1 Human subject research

Human subject research includes, interventional clinical trials, non-interventional (observational) studies and studies using data from previously conducted studies; and must not be a vehicle of disguised promotion.

12.1.1 Human subject research policy

GSK's corporate policy **POL-GSKF-408** (Conduct and public disclosure of human subject research policy) ensures all human subject research sponsored and supported by GSK consistently conforms to high ethical, medical and scientific standards. In addition GSK's corporate policy **POL-GSKF-411** (Investigator sponsored studies policy) provides GSK principles for the support of investigator-sponsored studies. The principles in these policies, relevant local laws and SOPs detailing business unit and local operating processes must be followed.

12.1.2 Human subject research studies

All human subject research studies sponsored or supported by GSK (for example investigator-sponsored studies) must have a legitimate scientific purpose. The following are prohibited:

- The conduct of studies for promotional purposes or as an inducement to support GSK products in any way. For example the following are prohibited:
  a) So called 'seeding studies' (studies with no scientific purpose which are conducted as a way for HCPs to gain experience of using a medicine).
  b) GSK support of investigator-sponsored studies in order to reward HCPs for recommending, prescribing, purchasing, supplying, selling or administering GSK products; or to persuade them to do so by supporting the study.
- The participation of sales, marketing or commercial staff in the study design, conduct or publication of study results (see **POL-GSKF-408** for further details regarding non-interventional health outcome studies).

12.2 Market research

Market research is the systematic gathering and interpretation of information about individuals or organisations using the statistical and analytical methods and techniques of the applied social sciences to gain insight or support decision making. It is distinct from clinical research.

- The rights of respondents are paramount, including rights to confidentiality, anonymity and the right to withdraw at any stage.
- Respondents must be able to provide voluntary, informed consent to data collection and use, based upon a clear understanding of the purpose of the data collection and the use(s) to which the data will be put.
- Market research must not be a vehicle for disguised promotion, it must be kept separate from any form of promotion.
- If the data gained from market research will be used for the purposes of promotion the market research data is subject to the same rules and regulations as any other data intended for promotion.
- If the data gained from market research is intended for publication, the publication should follow the principles in the International Committee Medical Journal Editors guidelines.
- Researchers must forward adverse events (that meet the reporting criteria) raised during the study in order to fulfil drug safety responsibilities, without compromising respondents' rights to anonymity and confidentiality. Respondents may provide consent to waive anonymity and confidentiality in the event of an adverse event/side effect being raised during the analysis of research.

12 Research activities
continued

- The requirements of **SOP-GSKF-400** (Procedure for identification and tracking of patient support programmes, market research and interactive digital media activities that may generate human safety information for GSK products) must be followed where applicable.
- Participants in market research may receive a fee for service based on Fair Market Value from GSK or through third parties (eg market research agencies). Market research must be conducted in accordance with local laws and regulation of the respondent's country as well as local/regional/central GSK market research operating procedures.

13 Relations with the general public, patient groups and the media

The scope of this clause covers relations with the general public, patient groups and the media in connection with GSK products or the related disease area post-authorisation. Interactions with these groups that relate to non-authorised or unapproved uses of GSK products must follow the Scientific engagement operating practice 'Scientific interactions with non-medical or scientific audiences' **STD-GSK-002**. **POL-GSK-301** (Protecting and mitigating risks from internal and external communication activities) applies to all interactions with these groups.

13.1 General public

13.1.1 Advertisement

GSK medicines for prescription must not be advertised to the general public unless such activity is expressly allowed under local laws or regulations. This prohibition does not apply to public health activities such as vaccination campaigns approved by the relevant licensing authorities.

Where advertising to the general public is permitted, advertising and promotion of any GSK medicine to the general public should not encourage unnecessary or inappropriate purchasing or use. Advertising must indicate, where applicable, appropriate limitations to the use of medicines. Language which brings about fear or distress must be avoided.

13.1.2 Information about GSK products

Where local laws permit information about GSK products to be provided to the general public, the information (including information on indications, side-effects, interactions with other medicines, proper use, reports of clinical research, etc.) provided must be balanced, accurate, and consistent with the necessary authorisation. It must not raise unfounded hopes of successful treatment or prevention, or be misleading with respect to the safety of the product. The provision of information on GSK products must not be intended or designed to encourage the patient to ask their HCP to prescribe a GSK product or other product, except in countries where advertising of the relevant product to the general public is expressly permitted.

13.1.3 Disease awareness

Subject to any applicable national laws or regulations, GSK may proactively provide disease awareness information to the general public about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public health for disease areas where GSK has an authorised product. Unless local laws allow, disease awareness information should not be provided to the general public where GSK has the only prescription-only medicine within that disease or therapy area.

Disease awareness information includes booklets on diseases and/or medicines supplied directly or via an HCP, media campaigns, mailings to patient organisations and disease awareness advertising.

The provision of disease awareness information must not be intended or designed to encourage the patient to ask their HCP to prescribe a GSK product or other product.

It is not permitted to associate HCP-directed promotional materials to public disease awareness campaign materials (eg via use of brand imagery).

Supplementary information

Information related to disease awareness campaigns must not contain any product branding and must include a statement that the individual must consult an HCP for personal medical advice. An acknowledgment of GSK sponsorship must be included.

13.1.4 New GSK medicines

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

13.1.5 Advice on personal medical matters

GSK employees must not answer requests from individual members of the public for advice on personal medical matters. All such enquirers must be referred to their treating HCP.

13.2 Patient advocacy groups/patient organisations

Business units and LOCs may support the work of patient organisations, consistent with local policies. They must ensure that their involvement is declared, transparent, that any conflicts of interest are effectively managed, that all the arrangements comply with this Code and local regulations, and that written contracts are in place.

GSK must publicly disclose a list of all patient organisations to which we have provided financial support and/or in kind support (eg resource support) in the preceding year, detailed to an individual project level. The percentage of the patient group's annual income that GSK's grant represents must also be declared. This is done on GSK's corporate website.

GSK must not create patient organisations, and GSK must not be the sole funding sponsor of a patient organisation or any of its major programmes. GSK must not provide more than 25% of the total grant and donation funding received by patient organisations during any calendar year and must not seek a direct return on investment from such funding. For patient groups representing rare diseases and start-up funding (funding in the first year) the maximum level of funding is 50%. Exceptions to these restrictions may be agreed by the LOC General Manager or, in the case of above country sponsorship, the Senior Vice President Government Affairs, Public Policy and Patient Advocacy (GAPPPA) or the Regional Medical Directors. GSK's funding and involvement must not exert actual or perceived undue influence on the activities of the organisation.

GSK must not seek endorsement for a GSK medicine for prescription. Unless local laws allow, GSK must not promote a GSK medicine for prescription to a patient group. Sponsorship of individuals in their capacity as representatives of patient organisations to attend congresses, conferences and other HCP meetings (events) is not permitted, unless:

- It is a medical conference where a patient organisation is prominently involved in the organisation of a conference, or where a medical conference has a work stream designed specifically for patients; or
- Where a representative of a patient organisation has been invited and sponsored to attend an event as a speaker.

The accountability for the relationship between GSK and patient organisations must be in either medical, external affairs or the patient advocacy team. Other departments can contribute to the day to day interactions between GSK and the patient organisation.

Supplementary information

Please refer to the SOP: GSK European and emerging markets Asia Pacific Standard Operating Procedure for engaging with patient organisations.

Written contracts must set out exactly what has been agreed including funding, and the duration of the agreement.

13.3 Media

Any interaction with the media must comply with **POL-GSK-301** Protecting and mitigating risks from internal and external communication activities.

Communications approval

Media materials must be reviewed and approved in advance in accordance with applicable local procedures, regardless of whether they have been previously approved according to global press material guidelines.

13.3.1 Accountability of third parties

GSK is responsible for information that is issued by public relations agencies or other third parties on GSK's behalf, and must ensure that any such information complies with the above requirements.

14 Digital communications

The following applies to all digital assets and external communication through digital channels, including and not limited to: websites, mobile applications, email, social media channels such as Facebook and Twitter, which are owned and/or controlled by GSK. This relates to post-authorisation activities only. For pre-authorisation activities please refer to the Scientific engagement operating practice "Using digital media for scientific interactions" **STD-GSK-002**.

14.1 Compliance with the global procedures for business use of digital channels

All external communication through digital channels by or on behalf of GSK must comply with the GSK Standard Operating Procedure **SOP-GSK-502** (Global procedures for business use of digital channels). This SOP is supplemented by additional control documents that provide clear guidance on the use of the many digital channels. Please refer to the Global Digital Risk Board for further information by contacting digitalrisk@gsk.com.

14.2 Digital content

14.2.1 Approval of digital content

All digital content, including all metadata (ie a set of data that describes and gives information about other content held within the digital channel), must be reviewed and approved in accordance with all applicable laws, regulations, industry codes and internal GSK policies. Review and approval must follow applicable local approvals procedure, as described in clause 4.2. Digital content must be regularly reviewed and updated as appropriate (in accordance with the local review process for promotional material).

All digital channels that allow content and/or media to be added by a user of the digital channel must be monitored for adverse events, off-label discussions, and any other inappropriate content in accordance with **SOP-GSK-502** (Global procedures for business use of digital channels) and **SOP-GSKF400** (Procedure for identification and tracking of PSP, MR and IDM activities that may generate human safety information for GSK products).

14.2.2 Intended audience

Where practical, each digital channel must clearly and prominently identify its intended audience ie audience type and geographic location (eg "This website is intended for German Healthcare Professionals").

14.2.3 Transparency

Any GSK communications through digital channels must be performed with full transparency of company affiliation. When GSK retains third parties to communicate on its behalf, such affiliation must be clearly disclosed. If GSK sponsors or funds communication through a digital channel, a description of the nature of sponsorship or funding must be clearly displayed.

14.3 Disease and health information

14.3.1 Disease awareness information for the public

Subject to applicable national laws and regulations and the requirements of clause 13.1.3 of this Code, digital channels may contain disease awareness information for the general public in therapeutic areas where GSK has an authorised product.

Unless local laws allow GSK medicines for prescription to be advertised to the general public, these sites may not link, directly or by inference, to any other websites (GSK-owned, controlled, or third party) containing information on GSK medicines for prescription.

14.3.2 Disease information for HCPs

Digital channels containing disease information (including any metadata related to the content) for HCPs must comply with clauses 5 and 6 of this Code and applicable national code(s).

14.4 Promotional information for HCPs

Promotional information (including disease information) on digital channels directed to HCPs must comply with this Code.

Where information relates to medicines for prescription, it must be clearly identified as information solely for HCPs as in clause 14.2.2 (intended audience) and, unless local laws allow GSK medicines for prescription to be advertised to the general public, access to such information must be restricted to HCPs (via the use of an access solution approved in that LOC).

14.5 Product information for patients and the general public (this sub-clause relates to medicines for prescription)

Subject to any applicable national laws and regulations and the requirements of clause 13.1.2, digital channels may include information for patients and the general public on GSK medicines for prescription. Where relevant, content intended for the public must be clearly separated from content intended for HCPs.

Supplementary information to clauses 14.4 and 14.5

Where information regarding medicine is provided on a digital channel, the digital channel must contain a clear hyperlink to the current prescribing information for each such medicine (and, where applicable, the patient information leaflet most appropriate for the intended audience). Users must be able to access the relevant document or page through no more than one 'click' (alternatively, the prescribing information and patient information leaflet, if one exists, may be provided directly on the digital channel. Consistent with clause 6.1, a link to the current prescribing information is not required for reminder advertising.

For a digital channel targeting an audience within a specific single country, the local prescribing information must be included or be available via a hyperlink as detailed above. For digital channels targeting a regional audience, users from a single country must be able to access their local prescribing information (or regional prescribing information if available).

14.6 Use of social media tools and digital channels

GSK staff must not use social networking sites such as Facebook or Twitter to promote GSK products or provide product information unless they are authorised to do so as described in **SOP-GSK-502** (Global procedures for business use of digital channels).

14.7 Data privacy

All digital media and content must conform to applicable legislation, code(s) and GSK requirements governing the privacy, security and confidentiality of personal information. Please refer to **POL-GSK-010**: Privacy of personally identifiable information.

15 Medical information

The global SOP on the provision of medical information to Healthcare Professionals and consumers (**SOP-54813**) must be followed.

15.1 Medical information service

Local Operating Companies must have a medical information service to compile and collate all information on GSK products which are available in their country and to provide answers to unsolicited questions that they receive from HCPs and consumers.

The fulfilment of requests for written medical information regarding GSK products must be provided through Medical Information.

15.2 Sales representatives

Sales representatives receiving unsolicited requests for off-label medical information, or those requiring a written response regarding a GSK product must forward such requests to the Medical Information function. Responses to such requests will be sent directly to the HCP requesting the information. Sales representatives must not:

- Deliver medical information responses to HCPs.
- Receive a copy of the medical information responses sent to HCPs, but can receive notification that their request has been answered.
- Request medical information responses for their own use, but must receive regular training on relevant on-label product information.

15.3 Members of the public

Members of the public requesting information regarding a GSK product can only be given product information that is contained within the relevant Prescribing Information or Patient Information Leaflet by Medical Information. For any personal medical advice they must be referred to their treating HCP for further information.

16 Definitions

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

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

16.3 GSK product
The term 'GSK product' means any product supplied or promoted by, or on behalf of GSK.

16.4 Grant
A grant is a financial award.

16.5 Healthcare Organisation (HCO)
The term 'Healthcare Organisation' 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.

16.6 Healthcare Professional (HCP)
The term 'Healthcare Professional' or '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.

16.7 Other healthcare staff
The term 'other healthcare staff' 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 for prescription. Other healthcare staff include 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.

16.8 Medicines for prescription
The term 'medicine for prescription' means any medicine (ie prescription and non-prescription medicines and vaccines) to be prescribed by a Healthcare Professional. Such medicines may also be available, where authorised, without prescription.

16.9 Medical education
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 Continuous 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.

16.10 Medical society
A medical society is 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.

16.11 Medicine
For the purposes of this Code, the term 'medicine' refers to prescription and non-prescription medicines and vaccines.

16.12 Patient advocacy groups/ patient organisations
These are non-profit making groups that are founded by patients, with a president, secretariat, executive board and medical advisory board, with a significant representation of patients or their carers on the board itself.

They typically undertake three types of activities:

- Assist their members by providing them with information and support to be able to better live with their diseases.
- Fundraise to ensure the organisation can accomplish its goals and objectives.
- Represent and advocate for the needs of patients with healthcare providers, governments, media and other influential parties.

16.13 Promotion
The term '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.

16.14 Scientific engagement
The interaction and exchange of information between GSK and external communities in order to advance scientific and medical understanding including the appropriate development and use of our products; the management of disease and patient care.

16.15 Transfer of value
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.

17 Glossary

Acronym	Description and definition
ABAC	Anti-Bribery and Anti-Corruption
CME	Continuous Medical Education
CPD	Continuous Professional Development
EMAP	Emerging Markets and Asia Pacific
EFPIA	European Federation of Pharmaceutical Industries and Associations
FMV	Fair Market Value
GAPPPA	Government Affairs, Public Policy and Patient Advocacy
GMAL	Global Medical Affairs Leader
GSK	GlaxoSmithKline
HCO	Healthcare Organisation
HCP	Healthcare Professional
LOC	Local Operating Company
MDL	Medicine Development Leader
MGEC	Medical Governance Executive Committee
R&D	Research and Development
RMCB	Risk Management and Compliance Board
SOP	Standard Operating Procedure
VDL	Vaccine Development Leader

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