GSK Code of Practice for Promotion and Customer Interactions

Effective: 2 July 2012

GSK's scientific engagement 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

1.0 Purpose

The purpose of this Code is to ensure that, following any necessary authorisation, 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.

GSK is committed to ensuring a clear distinction between Scientific Engagement and product promotion.

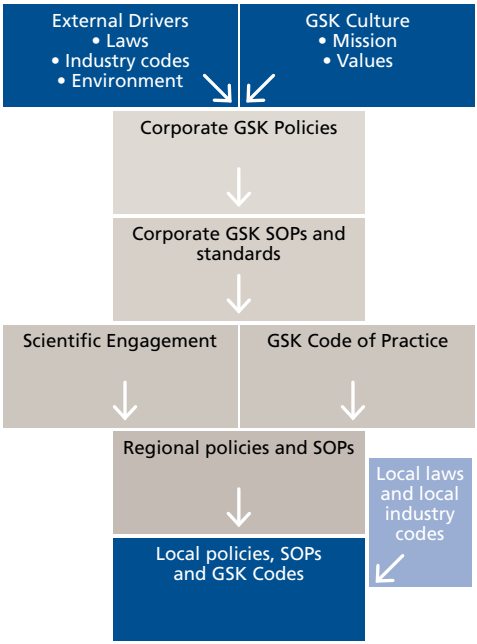
The activities listed below are always non-promotional and must comply with the relevant Scientific Engagement Operating Practices throughout the lifecycle of a product (i.e. pre- and post-authorisation):

- Advisory Boards
- Publications
- Congress Presentations
- Medical Education
- Provision of Medical Information

The activities listed below must comply with the Scientific Engagement Operating Practices in the pre-authorisation period. Post-authorisation, these activities must comply with this Code:

- Congress Sponsorships
- Interactions with HCPs
- Payers/Governments/Public Health Organisations
- Patient Advocacy Groups and Patient Engagement
- Media and Investor/Analyst Engagement
- Digital Media

Hierarchy of control frameworks



This Code supplements Policy POL-GSK-401 (Interactions with HCPs and Promotional Activities to HCPs) and 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).

This Code sets the minimum GSK standard. If local laws, industry codes or GSK policies set higher standards, the strictest requirement must always be applied

2.0 Scope

This Code applies to all GSK activities globally, including Pharma, GSK Vaccines, R&D, Consumer Healthcare. The Code includes the promotion of all GSK products to HCPs. This Code does not apply to the promotion of GSK products to the general public, where this is permitted under local laws.

- 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 latter 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 does not apply to legitimate commercial terms for the supply of products. Commercial terms must be consistent with the Anti-Bribery and Anti-Corruption (ABAC) Foundation Principles (see the Supplementary Information to Clause 3).

Supplementary Information

Please also see the GSK 'EMAP Rules for advertising and promotional practices of cosmetic products to the general public'.

3.0 General Principles

Our intentions and actions are driven by our values of patient focus, transparency, respect for people and integrity. In addition the 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 legal requirements;
- Promotional practices and activities must never bring discredit upon, or reduce confidence in, GSK or the pharmaceutical industry;
- Relationships or interactions with HCPs, Other Healthcare Staff, the general public, media and Government Officials must be intended to enhance the practice of medicine and ultimately benefit patients;
- 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;
- Nothing must be offered or provided in a way that has an inappropriate influence on the prescription, purchase, supply, dispensing or administration of GSK products;
- Financial benefit or benefit-in-kind (including grants, donations, subsidies, consulting contracts, educational items or practice-related items) must not be provided or offered with the intent of improperly rewarding or influencing the 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 prominent.

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 SOPs?

Transparency
- 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?

Proportionality
- 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?

No Conflict of Interest or Undue Influence
- 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?

Footnote
*For examples of conflicts of interest, refer to STD-GSK-001: GSK Standards of Conduct.

4.0 Responsibilities

4.1 Accountabilities

The heads of GSK business units, Centres of Excellence (CoE) and local operating companies (LOC) are accountable for ensuring that the requirements of this Code and all other applicable laws, codes, policies and SOPs are met. Implementation governance accountability 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

Where a third party is co-promoting or promoting a GSK product (i.e. GSK owns the necessary authorisation), the third party must comply with 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 get the third party to comply with 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.

4.1.1 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 LOC medical department, within 24 hours of initial awareness, in compliance with POL-GSK-400 (Management of Human Safety Information for GSK Products).

4.2 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.

4.3 Applicable Codes

Any promotion to, or activity or interaction with, any HCP that is 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 promotion or other activity or interaction is aimed at a HCP from a particular country, the laws, codes and policies of the HCP's country must be respected.

Supplementary Information

In order to comply with the EFPIA Code, any promotion 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.

4.4 Monitoring and Reporting

4.4.1 Monitoring

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

4.4.2 Breaches of this Code and Reporting

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

Employees have a duty to report to nominated senior management in each GSK business unit, without fear of repercussion, breaches of this Code that come to their attention. Concerns may also be reported to Human Resources, Legal, Corporate Security, or via GSK's Integrity Helpline & Confidential Reporting Line.

Any alleged breach of this Code, or of any local industry code of practice or applicable law or regulation by an employee of any GSK business unit must be reported to management promptly. If the breach is confirmed after investigation, appropriate follow up action must be taken. This may involve remedial training, disciplinary action, revision to procedures and policies, and/or strengthening of monitoring systems.

5.0 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.

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.

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.

In vitro, laboratory or animal data alone are not sufficient to substantiate a clinical claim.

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 products and activities of other companies must not be disparaged.

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, and the words “safely” or “safer” must never be used to describe a GSK medicine without qualification in promotional materials.

5.6 Reproduction of Artwork from Publications

All 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) Be authorised for use in accordance with local copyright law.

Supplementary Information

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

5.7 The Word 'New'

The word "new" 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 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 medical ethics or local laws. If the name, 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.

6.0 Information on Medicines for Prescription

6.1 Promotional Material

Any promotional material, printed or in an electronic format, must comply with legal and regulatory requirements and, unless prohibited by local requirements, must include at least the following information clearly and legibly:

- The name of the product (normally the brand name);
- The generic (international non-proprietary) name or the name of the active ingredients, using approved names where they exist;
- Essential product information, consistent with the marketing authorisation:
  a) the approved indication or indications for use;
  b) the dosage and method of administration;
  c) a succinct statement of the contraindications, precautions and side effects.
- A procedure for the reporting of adverse events (required in Europe and EMAP);
- A statement referring to the prescribing information or that full prescribing information is available on request;
- The name of the pharmaceutical company or the agent responsible for marketing the product;
- A unique tracking code;
- The date of preparation/approval, revision date or expiration date of the promotional item.

Supplementary Information

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

In Europe and EMAP&J the address of the pharmaceutical company or the agent responsible for marketing the product must be included on all promotional material.

6.2 Abbreviated Reminder Advertisement

A “reminder” advertisement is a short advertisement that contains a very limited amount of information. 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 active ingredients including the generic (international non-proprietary) name.
- The name and address of the company from which full information can be obtained.
- A statement that full prescribing information is available on request.
- A unique tracking code.
- The date of preparation/approval, revision date or expiration date of the promotional item.

7.0 Meetings Sponsored or Organised by GSK

The Scientific Engagement Operating Practice "Congress Sponsorships" must be followed for sponsorships of scientific and medical congresses (conferences) at international and local (country) levels that relate to unauthorised or unapproved uses of GSK products STD-GSK-002 (Scientific Engagement Standards).

Abstracts submitted to a congress and any resulting presentations (oral or posters) must comply with the Scientific Engagement Operating Practice "Congress Presentations" – STD-GSK-002 (Scientific Engagement Standards).

If the intent of the meeting is only to provide "Medical Education" as defined in the Scientific Engagement Operating Practice "Medical Education", then this Operating Practice must be followed STD-GSK-002 (Scientific Engagement Standards). Other meetings must not be referred to as "Medical Education". Clause 8.5 of this Code applies to "Medical Education" meetings.

This Code must be followed for all other meetings. It applies to GSK's sponsorship of, and participation in congresses, satellite symposia, GSK meetings and other third party meetings that relate to authorised products or uses of GSK products. This includes related disease or therapy areas.

Where GSK sponsors or organises a meeting, this fact must be disclosed in all the communications relating to the meeting and in any published proceedings. The declaration of GSK's role must be sufficiently prominent to ensure that those invited are aware of GSK's involvement. All GSK staff attending or participating in the meeting must be transparent about their employment by GSK.

7.1 Sponsorship of Congresses and Other Third Party Meetings

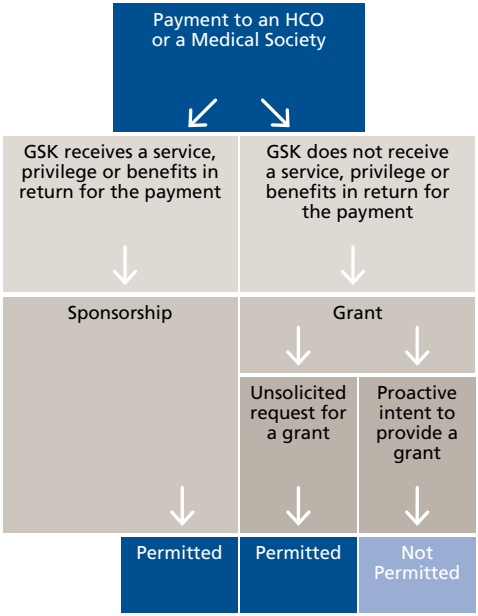
Congress sponsorship is financial support provided to independently organised congresses to further Scientific Engagement or secure appropriate satellite symposium and/or exhibition (booth) space.

Where the organiser of the third party meeting is a Healthcare Organisation (HCO) or Medical Society, and GSK receives no service, privileges or benefits in return for the payment or donation, 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).

Where GSK sponsors a meeting 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).

Sponsorships and Grants



Also refer to clause 9.1 of this code

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.

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

7.1.1 GSK Sponsored Satellite Symposia at Scientific or Medical Congresses

Satellite symposia are not permitted in disease areas where GSK does not already have an authorised product.

If the intent of the satellite symposium is only to provide "Medical Education" as defined in the Scientific Engagement Operating Practice "Medical Education", then this Operating Practice must be followed STD-GSK-002 (Scientific Engagement Standards). Clause 8.5 of this Code applies to "Medical Education" meetings.

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.

If a satellite symposium is not "Medical Education" it must be developed with the aim of providing medical and/or scientific information that is informative, fair-balance and of likely interest to the attending delegates. This information could relate to a recently authorised medicine or indication, or to the presentation of on-label study results. For any symposium, it must be the strength of the programme content that attracts a delegate to attend.

Supplementary Information

All satellite symposia and the accompanying budget must be under the accountability of Medical. The scientific and medical content of the symposium, and appropriateness of the speaker faculty and logistical arrangements (i.e. travel, venue, accommodation) must be formally approved by the host LOC Medical Director or designee. Logistical arrangements may be implemented by non-medical teams or a contracted vendor. Satellite symposia must comply with local codes of practice and congress regulations.

Satellite symposia are not permitted in the US.

7.1.2 Booths at Meetings

Booths may be considered for the purposes of either Scientific Engagement (scientific booth) or for promotional activities (commercial booth). Scientific booths must be implemented according to the Scientific Engagement Operating Practice "Congress Sponsorships" before and after authorisation. The requirements for commercial booths are provided in this Code.

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 familiar with the products and who can 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.

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

Prizes for quizzes are not allowed, except in EMAP where, if given, must comply with the requirements of an item of medical/ educational utility (see Clause 8.6).

7.2 GSK Stand-Alone Meetings

GSK stand-alone meetings are those initiated by GSK, which are not held in the context of a congress or other third party meeting.

GSK stand-alone meetings are not permitted in disease areas where GSK does not already have an authorised product.

If the intent of the GSK stand-alone meeting is only to provide "Medical Education" as defined in the Scientific Engagement Operating Practice "Medical Education", then this Operating Practice must be followed STD-GSK-002 (Scientific Engagement Standards). Clause 8.5 of this Code applies to "Medical Education" meetings.

GSK stand-alone meetings must comply with the requirements of this Code, including Clause 5, and all data presented and materials provided must be on-label. For any GSK stand-alone meeting, it must be the strength of the programme content that attracts a delegate to attend.

If a GSK stand-alone meeting is not "Medical Education", the purpose and focus of the GSK stand-alone meeting must be to provide scientific or educational information or provide information about GSK products. A GSK-stand-alone meeting may focus entirely on a GSK product.

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 (other than in response to an unsolicited request from the meeting organisers) 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 scientific components of a GSK meeting must account for at least two thirds of the total duration of the meeting.

8.0 Interactions with Healthcare Professionals and Other Healthcare Staff

Interactions with HCPs that relate to unauthorised or unapproved uses of GSK products must follow the Scientific Engagement Operating Practice "Interactions with Healthcare Professionals" (STD-GSK-002).

This Clause addresses all activities which involve or are directed at HCPs and interactions with HCPs, regarding GSK authorised products or related disease or therapy areas. These interactions must comply with this Code and with Policy POL-GSK-401 (Interactions with Healthcare Professionals and Promotional Activities to HCPs).

The requirements of this Clause also apply to GSK interactions and activities associated with authorised products or related disease or therapy areas which involve or are directed to Other Healthcare Staff. References in this Clause 8 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 within the scope of this SOP. For example, where necessary, when engaging a HCP to provide services or inviting or sponsoring a 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 by performing a conflicts of interest check as described in the ABAC Third Party Framework, Part A, section V.B. https://connect.gsk.com/sites/cec/ABAC/ABACTPF/Pages/Selection.aspx

Interactions with individual HCPs include:

- Interactions with HCPs for detailing purposes;
- Activities where a HCP is paid a fee for services (honorarium) or expertise provided to GSK;
- Where permitted, sponsorship of HCPs (e.g. 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 organization where they:

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

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

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

Where local laws permit, information about GSK authorised products may be provided 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.

8.1 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 prestigious 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 Clause 15 of this Code (Medical Information) and the Scientific Engagement Operating Practice 'Provision of Medical Information' (STD-GSK-002).

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

Briefing material for 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

Prior to product authorisation, individual 1:1 proactive/reactive discussions and meetings with contracted clinical study investigators, steering committee members, advisory board members, consultants etc to discuss topics related to clinical research or Scientific Engagement activity being conducted with GSK, must be conducted by GSK scientific/ Medical staff according to the requirements of the Scientific Engagement Operating Practice "Interactions with Healthcare Professionals (HCPs)". In the context of an advisory board, the Scientific Engagement Operating Practice "Advisory Boards" STD-GSK-002 must be followed.

This Clause specifies the requirements for the engagement of HCPs to provide services to GSK following product authorisation, 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 GSK must only be engaged to provide the services for which a legitimate GSK need has been identified. Information provided to a 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 a 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 a 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 US only, by such other GSK employee as may be specified in local SOPs).

8.2.2 Selection of a HCP to Provide Services

A HCP must be selected solely on the basis that the HCP has the qualifications, expertise and experience to provide the relevant services. Engagement of a 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 a 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

A HCP must be engaged by a written contract, signed by both GSK and the HCP prior to the HCP providing the service. The contract must be in a format approved by GSK Legal and must include the relevant ABAC clauses and disclosure provisions.

8.2.4 Engagement of HCPs by Business Units Other than the LOC in the HCP's Country

The local Medical Director or their designee must be consulted on any proposal to engage a HCP from their country and must have an opportunity to review any proposed meeting programme, logistic arrangements (i.e. class of travel, accommodation, and meals) and proposed fair market value fee 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 (i.e. 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.

Supplementary Information

Any intended engagement with a US HCP must use the US website for engaging HCPs https://www.gsk-ushcprequests.com/Login.aspx?ReturnUrl=%2fDefault.aspx to ensure appropriate checks are made.

The "External Expert Engagement Process" must be followed for EMAP&J Pharma and CoEs https://connect.gsk.com/sites/apjem_medical/PublishedDocuments/Forms/AllItems.aspx?RootFolder=%2fsites%2fapjem%5fmedical%2fPublishedDocuments%2fIntl%20Medical%2fScientific%20Engagement%20Process.

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 set by the LOC in the HCP's country. The basis for the local fee schedule must be documented and locally approved by the appropriate governance body (e.g. Risk Management and Compliance Board (RMCB)). GSK may also reimburse reasonable expenses incurred by the HCP in the provision of the services, subject to submission of receipts.

8.2.6 Annual Cap

Where regional guidance has been issued, each LOC must adhere to an annual maximum limit (cap) for the fees for service that can be paid directly to an individual HCP within their country. Other LOCs must provide guidance and implement annual caps.

8.2.7 Records

Each LOC must keep detailed records of the fees paid, and of expenses reimbursed, 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.

8.3 Sponsorship of HCPs

In countries where sponsorship of HCPs is permitted, GSK may provide financial support (sponsorship) to a HCP to enable their attendance at national or international meetings, including local or international medical educational meetings and congresses organised by third parties (e.g. scientific or medical congresses), GSK sponsored satellite symposia and GSK (stand-alone) meetings. Such sponsorship 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 sponsor a 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 sponsorship in response to an unsolicited request from a HCP who has a legitimate and particular reason to gain from or add to the scientific dialogue at the meeting – for example a 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 (e.g. 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.

Final selection and approval of recipients of sponsorship funding (including a documented rationale for selection) must be by Medical. Selection and approval must include appropriate checks on the HCP's credentials, and potential conflicts of interest. Any identified potential conflicts of interest must be considered and addressed before sponsorship is given.

There must be clear rationale for the number of HCPs sponsored to any given meeting. Sponsorship invitations and the number of delegates sponsored to any meeting must be reviewed and approved by Medical (or by the Medicines Development Leader (MDL) or equivalent if GSK does not have an authorised product in the therapeutic area).

A HCP must not receive more than two invitations to international congresses in a twelve 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 sponsorship provided to any one HCP must be set by local and area RMCBs.

Business units must consult the LOC in the HCP's country prior to sponsoring any HCP to attend a meeting, in order to ensure that caps are respected, and that information for disclosure is compiled.

In all cases, financial support must be limited to the payment of registration fees, reasonable travel and accommodation. Payment must not be made to the HCP, but must be made to the congress organiser, logistics agency, travel agent 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 a HCP to a meeting venue or to a hospitality event. 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 (e.g. travel plans).

Supplementary Information

GSK plans to make publicly available on an aggregate basis the financial details of sponsorship of HCPs in relation to attendance at meetings, in respect of activities in 2012 onwards. Sponsorship in this context includes registration fees, costs of accommodation and travel.

8.4 Other Interactions With HCPs

GSK Commercial, Medical or R&D 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

Discussion of products or uses which do not have the necessary authorisation must be carried out in accordance with the Scientific Engagement Operating Practice "Interactions with Healthcare Professionals (HCPs)" STD-GSK-002, and must not be conducted by or in conjunction with commercial staff.

Except as otherwise set out in this Clause, in other provisions of this Code, or in guidelines for specific roles (e.g. Medical Science Liaison Practice Guidelines), GSK Medical and R&D staff may not proactively offer or distribute information on GSK products, except where necessary in response to a particular safety issue or for the HCP to provide services.

GSK Medical and R&D Staff may also proactively initiate discussions with HCP experts with a pre-determined objective of gaining specific scientific or medical advice on an authorised product or indication in accordance with Scientific Engagement Principles POL-GSK-002 and relevant local policies and SOPs. As a general rule, R&D / Medical staff should not accompany sales representatives in the field to meet 1:1 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.

Supplementary Information

In the context of an advisory board, the Scientific Engagement Operating Practice "Advisory Boards" STD-GSK-002 must be followed.

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

Sponsorship of HCPs – For those countries where sponsorship is permitted and GSK provides sponsorship (see 8.3), this must be for economy or tourist class travel.

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 5 hours. Sponsored travel by train may be by business or first class.

Supplementary Information

HCP Sponsorship:
Neither premium economy nor business class sponsorship is allowed unless there are exceptional circumstances (e.g. 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 supported by GSK, or which GSK sponsors 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 & 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 4 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 CoEs must be approved by the CoE Medical Director.

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 4.3, 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 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 legal, 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 HCPs other than as a part of a scientific, educational, promotional or business meeting permitted under this Code. In all instances where provision or sponsorship of hospitality is appropriate, it must be incidental and secondary to the meeting itself and only provided to the 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.

8.6 Items of Medical/Educational Utility, Promotional Aids and Cultural Courtesy Items

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 required 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 a 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).

Items can be provided to HCPs for use by patients where required for the administration of a particular medicine (e.g. an Aerochamber).

Different geographical regions and business units within GSK have different requirements regarding Items of Medical/Educational Utility, Promotional Aids and Cultural Courtesy Items.

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.

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 a 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 branded gifts, gimmicks or 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. These must not carry product branding.

In EMAP:
Where permitted, only promotional aids from the fixed list (available on the EMAP Medical web site) can be used.

In the US and Japan:
Promotional aids are not permitted.

8.6.3 Cultural Courtesy Items

Cultural courtesy items for HCPs (i.e. items given to acknowledge significant national cultural or religious holidays) are not permitted, other than by exception in some countries in EMAP&J 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.

9.0 Interactions with Healthcare Organisations and Medical Societies

9.1 Grants and Donations

In the case of grants and donations, GSK does not receive any service, privileges or benefits in return for the payment or donation.

Grants and donations must never be given to individual HCPs or to a charity nominated by an HCP. Individual HCPs can receive sponsorship to attend meetings (see Clause 8.3).

GSK must only provide a grant or donation to a healthcare organisation or medical society in response to an unsolicited written request, for the purposes of supporting healthcare or medical or scientific research in accordance with this Code and applicable SOPs.

Before making any grant to a healthcare organisation 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.

Grants and donations to healthcare organisations and medical societies must be approved by a non-commercial function such as Medical or via a Grants & Donations Committee. The budget for grants and donations must sit within a non-commercial function, e.g. Medical. Grants and donations to healthcare organisations and medical societies must be tracked and, when required, made available for public disclosure.

GSK must not provide a grant to a healthcare organisation 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).

GSK must obtain written permission from the relevant healthcare organisation or medical society in advance (as part of their agreement with GSK) for the annual disclosure of details of any grants or donations, including the value, purpose and name of the recipient(s).

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 on 'Humanitarian Product Donation'.

GSK must not create a medical society. It is preferable that GSK is not the sole funding sponsor or the only healthcare company providing funding to a particular medical society. Exceptions may occur in the case of requests to help support activities associated with rare diseases and/or significant public health concerns. In such cases the country Medical Director or designee can make an exception.

Supplementary Information

GSK must understand any potential conflicts of interest that could arise as a result of the grant or donation, for example any potential conflicts of interest of individuals who have discretion over the use of funds provided. Any potential conflicts of interest must be carefully considered and managed before the grant or donation is made. Any potential conflicts of interest or red flags must be documented, together with how these are managed.

There must be a documented agreement, in a format approved by GSK Legal, between GSK and the healthcare organisation or medical society which sets out how the donation or grant will be made and how it will be used. See ABAC Framework – Third Party Procedures and Guidance; Annex IV for contract provisions to be included in this agreement, as appropriate. Any grants or donations must be in accordance with this documented agreement.

In the US, 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 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 or CoE Medical Director 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 (e.g. 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.

9.3 Healthcare Support Services

Where permitted, GSK may, under medical accountability, provide to healthcare organisations, healthcare support services as described in this Clause.

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.

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 or demonstrate 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 a healthcare professional, practice, administrative staff or other healthcare organisation.

Supplementary Information

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.

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 must sign a written contract with GSK which sets out the details of the service, including activities to be performed by the service provider and the responsibilities of the recipient. 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 and the relevant allied HCPs. The contract must include the contact name of the individual representative of GSK responsible for providing the service.

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. It is recommended that GSK also ensures that the relevant healthcare organisation is informed of the service provision, in particular where the service could have a budget impact. 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.

10.0 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, interactions with Government Officials that relate to unauthorised or unapproved uses of GSK products must follow the Scientific Engagement Operating Practice "Payers/ Governments/Public Health Organisations" STD-GSK-002.

11.0 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. 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 (e.g. 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 e.g. 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.

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 a 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.

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.

Supplementary Information

Within Pharma Europe, quantities of samples of medicines for prescription are limited to 4 samples per year per HCP for a restricted 2 year period post-launch. Each LOC within Europe must determine the launch date that will trigger the start of this 2 year sampling 'window' for each new product or indication.

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 (e.g. 'Responsible Pharmacist') working together with the local (or Area) RMCB (with input from Medical and 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 (e.g. access to medicine) must be separated from sampling and administered and controlled in a way that reflects their underlying intent (e.g. 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.

12.0 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;
- Participants in Market Research may receive a fair market value fee from GSK or through third parties (e.g. 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.

13.0 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 Practices "Patient Advocacy groups and Patient Engagement" and "Media and Investor/ Analyst Engagement" STD-GSK-002. POL-GSK-301 (External Communications to Investors and Media) applies to all interactions with these groups.

13.1 General Public

13.1.1 Advertisement

GSK medicines 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.

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.

Disease awareness information includes booklets on diseases and/or medicines supplied directly or via a 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 (e.g. via use of similar 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 a healthcare professional 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 healthcare professions 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

Please refer to the SOP: GSK European and Emerging Markets Asia Pacific Standard Operating Procedure for Engaging with 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 (e.g. 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 funding received by patient organisations during the Patient Organisation's financial 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 GAPPPA or the Regional Medical Directors Pharma Europe or EMAP&J. GSK's funding and involvement must not exert actual or perceived undue influence on the activities of the organisation.

GSK must not promote a GSK medicine for prescription to a patient group, nor seek endorsement for a GSK medicine for prescription.

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 organizations 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

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

Japan is not currently required to disclose funding to patient groups.

13.3 Patient Programmes Following Prescription

Compliance (or adherence) programmes for patients prescribed GSK products must only be administered following initial involvement and endorsement of a 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 (i.e. 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.

13.4 Media

Any interaction with the media must comply with POL-GSK-301 External Communications to Investors and Media; External Speaking Engagements.

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.

13.4.1 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.

14.0 Websites and Digital Channels

The following applies to websites and digital channels owned by GSK, and relates to post-authorisation activities. For pre-authorisation activities please refer to the Scientific Engagement Operating Practice "Digital Media" STD-GSK-002.

14.1 GSK Website Policy

The creation and maintenance of external facing websites and the inclusion of any GSK content on a third party website or digital channel must comply with GSK Standard Operating Procedure SOP-GSK-502 (Global Procedures for Business Use of Digital Channels).

14.2 Contents of Websites and Digital Channels

14.2.1 Review Cycle

All digital content, including all metadata (i.e. a set of data that describes and gives information about other data), 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 to be added by a person who is not a GSK employee must be monitored for adverse events and off-label discussions, in accordance with SOP-GSK-502 (Global Procedures for Business Use of Digital Channels).

14.2.2 Intended Audience

Each website must clearly identify its intended audience (e.g. audience type and geographic location).

14.2.3 Transparency

Any GSK-sponsored or funded on-line activity must include the GSK logo and a link back to the local corporate website where one exists, or to the global GSK Corporate website.

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, websites and other 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 or third party) containing information on GSK medicines for prescription.

Websites containing disease awareness information must advise users to consult a healthcare professional for personal medical advice.

14.3.2 Medical Education Information for HCPs

Websites and other digital channels containing medical education information (including any metadata related to the content) for HCPs must comply with applicable national code(s) and GSK's Scientific Operating Practice "Medical Education" STD-GSK-002.

14.4 Product information

14.4.1 Promotional Information for HCPs

Any information on websites or digital channels directed to HCPs that constitutes promotion must comply with this Code.

Where information relates to prescription-only medicines, it must be clearly identified as information for HCPs and, unless local laws allow GSK prescription-only medicines to be advertised to the general public, access to such information must be restricted to HCPs (e.g. via the use of log-in/passwords or via the access solution approved in the LOC).

14.4.2 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, websites and other digital channels may include information for patients and the general public on GSK prescription medicines. Brand names must be accompanied by international non-proprietary names. The website must always advise users to consult a HCP for further information. Where relevant, content intended for the public must be clearly separated from content intended for HCPs.

Supplementary Information

For each medicine, where information is provided, the website must contain a clear hyper-link to the current Prescribing Information and, where applicable, the Patient Information Leaflet most appropriate for the intended audience. Alternatively they must be provided directly on the website.

For a website targeting an audience within a specific single country, the local Prescribing Information must be included or available via a hyper-link. For websites targeting a regional audience, users from a single country must be able to access their local Prescribing Information (or regional Prescribing Information if available).

14.5 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.

In addition to SOP-GSK-502 (Global Procedures for Business Use of Digital Channels), please refer to GSK guidance for the use of social media tools and digital channels, including: *Global Guidance for the Business Use of Facebook* and *Global Guidance for the Business Use of Twitter.*

14.6 Data Privacy

Content placed on GSK websites 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.

15.0 Medical Information

The Scientific Engagement Operating Practice "Provision of Medical Information" STD-GSK-002 and SOP-WWD-0017: "Medical Information Responses to Health Care Professionals" 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 which 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.

16.0 Definitions

16.1 Donation
The term 'donation' refers to a non-monetary award.

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

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
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 (i.e. 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 Continuing Medical Education (CME) points to participants. Medical education is distinct from product focused meetings which are considered to be promotional. The term "Medical Education" is used only to describe an activity that complies with the Scientific Engagement Operating Practice on Medical Education.

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

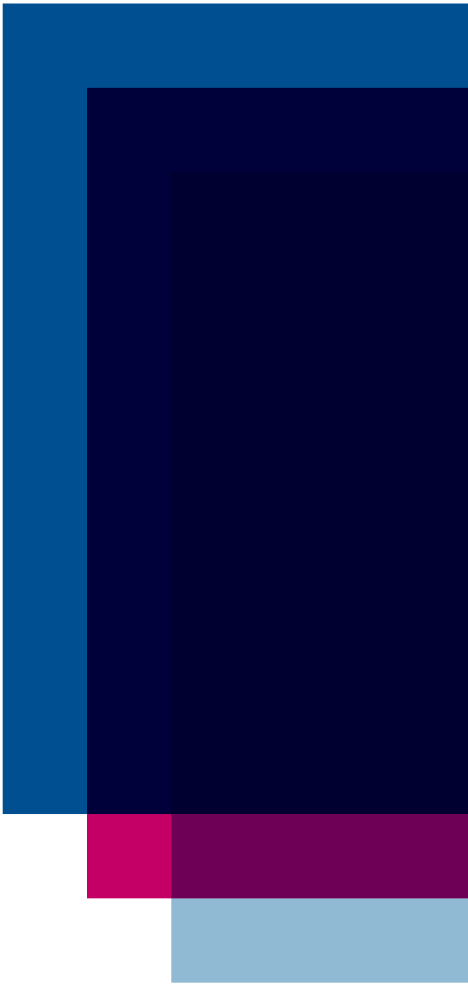
The term "promotion" refers to any activity undertaken by GSK or on its behalf that advertises or promotes the prescription, supply, sale, distribution or use of GSK products.

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.

17.0 Glossary

Acronym	Description and Definition
ABAC:	Anti-Bribery and Anti-Corruption
EMAP&J:	Emerging Markets, Asia Pacific and Japan
GAPPPA:	Government Affairs, Public Policy and Patient Advocacy
GM:	General Manager
GSK:	GlaxoSmithKline
HCP:	Healthcare Professional
MDL:	Medicines Development Leader
R&D:	Research and Development
RMCB:	Risk Management and Compliance Board



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