

## **CODE OF ETHICS**

ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINAL PRODUCTS

&

DISCLOSURE OF TRANSFERS OF VALUE BY PHARMACEUTICAL COMPANIES  
TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

as amended by the General Assembly of SFEE,

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## INTRODUCTION

The SFEE Code of ETHICS, hereinafter referred to as “the Code”, covers the promotion of medicinal products supplied only with a physician’s prescription. Promotion includes any activity undertaken, organised or carried out by a pharmaceutical company or with its authority, aimed to promote the prescribing, supply, sale, administration or consumption of the medicinal product(s) of a SFEE member company. The term “medicinal products”, as used in this Code, has the meaning set forth in Article 2 of Ministerial Decision ΔΥΓ3α/Γ.Π.32221 (Government Gazette 1049/B/29.04.2013), which transposed EU Directive 2001/83/EC, as amended by Directive 2011/62/EU, into national law.

The Code consists of three chapters and two annexes. Chapter A lays down the substantive provisions of the Code for the promotion of prescription-only medicinal products. Chapter B refers to the Disclosure of transfers of value by pharmaceutical companies to Healthcare Professionals and Healthcare Organisations, while Chapter C refers to the Code Compliance Monitoring Process. Annex I refers to the indicative calculation of Healthcare Professional (HCP) fees for services provided to pharmaceutical companies and Annex II refers to the registry of non-interventional clinical studies.

The text of the Code of Ethics is provided below (non-shaded text), along with guidance regarding compliance with the Code (shaded text).

The annexes and guidance constitute an integral part of this Code and must be complied with.

## CHAPTER A

### CODE OF ETHICS ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINAL PRODUCTS

#### Substantive Provisions

#### Article 1 Scope of the Code

**1.1** Chapter A of the Code of Ethics, hereinafter referred to as the “Code”, lays down the principles and procedures that must be complied with in the promotion of prescription-only medicinal products to HCPs (such as physicians, pharmacists, nurses, etc.), as well as in the provision of information to the public on general health issues.

This chapter does not address promotion procedures in relation to non-prescription medicinal products which are aimed at raising public awareness of such medicinal products. The said procedures are described in the respective Code of Ethics of the Association of Greek Self-Medication Industry (E/EX).

#### a. Included in the scope of the Code are the following:

- promotion of medicinal products directed at persons authorised to prescribe or supply medicinal products;
- medical sales representatives’ visits to persons authorised to prescribe or supply medicinal products;
- the supply of samples;

sponsorship of meetings for the promotion of medicinal products and/or scientific events directed at persons authorised to prescribe or supply medicinal products, including payment of travel and accommodation in connection therewith;; direct or indirect information of the general public advertisements in journals or by mail;

- activities of medical sales representatives, including any relevant material;
- provision of hospitality at professional or scientific events and meetings, for the purpose of promoting medicinal products;
- provision of medical information material, such as brochures, etc.;
- all other activities for the promotion of sales in any form whatsoever, such as participation in exhibitions, use of audio-visual material, films, disks, videos, electronic media, interactive data systems, etc.

**Note:** Radio, television and the daily and weekly press are not mentioned, since the promotion of prescription-only medicinal products to the general public through such media is prohibited.

#### b. Excluded from the scope of the Code are the following:

- the Summary of Product Characteristics (SPC) or the abbreviated Summary of Product Characteristics, for which the relevant provisions apply;
- the labelling and the package leaflet of medicinal products, for which the relevant provisions apply;
- factual and informative announcements and reference material relating, for example, to pack changes, adverse reaction warnings in the context of pharmacovigilance, as well as trade catalogues and price lists that do not include no product claims;
- information on health or diseases, provided there is no reference, either direct or indirect, to any particular

medicinal product;

- replies in response to individual enquiries from HCPs or to specific questions or comments;
- **replies to letters published in scientific journals, provided these relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature.**

### c. Definitions

For the purposes of this Code, the following definitions apply:

**“Medicinal product”** means:

- any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

**“Summary of Product Characteristics (SPC)”** is the summary approved by the competent authorities that have granted the marketing authorisation in accordance with the legislation in force.

**“Package leaflet”** is a leaflet containing information for the user which accompanies the package of medicinal products. It is approved by the competent authorities, along with the summary of product characteristics.

**“Labelling”** is any indication on the outer and/or immediate packaging (i.e. vial label, outer box).

**“Medical information”** (MI) is the provision of scientific information by pharmaceutical companies to healthcare scientists (e.g. physicians, dentists and pharmacists) with respect to the medicinal products marketed under their responsibility, aimed to ensure the proper use of such products, as authorised by the National Organisation for Medicines (EOF) or the European Medicines Agency (EMA), with a view to protecting public health. Medical information may be provided orally, in writing or by audiovisual or other technological media.

Medical information is regulated by the National Organisation for Medicines (EOF) and the present Code of Ethics.

Medical information material, which shall be notified to EOF, is any material that exclusively contains scientific information and is addressed to healthcare professionals. Printed and/or digital material developed in order to be used by social security funds, procurement offices of hospital and other healthcare providers responsible for approving the procurement and/or pricing of medicinal products is not medical information material.

The term **“Promotion”** encompasses any activity undertaken by a pharmaceutical company, or with its authority, which promotes the supply, sale or administration of its medicinal products.

The term **“Healthcare Professional”** (HCP) includes the members of the medical, dental, pharmaceutical or nursing professions, as well as any other person authorised to prescribe, supply or administer medicinal products in the course of their professional activities.

**“Over-the-Counter (OTC) medicine”** is a medicinal product which can be sold directly to the consumer without a medical prescription.

**“Medical Sales Representative”** is a health scientist or other scientist or any person having the required general and specific knowledge to orally communicate concrete, responsible and accurate information on medicinal products.

**“Medical press”** is any scientific or other journal addressed to HCPs.

**“Donation”** is a gift to a third party with no exchange in return.

**“Grant”** is a donation to a third party for educational or research purposes with no exchange in return, by which the donor does not acquire any formal advantage, i.e. notification after the name of the sponsor.

**“Business Sponsorship”** is the funding of a third party in return for business promotion.

### Article 2 Discredit to, and Reduction of Confidence in, the Industry

Promotional activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry in general or any specific pharmaceutical company.

### Article 3 Marketing Authorisation

It is prohibited to promote any medicinal product for which a marketing authorisation has not been granted. All medical information data with respect to a medicinal product must be consistent with the particulars information included in the summary of product characteristics (SPC).

The medical information with respect to a medicinal product:

- must promote the rational use of the medicinal product, presenting it objectively and without exaggerating its

properties; and

- must not be misleading.

#### **Unauthorised indications**

It is prohibited to promote indications which are not covered by the marketing authorisation or have not yet been approved.

### **Article 4 Medical Information addressed to HCPs**

#### **4.1 Content of medical information**

Any medical information with respect to a medicinal product, addressed to persons authorised to prescribe or supply the medicinal product, must include:

- essential information consistent with the summary of product characteristics (SPC);
- the supply classification of the medicinal product (i.e. prescription-only or non-prescription);
- the Yellow Card, as required by EOF;
- the selling price or indicative price of the various presentations.

The reimbursement rate by social security funds may also be included.

Medical information with respect to a medicinal product addressed to persons authorised to prescribe or supply medicinal products may include only the name of the medicinal product, or the international non-proprietary name – if applicable – or the trademark, in case the communication is exclusively intended as a reminder.

Promotion must be accurate, balanced, fair, objective and complete, in order to enable the recipient to form his/her own opinion of the therapeutic value of the medicinal product concerned. It should be based on the up to date assessment of all relevant findings and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Promotion must be capable of substantiation, which must be promptly provided in response to reasonable requests from HCPs. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. However, substantiation need not be provided with respect to the validity of elements approved in the marketing authorisation.

Promotion must encourage the rational use of medicinal products, presenting them objectively and without exaggerating their properties. Claims must not imply that a medicinal product or an active ingredient has some special merit, quality or virtue, unless this can be substantiated. Quotations from medical and scientific literature (texts tables and graphs) used in the promotional material must be faithfully reproduced and the precise sources must be indicated.

Any promotional material on a medicinal product, transmitted or delivered to persons authorised to prescribe or supply medicinal products, must include at least the information set forth in Article 4.2 and specify the date on which it was generated or last revised. In the event of any amendment to the SPC, the previous version of the printed material may be made available for a period of six months following the last revision of the SPC, with the exception of cases where the Urgent Safety Restriction and/or any other serious restrictions apply.

In particular, it is prohibited:

- to delete a part of a graph or table in a way that the remaining part provides misleading information;
- to remove parts of a study or the results in other treatment sub-groups;
- to remove the results of other therapeutic treatments;
- to alter the scale, so that the differences appear smaller or higher than they actually are;
- to omit the title, measurement units on the x/y axes and/or numbers in general.

Changes in graphic elements from tables and figures of articles are only acceptable if:

- the end result does not change the initial meaning of the original;
- clear reference is made to the fact that the original has been adapted; and
- changes concern dosage, indications etc. not approved and/or not marketed in Greece.

Graphs and tables must always be accompanied by a brief description of the design of the trial, the number of patients, statistically significant data when comparisons are made, as well as the definition of primary and secondary end points (especially if a graph/table/claim refers to secondary end points), e.g. a “multicentre, double-blind, with a duration of .... in *n* patients”, etc.

The presentation of the results of different studies in the same graph is not allowed, even if there are references to each study, because such graphs can be visually misleading.

In the case of competitive products, comparison between different clinical studies is not allowed (in terms of targets,

patients' characteristics, etc.).

## **4.2 Prescribing information and other mandatory information**

Prescribing information must be included in a clear and legible manner in all promotional material, excluding abbreviated advertisements (up to one page, see Article 5).

Prescribing information must constitute an integral part of the promotional material and must not be separate from it (see also Article 4.2.5).

Mailing lists must be kept up-to-date. Mailing lists must be kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with.

Subject to the applicable legislation, the use of faxes, e-mails, automatic calling systems, text messages and other electronic data communication methods is prohibited, except with the prior permission, or upon the request, of the recipient.

### **4.2.1 Prescribing information must comprise:**

- the brand name and the common name of the medicinal product;
- the qualitative and quantitative composition in active substances;
- the trade name and the registered office of the pharmaceutical company which is responsible for marketing the medicinal product (the marketing authorisation holder);
- the approved indications;
- the side-effects, warnings and contra-indications related to the indications promoted;
- any warnings approved or additionally imposed by the National Organisation for Medicines or the authority that issued the marketing authorisation;
- the method in which the medicinal product is distributed (i.e. for hospital use, under medical prescription, etc.);
- the marketing authorisation number and the holder of the marketing authorisation;
- the registration data of the product in the List of Prescribed Medicinal Products (optional);
- dosage.

Information provided with respect to the dosage, method of administration, adverse reactions, warnings and contra-indications, as well as any precaution which must be included in promotional documents or advertisements shall be presented in such a way as to enable the readers to assess their connection with the claims and indications of the product.

### **4.2.2 Leavepieces may include the Summary of Product Characteristics (SPC) in an integrated case, provided that it is explicitly stated that the Summary of Product Characteristics (SPC) is enclosed.**

In standard printed material, it is permitted to include the SPC (provided the SPC is extended) in a one-piece case, along with the printed material (e.g. last page/pocket), provided it is explicitly stated that the Summary of Product Characteristics (SPC) is enclosed.

In digital promotional material, it is permitted to attach the Summary of Product Characteristics (SPC) as a link, provided the respective location is expressly stated, e.g. "For the Summary of Product Characteristics (SPC), please click here".

### **4.2.3 In the case of audio-visual material, such as films, videos, etc. and in the case of interactive data systems, the prescribing information may be provided:**

- by way of a document which is made available to all persons to whom the material is shown or sent; or
- by inclusion in the audio-visual recording or in the interactive data system.

When the prescribing information is included in an interactive data system, instructions for accessing it must be clearly displayed.

### **4.2.4 In the case of audio material, i.e. material which consists of sound only, the prescribing information must be provided by way of a document which is made available to all persons to whom the material is played or sent.**

### **4.2.5 In the case of a journal advertisement where the prescribing information appears overleaf, a reference to where it can be found must appear on the outer edge of the first page of the other page of the advertisement.**

### **4.2.6 In the case of printed promotional material consisting of more than four pages, a clear reference must be given to where the prescribing information can be found.**

### **4.2.7 All promotional material other than abbreviated advertisements appearing in professional publications must bear on the lower edge of the last page a code number with the initials of the medicinal product, the series designation, and**



the month and year when the material was drawn up or last revised, and it must be certified in accordance with the principles specified in article 12 of the Code. Companies are obliged to keep all printed promotional material on record for three years.

Promotional material must be submitted by the issuing pharmaceutical companies to the National Organisation for Medicines (EOF) in accordance with the relevant provisions. Any submission of the material to EOF prior to its distribution shall not be interpreted as application for approval.

#### **Form of Medical Information printed material and protection of Health Scientists against possible offence**

- A)** All promotional material and activities must acknowledge the special nature of medicinal products and the professional standing of the addressees, who must be respected and protected from any offence. High ethical standards must be maintained at all times.
- B)** The name or photograph of a member of a health profession must not be used in any way that is contrary to the ethics of that profession.
- C)** The medical information material must not imitate the devices, copy, slogans or the general layout adopted by another pharmaceutical company in a way that is likely to mislead or confuse.
- D)** The medical information material must not include any reference to the National Organisation for Medicines (EOF), the European Medicines Agency (EMA) and the committees operating under the responsibility thereof, or under the responsibility of the Ministry of Health, unless this is required by the competent authorities.
- E)** Reproductions of official documents may be used in the context of medical information, provided they are presented intact, unabridged and without falsifications.
- F)** Extremes of format, size and cost of the promotional material must be avoided.
- G)** Postcards, other exposed mailings, envelopes or wrappers must not carry any text which could be considered by the general population as advertising, contrary to Article 20.
- H)** The telephone, text messages, e-mails and facsimile must not be used for promotional purposes except with the recipient's prior consent.
- I)** All material relating to medicinal products and their uses, distributed by a specific pharmaceutical company, must clearly indicate that it has been provided by that company.
- J)** The use of pictures, illustrations and, in general, artwork disorienting the readers or suggesting the superiority of a medicinal product is prohibited, if such superiority is not substantiated.
- K)** Reprints distributed on the pharmaceutical company's initiative constitute promotional material and must comply with the relevant provisions, i.e. be accompanied by the SPC quoting the respective code and by the yellow card. In addition, the copyrights of the authors must be respected.
- L)** The use of pharmacoeconomic studies in medical promotion material must be restricted, given that the goal of such material is to present data in relation to the treatment of patients and not provide information in general, or specifically economic information, which is more of relevance to the entities responsible for procuring and providing insurance coverage for medicinal products.

The use of pharmacoeconomic studies in promotional material is acceptable under the following conditions:

- the studies do not concern safety and efficacy issues;
- cost-efficiency comparisons must primarily be based on Greek data drawn from articles published in reliable medical and/or pharmacoeconomic journals. The methodology (assumptions) must also be stated.

The use of data from international studies, also published in reliable journals, must bear the disclaimer that no respective Greek data is available and that therefore the results must be interpreted with caution;

Ideally, such data should be in the form of processed information from organisations of internationally recognised standing (e.g. NICE, EU Guidelines etc.), with a clarification as to whether information on Greece is included;

It must be pointed out that the information was drawn from published pharmacoeconomic studies (or, respectively, experimental studies).

#### **Article 5 Advertisements**

Advertisements may only appear in professional publications, namely publications sent or delivered exclusively to health scientists and nursing personnel. Scientific journals and publications of the health sector, printed material of conferences, medical/pharmaceutical books, etc. fall under this category. A loose insert in such a publication (for instance, separate leaflets distributed through the medical press) is not considered abbreviated advertisement.

Advertisements are not permitted in audiovisual material or interactive data systems or on the Internet, including online journals. Systems and/or websites which cannot be accessed by HCPs without a password are exempted from this

prohibition; in such advertisements that contain claims, the SPC may be attached in a link with a clear indication of where it can be found, e.g. "For the Summary of Product Characteristics, please click here".

If two pages of an advertisement are not facing, neither of them must be misleading or false when read in isolation.

### 5.1 Abbreviated advertisement

Abbreviated advertisements are those exempted from the obligation to include the prescribing information of the medicinal product being promoted, provided they fulfil the requirements of this article.

Abbreviated advertisements must include the following information:

- the name of the medicinal product, which may be either a brand name or a non-proprietary name;
- the name and address of the marketing authorisation holder;
- the qualitative and quantitative composition in active ingredients;
- where additional information or claims are included, the contra-indications, warnings and adverse reactions must necessarily be stated;
- any warning issued by the National Organisation for Medicines (EOF) or the authority which issued the marketing authorisation, must be included in the advertisement,

a statement that further information is available on request by the marketing authorisation holder or in the summary of product characteristics (SPC), the package leaflet and the monograph of the medicinal product.

## Article 6 Information, Claims and Comparisons

**6.1** Pharmaceutical companies must provide to HCPs and appropriate administrative staff, upon request, accurate information on the medicinal products they market.

**6.2** Information, claims and comparisons must be correct, accurate, objective and unambiguous and must be based on relevant and comparable aspects of the medicinal products, as well as on an up-to-date evaluation of all the evidence, reflecting that evidence clearly. They must not be directly or indirectly misleading and they must not distort the scientific facts.

Direct or indirect promotion of misleading indications of the medicinal product, reference to outdated scientific data, putting forward inaccurate or unsubstantiated claims, misleading comparison with other medicinal products and generalisation of isolated observations are prohibited.

**6.3** Any information, claims or comparisons must be capable of scientific substantiation.

**6.4** The substantiation of any information, claim or comparison must be provided without delay, upon request, to a HCP or appropriate administrative staff of the healthcare system. However, substantiation need not be provided with respect to indications approved in the marketing authorisation.

**6.5** If the promotional material refers to published studies, clear references to literature must be provided.

**6.6** All artwork, including illustrations, graphs and tables, must conform to the letter and spirit of the Code. Graphs and tables must be presented in such a way as to provide a clear, fair and balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made. Medical information leaflets cannot bear illustrations irrelevant to the content thereof, misleading or implying any vague indications concerning the medicinal product. **6.7** Information and claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side effects, interactions with other medicinal products or toxic hazards. The word "safe" must not be used without detailed proper qualification.

**6.8** Exaggerated or all-embracing claims must not be made and superlatives must not be used, except for those limited circumstances where they relate to a clear fact about a specific medicinal product. Claims should not imply that a medicinal product or an active ingredient has some special merit, quality or property, unless this can be substantiated.

**6.9** The word "new" must not be used to describe a product or presentation which has been generally available or any therapeutic indication that has been generally promoted for more than 12 months.

**6.10** Trade names of products of other pharmaceutical companies must not be used without the prior consent of the marketing authorisation holder of the respective medicinal product.

**6.5.1** Scientific data and claims included in promotional material must be supported by **articles published in scientific books, journals and/or other printed and electronic publications.**

Literature sources should include **articles published in scientific books and journals, mainly in the English language.** Exceptions may be publications in journals of acknowledged scientific value in other internationally recognised languages (e.g. French, German or Spanish), in which case the company is obliged to provide a Greek translation of the article, upon request.

Bibliographic references must be clear and sufficiently complete to enable the reader to track the source. References must indicate the author, the book or journal title, the publication year, the issue/volume and the page(s). It is recommended that the companies follow the internationally accepted citation styles (e.g. Vancouver style, Harvard system).

If web sources are used:

- the respective reference must accurately lead to the source of information;
- the date of last access must be indicated;
- the relevant print-out must be kept on record by the pharmaceutical company.

Data from conference papers, poster presentations or e abstracts may be used only if:

- they have been presented in prestigious scientific conferences and have been approved by the scientific committee of the conference;
- the period that elapsed from the first presentation of the data in a conference does not exceed two years; if, two years after the conference the relevant study has not been published in full other than partial entries in publications, announcements or abstracts/poster presentations, the data in question shall not be used in any promotional material anymore;
- they are available on the website or the abstract book of the conference;
- they are accompanied by a clear bibliographic reference to the website or abstract book where it is published, and not just the name of the conference.

**6.5.2** Articles that have been accepted for publication and are in the process of being published (**in press**) may be used in promotional material, as long as they are identified as such in the relevant bibliographic reference.

**6.5.3** The use of unpublished data regarding the efficacy and safety of products (**data on file**) for promotional purposes is prohibited. Such data may constitute the subject-matter of discussions between HCPs and the scientific service of the pharmaceutical company, but cannot be included in promotional material. Only general data are acceptable, such as the total number of patients in clinical programmes where the medicinal product has been studied, the total duration of the clinical programme and financial data, i.e. data that only the company possesses and can provide upon request.

Where a claim is based on *in vitro* studies or tests in animals, the experimental nature of the data must be clearly stated.

**6.5.4** Data derived from studies in animals, in healthy volunteers or *in vitro* studies and pharmacologic remarks of questionable clinical significance must not be presented as evidence of clinical value or. If it is decided that such data must be presented, the type of the relevant data must always be stated (e.g. *in vitro* trial, data from a study in healthy volunteers, etc.).

**6.8.1** Superlatives and similar expressions, e.g. “the best”, “the strongest”, “THE analgetic”, “unique”, etc. are not allowed.

Exaggerated or all-embracing claims, e.g. “the key to success”, “works wonders”, “the only choice etc.”, are not allowed either.

Exaggerations as regards pharmaceutical properties, e.g. “only acts where needed”, “hits the heart of the problem”, “it only inhibits...”, are not allowed.

Any promotional material which contains claims must include at least one brief reference to significant safety downsides of the product and not only to its benefits, in order to provide a balanced view.

All claims in promotional material must be consistent with the approved indications of the product. Any claim for use of the product other than its approved indication, is prohibited. The use of data outside the approved indications in the SPC (e.g. clinical data under Article 5.1) is not allowed.

Safety and efficacy data which, according to the SPC, are subject to further post-authorisation study must not be used in promotional material unless this requirement is stated in the promotional material by way of a disclaimer. Class effects cannot justify the inclusion of indications not having been tested for the specific medicinal product.

Comparative claims of superiority or non-inferiority and the like are only permitted if they arise from the level of statistical significance in Head to Head, specially designed randomised comparative trials, published in peer-reviewed scientific journals, aimed at comparing the safety/efficacy parameters and other properties of the medicinal product (primary or secondary end points of the trial).

Hanging comparisons such as “it is better”, “better safety profile”, etc. without stating what the medicinal product is compared with are not allowed.

Along with comparisons and/or statistical data, the following must always be stated:

□ the statistical significance level (P/P value or confidence intervals) must be stated for data that are statistically non-significant;

□ further statistical data analysis, when such data have not been published (i.e. extrapolation of results by the company), is not allowed.

Where the clinical significance is not known, this must be stated on the same page.

All factors under comparison must be stated, accompanied by clarifications where and as necessary.

Data from patient registries must not be used as a basis for comparative claims. When such data are presented, the identity of the registry must be indicated and a clarifying notice to the following effect must be added: "The results shown here have been derived from a patient registry and not from a randomised trial involving direct comparison of therapeutic factors, therefore they do not suggest such comparison".

Reference to safety or efficacy data using a truncated quotation from a publication or presentation by an expert, e.g. "the medicinal product was effective and well tolerated", should be avoided when such data are not drawn from primary sources.

Generalisation of isolated remarks, e.g. data from case reports, is not permitted.

The use of off label data is not permitted, even if the data are indicated as such or are characterised as "more recent data".

Scientific data must be translated and presented unchanged and with absolute accuracy.

Cutting a part of a sentence in a way to alter its overall meaning is not allowed. Footnotes (e.g. with the use of an asterisk) that in whole or in part cancel the meaning of a sentence are not permitted. Footnotes must only be of a clarifying nature.

The use of high validity studies, such as the following, is recommended:

1. randomised controlled trials (RCTs) (with concealed allocation, double-blind) or systematic postreview thereof (post-analysis);
2. properly designed non-randomised controlled trials.
3. controlled observational studies (prospective or studies in patients-witnesses);
4. uncontrolled observational studies;
5. expert opinion based on pathophysiological mechanisms, or laboratory evidence, or consensus opinion without specific reference to critical evaluation and methodology.

## **Article 7 Disparaging references**

**7.1** The medicinal products and activities of other pharmaceutical companies must not be disparaged.

**7.2** The health professions and the clinical practice and scientific opinions of health professionals must not be disparaged.

## **Article 8 Disguised Promotion**

**8.1** Promotional material and activities must not be disguised.

**8.2** Clinical assessments, post-marketing surveillance, experience programmes and post-authorisation studies must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose.

**8.3** When a pharmaceutical company pays for or otherwise secures or arranges the publication of promotional material in a scientific journal, such material must not appear that constitute independent editorial material.

**8.4** Any material relating to medicinal products and their uses, whether promotional or not, which is sponsored by a pharmaceutical company, must not in any case include misleading or inaccurate statements and must clearly indicate that it has been sponsored by that pharmaceutical company.

## **Article 9 Distribution of Reprints**

**9.1** Reprints and quotations from medical and scientific literature or from personal communications must accurately reflect the meaning of the author.

**9.2** Quotations relating to medicinal products which are taken from public broadcasts, for example on radio and television, and from occasions such as medical conferences or symposia, must not be used without the formal permission of the speaker.

**9.3** Greatest care must be taken to avoid ascribing claims or views to authors, when these no longer represent the current views of the authors concerned.

**9.4** Unsolicited reprints distributed on the initiative of the pharmaceutical company constitute promotional material and

must conform with the relevant requirements i.e. be accompanied by the SPC stating the product code and by the yellow card. The copyrights of the author must also be respected.

#### **Article 10 Distribution of Promotional Material**

**10.1** Promotional material must only be sent or distributed to those categories of HCPs who need or are interested in the particular information.

**10.2** Pharmaceutical companies must exercise restraint on the frequency of distribution and the volume of promotional material in a way to respond to the need for effective information.

**10.3** Mailing lists must be kept up-to-date and conform with the data protection legislation. Requests from HCPs 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.

#### **Article 11 Certification of Promotional Material**

Before printing/distribution, promotional material must be certified in accordance with the provisions of the legislation in force. Pharmaceutical companies must have a scientific service which shall ensure the appropriate internal procedures for the certification of promotional material, thereby ensuring compliance with the legislation in force and the Code.

The scientific service personnel of the pharmaceutical company, including the members of staff involved in any way in the preparation or approval of promotional material, information to be provided to HCPs and to appropriate administrative staff or information to be provided to the general public, must fully observe the requirements of the Code.

It is recommended that the scientific service in charge of certifying the printed material be integrated into the medical affairs department of pharmaceutical companies, depending on the organisational structure of each company. The scientific service should preferably include a medical doctor or a pharmacist or other properly qualified HCP who will be responsible for approving all promotional material before release. Such person must certify that he/she has examined the final form of the promotional material and has found it to comply with the requirements of the law and the Code. The person in question cannot be a member of and/or report to the scientific information and promotion department and no conflict of interest must exist.

Material prepared by pharmaceutical companies which relates to medicinal products in general but is not intended to provide medical information on particular medicinal products, such as corporate advertising, press releases, market research material, financial information to shareholders, the Stock Exchange, educational/information material for patients, etc., must be certified in order to ensure compliance with the Code and the legislation in force..

Account must be taken of the fact that a non-promotional text/material may be used for promotional purposes. In this case, the material would be subject to the provisions of the Code.

The pharmaceutical company personnel and any person who is in any way connected with the company and is concerned with the preparation or approval of promotional material or activities must be fully conversant with the requirements of the Code and the relevant laws and regulations.

Pharmaceutical companies shall communicate to the First Instance Committee for Code Compliance the name and position of the person responsible for certifying the promotional material and to be contacted by the aforementioned Committee may contact on issues of compliance with the Code. Any change in this information must be promptly notified to the Secretary of the First Instance Committee.

Certification means that the signatories have examined the final form of the material and that, in their belief, it is in accordance with the requirements of the law and the relevant provisions of the Code, is consistent with the marketing authorisation and the summary of product characteristics (SPC) or the package leaflet, and is a fair and truthful presentation of the facts about the medicinal product.

Material used for a long time must be recertified at intervals of no more than two years, in order to ensure ongoing compliance with legislation in force and the Code.

The person responsible for marketing a medicinal product shall submit to the National Organisation for Medicines (EOF) a copy of all promotional material it issues, accompanied by the marketing authorisation and the summary of product characteristics (SPC). All material must include the date when it was drawn up or last revised.

Pharmaceutical companies must preserve all certified material, along with the relevant accompanying information, in the form certified and information indicating the persons to whom the material was addressed and the method of dissemination, for at least three years after their use, and be ready to submit them, upon request, to the National Organisation of Medicines (EOF) or the First Instance and Second Instance Committees for Code Compliance.

It is very important to keep record of audio-visual material as well, which shall be submitted to the National Organisation for Medicines (EOF) as is the case with printed material.

#### **Article 12 Medical Sales Representatives (Scientific associates)**

**12.1** Medical sales representatives must perform their duties responsibly and ethically.

**12.2** Medical sales representatives must be given adequate training by the employing company and have satisfactory scientific knowledge to be able to provide precise and complete information about the medicinal products they promote.

**12.3** Medical sales representatives must comply with the Code and legislative provisions in force. Pharmaceutical companies shall ensure the compliance of medical sales representatives.

During each visit to HCPs, medical sales representatives must provide to the persons visited or have available for them the summary of product characteristics (SPC) for each medicinal product they present, accompanied by information, under Article 4 of the Code, regarding price and reimbursement by social security.

Medical sales representatives must transmit to the pharmaceutical company's scientific service, which is provided for in Article 11 of the Code, any information they receive in relation to the use of the medicinal products they promote, in particular, reports of side effects, which must be promptly notified to the Pharmacovigilance Officer so that the appropriate legal steps can be taken, where required.

Medical sales representatives must ensure that the frequency, timing and duration of their visits to HCPs, together with the manner in which they are made, do not hinder the exercise of medical practice by the HCPs. The wishes of the persons on whom representatives wish to call and the time and place regulations and restrictions set by each hospital or clinic must be observed.

During an interview or when seeking an appointment for one, medical sales representatives must take reasonable steps to ensure that they do not mislead as to their identity or that of the pharmaceutical company they represent.

Pharmaceutical companies are responsible for the activities of their representatives, when such activities are performed within the scope of their employment.

Medical sales representatives must not employ any inducement or subterfuge to gain an interview with any HCP.

Medical sales representatives must, under the responsibility of the pharmaceutical company they work for, be taught the Code during their training period and periodically receive systematic training with respect to the products promoted.

### **Article 13 Medical Samples**

The production, import and free distribution of medical samples, irrespective of packaging, to physicians and dentists for information purposes, is permitted only pursuant to a special permission from the National Organisation for Medicines (EOF) in accordance with the provisions in force. The permission, granted in exceptional cases, determines the packaging, the overall quantity, the time and mode of distribution and any other information as necessary.

Pharmaceutical companies must have suitable control and calculation systems for the samples they distribute and for all medicinal products they handle through their representatives.

A sample cannot be larger than the smallest presentation of the medicinal product on the market.

All samples 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 (SPC).

The provision of samples distribution is not permitted for the following medicinal products: (a) medicinal products containing substances which are defined as psychotropic or narcotic by international conventions, such as the 1961 and 1971 United Nations Conventions; and (b) any other medicinal product for which the provision of samples is considered inappropriate by the competent authorities.

### **Article 14 Informational and Educational Material and Medical Use Material**

**14.1** It is permitted to offer item medical/educational devices/applications of insignificant value, up to EUR15 (per item) VAT included, closely associated with daily HCP practice such as:

- applications for mobile phones/computers which, due to their nature, are not characterised as medical technology products (e.g. they do not serve diagnostic or dosing purposes, etc.);
- anatomy and/or physiology models (physical or electronic, e.g. CD/DVD/locked USB);
- anatomy maps (physical or electronic, e.g. CD/DVD/locked USB);
- educational material for patients via the HCP in the form of supporting material, e.g. nutrition/exercise advice, or in the context of a disease awareness campaign approved by the competent authorities;
- printed or digital publications including guidelines from Scientific Societies – provided they do not describe outside the approved indications and dosage;
- printed or digital publications of therapeutic protocols.

All the above informational and educational material for medical use is considered promotional and must therefore be notified to EOF. Such material must not use the product brand name and/or include a direct or indirect advertising message, but only the company's logo.

In addition, the provision of educational material to healthcare professionals is not permitted, except for the items referred to in Article 14.1. The provision of educational material is only permitted in the form of donation to a legal person or entity (Article 16.3). This subparagraph shall enter into force on 1 January 2015. Any outstanding orders may be filled and hard copies in stock may be distributed until 31 December 2014.

**14.2** Any other donation, sponsorship or benefit in kind to HCPs is prohibited.



## **INDICATIVE LIST OF UNACCEPTABLE MEDICAL/EDUCATIONAL USE OBJECTS (effective from 1 January 2014)**

Antiseptic fluids

Surgical gloves/scrub hats/clothes

Catheters

Syringes/needles/tourniquets

Ultrasound gel

CPRs

MP3s

Stethoscopes

Prescription pads

ECG paper

Any personal objects

Organisers, notebooks, etc.

Stationery items

PC accessories

Other items

**As from June 1, 2014 the provision of promotional aids bearing the logo of a company or of a product, such as bags, notepads, pens, memory sticks, stationery, mouse pads, PC mouses, etc. is not permitted. This sentence shall enter into force on 1 January 2014. Any outstanding orders may be filled and items in stock may be distributed until 1 June 2014.**

### **Article 15 Scientific Service Responsible for Information**

**15.1** Pharmaceutical companies are required to have a scientific service (HCPs Information Department) responsible for providing information on the medicinal products they market. This service shall reply to all queries from patients/consumers, HCPs (physicians, pharmacists etc.), medical sales representatives or other sources (e.g. government agencies, scientific institutions, regulatory authorities).

**15.2** Pharmaceutical companies are required to have an organised system to receive, log, process, respond to and keep record of requests for medical information. That system must be in compliance with the relevant Greek legislation on the prohibition of advertising to the public and on the handling of sensitive personal data.

**15.3** Health scientists working in pharmaceutical companies and entrusted with the tasks relating to the provision of medical, scientific and non-promotional information and scientific and research literature updates, pharmacovigilance, pre- and post-authorisation clinical research & development, the staffing of non-promotional medical stands in scientific conferences and communication of scientific information to competent authorities shall belong and report to the medical and scientific departments of the companies and not to the marketing departments, in order to ensure objectivity and independence in the performance of the above tasks and a segregation of roles and responsibilities.

Pharmaceutical companies are required to be prepared to receive queries by phone, post, or e-mails or fax at the telephone numbers, postal or e-mail addresses which they have made publicly known (e.g. indicated on the package of their products). Therefore, they are required to check such media on a daily basis for any incoming inquiries (incoming calls, electronic/printed mail). The personnel in charge of receiving such messages must be trained to recognise requests for medical information and promptly forward them to the relevant scientific service for processing and response.

It is recommended that the scientific service in charge of processing and responding to requests for medical information be integrated into the medical affairs department of the pharmaceutical companies, depending on the organisational structure of each company. Preferably, it should include a physician or pharmacist or other health scientist.

Properly trained front-office personnel could be in charge of addressing inquiries that can be answered by reference to the approved product documentation.

Unusual or rarely asked questions, the answers to which are not found in the approved product documentation, may be forwarded to the competent Medical Advisor who will refer to more specialised sources of information.

Furthermore, each company may employ specially trained personnel that will reply to queries regarding specialised products, e.g. medical technology products.



It is recommended that pharmaceutical companies operate a logging system, electronic or not, for the unsolicited queries they receive. Such systems should record at least the following:

- ☐ Query and relevant product
- ☐ Contact details of inquirer
- ☐ Date of receipt of query
- ☐ Handler and response provided, with the precise reference source
- ☐ Date of response

Each pharmaceutical company is required to notify the Data Protection Authority of the creation, operation and process of a logger, indicating the following:

- full name, position, company name and address of handler;
- address where the log file is located;
- type of data, purpose of processing, retention period;
- data recipients, access rights;
- system characteristics and security measures.

The approval of the Data Protection Authority is necessary for the operation of the logger.

Moreover, companies are required to notify callers of the existence of the logging and archiving system and the purpose thereof, as well as their right to access, and object to, the contact details they have provided.

The scientific service must be trained and have access to those files that will enable it to provide a scientifically substantiated response. Moreover, it must be informed of any relevant change in the files. Finally, the scientific service must be trained in the field of Pharmacovigilance and Medical Devices Vigilance, so that the respective safety issues and pharmaco-technical complaints can be referred to the competent company departments within the predetermined time-schedules.

It is recommended that the scientific service be available on a 24-hour basis.

Each pharmaceutical company is required to document the procedure followed, so as to ensure that all aforementioned stages of receipt, processing, response and logging of medical information requests are in place and followed properly.

Replies to medical queries must be substantiated in a neutral and objective manner with precise reference sources, without any direct or indirect promotion of medicinal products. Answers may be given orally or in writing, as the case may be, but in both cases must be documented by the medical affairs department.

Answers must concern specific unsolicited queries and be limited to the scope of each queries.

Answers may rely on different sources, depending on the capacity of the inquirer:

#### **A) Patients – Patients Associations – General Public**

Answers to queries from patients and their relatives, patient associations or the general public must be initially based on the Package Leaflet, while the Summary of Product Characteristics (SPC) can also be used for further clarifications. Answers to frequently asked questions (FAQs) from patients must similarly be based on the Package Leaflet and the SPC. FAQs must be up-to-date and approved.

The only documents that may be provided to patients/consumers, upon request, are the package leaflets of the products.

By way of exception, the provision of further informational material to patients is permitted for prescription-only medicinal products, if this is provided for in the Risk Management Plan (RMP) approved by the Pharmacovigilance Department of EOF.

For queries concerning use outside indication, the patient must be referred to his/her treating physician and it must be made clear that the specific use is not envisaged by the approved product characteristics.

Finally, the answers, whether in writing or oral, must make clear that the information provided in response to the relevant query is intended for informational purposes and in no way can substitute advice from the treating physician or other qualified HCP.

#### **B) Healthcare Professionals (HCPs)**

Answers to queries from HCPs must be based on the SPCs and the product monographs. Standard answers to FAQs must also be based on the SPCs and the product monographs.

If these are not sufficient to fully answer the query, the department in charge may refer to literature, published articles,

and accessible and available conference abstracts. In this case, the source of information must be indicated and the copyrights to use such publications must be taken into account (see section 11c).

If the query cannot be answered by the already published literature and it is necessary to use unpublished data from the company's clinical trial records, this is possible, but it is recommended that such data be kept in the company concerned and be readily available upon request.

In exceptional cases and if so provided for, answers can be based on the product RMP and the respective training material.

For queries concerning a use outside indications, the answer must make clear that the use in question is not envisaged by the approved product characteristics and be accompanied by the SPC.

### **C) Medical Sales Representatives/Sales and Marketing**

Answers to queries from by a company's Medical Sales Representatives to its medical affairs department must be exclusively based on the SPCs.

#### **□ Scientific Literature Update**

This is the provision of scientific literature (in printed or electronic format) in reply to an incoming question from a HCP aimed exclusively to enhance his/her scientific knowledge.

#### **a. Non-promotional activity**

Scientific literature must only be sent upon request (ad hoc) and not in advance or as promotional aid. Scientific textbooks must be sent individually and reproduced exactly, and their source must be precisely indicated.

The use of literature for promotional purposes is subject to the Code provisions on promotion.

#### **b. Addressees, special remarks**

Answering external queries by provision of scientific textbooks is permitted only in the case of HCPs, upon request.

If an HCP requests that scientific literature information on a non-approved indication of a medicinal product be sent to him/her, the provisions of paragraph 11B shall apply.

For published research/clinical data on medicinal products that have not yet obtained a marketing authorisation, scientific information to HCPs may only be provided by the qualified staff of the Medical Affairs Department.

#### **c. Intellectual property rights (copyrights)**

It is the responsibility of each company, before reproducing and sending any scientific work (in printed or electronic format), to have demonstrable acquired from the owner of intellectual property rights permission to use such work.

The copyright applies even to databases, software applications and webpages (as to the form and content).

The copyright owner must consent before:

- I. a copyrighted work is photocopied;
- II. a copyrighted work is reproduced or distributed;
- III. a copyrighted work is converted (e.g. translated).

The mere acknowledgment of the copyright owner, without his/her proven permission to the use of his/her work does not avoid a copyright infringement and incurs severe penalties.

### **Article 16 Donations/Grants to Institutions, Organisations and Scientific Societies**

**16.1** Donations, grants and benefits in kind to foundations, institutions, organisations or associations that are comprised of HCPs or that conduct research are only allowed if: (i) they are made for the purpose of supporting healthcare, research, training, or the provision of better health services; ii) they are documented and kept on record by the company; iii) they do not constitute an inducement to prescribe, sell or purchase specific medicinal products.

**16.2** Donations or sponsorships are also allowed to:

**A1)** Hospitals established as legal persons in public law, NHS Health Centres and, in general Hospital Institutions which belong to the public sector and are supervised by the Ministry of Health or any other Ministry as appropriate, directly relate to the provision of health services, medical and educational goods and services that improve patient care and are to the benefit of patients and the National Health System, according to the legislation in force.

**A2)** medical societies/institutions/associations/unions established by HCPs as not-for-profit legal persons in private law,;

**A3)** patient associations, organised as civil society associations, not-for-profit associations and in accordance with the

provisions of the Code of Ethics for Patient Associations.

**A4)** Also permitted are grants to scientific and research programmes, of hospitals and universities, as well as to provide grants for awards and scholarships to health scientists.

**16.3** Donations, where allowed, may be in kind or in money. A donation in money must serve a specific purpose. e.g. to finance a research programme, educate HCPs, patients and patient caregivers or facilitate the recipient to purchase medical equipment or part of it. Donations in kind may involve medical equipment (instruments, devices) and reagents in the context of a research programme. For donations of computers and peripherals, detailed description and documentation shall be required. Donations for the construction/renovation of building facilities are not permitted. Donations in money cannot be aimed to serve the recipient's purposes "in general".

As of 1 January 2014 this category includes various medical or diagnostic instruments, scientific textbooks, electronic aids (mainly electronic connections to databases, supportive software and computers, books) exceeding €100 in value.

**16.4** The provision of the items and services described in this paragraph must not be performed in a way to serve as an inducement to prescribe, supply, approve, price or reimburse a medicine. It is permitted to mark with the pharmaceutical company's name the items donated to hospital institutions, but not the name of any medicinal product.

Compliance with the present section presupposes adherence to all procedures envisaged for the specific type of each transfer of value (donation, sponsorship, etc.) in the context of full disclosure and transparency, as well as to the relevant applicable rules and the tax legislation, in particular the Code of Tax Books and Records.

**16.5** Exempted from the scope of this article are hospitals established as legal persons in private law, as well as medical companies providing primary care services under Article 11 of Presidential Decree 84/2001, are excluded from the scope of the present article.

**16.6** Donation/grant requests must be submitted by the requesting organisation/medical society/university department/hospital department/patient association, etc., along with a detailed description substantiating the need, purpose and method in which the donation will be used, including the requested amount/cost.

The donor company shall examine the request and reply in writing or orally to the requesting party.

In the case of a positive reply, the following shall be required:

**1. An agreement in writing:** an agreement must be prepared and signed by both parties (legal representative of the pharmaceutical company or other person authorised by the Board of Directors, Chairperson of the medical society, Manager or Chairman of the Hospital, Vice-Dean/ELKE of the University). For contracts concerning donations to patient associations, the relevant provisions of the SFEE Code of Ethics on the relationships between pharmaceutical companies and patient associations shall apply.

**2. Extract from a decision of the governing body** of the Medical Society, Patient Association, Hospital, NHS, or of the Rector's Council or Faculty (for Universities), etc., indicating the acceptance of the donation by the recipient.

Upon receiving the donation from the donor, the recipient must confirm the taking of delivery/purchase/procurement of the goods or services or the implementation/progress of the research work, and, more generally, prove the use of the donation for the agreed purpose.

**16.7.** Pharmaceutical companies are required, on an annual basis and on SFEE's website, to disclose information about their donations, sponsorships, or benefits in kind. To this end, every year and by 31 March at the latest member companies must transmit data on the donations they made during the preceding year at [donations@sfee.gr](mailto:donations@sfee.gr) in order to be publicly disclosed.

**16.8** Requests by the above institutions to pharmaceutical companies for a donation to a third party shall not be accepted or considered.

Donations of medicinal products within the context of corporate social responsibility actions undertaken by individual member companies or through SFEE are exempted from this donation procedure and must abide by the approval procedures provided for by the National Organisation for Medicines (EOF).

**16.9** Donations/grants (educational or research grants or donations in kind) must not exceed 1% of the total annual turnover of a pharmaceutical company.

If such donations/grants are made on the initiative of the parent company of a multinational group, they shall be calculated in the expenses of the local subsidiary, subject to their approval by the Managing Director (legal representative) of such subsidiary.

Donations or grants in the above spirit that are offered directly to a HCP (natural person) or to a third party designated by a HCP are not allowed.

## **Article 17 Eligibility of physicians to participate in scientific events**

Eligibility of physicians and other scientific staff of the NHS and university physicians employed in clinics of NHS hospitals or universities to participate in the events referred to in A, B, C, D and E below is regulated by currently

applicable legislation.

Hospitality at events shall always be strictly limited to the main scientific objective of the event and must not be extended to persons other than HCPs who meet the requirements for participating in the said scientific events.

## **Definitions of Scientific Events**

### **A. Conferences of scientific content**

Conferences of scientific content are conferences, seminars and similar continuing education events held by state entities, including universities and public hospitals (clinics, laboratories, government agencies and social security organisations and health units), non-profit scientific associations, as well as non-profit scientific institutions, public or private law legal entities, associations of health scientists, and scientific unions, irrespective of legal form. These can be held in Greece or abroad and their entire programme is exclusively of scientific content (medical / dental / pharmaceutical / nursing / public health / health services).

Included in this category are all respective events which are held in Greece or abroad by foreign agencies and which are sponsored by companies with registered office in Greece.

Also included are scientific events which are organised by Hospitals, University Clinics, laboratories and NHS clinics having capacity to individually or jointly organise such events. The duration of such events must not exceed two days and sponsorship by any individual company may amount up to EUR 2,500 (in total, VAT included) and, in aggregate for all sponsors, EUR 10,000 (VAT included). These events may be held up to three times per year, with free participation; they must be held in a venue close to the city or town where the organising entity is located (preferably, at the auditorium of the hospital); where the event is held in hospital facilities, company stands, banners etc. are not allowed.

Greece-wide conferences should not be held more than once a year for any given profession. Their duration should be at least three days with a scientific agenda of at least eight hours per day and should be held in an easily accessible venue.

Type A scientific events cannot be exclusively sponsored by a single pharmaceutical company (except where the subject-matter of the event is rare diseases).

### **B. Type B scientific update events**

Conferences, seminars and similar events aiming at the provision of scientific updates are those events hosted by pharmaceutical companies in collaboration with type A entitled agencies, thereby ensuring the participation of all interested scientists. These are held in Greece, and their entire programme is focused on scientific matters within the scope of EOF's responsibility.

### **C. Type C scientific update events for medicinal products**

One-day conferences, seminars, and similar events providing updates on medicinal products within the framework of their promotion mean those events hosted by any means (including on an internet-based platform) by pharmaceutical companies, which take place in Greece and their programme primarily aims to update HCPs on medicinal products.

Civilian or military medical doctors may participate as speakers in type C events for the promotion of sales, organised by pharmaceutical companies.

### **D. Type D domestic scientific update events**

(a) Non-promotional, purely educational scientific events (Type D) are organised in Greece and fully sponsored by foreign-based companies manufacturing or marketing products within EOF's scope and constitute specialised fora, with a complete scientific programme, bringing together speakers of high calibre (e.g. training seminars for speakers and/or for writers of scientific articles and/or treatises, CMEs, research programmes, etc.)

Type D Events are not subject to any limits as to the number of foreign participants or participations.

Type D events organised by foreign companies offering products under EOF's jurisdiction are not subject to any time limitations as regards the submission of applications (Type D application form).

(b) Non-promotional, purely scientific events (Type D) organised in Greece and fully sponsored by Greek-based companies manufacturing or marketing products within the scope of EOF and constitute specialised fora, with a complete scientific programme, bringing together speakers of high calibre (e.g. training seminars for speakers and/or for writing scientific articles and/or theses, CMEs, research programmes etc.). They are held at the company's registered office. The number of participants in Type D scientific events organised by companies offering products under EOF's jurisdiction with registered office in Greece can be unlimited, with a maximum of ten (10) events per company per year.

The organisation of Type D events by Greek-based companies is subject to the same time limitations concerning the submission of applications as for Type B and C events (Type D application form). Hospitality is not normally provided, except in the special case of HCPs coming from remote areas of the region and for one night provided that the

programme exceeds five hours in duration.

For Type D events, if the cost is exclusively covered by the company offering products under EOF's jurisdiction (Foreign) or the foreign parent company, no submission of ex post cost data is required.

If the event is organised by a company with registered office in Greece (paragraph D, case b), the ex post cost data shall be submitted to EOF by the organising company within two months of the date of the event, along with the event's final programme, number of participants and copies of expense documents, if requested.

The subsistence and accommodation limits for Type A Domestic Conferences also apply in this case.

#### **E. Granting of access to conferences and other scientific, educational and/or research events via the internet**

Given the widespread use of technology, SFEE encourages and supports the use of technology as an extension of the educational opportunities offered by its members.

**Individually:** Pharmaceutical companies may support HCPs, including NHS and University HCPs, by paying the cost of access codes that will allow them to attend conferences and other scientific, educational and/or research events through the internet from their personal computers.

**In groups:** Pharmaceutical companies may organise group attendances for HCPs, including NHS and University HCPs, in order to attend important conferences and scientific, training and/or research events via the internet.

With regard to domestic events, group attendance via the internet must be included from the beginning in the conference's programme as submitted to EOF by the organising entity; thereby, it shall be authorised together with the scientific event itself and no separate permission by EOF shall be required. The costs of the venue and the facilities will be borne by the pharmaceutical company. Only coffee/refreshments may be offered in such group attendances.

#### **F. Expenses for the promotion of medicinal products**

According to Article 123 of Ministerial Decision ΔΥΓ3α/Γ.Π 32221 (Government Gazette B 1049/29.4.2013), which transposed EU Directive 2001/83/EC, as amended by Directive 2010/84/EU, into national law, in conjunction with Ministerial Decisions Y6α28403/2001 and Y6α116328/2002 as currently in force, recipients of promotional actions funded out of the promotional budgets of pharmaceutical companies may only be the persons authorised to prescribe or supply medicinal products. For instance, based on the above legal framework, the following apply:

The promotional expenses of pharmaceutical companies include sponsorships for hosting events by scientific agencies the subject-matter of which exclusively or predominantly – relates to the supply or promotion of medicines. These expenses must concern the promotion of specific products through events, exhibitions, print material, stands, etc.

Promotional expenses also include the expenses for hosting the events (lease of venue, conference material, audiovisual equipment, hospitality for organising entities and guests, catering).

Promotional expenses do not include any HCP travel and registration costs for scientific events held in Greece or abroad, or any sponsorship for events held by entities whose object is not related with the supply or promotion of medicines.

#### **G. Events in which a pharmaceutical company organises a series of meetings (group sale):**

With a small number of private HCPs (up to 10)

With strictly scientific topics

With a short duration (approximately 1.5 hour) and without overnight stay

Concerning the company's products

The speaker is an internal associate of the company

Such meetings are not considered type C events and do not require approval from EOF, provided that their scientific aspect supersedes the social one. Promotional meetings held exclusively inside hospitals for hospital physicians are not considered type C events and do not require approval from EOF, only from the hospital. The speaker is always a member of staff of the company. These events require approval from the Clinic Director.

#### **Article 18 Provisions on the organisation of Type A scientific events**

EOF is entitled to conduct inspections during conferences or events via its own staff or in co-operation with the competent tax authorities and, where it verifies that its approval has been infringed in case the approved provisions are not observed, may suspend the organising entity from future events for a period of two years. The same applies to cases where the ex post financial report reveals a serious overrun of the actual costs (over 25%) compared to the approved budget. Such decisions on the part of EOF may be appealed in accordance with the applicable procedures.

SFEE may conduct inspections in scientific Type A events via its authorised officials or external associates, in order to verify the compliance of member companies with the provisions of the present Code. The inspection results will be

communicated to the SFEE First Degree Committee for the Observance of the SFEE Code of Ethics, which will take action in cases of non-compliance.

Domestic type A conferences are assessed by the SFEE committee for the evaluation of conferences and the results are posted on SFEE's e-platform ([scientific.events.sfee.gr](http://scientific.events.sfee.gr)). The committee shall be set up by decision of the Board of Directors of SFEE and shall comprise the Compliance Officers of member companies and the Legal Advisor of SFEE, who will participate without the right to vote. The committee and its decisions shall be supervised by the Board of Directors of SFEE. Member companies are recommended to take into account the SFEE committee's evaluation for each conference before they decide to participate in any manner and consult the files posted on the platform (programme, sponsorships, etc.).

Scientific events are uploaded to SFEE's platform for evaluation, at least 30 days before the date of the event, to enable the timely commitment of companies with the organising entities.

**18.1** All entitled entities interested in organising type A scientific events must submit a request to the National Organisation for Medicines (EOF) on the last working day of September, January, March, May and November, accompanied by the following:

- (a) name of organising entity;
- (b) name of the scientific project coordinator;
- (c) title and main topics;
- (d) time and place of the event;
- (e) initial budget (revenue and expenses, sources of revenue and expenses)

In the case of a cycle of events held within the same 12-month period, a single application for all such events shall be submitted.

**18.2** Every October, February, April, June and December, EOF will announce and publish its approvals for events to be held within the following 12 months in Greece and for international events.

Within four months of the end of a type A scientific event, the organising entity shall submit to the National Organisation for Medicines (EOF) the final programme of the event, the ex post financial review, the list with the sponsors and the amounts of sponsorship, the number of registered participants and a solemn declaration according to the law in force, by which they will declare that the revenue and expenses data stated in the financial report are true.

Moreover, they must submit to EOF certified copies of the supporting documents upon request.

The initial budget must not be exceeded by more than 25%, unless this is fully justified by a proportional increase in the magnitudes of the scientific event.

EOF will publish at its website the title of the event, the organising scientific entity and the amounts and sources of sponsorships.

**18.3** An objection against a rejecting decision can be submitted to the Secretariat of EOF's Scientific Committee for the Evaluation of Conferences within 10 days of the date when the decision was notified.

**18.4** As regards organisation of type A events abroad by Greek scientific entities or international bodies based in Greece, EOF will grant its approval only if there are sound scientific reasons (e.g. international obligations) and if there is a co-organising entity abroad sharing the expenses by at least 50%, excluding travel and accommodation expenses for Greek scientists.

**18.5** Sponsorships shall be deposited in an account held by the beneficiary scientific entity, or in the Special Account for Research and Development (ELKEA) of the relevant Y.PE. (Health Region) in the case of clinics and laboratories of state hospitals, or in the Special Account for University Research (ELKE) in the case of universities and higher education colleges, and a receipt shall be issued in the name of the sponsor.

If the scientific organising entity is not competent or in view of its may not due to the nature of its legal form issue such receipts, it is entitled - under a valid contract signed with the Professional Conference Organiser, that should be explicitly mentioned in the EOF approval - to assign to the Professional Conference Organiser the entire financial management of the conference (collection of sponsorships, invoicing of the sponsors and issuance of the relevant tax documents for the sponsors). In this case, the invoicing of all services for the conference to the pharmaceutical company will only be performed by the Professional Conference Organiser.

After the event, the contractor PCO must proceed to settlement, issue a respective report and return any surplus to the scientific entities involved.

The contract concluded between the two parties must include the following:

Complete details of the contracting parties (registered office, name, VAT/Tax Registration Number, Tax Office, legal form, legal representation, etc.)



Accurate financial data (budget corresponding to the data of the application, PCO remuneration and any other data). In general, the contract must be precisely depicted and described by the data.

**18.6** The international or global scientific events organised in Greece by foreign entities:

(a) are not subject to any deadline for the submission of applications,

(b) the decisions approving these events shall be published within one month at the latest of the date when the application is submitted;

(c) the granting of honoraria to invited foreign speakers shall not be subject to the obligation of depositing them to the ELKE or ELKEA accounts;

(d) financial report data shall be submitted to EOF, if scientific bodies from Greece are co-organising entities and the scientific events are sponsored by pharmaceutical companies operating in Greece.

**18.7** For scientific events providing information to the public, which are organised by scientific bodies, EOF's approval is not required, unless they are sponsored by pharmaceutical companies.

**18.8** The coverage by pharmaceutical companies of accommodation expenses for physicians or other health professionals participating in type A scientific events held abroad is permitted upon EOF's approval. To obtain approval for physicians' participation in such scientific events abroad, the sponsors must submit to EOF a special application form.

**18.9** The applications for the participation of physicians or health care professionals to type A events (abroad/in groups or individually) shall be submitted to EOF during the first ten days of each calendar month (**not applicable for PCOs and individuals**).

**18.10** Participation of physicians or health care professionals in scientific events in Greece

For the participation in scientific events in Greece, the sponsoring companies shall submit in the form of a report and within two (2) months after the scientific event is held, a list with the names and specialisations of the participants and the final cost per convener.

Hospitality costs include only registration fees, accommodation and subsistence costs and the travel costs for participants travelling from their place of practice to the venue of the event. Hospitality must be reasonable in terms of level and cost, in view of market prices and the main scientific objective of the event.

EOF sets limits to the costs of participation and the number of type A events in Greece and abroad which a company can sponsor for each health professional per year.

**18.11** Pharmaceutical and other companies may offer remuneration (honorarium) to HCPs invited to speak or chair meetings at Type A scientific events, provided that the organising entities inform EOF of the full name, specialty, professional body and amount of the honorary fee per speaker. Any honorarium shall be deposited to the entities foreseen by the legislation in force, which shall transfer it to the beneficiary after the appropriate deductions and, at the end of the year, issue a relevant income certificate to be used by the beneficiary for tax purposes. Physicians and other health professionals who receive honoraria for a speech in an event must mention this fact in a conflict of interest statement submitted to the organising committee of the event and, for a period of two years, (a) at the beginning of their speech and (b) in any subsequent publication, in Greek or international journals, related to any products of the company that paid the honorarium.

**18.12** The applications for all Type A, B and C scientific events and the applications for the participation of physicians or other health care professionals to scientific events abroad (Type A) must be submitted to EOF at least one month before the event takes place (for example, if an application is submitted in January, it may concern the scientific events which will take place at some time between 1 March and the end of the year).

**18.13** It is mandatory for one-day events and scientific events other than conferences organised by departments of the NHS or University Faculties to offer free admission and to be held within the prefecture in which the organising entity is located.

## **Article 19 General principles for organising conferences in Greece and abroad**

### **A. General principles for conferences held in Greece and abroad**

SFEE supports and encourages the participation of increasingly more resident physicians in all categories of training and scientific events sponsored by its members, ensuring that the continuing education it already provides can be an effective investment for the future.

Failure to comply with the following rules entails the imposition of sanctions in accordance with the SFEE Code enforcement procedure (see Chapter C).

Pharmaceutical companies are permitted to cover the participation costs of HCPs, including travel, registration, accommodation and meals, subject to approval from EOF and from their employers.

Physicians employed in NHS hospitals and Health Centres are required to obtain permission from the hospital or Health Centre; university physicians must obtain permission from the supervising authority; physicians contracted with a Social Security Organisation (paid employment) must obtain permission from the Directorate of the Social Security Organisation.

The sponsorship package for the conference offered by the pharmaceutical companies must not include the participation and hospitality costs of participant HCPs and speakers (air travel or other travel, registration fee, accommodation), nor any honoraria to persons invited to speak or chair meetings. Also, the sponsorship package shall not include: bags, notebooks, pens, badges, lanyards etc. according to the provisions of Article 14 of this Code.

Upon completion of the event, pharmaceutical companies must request from the sponsored HCP a copy of the participation certificate.

An essential prerequisite for the participation of a HCP in scientific events/conferences is the submission of a certificate issued by his/her employer, certifying that the HCP has been granted leave for educational purposes, and the completion of the special EOF form indicating the number the HCP's participations sponsored by any pharmaceutical company during the current year.

If the scientific event/conference is held on a weekend, the HCP is required to notify the employment agency of his/her participation.

HCPs are entitled to participate only in conferences related to their specialty or similar specialties.

It is not allowed to use venues that are renowned for their entertainment facilities or are extravagant (e.g. spas, resorts, casinos, etc.).

It is prohibited to organise or participate in entertainment events (excursions etc.) in connection with a scientific event

The participation of accompanying persons in any activity of the pharmaceutical company is not allowed, even if they pay for themselves. (An accompanying person means any person other than HCPs who qualify as participants in their own right).

The following cases are excluded from the said restriction concerning the maximum number of annual participations of HCPs in conferences held in Greece and abroad:

- a. HCPs in the capacity of "speaker", "chair at meetings", "member" of the organising committee or "author" of a work (listed first, second or last on a paper or poster presentation), already approved as such and announced in the event.
- b. HCPs participating in international clinical trials approved by EOF (the head of the programme and the physician conducting the trial). Investigator meetings are excluded.
- c. HCPs participating in targeted training activities e.g. participation in special workshops (training on special endoscopic or operating techniques), research seminars, single-subject training courses (e.g. European Respiratory school on monitoring airways diseases), excluding PCOs and individuals.

In all the above exceptional cases, the HCP must fill in a special application form in order to obtain special permit (EOF form). The application must include the following: full name, specialty, employer and social security number of the sponsored HCP, title and place of the activity in question, the supporting evidence of his/her participation in the activity. For participation in international clinical trials, the approving decision of EOF must also be attached.

The above information must be submitted to EOF by the pharmaceutical company undertaking to sponsor the applicant(s).

Financing of scientific events by pharmaceutical and other companies must take the form of a deposit in an account held with an accredited bank, as per the applicable Code of Tax Books and Records. This account must be opened by the Conference's Hosting Committee or by the BoD of the Scientific Society or by another institution – where applicable – in accordance with its statute, in its name. If there is written assignment to a Professional Conference Organiser (this should be mentioned in EOF's permission or, if the assignment is subsequent to the permission, it should be notified to the financing pharmaceutical companies), the deposit may be made to the account of the PCO.

#### **Limits on hospitality to HCPs at scientific events held in Greece or abroad**

Hospitality for HCPs in scientific events held in Greece and abroad must be strictly limited to the main scientific objective of the event, which supersedes the social one.

For air travel, economy class tickets must be offered, and business class tickets may be offered only if flights exceed 4 hours, if there is such a possibility.

The cost of meals per participant should not exceed EUR 70 (excluding VAT) per day abroad and EUR 70 (including VAT) per day in Greece. The same cost of meal applies also for foreign HCPs who participate in scientific events held in Greece. Accommodation costs must not exceed EUR 250 (excluding VAT) per day in 4-star hotels abroad and EUR 140 (including VAT) in Greece. In this price (EUR 140) breakfast is included. The final amount charged by the Professional Conference Organiser or the scientific society to the pharmaceutical company cannot exceed the above-



mentioned amounts. The venue must be suitable for professional events and a conference hall for these events is compulsory. For conferences held in Greece, the use of venues, and accommodation of HCPs in, 5-star hotels is prohibited.

It is permitted to hold a conference:

- all 5-star hotels located in the capitals in the prefectures of Greece, which have a conference hall, provided they meet the cost requirement under the Code as to the daily cost of accommodation (including VAT and breakfast) and subject to the provisions of seasonality;
- all 4-star hotels which fulfil the cost requirement under the Code and have a conference hall, subject to the provisions on seasonality.
- in exceptional cases, hotels located outside the capital of a prefecture, if they meet the needs of the conference and following the positive opinion of the Conferences Committee of SFEE.

In order to justify the overnight stay of the participants, a scientific programme of at least 4 hours is required. In addition, the number of stays per conference must be justified by the duration and allocation of the scientific programme.

Scientific events cannot be held in touristic destinations during the respective high seasons, i.e. during the summer season (20/6 to 15/9) and during the winter season (15/12 to 15/1), and under no circumstances in skiing destinations for the period from 15/12 to 15/3.

The same restrictions apply for Type B and C events.

The maximum financing amount per pharmaceutical company with registered office in Greece and per event may not exceed the following limits:

<b>Type of conference Type held in Greece</b>	<b>Maximum limit (including VAT)</b>
Worldwide/International*	Up to €50,000
Panhellenic Conferences (One per acknowledged specialty of the Central Health Council with a three days/8h programme for each day)	Up to €30,000
Regional Conferences (two days/ 8h programme for each day)	Up to €20,000
One-day Scientific Events (scientific programme of at least 4 hours)	Up to €10,000
Scientific events held by Hospitals, University Clinics, NHS clinics, Scientific events held by Hospitals, University Clinics, laboratories, NHS clinics, private hospitals and clinics (a programme of at least 4 hours per day)	Up to €2,500 (VAT included) per company, with a maximum limit of €10,000 (VAT included) in total for all companies

\* Organised by a foreign scientific entity alone or jointly with a scientific agency in Greece, as set out in EOF's approval.

The above maximum limits concern support to scientific events/congresses by pharmaceutical companies in the form of stands, satellite symposia, lectures, advertisement etc., as well as overall funding. These amounts do not include speaker fees or accommodation for participants. Furthermore, the conference registration fee may not exceed the historical registration fee and, in any case, for domestic conferences the registration fee should not exceed the amount of EUR 200 (excluding VAT). The EUR 200 limit does not apply for worldwide/European conferences held in Greece.

The registration fee must include at least: admission, certificate of attendance and conference material (e.g. bags, notebooks, pens, CDs, books, programme, badges, lanyards). The above cannot be included in the sponsorship package.

The participation and accommodation package for healthcare professionals may include the registration fee, the cost

of accommodation and meals and, optionally, the cost of travel and insurance.

All entities involved in hosting scientific events are recommended to prepare the relevant budgets with due prudence.

## **B. Conferences held abroad**

SFEE supports and encourages participation in conferences held in Europe only, except for certain international conferences held outside Europe that have been acknowledged by the international scientific community and are well-established in a specific field (e.g. oncology).

International conferences are those held in the US and Canada), and the number of participants per company and conference may not be larger than ten (10). Participation in big worldwide conferences of recognised scientific standing held to countries other than the US and Canada is permitted. In these cases, the maximum number of participants per company and per conference may not be larger than five (5).

As regards to European conferences, pharmaceutical companies must abide by this Code of Ethics, which has been harmonised with the respective EFPIA Code of Ethics, as well as by the Code of Ethics of the hosting country.

The maximum number of HCPs participating in international conferences held in Europe may not exceed 30 per conference per company.

Pharmaceutical companies must state the following in the application form submitted to EOF for the approval of HCP participation in a scientific event/conference held abroad: full name, specialty, employer, social security number, email address and a solemn declaration of the applicant stating the number of his/her participations sponsored by any pharmaceutical company during the current year.

HCPs may be sponsored by pharmaceutical companies for participation in a conference or a scientific event held abroad up to three times per year ( of which at least two times within Europe), subject to exceptions (a) to (c), Section A of the present article.

It is not permitted to participate in conferences held abroad when a 5 star accommodation is provided.

## **C. Conferences held in Greece**

The annual number of sponsored HCP participations in Type A scientific events/conferences held in Greece may not exceed five (5), subject to exceptions (a) to (c), Section A of the present article.

Certification of attendance of HCPs for events held in Greece:

- ☐ The conference organising entity offers computers, name lists and participant barcodes.
- ☐ Upon arrival, participants register themselves and receive an access card (e.g. full name/capacity/country and bar code).
- ☐ At the entrance of each hall there is card reader.
- ☐ If CMEs are foreseen, these are credited to the participants accordingly.
- ☐ Upon conclusion of the conference, the participant obtains a certificate of attendance, after having completed at least 60% of the total programme hours and the CME credits according to attendance. Workshops and scientific events with less than 100 participants are excluded. The HCP is responsible for submitting the certificate of attendance.

Satellite conferences sponsored by pharmaceutical companies do not entail credits.

Sponsorship of HCP participation and domestic conferences in general are permitted, provided that the event has been approved by EOF, the venue is appropriate for business purposes, has a conference hall for the event and is in line with the seasonality criterion, the daily accommodation cost does not exceed EUR 140 and the Conferences Committee of SFEE has issued a positive opinion on the conference.

Each company is recommended to draw up a list of acceptable hotels based on the above criteria. With regard to domestic conferences, the Committee for the Code of Ethics and Transparency of Article 2.1, Chapter C of the present Code issues an opinion and posts on SFEE's website a list similar to the one issued by EFPIA ([e4ethics\)\(scientific.events.sfes.gr\)](http://e4ethics.scientific.events.sfes.gr).

## **Business meals with HCPs**

It is permitted to organise business meals outside the scope of scientific events in places appropriate for the purpose of the meeting. In any case, the daily cost per meal and per person cannot exceed EUR 70, including VAT.

## **Provisions on the organisation of Type B and C scientific events**

**19.1** All agencies eligible for, and interested, in hosting Type B or C events should submit an application for approval to EOF within the first ten days of every odd -month and before the event is held. The application must include:

- (a) Name of the company (and partner scientific entity for Type B events)

- (b) Programme of the event
- (c) Time and place of the event
- (d) Initial budget

**19.2** Applications regarding Type B and C events must be submitted to EOF within the first 10 days of every odd month and no less than one month prior to the intended date of the event (e.g. an application submitted in January may cover events that will take place at some time between 1 March and the end of the calendar year).

**19.3** An essential prerequisite for the approval of Type B events requiring overnight stay is that their educational programme includes daily sessions with total duration of at least 4 hours per day. The same applies for Type C events.

**19.4** The specialty, field or clinical practice of participating physicians must be relevant to the subject of the event.

**19.5** Type C events are approved only if their purpose is to promote medicines, as specified in Joint Ministerial Decision ΔΥΓ3α/Γ.Π. 32221 (Government Gazette 1049/B/29.4.2013).

**19.6** Type B, C or D events must not be held abroad by pharmaceutical companies established in Greece.

**19.7** Hospitality for participants should not include purely entertainment events. Venues should be selected carefully and based on their conference facilities rather than recreation or entertainment facilities.

**19.8** The participation of physicians in Type C events is only allowed in the cases foreseen by the legislation in force.

**19.9** Pharmaceutical companies may grant honoraria to HCPs invited to speak or chair meetings at Type B, C and D scientific events according to the terms specified in the applicable Circular of EOF on Type A events.

Pharmaceutical companies may grant honoraria to HCPs invited to speak or chair meetings at Type A scientific events, subject to the obligation to notify EOF of the full name, specialty, employer, social security number (AMKA) and honorarium amount of each speaker.

Any honorarium shall be deposited to the entities foreseen by the legislation in force, which shall transfer it to the beneficiary after the appropriate deductions and, at the end of the year, issue a relevant income certificate to be used by the beneficiary for tax purposes.

**19.10** After the end of the scientific event and within 2 months, the pharmaceutical company must submit to EOF the final programme of the event, the number of participants, the final budget and copies of expense vouchers upon request.

## **Article 20 Promotion addressed to the public**

**20.1** It is prohibited to address promotions to the public for medicinal products supplied with medical prescription only.

This prohibition does not apply to information campaigns approved by the competent authorities.

**20.2** If individual members of the general public ask for advice on personal medical issues, they must be advised to consult an HCP.

## **Article 21 Fees for service**

Contracts between pharmaceutical companies and institutions, organisations or HCP associations under which the institutions, organisations or associations provide to pharmaceutical companies any kind of services or any kind of sponsoring not covered by Article 16 or otherwise by the present Code, are permitted only if such services (or any other sponsorship): (i) are provided with the aim to support healthcare or research; and (ii) do not constitute an inducement for the parties involved to prescribe or supply specific medicinal products.

## **Article 22 Provision of Consulting Services or similar collaborations between HCPs and the Pharmaceutical Industry**

**22.1** Subject to the relevant provisions that apply to NHS physicians and university physicians, and also subject to Article 6, paragraph 4 of ILw 3418/2005 (Government Gazette 287/A/2005) on the Code of Medical Ethics, pharmaceutical companies may request from physicians the provision of advisory services or expert services or other similar services that are directly related with their specialty.

**22.2** The provision of such services must not jeopardise the clinical independence of the advisor or of the collaborating physician, who must always be bound by the ethical obligation to take independent medical decisions and exercise the medical profession for the benefit of patients. The service provided by the HCP must cover a verified scientific/research need for the pharmaceutical company.

**22.3** The collaboration/service shall be governed by an agreement between the pharmaceutical company and the collaborating HCP. Any honorary fee shall be deposited to the entities foreseen by the legislation in force, which shall transfer it to the beneficiary after the appropriate deductions and, at the end of the year, issue a relevant income certificate to be used by the beneficiary for tax purposes. In any case, HCP fees must be paid as described above and not through third parties (e.g. scientific societies).

**22.4** When the physicians-advisors present views or results to third parties concerning the medical/ pharmaceutical part of their advisory services, a declaration of interest/conflict of interest statement must be presented, in order to ensure transparency towards all parties involved.

**22.5** Pharmaceutical companies may engage HCPs as experts or scientific advisors either individually, for services such as lectures and chairmanship at scientific meetings, employment in medical/scientific studies, clinical trials or educational services, participation in meetings of advisory bodies and participation in market research, where such participation includes remuneration and/or coverage of travel expenses.

For market research among HCPs, Article 24 of the present Code shall apply.

The arrangements for those advisory services must meet all the following criteria:

**(a)** Prior to the commencement of services, a written contract must be signed, specifying the nature of the services to be provided, subject to point (g) below, the basis for payment of those services.

**(b)** Before services are requested and respective agreements are signed with the experts, a legitimate need for those services must have been clearly identified. **(c)**

The criteria for selecting experts must be directly related with the identified need, and the persons responsible for selecting the experts must have the experience necessary to assess whether the particular HCPs meet those criteria.

**(d)** The number of HCPs who will provide services must not be greater than the number that is reasonably necessary to achieve the identified need.

**(e)** The contracting pharmaceutical company must keep records of the services provided by the experts.

**(f)** The payment of a fee to the HCP in return for the service provided must not constitute an inducement to prescribe, sell or supply a specific medicinal product; and

**(g)** The compensation for the services must be reasonable and correspond to the level that is usual for those services (see Annex I concerning the indicative calculation of HCPs' remuneration for services provided to pharmaceutical companies). Therefore, token consultancy arrangements must not be used to justify any amounts paid to HCPs for unlawful purposes. Pharmaceutical companies are invited to use internal processes and establish scales of fair market value for payments made with regard to standard services and HCP categories, considering the status/rank of the HCP, the time of engagement (preparation and participation) and the type of service provided.

**(h)** HCPs must be selected on the basis of their qualifications and capacity to provide the service required. The criteria for selecting a HCP may include:

Clinical experience in the treatment, in the product and/or in the relevant scientific issue

Scientific reputation

Academic work

Publications

**(i)** A maximum annual limit is set per HCP for the provision of services to a pharmaceutical company. The maximum annual fee may not exceed EUR 5,000, excluding VAT and further deductions. Any amounts concerning payments for the conduct of clinical research are not included. The above limit does not include fees for services rendered abroad and paid for by foreign companies.

In their written contracts with the experts, pharmaceutical companies are strongly encouraged to include provisions regarding the obligation of experts to declare their contractual relationship with the pharmaceutical company whenever they write or speak in public about a matter that is the subject matter of the agreement with the pharmaceutical company or any other issue related to that company. Similarly, pharmaceutical companies employ, on a part-time basis, HCPs who continue practising their profession, are strongly encouraged to ensure that those persons are obliged to declare their employment arrangement with the pharmaceutical company whenever they write or speak in public about a matter that is the subject of the a of the employment or any other issue related to that company.

Meetings held with a small number of physicians, in order to provide their opinions on scientific issues (scientific advisory boards), get updated on newer data about clinical trials in which they participate as investigators (investigator meetings) and/or contribute their acknowledged experience on scientific issues, i.e. illnesses, epidemiological data, etc. (consultant meetings) and are organised by the medical affairs department of a company do not require approval from EOF, provided that the scientific aspect supersedes the social one.

## **Article 23 Patient Education and Support Programmes**

The key requirements that must be met are:

i. Observance of the Pharmacovigilance obligations

ii. Observance of the law on sensitive personal data

iii. The purpose and description of the programme must be consistent with the SPC, and the programme must not be

promotional

iv. The use of printed instructions to the HCPs participating and the patients must comply with the applicable laws and the circulars of EOF on medical information and advertisement.

v. The Medical affairs departments of the companies must be responsible for the approval and/or supervision of programmes

Programmes may be implemented by means of outsourcing to third-party providers, authorised by the Data Protection Authority.

#### **Article 24 Market research**

Market research refers to any organised effort to collect information about the market and consumers of products or services.

Market research is a valid method for recording the data and characteristics of the pharmaceutical market.

Market research can be conducted:

☐ either through questionnaires to which subjective answers are given by a sample that is representative of the reference population, i.e. the HCPs;

☐ or through questionnaires given to groups comprising a representative sample of the population under examination (focus groups - qualitative market research), i.e. the HCPs, in order to obtain a synthesis of answers.

Market research must be unbiased, must not be focused on promoting sales, and must not aim at influencing the opinion of the participating HCPs.

In each market research, care must be taken to ensure the random and representative selection of the participating HCPs.

The data collected from HCPs and referring to patients must be in aggregate form. No personal patient data must be collected during market research, since this is regarded as a non-interventional/pharmaco-epidemiological study, governed by the rules described in Article 26 of the present Chapter of the Code.

Market research does not include any patient enrolment and/or randomisation.

Market research cannot be retrospective/prospective; it is a snapshot.

Information and statistical results of market research may be used for promotional purposes, provided that the identity of the research (who, when, where, which sample) is clearly stated. In any case, the collection and the use of research data must be clearly distinct processes.

Market research must be conducted in a manner that does not affect the credibility and reputation of the pharmaceutical industry.

Market research is usually conducted by certified market research companies, which must abide by the principles of ESOMAR/ EphMRA (European Society of Market Research, <http://www.ephmra.org>).

When the collection of data in the context of market research is conducted by a pharmaceutical company, the principles of ESOMAR/EphMRA should be followed. In this case, no fee is provided for HCPs participating in the research.

Medical sales representatives may not be involved in the conduct of market research.

When pharmaceutical companies enter into contracts with market research companies, they may grant to Healthcare Professionals a reasonable compensation with regard to the time spent, which may not in any case exceed two hours.

#### **Article 25 Interventional Clinical Trials**

**25.1** Collaboration between the pharmaceutical industry and physicians in carrying out clinical interventional trials is of crucial importance for the development of medicinal products, thorough knowledge of their properties and their optimal use in the best interest of patients.

**25.2** In interventional clinical trials, the following principles must be applied:

**a)** All persons participating must respect the ethical and professional principles and guidelines, such as the Helsinki Declaration and ICH guidelines for Good Clinical Practice.

**b)** Each interventional clinical trial must have a relevant scientific and therapeutic purpose. It must not be performed with a view to increasing sales or prescribing. The purpose of the trial must always be the improvement of therapeutic, diagnostic methods and/or medical knowledge in the best interest of patients.

**c)** The purpose of the interventional trial must be declared in advance. Trial protocols must be compiled in such a way as to ensure achievement of the objective of the trial and valid conclusions.

- d)** Interventional clinical trials are carried out only upon approval by the competent authorities (National Organisation for Medicines - EOF) and the National Ethics Committee.
- e)** The sponsor must be known to patients participating in the trial.
- f)** The physician must not receive any remuneration or compensation for the mere inclusion of patients in interventional clinical trials.
- g)** The physician may receive remuneration for his/her work in the interventional trial. Remuneration must be given in connection with the work provided and must be notified to the National Ethics Committee and the National Organisation for Medicines (EOF) supervising the trial. Remuneration must not be connected with the expected outcome of the trial. Remuneration shall be effected either by means of special ELKE or ELKEA accounts or by means of legal invoices for the provision of services, where applicable.
- h)** All data on safety and efficacy with respect to medicinal products must be truthfully published on the internet - at least in summary - irrespective of the trial outcome, within one year following trial completion. Other important clinical results must also be published in the same way.
- i)** In publications, lectures and other presentations, the identity of the sponsor must be known.
- j)** The physician may receive remuneration for lectures relating to the interventional clinical trial and the results thereof.
- k)** When presenting interventional clinical trials, the physician must make known his connections to all pharmaceutical companies of the therapeutic area covered by his/her lecture.

**25.3** A necessary condition for the acknowledgement of any clinical trial or investigation is documentation through corresponding scientific results or findings.

#### **Article 26 Non-Interventional Trials / Pharmaco-Epidemiological Studies**

**26.1** A non-interventional/pharmaco-epidemiological study of a marketed medicinal product is a trial in the course of which the medicinal product is prescribed in the usual way according to the terms of the marketing authorisation. The allocation of patients to a specific therapeutic strategy is not decided a priori by the trial protocol, but falls under the current practice, and the prescription of the medicinal product is clearly distinct from the decision to include a patient in the trial. No further diagnostic or follow-up procedure will be applied on the patients, and epidemiological methods will be used to analyse the data collected according to the principles of Vol 9A.

**26.2** Non-interventional/pharmaco-epidemiological studies for medicinal products of prospective or retrospective nature, involving the collection of patient data by a HCP or under his/her authorisation or by groups of HCPs specifically for this trial, must comply with all the following criteria:

- a)** The trial is conducted for a scientific purpose.
- b)** (i) There is a trial protocol and (ii) there are written contracts between, on one hand, the HCPs and/or the institutions where the trial shall be conducted and, on the other hand, the pharmaceutical company which is sponsoring the trial, defining the nature of the services to be provided and the basis for compensation of such services under point (c) below.
- c)** Any compensation provided must correspond to the value of the service offered.
- d)** The trial protocol must be submitted for evaluation to the competent committees (scientific or ethics committees) and uploaded to an online registry of clinical trials, freely accessible by the public.
- e)** Confidentiality of personal data, including the collection and use of personal data, is subject to the provisions in force.
- f)** The trial must not constitute an inducement to prescribe, sell or supply a specific medicinal product.
- g)** The trial protocol must be approved by the scientific service of the pharmaceutical company, and the trial must be monitored by the scientific service of the pharmaceutical company, as described in Article 15 of the present Chapter of the Code.
- h)** Before the beginning of a trial, its basic characteristics must be recorded in a special registry freely accessible by the public.
- i)** Trial results must be analysed by the contracting pharmaceutical company or under its authorisation and the summaries of this analysis must be made available to the company's scientific service within a reasonable time period (as described above in the Article 15 of the Code). The said service must keep record of these reports for a reasonable period of time. The pharmaceutical company must send a brief report to all HCPs participating in the trial and must record it to a special registry of non-interventional/pharmaco-epidemiological studies. Should significant results for the benefit-risk assessment arise from the trial, the brief report must be promptly forwarded to the National Organisation for Medicines (EOF).
- j)** Medical sales representatives may not be involved in the conduct of the trial.

**26.3** The only type of non-interventional/pharmaco-epidemiological studies which will henceforth be submitted to EOF are the non-interventional post-authorisation safety/efficacy studies required by the competent authority either upon or later than the granting of the marketing authorisation and which are subject to EOF's prior approval.

**26.4** To the extent practicable, pharmaceutical companies are encouraged to comply with Article 26.2 for all other types of trials covered by Article 26.1 of the present Chapter of the Code, including epidemiological trials and registries and other trials that are retrospective in nature. In any case, such trials are subject to Article 21 of the present Chapter of the Code.

**26.5** Further details on the special Registryr where the non-interventional/pharmaco-epidemiological trials shall be recorded, as well as on the criteria and conditions that must be fulfilled by the non-interventional/pharmaco-epidemiological trials are provided in Annex II of the present Code.

## **Article 27 Internet-Digital Applications**

There are various types of promotional material provided via the internet. The most frequently used types are the following:

Websites

Digital presentation of «eDetailing» Promotion Forms

E-Newsletter/E-mailing to HCPs

Social Media

In any case, the current legislative and regulatory framework must be applied, as established by pharmaceutical laws and the relevant circulars of EOF, as well as legislation governing personal data protection and copyrights.

As for any type of promotional material, digital material must:

Be subject to the standard procedures of each company, so as to be controlled/certified by the competent company departments (legal department approval may also be required, apart from the scientific department approval);

Be submitted to EOF, if it falls into the scope of the relevant provisions.

Below follows a detailed description of indicative management methods for each type of promotional material.

### **Websites**

#### **Website types**

##### **1. Websites of Pharmaceutical Companies addressed to the public**

**a. The main corporate website** that can include the profile, history and news on the social activity of the company, as well as a list of products with the respective approved package leaflet.

It may also include texts informing the public on prevention and health issues, but it must not connect them with the respective medicinal products that might be offered and/or their package leaflets.

The material included must be primarily approved according to the internal procedures of the company. The same applies for any change or addition to the website.

The texts and pictures, as well as any material revision thereof, must be submitted to EOF in accordance with Circular 43631 /14-6-2012 (and its future amendments, if any) and comply with such Circular (see b(I) to b(VI) below).

**b. Websites of pharmaceutical companies including exclusively informative texts on prevention and health issues.** The texts and pictures, as well as any material revision thereof, must be submitted to EOF in accordance with circular 43631 /14-6-2012 (and its future amendments, if any) and comply with such Circular i.e.:

I. There will be no direct or indirect promotion of medicinal products. Therefore, there will be no references to trade names and/or names of active substances of medicinal products, nor any references to therapeutic options connected to general pharmacological groups.

II. Texts and information will be quoted in a neutral and objective manner with precise reference sources.

III. A phrase to the following effect: "This is intended for general information purposes and is no substitute for advice from a physician or another competent HCP" will be included.

IV. The sources of the information included will be kept on record by each pharmaceutical company and be made available to EOF, upon request.

V. For reasons of transparency and responsibility, there will be clear reference of the pharmaceutical company responsible for providing the information. No disclaimer by the pharmaceutical company is permitted for the information included in the information campaign.

VI. The texts and graphs prepared will be signed by the physician of the pharmaceutical company in charge, whose



name will be notified to EOF.

## **2. Websites of Medical Societies addressed to the public, including texts for public information on health prevention-promotion issues and financially supported by a pharmaceutical company.**

Texts and pictures, as well as any substantial updating thereof, must be submitted to EOF in accordance with Circular 43631 /14-6-2012 (and its future amendments, if any) and comply with such Circular. Medical Companies websites may include references to therapeutic options – but not any direct or indirect promotion of medicinal products – under the following conditions:

All currently available therapeutic options, pharmaceutical or not, applied alternatively or supplementarily, must be mentioned (e.g. proper nutrition, exercise, surgical intervention, etc.).

Pharmaceutical options references must extend up to the level of the pharmacological group.

The name of the Medical Societies will be referred and, in a less conspicuous position, the name of the pharmaceutical company sponsoring the website.

As for the rest, the provisions laid down in points b(II) to b(IV) of the present section apply.

## **3. Websites exclusively addressed to HCPs and concerning medicinal products supplied with or without prescription and/or other scientific issues**

Measures must be adopted in order to ensure that only those professionally dealing with health issues will have personal access via a user name and a password.

Access details may be granted to a specific HCP population, fully controlled by the pharmaceutical company or, alternatively, registration at the website must be permitted, so as to enable periodic qualitative credibility control of the system by the pharmaceutical company.

In any case, the material included in such corporate websites must be primarily approved in accordance with the internal procedures of the company, as is the case with the promotional material. The same applies for any change or addition to the website.

The material posted must comply with the respective provisions on the promotion of medicinal products (case law and Article 11 of the present Chapter of the Code), be certified by the company's Scientific Department and be notified to EOF 8 days after the date it is first posted.

The approved SPC of the products must be accessible, posted in a visible place on the website and updated after every revision.

In addition, attention is drawn to the following:

- a) In the case of interactive communication with the HCPs and collection of personal data, this must be performed in accordance with the applicable legislation and with the consent of the HCPs (a relevant record must be kept by the pharmaceutical company).
- b) In the case of accompanying questions digitally recorded with free text fields and, if these fields fall into the category of market research, they must be approved in accordance with the respective clause of the present Chapter of the Code.
- c) Special care must be taken to ensure pharmacovigilance and adverse reaction reporting – within the time periods provided for by the law, as appropriate – through the special platform and the yellow card, either in printed or in digital form. Clear indication of the contact details of the respective pharmacovigilance department is required.
- d) Copyright protection, when content is used whose copyrights are not owned by the person in charge of the website.
- e) If the website offers a functionality that qualifies as a medical technology product; the relevant legislation must be taken into account.
- f) If links to other (third-party) websites are included, the user must be clearly informed that he/she is led away from the company's website.
- g) For the use of website cookies, permitted only with the user's consent and after he/she is properly informed according to the legislation in force (excluding the cases set out in Opinion 4/2012 of the Working Party of Article 29, EU Directive 95/46).**

### **Digital presentation of Promotional Material “eDetailing”**

eDetailing is the presentation of digital promotional material - or eDetails - via electronic media (including, but not limited to, the Web, CDs, Videos, Webcasts, tablet PCs, Smartphones) to HCPs in the context of promotion and provision of information.

eDetails must be sent only to those categories of HCPs who need them or that are concerned or for whom they are purported. Pharmaceutical companies are obliged to regulate the distribution frequency of eDetails in a manner that



corresponds to the need for essential information.

eDetails follow the certification procedure set out in Article 11 (Certification of Promotional Material) of the present Chapter of the SFEE Code and submission to the National Organisation for Medicines, as described in Article 11 of the present Chapter of the Code, can be performed digitally through the Web or digital storage media.

During the conduct of eDetailing activities, care must be taken: (a) to treat any sensitive personal data in accordance with the applicable laws; (b) to ensure pharmacovigilance in the case of accompanying questions digitally recorded with free text fields; (c) to respect copyrights when the marketing authorisation holder of the medicinal product is not the copyright owner of content used; (d) to consider the case that the eDetail might be characterised as a medical device; (e) to ensure clear communication with the pharmacovigilance department of the marketing authorisation holder of the medicinal product; and f) in case the eDetail can be characterised as a promotional gift in the sense of Article 14 of the present Chapter of the Code (Informational and Educational Material and Medical Use Material).

For the purposes of safeguarding transparency and trust in the medical sales representative profession, the following rules must be observed:

- The approval of the promotional material included in the electronic media (iPad, iPhone, etc.) must comply with Chapter VIII of Ministerial Decision ΔΥΓ 3α/Γ.Π 32221 (Government Gazette 1049/B/29.4.2013) implementing Directive 2001/83 as amended, the respective article of the present Chapter of the SFEE Code of Ethics and the relevant circulars of EOF.
- The Marketing Authorisation Holder must have ensured that the electronic material “locks”, so as to avoid potential connection with the HCP’s electronic devices and sharing of non-approved material.
- The Marketing Authorisation Holder must also take all necessary measures to:
  - prevent free access to websites during the promotional visit;
  - prevent downloading of non-approved material and provision thereof to the HCP;
  - ensure that the promotional material contained in the electronic media indicates in readily visible and accessible part of the first/home page the latest Summary of Product Characteristics (SPC), which may become available to the HCP upon request;
  - ensure, if the promotion involves the provision of gifts or software applications, that these comply with the respective article of the present Chapter of the SFEE Code of Ethics;
  - keep record of the electronic promotional material in accordance with the internal archiving procedures of the Marketing Authorisation Holder.

The procedure for submitting electronic promotional material to EOF remains the same. Electronic submission is encouraged.

EOF reserves the right to perform ex officio or unscheduled audits on the electronic promotional material.

## **E-Newsletters/E-mails to HCPs**

### **1. Upon the request of the HCP**

Please refer to the respective section of this manual on Medical Information (article 4 of the present Chapter of the Code).

### **2. Unsolicited (on the initiative of the pharmaceutical company)**

#### **GENERAL**

The regular supply of information to HCPs via e-mail on the initiative of pharmaceutical companies is permitted provided that (general requirements applying to Articles 2.A & 2.B below):

1. The recipient HCPs have consented in writing or electronically to receive such type of information by e-mail or by any other medium (the nature of information and the type of the medium must be stated in the written consent). Consent documents are kept on record.
2. The pharmaceutical company observes all obligations with regard to personal data.
3. Messages sent include an opt out feature, so that if the HCP no longer wishes to receive such information, he/she can be removed from the mailing list.
4. In the case of interactive messages, i.e. where the HCP can reply, care must be taken to ensure appropriate collection, recording and reporting of queries. If this is not possible, the dispatch must be performed in a manner that prevents replies (no reply).
5. In all messages, the recipient must be clearly informed that the specific message is exclusively addressed to HCPs, he/she receives it because he/she has agreed to and that the pharmaceutical company may not be held liable for the dispatch of the message to non-HCPs. The type of dispatch must be carefully planned beforehand by the

pharmaceutical company.

**6. Pharmaceutical companies are required to regulate the frequency of eNewsletters in a manner corresponding to the need for essential information per therapeutic category.**

**2.A. From the Scientific/Medical Affairs Department**

The periodic dispatch of messages including **literature updates** on the initiative of pharmaceutical companies may be performed only by the scientific/medical affairs department following internal approval by the head of that department in accordance with the standard procedures of each pharmaceutical company.

The content of the eNewsletter must refer to data on a disease and the approved medicinal products of each company and not to data on competitors' products.

The unsolicited dispatch of literature updates regarding uses outside the indications stated in the package leaflet is not permitted. Such literature update is only permitted as a reply to a question formally asked by an HCP and documented by the company and may only be performed by the Medical Information or the Medical Affairs Department (see previous section).

Treating physicians may further request and obtain the full publication, subject to all relevant legislative and regulatory requirements.

In any case, the procedure for the acquisition of the rights on the articles sent must be followed, depending on their use.

**2.B. From the Marketing Department**

All messages sent by the Marketing Department constitute eDetailing promotional material (medical information) and the provisions of the respective article of the Code shall apply.

**Medical information** messages may be sent by the Marketing Department, provided that all requirements applicable for promotional material are met (including consistency with the indications, certification by the scientific/medical affairs department of the company and notification to EOF within 8 days from their first dispatch).

**In any case, the procedure for the acquisition of the rights on the articles sent must be followed, depending on their use.**

**Social Media**

**Using social media – Facebook and Twitter**

The use of social media is continuously growing and both consumers and HCPs use these channels as means of information for health-related issues.

Social media such as Facebook and Twitter enable pharmaceutical companies to establish interactive communication with a wide public of consumers and HCPs and can prove very effective information and communication tools. Nevertheless, the use of social media must be examined carefully in terms of quality assurance and validity and purpose of the information provided.

**KEY PRINCIPLES FOR THE MANAGEMENT OF POTENTIAL RISKS ENTAILED BY THE USE OF SOCIAL MEDIA**

**Social media management:**

In any case, the decision to create corporate Facebook pages/ Twitter accounts and the approval of their content must go through the internal approval procedure of each company by an authorised team comprising members from all departments involved (e.g. Medical Affairs, Pharmacovigilance, Marketing, Compliance, Legal Department, E-business, Communications), so as to ensure the quality and validity of the information transmitted outwards in accordance with the principles of the present Chapter of the SFEE Code of Ethics for the promotion of medicinal products, as well as with the applicable legislative provisions on information and promotion of medicinal products to healthcare professionals by pharmaceutical companies and on public information with regard to diseases.

Only the staff authorised by the management of each company to conduct external communications (e.g. members of the Communications Department) may contact consumers or HCPs on behalf of the company via Facebook or Twitter.

Facebook pages/ Twitter accounts of pharmaceutical companies must be created via a Facebook profile/ Twitter account for professional and not for personal use.

An alternate “administrator” must be appointed for every pharmaceutical company officer authorised to manage the company's Facebook pages/ Twitter accounts, so as to ensure constant compliance with the principles, procedures and standards governing the use of Social Media.

Corporate Facebook pages and Twitter accounts must be constantly updated and any pages inactive for a period exceeding 6 months must be deactivated by the main administrator.

### **Transparency assurance:**

All corporate Facebook pages and Twitter accounts must clearly state their association with the respective company via the name of the page/account or the use of a brand/corporate logo.

Third parties who may communicate on behalf of a company must accompany their communication with a disclaimer notice, approved by the legal department of the company.

### **Approved Content and Disclaimer Notice:**

Any communication material used in social media which concerns pharmaceutical products must be approved through the standard approval procedures of each company and must be governed by the principles of Article 4 (Medical Information addressed to healthcare professionals) of the present Chapter of the Code.

Any communication material used in social media aimed at informing the public on diseases must comply with EOF Circular No. 43631/14.06.2012.

The communication of information not included in the approved indications of the medicinal products is prohibited.

All corporate Facebook pages and Twitter accounts must be submitted along with their content to EOF for approval before publication, and EOF will, in turn, notify its approval or not within 30 days.

All corporate Facebook pages and Twitter accounts must include clear instructions explaining the manner in which Adverse Effects must be reported, as well as the contact details of the respective Pharmacovigilance Department of the Marketing Authorisation Holder of the medicinal product.

Corporate Facebook pages/ Twitter accounts must include a "Terms of Use" statement, approved by the Legal Department, substantially in the form of the following template:

### **TERMS OF USE FOR FACEBOOK/TWITTER**

The company [ ] follows Facebook/Twitter rules, as well as its own rules for the posting of information and comments. The company [ ] reserves the right to remove comments, graphs, videos, pictures and any other content which:

- is defamatory;
- violates the copyrights of another party;
- promotes illegal actions;
- is misleading;
- contains offensive, improper, disrespectful or threatening comments;
- is spam or intends to technically disrupt this page;
- provides non-approved medical information;
- is irrelevant with the subject matter.

The company [ ] reserves the right to restrict access to this page to any person who repeatedly makes comments that fall into the above categories.

The company [ ] is not responsible for the validity of any views, information, advice or comments on this page, which have not been directly communicated by the company.

If you notice any adverse effect during the use of this product, please inform your physician and contact us at [contact number].

### **Reporting Adverse Effects**

All corporate Facebook pages and Twitter accounts must be checked at least every 24 hours, 7 days a week, for possible reporting of adverse effects and violation of the terms of use.

### **Personal Data**

When personal data are collected, the consent of the persons to whom the personal data refer must be obtained through the consent application provided by Facebook and Twitter, and the manner in which such data will be used by the company must be clearly explained.

Any Personal Data collected via Facebook or Twitter must be handled in accordance with the applicable law and the internal procedures of pharmaceutical companies.

### **Article 28 Compliance with the Principles of the Code**

For all their activities falling within the scope of application of the present Chapter of the Code, pharmaceutical companies are obliged to ensure compliance with the provisions thereof.

## CHAPTER B

### DISCLOSURE OF TRANSFERS OF VALUE BY PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

#### INTRODUCTION

Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) with whom pharmaceutical companies work, provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and scientific experience. This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and society at large. Healthcare Professionals and Healthcare Organisations should be fairly compensated for the legitimate expertise and services they provide to the industry.

Medicinal products developed by the industry are complex products designed to address the needs of patients. In parallel, the pharmaceutical industry supports the education of HCP about medicines and the diseases they treat, to the benefit of patients. The pharmaceutical industry sponsors high-caliber scientific events for the education of HCPs and the exchange of knowledge among HCPs and the industry.

SFEE believes that interactions between the pharmaceutical industry and HCPs have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a HCP to prescribe a medicine is one of the pillars of the healthcare system. SFEE recognises that interactions between the industry and HCPs can create the potential for conflicts of interest. Consequently, SFEE adopted the present Chapter of the Code of Ethics and other guidelines (reflected in the relevant Q&As) to ensure that these interactions meet the high integrity standards that patients, the state and other stakeholders expect.

In the context of the European Commission initiative on Ethics and Transparency in the pharmaceutical sector, the industry's self-regulation must respond to the growing need of society for more integrity and transparency, in order to continue to be effective.

This Chapter of the Code requires the detailed disclosure of the nature and size of any transfer of value to HCPs and HCOs. In this manner, SFEE aims to ensure transparency and build confidence in the relationships of its member pharmaceutical companies with HCPs and HCOs.

This Chapter of the Code shall take effect from 1 January 2016, starting with the disclosure of transfers of value made during the calendar year 2015.

#### SCOPE OF THE CODE

The present Chapter of the Code governs the disclosure of transfers of value effected by pharmaceutical companies (whether resident in Greece or abroad) to HCPs and HCOs resident in Greece. The present Chapter applies in parallel with Chapter A of the Code and the "SFEE Code of Ethics for the Relationships between Pharmaceutical Companies and Patient Associations". Consequently, it applies to all SFEE member companies. Pharmaceutical companies which are not members of SFEE may voluntarily adhere to this Chapter of the Code, if they so wish, by submitting a declaration to this effect to the President of SFEE. Such companies will be set out in a separate list, which shall be updated regularly and shall constitute part of the Code. All articles of the Code shall fully apply to the said companies.

The definitions at the end of this Chapter constitute an integral part of the Code.

#### ARTICLE 1 DISCLOSURE OBLIGATION

**Section 1.01. General Disclosure Obligation.** Subject to the terms of the present Code, each Member Company shall document and disclose all Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 3. A condition for the disclosure is the written consent of the recipient. If the recipient does not consent to the disclosure of the transfer of value, the pharmaceutical company shall make an aggregate disclosure. The recipient may on serious grounds revoke in writing his/her consent once given.

**Section 1.02. Exclusion from the Disclosure Obligation.** Excluded from the scope of the disclosure obligation described in Section 1.01 of this Code are transfers of value that: (i) are solely related to over-the-counter medicines;

(ii) are not listed in Article 3 of this Code, such as meals and drinks (see Article 19, Chapter A of the Code), medical samples (see Article 13, Chapter A of the Code) and medical utility items of insignificant value set out in Article 14, Chapter A of the Code; and

(iii) are part of ordinary course purchases and sales by and between pharmaceutical companies and HCPs engaging in the business of medicine trading (such as pharmacists, wholesalers) and/or HCOs, i.e. financial transactions within the distribution chain of medicinal products.

#### ARTICLE 2 FORM OF DISCLOSURE

**Section 2.01. Annual Disclosure Cycle.** Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the "Reporting Period"). The first Reporting Period shall be the calendar year 2015 and the first disclosure shall take place in 2016.

**Section 2.02. Time of Disclosure.** Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period and the information disclosed shall remain available in the public domain for a minimum of 3 years after the time such information is first disclosed in accordance with Section 2.04.

**Section 2.03. Disclosure Template.** Subject to Section 2.04, disclosures shall be made using a standardised template which is consistent with the provisions of the present Chapter of the Code.

**Section 2.04. Platform of Disclosure.** Disclosures shall be made on SFEE's website by every Member-Company in accordance with Section 2.05, and shall be unrestricted and publicly available. Disclosure of all data shall be effected on 1 July of each year or on the first business day following that date, on SFEE's platform.

**Section 2.05. Applicable National Code.** Disclosures for all HCPs and HCOs resident in Greece shall be made pursuant to the present Code. If a pharmaceutical company is not resident or does not have a subsidiary or an affiliate in Greece, it shall disclose such transfers of value to HCPs or HCOs resident in Greece in a manner consistent with the present Chapter of the Code.

**Section 2.06. Language of Disclosure.** Disclosures shall mandatorily be made in the Greek language.

**Section 2.07. Documentation and Retention of Records.** Each Member Company shall document all Transfers of Value required to be disclosed pursuant to Section 1.01 and maintain the relevant records of the disclosures made under this Code for a minimum of 5 years after the end of the relevant Reporting Period.

### ARTICLE 3 INDIVIDUAL AND AGGREGATE DISCLOSURE

**Section 3.01. Individual Disclosure.** Except as expressly provided by this Chapter of the Code, transfers of value shall be disclosed on an individual basis. Each Member Company shall disclose, on an individual basis for each clearly identifiable recipient (name, surname, Tax Registration No), the amounts of transfers of value to such recipient in each Reporting Period which may be reasonably allocated to one of the following categories.

#### 1. Transfers of value to HCOs related to:

**a. Donations and grants:** Any kind of donation or grant (either cash or benefits in kind) governed by with Article 16, Chapter A of the Code.

**b. Sponsorship of Events:** Sponsorships of events organised by HCOs or PCOs such as:

i. Group registration fees for HCPs (when participating HCPs are not selected by the sponsor, but by the organising entity); ii. Amount of sponsorship, as specified in agreements with HCOs or third parties appointed by an HCO to manage an event, provided that the sponsorship is not intended for a specific HCP.

**Note:** Any costs related to the participation of a HCP in a conference in a special capacity (speaker, moderator, etc.) referred to in the sponsorship agreement between the company and the organising entity of the event, shall be published on an individual basis by the sponsor company (after the signing of the relevant agreement), taking into account the relevant restrictions.

**c. Fees for service and consultancy.** Fees resulting from or related to contracts between Member Companies and HCOs, under which HCOs provide any type of services to a Member Company or any other type of funding not covered in other categories (e.g. fee for service and consultancy which is payable directly to a HCP). Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

#### 2. Transfers of value to HCPs related to:

**a. Events,** such as:

i. Registration fee

ii. Travel and accommodation expenses (*to the extent permitted by Article 19, Chapter A of the Code*).

**b. Fees for Service and Consultancy.** Fees resulting from or related to contracts between Member Companies and HCPs, under which HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

**Section 3.02. Aggregate Disclosure. Payments related to Research and Development activities.** Transfers of value which cannot be disclosed individually, due to a lack of the recipient's consent or revocation of consent once given, shall be disclosed on an aggregate basis. In addition, transfers of value concerning Research and Development activities for each Reference Period shall be disclosed by each Member Company on an aggregated basis. Costs related to events that are auxiliary to activities falling within the scope of this section (e.g. investigator meetings) shall be disclosed on an aggregate basis.

**Section 3.03. Non Duplication.** Where a transfer of value required to be disclosed pursuant to Section 3.01 or 3.02 is made to an individual HCP indirectly via an HCO.s, such transfer of value shall only be disclosed once. To the extent possible, such disclosure shall be made on an individual basis, indicating the name of the HCO in accordance with

Section 3.01(2).

**Section 3.04. Methodology.** Each Member Company shall publish a note summarising the methodology applied for the disclosure and identification of transfers of value for each category described in Section 3.01. The note, which shall include a general summary, shall describe the methodology applied and include the handling approach of multi-year contracts, VAT and other tax issues, currency issues and other issues related to the timing and amount of Transfers of Value for the purposes of the present Chapter of the Code.

#### ARTICLE 4 ENFORCEMENT

**Section 4.01. Applicability and Sanctions.** The provisions of the present Chapter of the Code are binding on Member Companies. Non-compliance with such provisions shall entail the imposition of sanctions provided for in Section 4.02 below. Chapter C of the present Code on the complaints procedure shall apply by analogy.

**Section 4.02. Sanctions.** The First-Instance Committee of Article 1, Chapter C (Compliance Monitoring Process) of the present Code, if, after examining an allegation/complaint received by it rules that there is a violation of Articles 1, 2 and 3 of this Chapter B of the Code, may impose to the non-compliant SFEE member company- the following sanctions, which shall be enforced after the period for referring the case to the Second-Instance Committee has elapsed without effect or after the issuance of the decision of the Second-Instance Committee, unless the respondent accepts the violation or part thereof:

(a) Prompt publication of the text of the decision on SFEE's website.

(b) A financial penalty of up to EUR 25,000. This amount shall be deposited by the pharmaceutical company to a dedicated bank account held by SFEE. The Second Instance Committee of Article 1, Chapter C of the present Code may impose to a SFEE member company that does not comply with the decision of the First Instance Committee a financial penalty of up to EUR 50,000, further to the sanctions mentioned above. These amounts shall be deposited by the pharmaceutical company to a dedicated bank account held by SFEE, not later than 30 business days of the date of issuance of the decision.

In the event that the SFEE member company has not complied, or has not properly complied, with the sanction imposed on it by the Second Instance Committee, the Second Instance Committee shall meet upon request of the complainant and shall decide on further sanctions, which may amount up to three times the initially imposed sanction.

In the event that the SFEE member company still fails to comply with the decision of the Second Instance Committee, the latter shall refer the issue to the Disciplinary Board of SFEE, which may decide the expulsion of the member.

#### Definitions used in Chapter B regarding the Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations

##### Donations and Grants

Collectively, means donations and grants (either cash or benefits in kind) for the promotion of prescription and non-prescription medicinal products..

##### Events

All promotional, scientific or professional meetings, congresses, conferences, board meetings, symposia and other similar events that are not associated with Research & Development (including, but not limited to, advisory board meetings, focus groups, type A, B, C & D events in accordance with EOF Circulars, as applicable from time to time, on scientific events) organised or sponsored by or on behalf of a company (Articles 17, 18 and 19, Chapter A of this Code).

##### Healthcare Professionals (HCPs)

Any natural person that is a member of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Greece. For the avoidance of doubt, the term "Healthcare Professional" includes: (i) any official or employee of a government agency or other organisation (whether in the public or in the private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a SFEE Member Company whose primary occupation is that of a practising HCP. This latter category excludes: (a) all private physicians having a lasting collaboration with a SFEE member company SFEE under an employment contract, an agency contract agreement or contract for work; and (b) all wholesalers or distributors of medicinal products.

##### Healthcare Organisations (HCOs)

Any legal person:

(i) that is a healthcare, medical or scientific association (scientific society or an association of HCPs) or healthcare organisation (irrespective of the legal or organisational form), such as a hospital, clinic, foundation, university or other educational institution or learned society of any type (e.g. NGOs) sponsored by pharmaceutical companies (except for patient associations within the scope of the SFEE Code of Ethics on the Relationships between Pharmaceutical



Companies and Patient Associations), which has registered office or is active in Greece; or

(ii) through which one or more HCPs provide healthcare services, including private Primary Healthcare Providers (Presidential Decree 84/2001, Gov. Gazette 70/A/10.4.2001).

#### **Medicinal Products**

Medicinal products as used in this Code are those products specified in Article 2 of Ministerial Decision ΔΥΓ3α/ΓΠ32221/29.4.2013 (Gov. Gazette 1049/B/2013) as currently in force, including immunological medicinal products, radiopharmaceuticals and medicinal products derived from human blood or plasma, for which a marketing authorisation has been granted pursuant to Directive 2001/83/EC, as currently in force.

#### **Recipient**

Any HCP or HCO whose primary practice, principal professional address or registered office is in Greece.

#### **Service and Consultancy**

Education/Training (in-house for company employees or externally to other HCPs), advisory boards (non-medical: commercial advisory boards or pharmaco-economics expert panels), speeches/lectures, general consultancy (regarding medical information brochures, preparation of programmes for informing HCPs and/or the public on diseases).

The above term indicatively includes: education, market research, article authoring, translation, planning/co-organisation of scientific events.

#### **Research and Development transfers of value**

Transfers of value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (*as defined in the OECD Principles on Good Laboratory Practice*); (ii) clinical trials (phase I, II, III & IV, as defined in Directive 2001/20/EC); and (iii) prospective non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Articles 25 and 26, Chapter A of this Code).

#### **Transfer of value**

Any transfer of objects and rights, either in the form of fee for service or in the form of a grant for an educational/training activity. The definition includes all direct or indirect transfers of value, whether in cash, in kind or otherwise, made for promotional or other purposes, in connection with the development and sale of generic or branded medicinal products, intended exclusively for human use. **Direct** transfers of value are those made directly by a Member Company for the benefit of a Recipient. **Indirect** transfers of value are those made on behalf of a Member-Company for the benefit of a Recipient, where the Member-Company is known or can be identified by the Recipient.



## CHAPTER C

### COMPLIANCE MONITORING PROCEDURE

#### 1. Introduction

The bodies monitoring compliance with the present Code of Ethics are:

The First Instance Committee for Code Compliance, hereinafter referred to as the First Instance Committee, which examines allegations/complaints filed on two levels, as follows:

(a) A mediation procedure, where the First Instance Committee is represented by its Chairperson and Secretary, acting at this stage as mediators for the amicable settlement of the dispute arising between the opposed parties.

(b) A procedure before the First Instance Committee in plenary session (discussion and decision on the allegation/complaint).

The Second Instance Committee for Code Compliance, hereinafter referred to as the Second Instance Committee, which reviews allegations/complaints following a decision of the First Instance Committee and application for referral filed by the interested parties.

The Disciplinary Board of SFEE, which addresses with cases of pharmaceutical companies referred to it upon request of the Second Instance Committee and can consider expulsion of the member company from SFEE.

#### 2. Structure, Responsibilities and Complaints Procedure of the First Instance Committee

**2.1** Monitoring of compliance with Chapters A and B of the Code is entrusted to the First Instance Committee, which shall be competent to rule on allegations/complaints about Code violations. In addition, it shall be responsible for any settlements or other arrangements in the context of compliance with the Code.

The First Instance Committee is assisted in its work by the competent Committee of the SFEE Code of Ethics and Transparency, which is responsible for providing advice, guidance and training on the stipulations of the Code. The term of office of the said committee is 18 months. In addition, it provides support both to the First Instance and to the Second Instance Committee for Code Compliance with regard to technical issues.

The Code of Ethics and Transparency Committee consists of 9 members and their alternates and is set up by decision of the Board of Directors.

In the context of compliance with the SFEE Code of Ethics, member companies can file complaints for any violation by mail, personally, or via e-mail at: [complaints@sfee.gr](mailto:complaints@sfee.gr). Complaints may be named or anonymous. The legal department of SFEE will receive the complaints and ensure anonymity. A complaint shall not be deemed anonymous if the complainant states his/her name but requests that it remain confidential.

**2.2** The First Instance Committee is appointed by the Board of Directors of SFEE. The term of office of those of its members who are representatives of SFEE member companies is 18 months and may be renewed by decision resolution of the SFEE Board of Directors. The term of office of the other members of the First Instance Committee is 3 years and may be renewed by decision of the SFEE Board of Directors.

The First Instance Committee comprises:

- its Chairperson, appointed by consensus of the Committee ;
- a lawyer, as Secretary;
- two former General Managers of Pharmaceutical Companies;
- a specialised Scientific Officer (external advisor);
- the respective alternates of regular members.

**2.3** Pharmaceutical companies shall make every possible effort to settle disputes before filing an allegation/complaint to the First Instance Committee.

An allegation/complaint may be made by the following:

1. Any natural or legal person affected by the violation of the provisions laid down in Chapters A and B of the present Code is entitled to file an allegation/complaint before the First Instance Committee, which shall convene ad hoc and decide on the matter. Allegations/complaints may be named or anonymous. The identity of the complainant may be kept confidential, if he/she so wishes, and shall only be disclosed with his/her consent.

2. The SFEE Board of Directors may on its own initiative file an allegation/complaint to the First Instance Committee, when a violation of the Code is brought to its attention.

3. The First Instance Committee may file an allegation/complaint on its own initiative, when a violation of the Code is brought to its attention.

4. Notwithstanding the above, it is possible to file an anonymous allegation/complaint at the discretion of the complainant.

5. Furthermore, it is possible to file an allegation/complaint directly at EFPIA offices in Brussels.

6. An allegation/complaint may also be filed by an EFPIA member Association of Pharmaceutical Companies.

**2.4** Allegations/complaints under points 5 and 6 above shall be filed to the Legal Department of SFEE within a reasonable period of time, which may not exceed six months from the occurrence of the action that is the subject matter of the allegation/complaint.

As soon as it receives the anonymous complaint, the Legal Department of SFEE, shall promptly forwards it to the Chairperson of the First Instance Committee, who, as a first approach, shall examine the anonymous complaint to ascertain if it is sufficiently precise or vague. Vague complaints shall be on record as non-cases.

If the complaint is sufficiently precise, the Chairperson of the First Instance Committee shall gather the necessary factual evidence. The Chairperson of the Committee, if he/she deems it necessary, may request the assistance of a member of the 9-member Committee referred to in Article 2.1 in the collection of evidence. The company concerned may also be invited in order to assist in the evidence collection process. Thereafter, the Chairperson shall decide if the complaint will be brought before the First Instance Committee in Plenary Session, in order to be discussed.

**2.5** Allegations/complaints filed with EFPIA and concerning activities of SFEE member companies shall be forwarded by EFPIA to the Legal Department of SFEE, which shall register them on the same day in its book of allegations/complaints and inform by fax or e-mail the First Instance Committee Chairperson and Secretary of the received allegation/complaint. Subsequently, the procedure provided for in Article 2.8 below shall be initiated before the First Instance Committee.

**2.6** Allegations/complaints regarding cases 1-4 of Article 2.3 shall be filed with the SFEE Legal Department and registered on the same day in the book of allegations/complaints.

**2.7** The SFEE Legal Department shall notify the allegation/complaint to the members of the First Instance Committee and to the pharmaceutical company concerned.

**2.8** The discussion of the allegation/complaint before the bodies monitoring compliance with the Code shall not be suspended as a result of the fact that a case with the same subject matter is pending before the National Organisation for Medicines (EOF) or civil courts having jurisdiction.

**2.9** During the Mediation Procedure, an amicable settlement of the dispute is attempted. If an amicable settlement is achieved, the disputing parties and the members of the First Instance Committee other than those involved in the mediation shall be notified in writing.

**2.10** In the event that the Mediation Procedure fails, the allegation/complaint shall be referred to the First Instance Committee in Plenary Session by letter of the Chairperson of such Committee, addressed to the other members and to the disputing parties. The Committee shall meet in plenary session within 20-30 working days at the latest following the date of the letter sent by the Chairperson, which shall be accompanied by a letter of the Secretary of the First Instance Committee enclosing all the documentation provided by the disputed parties.

**2.11** The First Instance Committee shall be in quorum if at least four of its members attend. The decisions shall be taken by majority vote. If majority is not reached, the vote shall be repeated. If again a majority is not reached, the vote of the Chairperson of the Committee shall prevail. At the conclusion of the meeting the First Instance Committee, the Secretary of the Committee, jointly with the Chairperson and the rest of the members shall draft the decision text, which shall be entered in the book of decisions of the First Instance Committee duly signed by the Chairperson and the members thereof. The decision shall be thereafter notified by the Legal Department of SFEE to the pharmaceutical company concerned and to the complainant.

**2.12** The Chairperson of the First Instance Committee may, during the meeting, invite for a hearing any person whom he/she may deem to be of help in decision making regarding the allegation/complaint filed before the Committee. The Chairperson of the First Instance Committee may consult expert advisors on any issue within the scope of the First Instance Committee. Expert advisors may be requested to attend the proceedings of the First Instance Committee, without the right to vote.

**2.13** If a member of the First Instance Committee has filed before the Committee an allegation/complaint against a company or works for a pharmaceutical company which has filed an allegation/complaint before the First Instance Committee, that member shall be excluded from the meeting discussing the case. The same applies when a member of the First Instance Committee works for a company against whom an allegation/complaint was filed before the First Instance Committee. The place of the excluded member for the specific meeting shall be taken by the respective alternate member.

**2.14** If either of the disputing parties or both of them do not accept the decision of the First Instance Committee, they reserve the right to apply for referral of the allegation/complaint to the Second Instance Committee within 30 working days of the notification of the decision.

**2.15** The application for referral must be filed with the Legal Department of SFEE, which shall communicate it on the same day by e-mail or fax to the Chairperson and the Secretary of the Second Instance Committee.

### **3. Hearing of allegations/complaints before the Second Instance Committee**

**3.1** The Second Instance Committee is appointed by the Board of Directors of SFEE. The term of office for the officers of the pharmaceutical companies - members of SFEE in the Second Instance Committee is 18 months and may be renewed by decision of the Board of Directors of SFEE. The term of office for other members of the Second Instance Committee is 3 years and may be renewed by decision resolution of the Board of Directors of SFEE.

#### **The Second Instance Committee comprises:**

- a member of the judiciary or a person appointed by consensus, as Chairperson of the Committee;
- a lawyer, presumably familiar with medical and pharmaceutical issues, as Secretary of the Committee;
- two doctors, selected by draw ad hoc for each allegation/complaint from a list of doctors (clinicians and otherwise) established and approved by Board of Directors of SFEE;
- two Pharmacology Professors, preferably retired or active faculty members;
- one former General Manager of a pharmaceutical company; and
- their respective alternates.

**3.2** The Second Instance Committee convenes within 15 working days at the latest after being notified by the SFEE Legal Department of the application for referring the allegation/complaint. After examining the case, the Committee shall issue a decision, which is binding on the disputing parties.

**3.3** The Second Instance Committee shall be in quorum when at least 5 of its members attend. However, there must always be one representative from each of the categories described in Article 3.1. Decisions shall be taken by majority vote.

**3.4** The Chairperson of the Second Instance Committee may invite for a hearing at the meeting of the Committee any person whom he/she may deem to be of help in decision making on application for referral of the allegation/complaint.

**3.5** The Chairperson of the Second Instance Committee may seek advice from expert advisors on any issue within the scope of the Second Instance Committee.

**3.6** Expert advisors may be asked to attend the proceedings of the Second Instance Committee, without the right to vote.

**3.7** If a member of the Second Instance Committee has filed before the First Instance Committee an allegation/complaint against a pharmaceutical company or works for a pharmaceutical company that has filed an allegation/complaint before the First Instance Committee, which is discussed before the Second Instance Committee, that member shall be excluded from this particular meeting and be replaced by an alternate member of the same category. The same applies in the case that a Second Instance Committee member works for a pharmaceutical company against which an allegation/complaint was filed before the First Instance Committee, which is under discussion in the Second Instance Committee.

**3.8** Similar issues of allegations/complaints shall be addressed in the same manner. If an allegation concerns an issue which has recently been addressed by the Second Instance Committee, the Chairperson thereof may accelerate the procedure, e.g. by requesting the pharmaceutical company concerned to promptly provide documentation prior to the first meeting of the Committee.

**3.9** Each representative of a SFEE member company is entitled to one membership in both Committees, either as a regular or as an alternate member.

**3.10** The members of the First Instance and the Second Instance Committees, as well as any expert advisors attending, shall be compensated by SFEE for their participation in the meetings of the said Committees. The amount of the compensation shall be agreed upon by the Committee members and the SFEE Board of Directors. Persons working for SFEE member companies shall not be entitled to compensation, when participating in the First Instance or the Second Instance Committee.

### **4. Sanctions**

**A.** The First Instance Committee, if, after examining the allegation/complaint, judges that there is a violation of any articles of the Code, may impose to a member company that fails to comply with the provisions of Chapter A of the Code the following sanctions, which shall be enforced after the deadline for filing an appeal has elapsed without any action or after the decision on the appeal, unless the respondent has accepted the violation or part thereof:

- a) Prompt publication of the decision on SFEE's website;
- b) Correction of the non-compliant promotional material and obligation of the pharmaceutical company concerned to send the corrected material to its addressees, accompanied by a letter stating the amendments;

- c) Publication of the decision text, depending on its subject, in relevant scientific journals that are addressed to HCPs;
- d) A financial penalty of up to EUR 25,000.

Following the issuance of the First Instance Committee decision, the disputing parties reserve the right, within 30 business days of the date when the decision is communicated to them by SFEE's Secretariat, to file an application for referring the case to the Second Instance Committee (see Article 2.15) of the Code Compliance Monitoring Procedure.

The above sanctions shall be enforced if the deadline provided for in Article 2.15 of the SFEE Code Compliance Monitoring Procedure for referring an allegation/complaint to the Second Instance Committee elapses without any action.

**B.** The Second Instance Committee may impose on a SFEE member company – not complying with the decision of the First Instance Committee the sanctions set out in Article 4A above, as well as a financial penalty of EUR 50,000 and publication of the relevant decision on SFEE's website. Those amounts shall be deposited by the pharmaceutical company in a dedicated bank account held by SFEE, within 30 working days at the latest of the issuance of the decision.

In the event that the SFEE member company still fails to comply with the decision of the Second Instance Committee, the latter shall refer the issue to the Disciplinary Board of SFEE, which may decide on the expulsion of the member. This decision shall be published at SFEE's website.

#### **5. Failure to comply, or to properly comply, with a decision of the Second Instance Committee**

In the event that a pharmaceutical company-member of SFEE fails to comply, or to properly comply, with the sanction imposed on it by the Second Instance Committee, the Second Instance Committee may, upon special request of the complainant, meet and decide to impose further sanctions, which may amount to up to three times the initially imposed sanction. If the SFEE member company still fails to comply with the decision of the Second Instance Committee, the latter shall refer the issue to the Disciplinary Board of SFEE which may decide on the expulsion of the member.

In any event, failure to comply, or to properly comply, with the decision shall be notified to the National Organisation for Medicines (EOF).

#### **6. Non-member pharmaceutical companies**

**6.1** Pharmaceutical companies which are not members of SFEE may voluntarily adhere to the Code if they so wish, by submitting a declaration to this effect to the President of SFEE. Such companies will be set out in a separate list, which shall be updated regularly and shall constitute part of the Code. All articles of Chapters A and B of the present Code shall fully apply to the said companies.

**6.2** Allegations/complaints against non-member companies shall be examined as provided for in Chapter A of the present Code. After verifying the violations, the First Instance or Secondary Instance Committee may proceed to the following:

- report the non-compliant company to the National Organisation for Medicines;
- publicly disclose the case on SFEE's website.

#### **7. Annual report to EFPIA**

The Secretary of the First Instance Committee shall prepare and forward to the EFPIA Code Committee an annual report summarising the allegations/complaints handled during the past year by SFEE's First Instance and Second Instance Committees.

## ANNEXES

- I) Table of indicative calculation of HCP fees for services provided to pharmaceutical companies
- II) Registry of non-interventional studies

## ANNEX I

### 1. Indicative calculation of HCP fees calculation for services provided to pharmaceutical companies, depending on status/rank:

Status/Rank	Indicative fee per medical visit (gross/assumed duration of visit: about 30 minutes)
A. Academics	
Professors	EUR72
Associate Professors	EUR60
Assistant Professors	EUR48
Lecturers	EUR36
B. NHS-affiliated Specialists(Consultants)	
Coordinating Directors	EUR64
Directors (Heads of Department/Clinics)	EUR60
Attending physician - rank I	EUR48
Attending physician – rank II	EUR36
Attending physician – rank III	EUR24
C. Nursing and paramedical professions	EUR36

**Μορφοποιήθηκε:** Γραμματοσειρά: Arial, 10 στ., Αγγλικά (H.B.)

**Μορφοποιήθηκε:** Γραμματοσειρά: Arial, 10 στ., Αγγλικά (H.B.)

The above rates have been determined in accordance with Ministerial Decision oik.72944 (Gov. Gazette 1958/B/12.8.2013) for HCPs, excluding nursing and paramedical professions, for which the fees are determined at half the fees of Professors.

### 2. Indicative calculation of HCP fees for services provided to pharmaceutical companies, depending on time of involvement (in hours) per service:

	Attendance	Preparation	Travel	Total
Speaker in a conference	3.5	3	1.5	8
Presentation / training	4	3		
Participation in an Advisory Board	8	2		

<b>Article writing</b>	10
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<b>Protocol writing</b>	40
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According to the internal procedures applied for deriving reasonable remuneration levels, by market standards, hourly remuneration rates are based on the fee received by HCPs for examining a patient in the outpatient Hospital clinics.

Finally, the HCP's fee for out-of-job engagements may not exceed his/her regular hourly pay in his/her permanent/main job.

## ANNEX II

### Registry of Non-Interventional Trials

#### On-line Registry of Non-Interventional Trials posted on SFEE Website

##### 1. Description

Recording of all non-interventional trials conducted by the sponsor (SFEE member pharmaceutical company), with description of planning, targets and time schedules

Recording of personal details of researchers and of their remuneration

Recording of the number of patients scheduled to participate

Each trial is posted by the SFEE member sponsor and is assigned a unique reference code per sponsor and trial, enabling follow-up

Posting of the relevant details and approvals of the Auditing Board of non-interventional trials as well as the results thereof upon their conclusion

A relevant manual by the SFEE's Committee of Medical Directors will be available as soon as the online registry becomes operative.

##### 2. Statistical planning of Non-Interventional Trials

Based on the primary target of the trial, the scientific and methodological criteria must be fulfilled

Based on EMA guidance dated Nov 2011, ENcPP standards & guidelines

Based on Directive 28/2005, envisaging specific types of trials.

##### 3. Types of Non-Interventional Trials

Types of non-interventional trials:

The types provided for in EU guidelines and the EMA algorithm, Annex 1: Decision tree to establish whether a trial is a "clinical trial", March 2011, must be observed.

The number of participants in non-interventional trials must be calculated based on the primary scientific target and according to a robust sampling methodology

##### 4. Remuneration in the context of Non-Interventional Trials

Reasonable value in accordance with market standards. Hourly rates for researchers are calculated on the basis of the range of reasonable remuneration for a private physician, depending on specialty and therapeutic field.

	Indicative rates
Gross remuneration of researcher per hour	EUR50-90
Gross remuneration of study coordinator per hour	EUR20-40
Training on the filling in of electronic CRF (one-off)	EUR190-290
Preparation and review of files (one-off)	EUR270-430

##### 5. Table of differences between clinical trials, non-interventional clinical research and market research

Non-interventional studies involving medicine administration	Non-interventional studies not involving medicine administration – Epidemiological	Market research among HCPs	Clinical Trials
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	<b>studiee</b>			
<b>Collection of patients' personal data</b>	Yes	Yes	No – Only aggregated patient data are collected	Yes
<b>Requires statistical calculation of the number of patients and epidemiological analysis</b>	Yes	Yes	No, but the persons asked must be a random sample from the reference population	Yes
<b>Selection of patients</b>	One or more selection criteria	One or more selection criteria	One or more groups of patients are selected and cumulatively evaluated	The group must be selected based on qualification and disqualification criteria
<b>Patients are randomised in treatments</b>	No	No	No	Usually
<b>Retrospective/ prospective</b>	Retrospective or prospective	Retrospective or prospective	Snapshot – synchronic	Prospective
<b>Requires supervision</b>	Possibly – depending on the design	No	No	Yes
<b>Requires approval from the National Organisation for Medicines (EOF)</b>	No (apart from exceptions, see Article 29.3)	No	No	Yes
<b>Requires clinical research ethics approval</b>	Yes	Yes	No	Yes
<b>Requires written consent of patient</b>	Yes, unless the Ethics Committee/ the Supervising Board of the Hospital decides otherwise	Yes, unless the Ethics Committee/ the Supervising Board of the Hospital decides otherwise	No	Yes
<b>Adverse effects may be monitored</b>	Yes	N/A - they do not concern the medicine. The HCPs report any adverse effects.	The HCPs report any adverse effects	Yes
<b>Comparison with competitive medicines is allowed</b>	Yes, but with reduced reliability due to increased risk for systematic errors (bias)	N/A - they do not concern the medicine	No	Yes
<b>The main features are published before</b>	Yes, in SFEE's Registry of non-	Yes, in SFEE's Registry of non-	No	Yes, at clinical trials.gov

<b>commencement</b>	interventional trials	interventional trials		
<b>Results may be published</b>	Yes, at least in SFEE's Registry of non-interventional trials	Yes, at least in SFEE's Registry of non-interventional trials	Yes	Yes, requirement for pharmaceutical companies
<b>Participation of medical sales representatives in the conduct</b>	Only with a supportive role, under the supervision of the Company's Scientific Department and without being related to any form of promotion	Only with a supportive role, under the supervision of the Company's Scientific Department and without being related to any form of promotion	Yes, but their participation excludes remuneration to HCPs being questioned	Not allowed