

# Pharmaceuticals Europe

## GSK European Promotion of Medicines Code of Practice

2<sup>nd</sup> Edition 2007



GlaxoSmithKline

## Contents

### PAGE

- 1 Introduction
- 2 Scope of the Code and Definition of Certain Terms
- 2 Marketing Authorisation
- 2 Information to be Made Available
- 3 Promotion and its Substantiation
- 4 Causing Offence and Disparaging References
- 5 Sponsorship
- 5 Distribution of Promotional Material
- 5 Scientific Service Responsible for Information
- 5 Medical Representatives
- 6 Provision of Medicines and Samples
- 7 Gifts
- 8 Meetings and Hospitality
- 9 Grants and Donations
- 9 Consultants
- 10 Market Research, Observational Studies and Clinical Trials
- 10 Relations with the General Public and the Media
- 11 Websites
- 12 Training, Monitoring and Reporting

## 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 is carried out in a responsible, ethical, professional and legal manner. 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 Medicines
- 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 promotion of medicines and vaccines to health professionals and to appropriate administrative staff and to information made available to the general public about medicines and vaccines so promoted.
- 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 travelling 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.

### It 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 labelling 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 authorisation.
- 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, 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 calling on members of the health professions and appropriate administrative staff in relation to the promotion of medicines.
- 1.7 Each Company must appoint a senior employee to be responsible for ensuring that the Company meets the requirements of this Code and all applicable local codes, laws and regulations.

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

### Clause 2.2 **Off Label**

The promotion of indications not covered by the marketing authorisation for a medicine is prohibited. GSK may possess or publish information regarding indications for a medicine outside the indications specified in the marketing authorisation ("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;
  - the legal classification for the supply of the medicine.
- 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. 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 Responsible for Information**

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.

**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.

**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 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.
- 10.2 Samples must only be supplied in response to written requests which have been signed and dated.

#### Clause 10.2 **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.

- 10.3 A sample of a medicine must be no larger than the smallest presentation of the medicine on the market in the country where the medicine is being promoted. The maximum number of samples per health professional per year is usually set by national laws.
- 10.4 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.
- 10.5 Samples distributed by medical representatives must be handed direct to the health professionals requesting them or persons authorised to receive them on their behalf.
- 10.6 The provision of medicines and samples in hospitals must comply with individual hospital requirements.
- 10.7 Companies must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by medical representatives.
- 10.8 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 as an inducement to prescribe, supply, administer, recommend buy, or sell any medicine, subject to the provisions of Clause 11.2.

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

- 11.2** Promotional items, whether related to a particular medicine, or of general utility, may be distributed to health professionals and to appropriate administrative staff, provided that the promotional item is inexpensive AND relevant to the practice of their profession or employment.
- 11.3** The prescribing information for a medicine as required under Clause 3 does not have to be included on a promotional aid if the promotional aid includes no more than the following about the medicine:
- the name of the medicine;
  - an indication that the name of the medicine is a trade mark;
  - the name of the company responsible for marketing the product.
- 11.4** Subject to applicable national laws and regulations, non-promotional medical and educational services (which may include the supply of equipment, other goods or materials, other than medicines) which enhance patient care, or benefit a national healthcare system while maintaining patient care, may be provided to health professionals, or administrative staff. Medical and educational services must not bear the name of any medicine.

### Clause 11.4 **Provision of Medical and Educational Services**

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.

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 legislation 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.

## Clause 12 **Meetings and Hospitality**

**12.1** 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 such meetings. Hospitality must be secondary to the purpose of the meeting. The level of hospitality offered must not be out of proportion to the occasion. It must not extend beyond health professionals or appropriate administrative staff.

### Clause 12.1 **Meetings and Hospitality**

The provision of hospitality includes the payment of reasonable, actual travel costs which a company may provide to sponsor a delegate to attend a meeting. The payment of travel expenses and the like for persons accompanying the delegate is not permitted.

The payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel, for speakers, is permissible.

Pharmaceutical 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 centres, launch meetings for new products, management training courses, meetings of clinical trialists, patient support group meetings, satellite symposia through to large international meetings organised by independent bodies with sponsorship from pharmaceutical companies.

With any meeting, certain basic principles apply:

- the meeting must have a clear educational content;
- the hospitality associated with the meeting must be secondary to the purpose of the meeting, must be appropriate and not out of proportion to the occasion and any hospitality provided must not extend to a spouse or other accompanying person unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant at the meeting in their own right;
- spouses and other accompanying persons must not be invited, unless qualified as above, but if they do accompany an invitee they must not attend the actual meeting and must not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.

Administrative staff may be invited to meetings where appropriate. For example, receptionists might be invited to a meeting in a general practice when the subject matter relates to practice administration.

Meetings organised for groups of health professionals and/or for administrative staff which are wholly or mainly of a social or sporting nature are not permitted.

Meetings organised by pharmaceutical companies which involve country health professionals at venues outside that country are not necessarily unacceptable. There have, however, to be valid and cogent reasons for holding meetings at such venues. As with meetings held in the country, in determining whether such a meeting is acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, hospitality provided and the like. As with any meeting it should be the programme that attracts delegates and not the associated hospitality or venue.

- 12.2** When meetings are sponsored by pharmaceutical companies, 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.

## Clause 13 Grants and Donations

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. GSK Companies may provide such grants or donations provided that they are 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.

## 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. Such 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. Venues and circumstances of any meetings with consultants must be conducive to the services provided and the primary focus of the meetings. Any hospitality offered must not be out of proportion to the occasion.

- 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.

#### Clause 15 **Market Research, Observational Studies and Clinical Trials**

Market research activities, observational studies, clinical trials and the like, must not be used as disguised promotion.

#### Clause 15 **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.

#### 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 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.

Companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, including funding, in relation to every significant activity, or ongoing relationship.

For more information on GSK rules and guidelines on dealing with patient organisations see GSK Global Code of Conduct – Principles of working with Patient Groups on the Patient Advocacy Europe website, myGSK – Patient Advocacy Europe.

- 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 **Websites**

- 17.1 **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 updated.
- 17.2 **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.
- 17.3 **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.
- 17.4 **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. Brand names must be accompanied by international non-proprietary names. The website must always advise persons to consult a health professional for further information.
- 17.5 **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).
- 17.6 **Privacy:** The website must conform to applicable legislation and code(s) governing the privacy, security and confidentiality of personal information.
- 17.7 **GSK website policy:** when creating and maintaining external facing websites, companies must comply with Corporate Policy POL-GSK-502 External Facing Systems.

## Clause 18 **Training, Monitoring and Reporting**

- 18.1 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.
- 18.2 Training:** Each manager is responsible for ensuring that their staff receive the necessary training on compliance with the Code.
- 18.3 Systems, procedures and policies:** Each GSK company or business unit must have appropriate written policies and procedures to cover the various elements of promotional activities covered by the Code.
- 18.4 Monitoring:** Each GSK company or business unit must monitor compliance with the Code by means of management, or independent, audits and reviews.
- 18.5 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.
- 18.6 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.
- 18.7 Reporting**
- 18.7.1 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.
- 18.7.2 Regionally:** A quarterly report from each GSK company or business unit of confirmed breaches must be submitted to the Pharmaceuticals Europe Compliance Officer, summarising the nature of the breach and what follow up actions have been/are being taken.



