

GSK PHARMACEUTICALS EUROPE CODE OF PRACTICE ON PROMOTION OF MEDICINES AND INTERACTIONS WITH HEALTH PROFESSIONALS

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INTRODUCTION

Ensuring High Standards

The aim of the Code is to ensure that the promotion of medicines to health professionals and to appropriate administrative staff and interactions between GSK and health professionals is carried out in a responsible, ethical, professional and legal manner, such that health professionals and the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients. The Code sets a minimum standard. Where local laws and codes of practice set higher standards, or more specific conditions, they must take precedence over the Code.

GSK must ensure that all relevant personnel are appropriately trained in the requirements of the Code and have comprehensive internal procedures under which all promotional material and activities are reviewed to ensure compliance with the Code and the law.

The Code incorporates the principles set out in:

- the International Federation of Pharmaceutical Manufacturers Associations' (IFPMA) Code of Pharmaceutical Marketing Practices
- the European Federation of Pharmaceutical Industries' Associations' (EFPIA) European Code of Practice for the Promotion of Prescription-only Medicines to, and interactions with, Healthcare Professionals.
- the Code of Practice of the Association of the British Pharmaceutical Industry
- the European Directive on the Community code relating to medicinal products for human use (2001/83/EC) and

- GlaxoSmithKline Policy POL–GSK–401, Pharmaceutical Marketing and Promotional Activities

Guidance on the interpretation of the Code appears as supplementary information in boxes immediately after the relevant clause.

Clause 1 - Scope of the Code and Definition of Certain Terms

1.1 This Code applies to the marketing activities of GSK LOCs and GSK Pharmaceuticals Europe business units, including:

- the promotion of medicines and vaccines to health professionals and to appropriate administrative staff;
- interactions with health professionals; and
- information made available to the general public about medicines and vaccines.

1.2 The term ‘promotion’ means any activity undertaken by GSK, or with its authority, which promotes the prescription, supply, sale or administration of its medicines. It includes:

- journal and direct mail advertising
- the activities of medical representatives including detail aids and other printed material used by medical representatives
- the supply of samples
- the provision of inducements to prescribe, supply, administer, recommend or buy medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality for promotional purposes
- the sponsorship of promotional meetings
- the sponsorship of scientific meetings including payment of traveling and accommodation expenses in connection with these meetings
- the provision of information to the general public either directly or indirectly, and
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, radio, television, the Internet, electronic media, interactive data systems and the like.

‘Promotion’ does not include:

- replies made in response to individual enquiries from health professionals or appropriate administrative staff or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry and are not promotional in nature;
- factual, accurate, informative announcements and reference material concerning licensed medicines and relating, for example, to pack changes, adverse-reaction warnings, trade catalogues and price lists, provided they include no product claims;
- information supplied by GSK to national public organisations, provided the information is factual, accurate and not misleading;
- summaries of product characteristics;
- European and national public assessment reports;
- the labeling on medicines and accompanying package leaflets in so far as they are not promotional for the medicines concerned;
- information relating to human health or diseases provided there is no reference, either direct or indirect, to specific medicines.

- 1.3 The term 'medicine' means any branded or unbranded medicine or vaccine intended for human use which requires a marketing authorization.
- 1.4 The term 'health professional' includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may prescribe, purchase, supply or administer a medicine.
- 1.5 The term 'appropriate administrative staff' includes practice managers, hospital management and formulary members or directors.
- 1.6 The term 'medical representative' means a representative of GSK who calls on or meets with members of the health professions and appropriate administrative staff in relation to the promotion of medicines.
- 1.7 The term 'company' means each GSK LOC and each GSK Pharmaceuticals Europe business unit.
- 1.8 Each company must appoint a senior employee to be responsible for ensuring that the company meets the requirements of this Code, the applicable Code of the Country within which the company resides and all other applicable local codes, laws and regulations.
- 1.9 Each company is responsible for ensuring that agencies and other suppliers (such as contract sales forces, consultants, market research agencies, advertising agencies, medical communication agencies and PR agencies) comply with this and other relevant Codes when undertaking work commissioned or otherwise funded by the company.

Clause 2 - Marketing Authorisation

- 2.1 A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply.

Clause 2.1 Marketing Authorisation

The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited, provided that such information or activity does not constitute promotion.

- 2.2 Subject to the local laws and codes of practice in the host country, at an international event, promotional information on exhibition stands may refer to medicinal products or indications which are not approved in the host country provided that the promotional material:

- contains a suitable statement indicating the countries in which the medicine / indications are approved; and
- makes clear that the medicine or indication is not registered locally; and
- where it refers to prescribing information, includes an explanatory statement indicating that registration conditions differ between countries.

- 2.3 The promotion of a medicine must be in accordance with the terms of its marketing authorization and must be consistent with the particulars listed in its summary of product characteristics.

Clause 2.3 – Off Label

The promotion of indications not covered by the marketing authorization for a medicine is prohibited. GSK may possess, or publish information regarding indications for a medicine outside the indications specified in the marketing authorization ('off-label indications'). If a medical representative receives a request from a health professional for information regarding off-label indications, the medical representative must refer the request to the scientific services department (see [Clause 8](#)) and for the department to respond to the health professional.

Clause 3 - Information to be Made Available

- 3.1 Subject to applicable national laws and regulations, any promotional material must include the following information clearly and legibly:
- essential information compatible with the summary of product characteristics (for example – provision of the Prescribing Information in the UK);
 - the legal classification for the supply of the medicine;
 - mechanism for the reporting of adverse events if required
- 3.2 In accordance with national law, where the promotional material is intended only as a reminder, the requirements of Clause 3.1 need not be complied with, provided that the promotional material includes no more than the name of the medicine, its non-proprietary name, or the trademark.

Clause 4 - Promotion and Its Substantiation

- 4.1 Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicine concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission, or in any other way.
- 4.2 Promotion must be capable of substantiation, which must be promptly provided in response to reasonable requests from healthcare professionals. Substantiation as required by this Clause 4 need not be provided, however, in relation to the validity of indications approved in the marketing authorisation.
- 4.3 Promotion must encourage the rational use of medicines by presenting them objectively and without exaggerating their properties. Claims must not imply that a medicine, or an active ingredient, has some special merit, quality or property unless this can be substantiated.
- 4.4 When promotion refers to published studies, clear references must be given.

- 4.5 Any comparison made between different medicines must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.
- 4.6 Promotion about side-effects must reflect available evidence, or be capable of substantiation by clinical experience.
- 4.7 All artwork, including graphs, illustrations, photographs and tables taken from published studies that are included in promotional material must:
- 4.7.1 Clearly indicate the precise source(s) of the artwork;
- 4.7.2 Be faithfully reproduced; except where adaptation or modification is required in order to comply with any applicable national code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.
- 4.8 The word “safe” must never be used to describe a medicine without proper qualification.
- 4.9 The word “new” must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than one year.
- 4.10 It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency.

Clause 5 - Causing Offence and Disparaging References

- 5.1 Promotional material and activities must recognise the professional standing of the audience to which they are directed and must not be likely to cause offence.
- 5.2 The medicines, products and activities of other pharmaceutical companies must not be disparaged.
- 5.3 Health professionals and the clinical and scientific opinions of health professionals must not be disparaged.

Clause 5.2 and 5.3 – Disparaging References

Much pharmaceutical promotion contains comparisons with other products and, by the nature of promotion, such comparisons are usually made to show an advantage of the promoted product over its comparator. Critical references to another company's products which are accurate, balanced, fair and can be substantiated, are acceptable. Unjustified knocking copy in which the products or activities of a competitor or health professional are unfairly denigrated is prohibited.

Clause 6 - Sponsorship

Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. This declaration should be sufficiently prominent and should accurately reflect the nature of GSK's involvement. The only exception to this is market research material

which need not reveal the name of the company involved but must state that it is sponsored by a pharmaceutical company.

Clause 7 - Distribution of Promotional Material

- 7.1 Promotional material for a prescription only medicine must only be sent or distributed to health professionals.
- 7.2 Mailing lists must be kept up to date. Requests to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at the addressee's request or with their permission.
- 7.3 Telephones, text messages, email, telemessages, facsimile, automated calling systems and other electronic data communications must not be used for promotional purposes, except with the prior permission of the recipient.

Clause 8 - Scientific Service

- 8.1 Companies must have a scientific service to compile and collate all information, whether received from medical representatives or from any other source, about the medicines which they market, and to provide answers to questions which they receive from health professionals directly or via GSK medical representatives.
- 8.2 Companies must also have a scientific service which is responsible for the approval and oversight of any observational or clinical study sponsored or supported by the company (including approval and oversight of any responsibilities assumed by medical representatives).

Clause 9 - Medical Representatives

- 9.1 Medical representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote.
- 9.2 Medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code.
- 9.3 Medical representatives must not employ any inducement or subterfuge to gain an interview. No fee may be offered for the grant of an interview. Frequency and timing of interviews should not cause inconvenience.

Clause 9.3 - Inducements

'Inducements' should be interpreted broadly and not limited to direct financial or beneficial inducements to the health professional. For example, donations to charities in return for medical representatives gaining interviews are prohibited. Further, reply paid cards which refer to medical representatives delivering items which have been offered to health professionals or appropriate administrative staff should explain that there is no obligation to grant the representative an interview when the item is delivered.

- 9.4** Medical representatives must transmit immediately to the company's scientific service (referred to in [Clause 8](#)) any information which they receive in relation to the use of the medicines which they promote, particularly reports of side-effects and any requests for information which they receive.
- 9.5** Medical representatives must provide, or have available to provide if requested, a copy of the summary of product characteristics for each medicine which they promote.
- 9.6** Companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote.

Clause 9 - Contract Medical Representatives

Companies using contract medical representatives are responsible for their conduct and must ensure that their employer ensures that they comply with the provisions of this and all other relevant clauses in the Code.

Clause 10 - Provision of Medicines and Samples

- 10.1** A limited number of samples of a product may be provided on an exceptional basis for a limited period of time. The maximum number of samples per health professional per year and the period during which samples may be distributed is usually set by national laws and codes of practice.
- 10.2** Samples of a product must only be provided to a health professional qualified to prescribe that product. They must not be provided to administrative staff. Samples must not be provided as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.
- 10.3** Samples must only be supplied in response to written requests which have been signed and dated.

Clause 10.3 - Sample Requests

This clause does not preclude the provision of a preprinted sample request form bearing the name of the product for signing and dating by the applicant.

- 10.4** A sample of a medicine must be no larger than the smallest presentation of the medicine on the market in the country where the sample is being provided.
- 10.5** Each sample must be marked 'free medical sample – not for resale' or words to that effect and must be accompanied by a copy of the summary of product characteristics.
- 10.6** Samples distributed by medical representatives must be handed direct to the health professionals requesting them or persons authorized to receive them on their behalf.
- 10.7** The provision of medicines and samples in hospitals must comply with individual hospital requirements.
- 10.8** Companies must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by medical representatives.

10.9 Medicines which are sent by post must be packed so as to be reasonably secure against being opened by young children and be clearly addressed for the exclusive attention of the intended health professional addressee. Unsolicited medicines must not be sent through the post.

Clause 10 - Definition of Sample

A sample is a small supply of a medicine provided to health professionals so that they may familiarise themselves with it and acquire experience in dealing with it and may be used in treatment.

A small sample which is provided only for identification or similar purposes and which is not intended to be used in treatment may be provided to any health professional but is otherwise subject to the requirements of Clause 10.

Free goods and bonus stock provided to pharmacists and others are not samples. Neither are starter packs classified as samples.

Starter packs are small packs designed to provide sufficient medicine for a health professional to initiate treatment in such circumstances as a call out in the night or in other instances where there might be some undesirable or unavoidable delay in having a prescription dispensed. It follows from this that the types of medicines for which starter packs are appropriate are limited to those where immediate commencement of treatment is necessary or desirable, such as analgesics and antibiotics. The quantity of medicine in a starter pack should be modest, only being sufficient to tide a patient over until their prescription can be dispensed.

Clause 11 - Gifts

11.1 No gift, benefit in kind, or pecuniary advantage may be offered or given to health professionals, or to administrative staff, subject to the provisions of Clause 11.2 or otherwise as permitted under this Code.

Clause 11.1 - Gifts

Items provided on long term or permanent loan to a health professional, or a practice, are regarded as gifts and are subject to the requirements of this clause.

The prohibition on gifts to health professionals and administrative staff extends to pens and pads.

The use of competitions, quizzes and such like and the giving of prizes are not acceptable methods of promotion and are prohibited.

The giving of a gift, benefit in kind or pecuniary advantage includes not only the giving of the gift to an individual, but also the giving of a gift or service on behalf of that individual to someone else, or some other entity, e.g. to a hospital or charity.

Celebratory gifts, whether in respect of a personal event such as a birthday or a cultural event, such as New Year, Easter or a national remembrance day, are not permitted.

Gifts should not be given to any other persons with whom GSK employees engage in the course of the company's business e.g. clinical trial investigators, government and regulatory officials and suppliers.

11.2 No promotional items may be distributed to health professionals or to administrative staff. The only exception to this relates to the use of pens and pads at GSK-sponsored medical educational meetings, where they can be issued for the convenience of attendees. Any branding of pens and pads for this use should be branded as GSK only.

11.4 Subject to applicable national laws and regulations, non-promotional medical, educational services and items which enhance patient care, or benefit a national healthcare system while maintaining patient care, may be provided to health professionals, or administrative staff. Medical, educational services and items must not bear the name of any medicine.

Clause 11.4 – Provision of Medical, Educational Services and Items

Clause 11.1 does not prevent the provision of medical and educational services, provided such services enhance patient care or benefit a national healthcare system, while maintaining patient care and do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicines..

Medical and educational services may bear a corporate name. The involvement of a GSK company in such activities must be made clear to relevant health professionals and/or administrative staff receiving the services.

It is recommended that companies consider using staff other than medical representatives to provide, deliver, or demonstrate medical and educational services.

If medical representatives are used to provide, deliver, or demonstrate medical and educational services, then this must not be linked in anyway to the promotion of medicines.

Neither the company nor its medical representatives may be given access to data/records that could identify or could be linked to particular patients.

The remuneration of those not employed as medical representatives, but who are sponsored or employed as service providers in relation to the provision of medical and educational services must not be linked to sales in any particular territory, or place, or to sales of a specific medicine, or medicines and, in particular, must not include a bonus scheme linked to such sales. Bonus schemes linked to a company's overall national performance, or to the level of service provided, are acceptable.

Companies must ensure that patient confidentiality is maintained at all times and that applicable data protection legislations is complied with.

Service providers must operate to detailed written instructions provided by the GSK company. The written instructions must set out the role of the service provider and should cover patient confidentiality issues. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

A recipient of a service must be provided with a written protocol or agreement setting out what the service provider and recipient have agreed. The identity of the sponsoring company must be given.

Any printed material designed for use in relation to the provision of medical and educational services must be non-promotional. All printed materials must identify the sponsoring company.

Where medical and educational services are provided in accordance with this Clause 11, medical and educational items (other than medicinal products) may be provided as part of those services.

Medical and educational items are those which enhance the responsible use of medicines in therapy areas within which GSK operates. Medical and educational items should not be branded with a product brand, but should be unbranded or carry the GSK brand only. The maximum cost should be 10 Euros.

The only items permitted are those in the following list:

- *Anatomical models for GSK therapy areas*
- *Text books for GSK relevant therapy areas*
- *Educational CDs/leaflets, posters, newsletters*
- *Calculators for GSK relevant therapy areas, e.g. BMI, lung function, osteoporosis, dosage calculators, as long as the calculator is specific and can only be used for that purpose (i.e. it is not a general calculator, which has a 'BMI' calculating function)*
- *Monitoring or training devices i.e.*
 - *In check devices and mouth pieces*
 - *Lung capacity disc*
 - *Lung age monitor*
 - *COPD predictor*
 - *Peak flow meters and mouth pieces*
 - *Discus trainers and demonstrators**
 - *Accuhaler trainers**

**These items are for use with a specific GSK product and so should carry the product brand for ease of identification.*

Clause 12 - Meetings and Hospitality

12.1 Companies may organize or sponsor a meeting of health professionals where the meeting has a clear educational or scientific content.

Clause 12.1 - Meetings

Companies may appropriately sponsor a wide range of meetings. These range from small lunchtime audio-visual presentations in a group practice, hospital meetings and meetings at postgraduate education centers, launch meetings for new products, management training courses, meetings of clinical trial-lists, patient support group meetings, satellite symposia through to large international meetings organized by independent bodies with sponsorship from pharmaceutical companies.

Companies may participate in and/or sponsor health professionals to attend events organized by third parties, subject to the requirements of the [Congress SOP](#) and local laws and codes of practice.

Companies may also arrange meetings at which health professionals, acting as consultants to the pharmaceutical company, provide advice as experts. (See [Clause 14.](#))

Any meeting organized or sponsored by GSK for health professionals must comply with the local requirements of both the host country where the meeting is held and the home country of the health professionals invited by GSK to the meeting. Where the GSK company organizing or sponsoring the meeting is based in a third country, the meeting must also comply with the laws of the country in which the GSK company is based.

12.2 When meetings are sponsored or organized by a company, that fact must be disclosed in all of the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

12.3 Companies must not provide hospitality to health professionals and or appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other meetings which may be organized or sponsored by a company under this Code or by way of sponsorship of a delegate to attend a congress, in accordance with the [Congress SOP](#). Hospitality must be secondary to the purpose of the meeting.

Clause 12.3 - Hospitality

For any meeting, it should be the programme that attracts a delegate to attend and not the associated hospitality, venue or location.

Any hospitality provided must comply with the following requirements, subject to any more stringent requirements of the applicable local laws and codes.

Hospitality provided by GSK

- *Hospitality must be secondary to the scientific, education or, in the case of an advisory board, business purpose of the event.*
- *The level of hospitality offered must be reasonable and not be out of proportion to the occasion. It must not extend to any guest of the invited health professional. The applicable local codes may provide guidance on the level of hospitality that is “reasonable”.*
- *Meetings which are wholly or mainly of a social or sporting nature are not permitted. Sponsored meals must not include entertainment and no entertainment activities may be sponsored.*
- *Venues must be appropriate for a business meeting. Meetings should not be held at venues which could reasonably be perceived as lavish or extravagant for a business meeting or conference, or venues which are renowned for their entertainment facilities.*
- *The applicable local code may give further guidance on which venues are appropriate, and which are extravagant or renowned, and therefore not appropriate*

for events organized or sponsored by GSK.

- *The meeting location should be selected to minimize the travel time for attendees.*

For further detail, please see the Congress SOP and the Engaging HCPs SOP

Clause 13 - Grants and Donations

13.1 Companies periodically receive requests from health professionals for funding, including research grants, practice improvement grants and funding to purchase essential equipment or services, or donation of such equipment or services etc.

13.2 Companies may provide such grants or donations to organizations or associations that are comprised of health professionals and/or that provide healthcare or conduct research provided that the grant or donation:

- is requested in writing by the organization or association, and such request has not been solicited by GSK;
- is made for the purpose of supporting healthcare or research.
- is documented and kept on record by GSK; and
- is NOT provided or offered to a health professional in exchange for prescribing medicines or for a commitment to continue prescribing medicines. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health professional's prescribing practices.

13.3 Grants and donations to individual health professionals for their personal benefit are not permitted.

Clause 13 – Grants and Donations

Clause 13 covers any donation, grant or benefit in kind where GSK provides funding or a donation in kind but is not involved in the activity for which the funding or donation is provided and receives no service from the health institution in return for the funding provided.

Where GSK provides a medical or educational service (or pays a third party provider to provide that service), [Clause 11.4](#) applies.

Clause 13 does not prevent the sponsorship of a health professional to attend an educational meeting or scientific congress. In this case, the sponsorship (for example congress fees) should be paid directly to the meeting or congress organizers.

Relevant SOPs

For further detail, please see the Grants and Donations SOP

Clause 14 - Consultants

- 14.1** It is acceptable for GSK companies to employ health professionals as consultants or advisers to provide services or advice which the companies consider necessary and could not be provided by other professionals or advisers. The legitimate need for the services should be clearly identified prior to selecting and entering into agreements with prospective consultants. Consultants should be selected based on appropriate criteria and by persons with the relevant expertise. Consultancy arrangements should be recorded in an appropriate written contract and the consultant provided with reasonable compensation and reimbursement of expenses, including reasonable travel and accommodation expenses.
- 14.2** No consultancy shall be provided or offered to a health professional in exchange for prescribing medicines or for a commitment to continue prescribing medicines. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health professional's prescribing practices.
- 14.3** Any meeting attended by consultant health professionals and associated hospitality must comply with [Clause 12](#).

Relevant SOPs

Any engagement of a health professional as an expert, including arrangements for any meeting and associated hospitality, must comply with the Engaging HCPs SOP and, where applicable, the Process on Engaging Healthcare Professionals from another country.

Clause 15 - Market Research, Observational Studies and Clinical Trials

- 15.1** Market research activities, observational studies (including retrospective non-interventional studies), clinical trials, post marketing surveillance, collaborative research trials and the like, must not be used as disguised promotion.

Clause 15.1 - Market Research

Market research is the collection and analysis of information and must be unbiased and non-promotional. The use to which the statistics or information is put may be promotional. The two phases must be kept distinct.

Limited market research does not fall within [Clause 14](#) provided that the health professional is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and provided that remuneration is minimal. The local code of practice will usually provide guidance on what level of remuneration is "minimal".

If a health professional is consulted in a recurring manner or if remuneration is more than minimal, [Clause 14](#) will apply.

Note that the company is responsible for the activities of its market research agencies.

- 15.2 An arrangement for an institution, organization or association of health professionals to undertake any study or to perform any other service for a company is permitted only if the study, services or funding provided by a company do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. The service must be provided for the purpose of supporting healthcare or scientific research.
- 15.3 Any observational study, non-interventional study, epidemiology study, clinical trial, post-marketing surveillance, collaborative research trial or similar activity must be approved in advance and supervised by the company's scientific service (see [Clause 8](#)).
- 15.4 Where the study is sponsored by the company, the study results must be analysed and summarised by or on behalf of the company, and the results made available to the company's scientific service (see [Clause 8](#)). The company should send the summary report to all health professionals that participated in the study.
- 15.5 Medical representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

Clause 15.2 – 15.5

Observational or clinical studies, including collaborative research studies, must be conducted in accordance with applicable R&D policies and applicable local requirements in the country where the study is to be carried out.

Studies must have an identified scientific purpose and written protocol. There must also be a contract between GSK and the institution or health professional that carries out the study, setting out the respective responsibilities and the basis for payment (based on fair market value).

Clause 16 - Relations with the General Public and the Media

- 16.1 Medicines must not be advertised to the general public if they are prescription only medicines or are medicines which, though not prescription only, may not legally be advertised to the general public. This prohibition does not apply to vaccination campaigns carried out by companies and approved by health ministers.
- 16.2 Information about medicines which is made available to the general public either directly or indirectly (and does not have the purpose of promoting the medicines) must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine.
- 16.3 GSK companies may work with patient organisations, but when doing so must ensure that the involvement of the company is made clear and that all of the arrangements are clearly documented and comply with the Code. This includes the need to declare sponsorship ([Clause 6](#)) and the prohibition on advertising prescription only medicines to the public ([Clause 16.1](#)). [Clause 12](#), which covers meetings for health professionals

and appropriate administrative staff, also applies to GSK companies supporting patient organisation meetings.

Clause 16.3 - Relationships with Patient Organisations

GSK companies may interact with patient organisations, or any user groups such as disability, carer, or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patients and carers. Any involvement a company has with any such organisation must be declared and transparent.

Any involvement by GSK with a patient organization must comply with the SOP for Engaging with Patient Organisations

16.4 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer recommended to consult his or her own doctor.

16.5 The introduction of a new medicine must not be made known to the general public until reasonable steps have been taken to inform the medical and pharmaceutical professions of its availability.

16.6 Companies are responsible for information about their medicines which is issued by their public relations agencies.

Clause 17 – Engaging with Public Officials

Meetings may be held with public officials for the purpose of discussing legitimate GSK business in an open and transparent manner.

The giving or offering of gifts, benefits in kind or pecuniary advantages to public officials is prohibited. (See [Clause 11.1](#) of this Code).

For further guidelines on engaging with public officials, see the Europe Pharma GAEC – Training Manual: Engaging with Public Officials.

Generally, see GSK-POL-007 on Preventing Corrupt Practices and Maintaining Standards of Documentation.

Clause 18 – Websites

18.1 Contents of Websites. Subject to any applicable national laws and regulations, information included in a GSK company website must be regularly updated and must clearly display, for each page and/or item, as applicable, the most recent date as of which such information was up-dated. GSK websites must be clearly identifiable as having been produced by GSK

18.2 Health education information. Websites may contain non-promotional health education information about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public

health. They may refer to medicines, provided that the discussion is balanced and accurate. Websites containing health education information must always advise persons to consult a health professional for further information.

- 18.3 Information for health professionals.** Any information on websites directed to health professionals that constitutes promotion (as defined in the Code) must comply with the applicable national code(s) and any other industry codes of practice governing the content and format of advertisement and promotion of medicines. Such information must be clearly identified as information for health professionals, but need not be encrypted or otherwise restricted.
- 18.4 Non-promotional information for patients and the general public.** Subject to any applicable national laws and regulations, websites may include non-promotional information for patients and the general public on products distributed by the company (including information on their indications, side-effects, interactions with other medicines, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each medicine that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet or a clear hyper-link to the same. Brand names must be accompanied by international non-proprietary names. The website must always advise persons to consult a health professional for further information.
- 18.5 Scientific Review** – Companies must ensure that scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the applicable national code(s).
- 18.6 Privacy** – The website must conform to applicable legislation and code(s) governing the privacy, security and confidentiality of personal information.
- 18.7 GSK website policy** – when creating and maintaining external facing websites or including any GSK content on a third party website, companies must comply with Corporate Policy POL-GSK-502 External Facing Systems

Clause 19 – Training, Monitoring and Reporting

- 19.1 Communications.** All medical representatives and other GSK staff concerned with the preparation and approval of promotional material, and information to be provided to health professionals and appropriate administrative staff, or to the public, must be fully conversant with the requirements of the Code. All such personnel must have access to a copy of the Code and any supplements to, or revisions of, the Code.
- 19.2 Training.** Each manager is responsible for ensuring that their staff receives the necessary training on compliance with the Code.
- 19.3 Systems, procedures and policies.** Each GSK company or business unit must have appropriate written policies and procedures to cover the various elements of the activities covered by the Code.
- 19.4 Monitoring.** Each GSK company or business unit must monitor compliance with the Code by means of management, or independent, monitoring and reviews.

19.5 Individual Responsibility. Employees have a duty to report, without fear of repercussion, breaches of the Code that come to their attention to nominated senior management in each GSK company or business unit.

19.6 Management Responsibility. Each manager will be held accountable for Code breaches committed by representatives, or staff, for whom the manager is responsible, when the manager knew, or should have known, that such activities were taking place in contravention of the Code.

19.7 Reporting.

19.7.1 Locally. Any alleged breach of the Code or any local pharmaceutical promotional code of practice, law, or regulation by a GSK company, business unit or employee must be reported to local management promptly. After investigation, if the breach is confirmed, appropriate follow up action must be taken - this may involve remedial training, disciplinary action, revision to the procedures and policies, and or strengthening of the monitoring systems.

19.7.2 Regionally. A quarterly report from each GSK company or business unit of confirmed breaches must be submitted to the Pharmaceuticals Europe Compliance Officer, summarizing the nature of the breach and what follow up actions have been/are being taken.