

## SFEE CODE OF ETHICS



Effective Day: 20.04.2024

All amendments to the SFEE Code of Ethics (i.e. the verbal inclusion of the «host country principle», amendment of Section 3.1.7., addition of new Sections 7.17., 7.18. and 7.19., amendment of Sections 11.11. b) and 11.14. and addition of Sections 35.7. and 35.8. and further amendments to the Appendices) are effective from the day following the date of the 19.04.2024 Annual General Assembly of SFEE's Member, i.e. from 20.04.2024 onwards.

Exception solely for international scientific events jointly organized with a Greek entity: the relevant amendments apply to all scientific events (co-organized with a Greek entity) held from 01/09/2024 onwards.

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## ★ DEFINITIONS

**“Research and Development Fees”** fees paid to HCPs and HCOs in relation to planning or conduct of (i) non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice)<sup>1</sup>; (ii) clinical trials (phase I, II, III & IV, as defined in the national and EU legislation);<sup>2</sup> and (iii) non-interventional studies that are prospective in nature and involve patient data collection by or on behalf of individual, or groups of, HCPs specifically for the study. (see also Articles 15 and 16, Chapter 1, of this Code).

**“Recipient “(of Transfer of Value)”** Any HCP or HCO whose primary practice, principal or temporary residential address or registered office is in Greece.

**“Donation”** any grant of cash, assets and/or services of any nature to third parties (legal entities), intended to support healthcare, research and/or education, with no exchange in return there being offered to the donor and/or any third parties.

**“Host Country Principle”** refers to the primacy of the monetary threshold for a meal (food and beverages) set by the relevant Member Association in its National Code. The monetary threshold set in the country where the Event takes place must prevail.

**“Deed in writing”** where the provisions of this Code provide for the obligation of a deed in writing, this means any document which is dated and signed by hand or bearing an electronic signature.

**“Patient Organisation Representative (PO Representative)”** a natural person authorised to represent a PA and express its collective views on any particular matter or therapeutic category.

**“Patient Organisation (PO)”** a non-profit organisation which represents and supports the needs of human beings suffering from medical conditions.

**“Healthcare Professional (HCP)”** this term includes any natural persons being characterised as Healthcare Professionals under the applicable laws,<sup>3</sup> exercising their practice or having their primary establishment in Greece, and being empowered to prescribe, purchase, dispense,

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1 – <https://www.aade.gr/sites/default/files/201909/%CE%95%CE%B3%CF%87%CE%B5%CE%B9%CF%81%CE%AF%CE%B4%CE%B9%CE%BF%20%CE%B3%CE%B9%CE%B1%20%CF%84%CE%B7%CE%BD%20%CE%9F%CF%81%CE%B8%CE%AE%20%CE%95%CF%81%CE%B3%CE%B1%CF%83%CF%84%CE%B7%CF%81%CE%B9%CE%B1%CE%BA%CE%AE%20%CE%A0%CF%81%CE%B1%CE%BA%CF%84%CE%B9%CE%BA%CE%AE.pdf>

2 – Joint Ministerial Decision no. Γ5/59676/2016 implementing Regulation (EU) no. 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

3 – See Article 4 of Law 4238/GG A, 38/17.02.2014, which characterises the following persons as Healthcare Professionals (HCPs): family physicians and physicians of other specialties, dentists and other healthcare professionals such as midwives, health visitors, nurses, social workers, physiotherapists, dietitians/nutritionists, psychologists, occupational therapists, medical laboratory technologists, medical and biological laboratory assistants, medical equipment operators.

recommend or administer medicinal products as part of their practice, subject to Chapter 1 (Promotion of Prescription-Only Medicines to HCPs), where the term “HCP” is narrower in scope, consistent with the decision transposing the Community Code on Medicinal Products (Joint Ministerial Decision ΔΥΓ3α Γ.Π. 32221/2013) and includes any parties among the above being legally empowered to prescribe or dispense medicinal products.

For the avoidance of doubt, the term “Healthcare Professional” includes, subject to Chapter 1, the following:

- (a) any official or employee of a government agency or other organisation (whether in the public or in the private sector) who is empowered to prescribe, purchase, dispense or administer medicinal products and
- (b) any employee of a PC being a HCP whose primary occupation is that of practising a healthcare profession (e.g. physician, nurse, dentist etc.).

This excludes:

- (i) all other (HCP or otherwise) full-time employees of the PC under an employment contract, an agency contract or a contract for work; and
- (ii) all wholesalers or distributors of medicinal products.

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

**“Scientific Events”** scientific meetings addressing a specific topic, attended by HCPs, which are intended to promote scientific discussion on medicinal products, therapies and human health in general. Depending on their topic, duration and geographic range, scientific events may be distinguished in conferences, seminars or one-day events and local, regional, Panhellenic or international. They may be held in Greece or abroad and they are organised either by third-party (government or other) organisations or by PCs. They are governed by the regulatory framework introduced from time to time by the competent Regulatory Authority in accordance with the law. If organised by third-party organisations, they may be financially supported through sponsorships from PCs, subject to the terms of the applicable laws and regulations and the Code provisions.

**“Scientific Information/Promotion”** is the provision of scientific information by pharmaceutical companies (PCs) to HCPs to whom PCs are allowed to promote prescription-only medicinal products which are marketed under their responsibility, with a view to ensuring proper use of such products, as such use is authorised by the National Organisation for Medicines (EOF) or the European Medicines Agency (EMA), with a view to protecting public health. Scientific Information may include any activities which are undertaken, organised or sponsored by a PC (or under its instructions) and are intended promote the prescription, dispensation, sale, administration or consumption of its medicinal products. Scientific information may be provided orally, in writing or by audio/visual or other technological media.

**“Scientific Healthcare Organisation (HCO)”** this term includes:

Any legal person:

- (a) which is a healthcare, medical or scientific association (scientific society or an association of HCPs) or healthcare organisation (irrespective of its legal or organisational form), such as a hospital, clinic, foundation, university or other educational institution or society of any type sponsored by pharmaceutical companies (except for POs within the scope of Chapter 4 hereof), having its registered office or carrying out activities in Greece; or
- (b) through which one or more HCPs provide healthcare services, including private Primary Healthcare Providers.

**“Contribution to costs related to Events”** is the provision of financial support, without exchange in return, by pharmaceutical companies to HCPs or PORs, intended to cover any transportation / accommodation / board expenses and/or registration fees required to attend a Scientific Event organised by a PC or a HCO.

**“Medical Information”** is the supply of oral or written scientific information, whose contents and intended use are not howsoever associated with the Promotion of medicinal products. Any scientific information including references to off-label products may not be forwarded to HCPs. This shall not apply to any situations where the information concerned is supplied in reply to written inquiries submitted by the HCPs through the PCs’ medical departments.

**“Medical Press”** is any scientific journals, websites and other information media addressed specifically to HCPs.

**“SFEE Code of Ethics/Code”** The Code of Ethics of the Hellenic Association of Pharmaceutical Companies, including any Annexes thereto.

**“Over-the-Counter (OTC) Medicines”** means any medicinal products administered without a medical prescription.

**“Transfer of Value”** is any transfer of value 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 prescription-only Medicinal Products intended exclusively for human use. Direct transfers of value are those made directly by a PC for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a PC for the benefit of a Recipient or through a Third Party, where the Recipient is known or can be identified by the PC.

**“Summary of Product Characteristics (SPC)”** is a summary of the characteristics of each medicinal product addressed to HCPs, which is approved by the competent authorities that have granted the marketing authorisation in accordance with the applicable legislation.

**“Service and Consultancy”** means education/training (in-house for company employees and/or externally to other HCPs), Advisory Boards (advisory boards or pharmaco-economics expert panels of any kind), expert or technical advice, Speeches/Lectures, design/co-planning of scientific events and/or general consultancy (i.e. regarding medical information brochures and/or public awareness brochures on diseases, scientific articles, translations etc.

**“SFEE”** The HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

**“Medical Sales Representative”** is a natural person assigned by a PC the task of offering Scientific Information/Promotion services to HCPs and HCOs in relation to medicinal products, always in accordance with authorised prescription information.

**“Scientific Information/Promotion Material”** is any material containing exclusively scientific information and addressed to HCPs having a legal right to prescribe or administer medicinal products. Any brochures and/or digital material created by PCs for use by social security organisations, Hospital suppliers and other agencies responsible for authorising procurements and/or pricing Medicinal Products, which do not constitute Scientific Information/Promotion Material.

**“Pharmaceutical Company(-ies) (Pharma Company/ies)”** The SFEE member companies and any other non-SFEE members pharmaceutical companies adhere to this Code.

**“Medicine” or “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.

**“Package leaflet”** is a leaflet containing information for the user, enclosed in each package of a Medicinal Product, which is approved by the Competent Authorities that granted marketing authorisation in accordance with the applicable laws.

**“Sponsorship”** is any support/funding offered to a legal person for any reason or cause, for which the sponsor receives solely product and/or business promotion by way of consideration/advantage.

**“EFPIA”** *European Federation of Pharmaceutical Industries and Associations.*

«**IFPMA**» *International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).*



## \* ETHICAL PRINCIPLES

- As pharmaceutical companies, we work in collaboration with various stakeholders including HCPs, HCOs, POs and their Representatives, regulatory authorities, governments and the public to improve health and quality of life.
- We continuously invest in research and development to deliver new treatments for medical needs and improving the quality of treatment.
- As commercial organisations, we encourage competition and economic development to sustain investment and foster innovation.
- We believe in what we do and know that there is somewhere a patient whose health and well-being is, directly or indirectly, dependent on our work.
- We aim at creating an environment where our stakeholders and the general public, consider pharmaceutical companies as trusted partners.
- In addition to complying with extensive legal requirements (i.e. laws and regulations applicable to our industry such as pharmaceutical, competition, intellectual property and data protection laws as well as anti-bribery and anti-corruption legislation), the pharmaceutical industry has agreed to comply with additional standards in its self-regulatory codes and joint positions.<sup>4</sup>
- For SFEE and its Members, self-regulation means being fully committed to define the highest ethical standards through this Code, where breaches are not tolerated.
- Self-regulation includes the concept of continuous challenge for us to exceed society's expectations and openness regarding suggestions from others on how we might further strengthen confidence in our industry.
- Stakeholders who share the values and principles enshrined in this self-regulation are invited to adhere to these rules and guidance.

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4 – Law 2251/1994, Article 9a “d f) code of conduct: any agreement or set of rules which is not imposed by the law or any regulatory or administrative provision and regulates, in respect of one or more specific business practices or business fields, the conduct of the suppliers who subject themselves to that code.  
e g) Code owner: any entity, including a supplier or a group of suppliers, who is responsible for drafting and revising a code of conduct and/or monitoring compliance therewith by any parties who subject themselves to that code,

This Code demonstrates our commitment to the following rules of ethics:

- **PATIENTS ARE AT THE HEART OF WHAT WE DO.** We aspire to ensure that everything we do will ultimately benefit patients. Our primary contribution to society is to make high quality Medicinal Products and to encourage their appropriate and rational use in the care pathway.
- We act with **INTEGRITY**, interact in a responsible manner and aim to ensure that our communications with stakeholders are accurate, legitimate and balanced. We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.
- We interact with all our stakeholders with **RESPECT**. We commit to approach our stakeholders in an open manner, with a responsive, constructive and learning attitude and mutual respect. We value the importance of independent decision-making by stakeholders, based on evidence and including patient interest. With respect to society, we listen to what is expected from us and adapt our way of working accordingly. We follow applicable laws and make ethical judgements when processing Personal Health Data.
- We seek to ensure that **TRANSPARENCY** is respected. We are open about our activities and interactions and encourage stakeholders to act with the same openness.

## \* INTRODUCTION

- This Code of Ethics (hereinafter: “Code”) consists of six Chapters and four Annexes, which form an integral part hereof. **Chapter 1** contains provisions on the Promotion of Prescription-Only Medicines; **Chapter 2** regulates the interactions between PCs with HCPs, HCOs and POs; **Chapter 3** contains provisions with regard to more specific categories of interactions between PCs and HCPs, HCOs and POs; **Chapter 4** provides for the interactions between PCs and POs; **Chapter 5** contains provisions with regard to Disclosure of Transfers of Value from PCs to HCPs and HCOs; and **Chapter 6** provides for the Implementation Monitoring Procedure. **Annex I** contains all kind of sponsorship limits, HCP participations etc. with regard to Scientific Events; **Annex II** provides an indicative calculation of fees payable to HCPs for services rendered PCs; **Annex III** refers to the registry of non-interventional clinical studies and **Annex IV** contains the Disclosure template.
- SFEE promotes free, arms’ length competition among PCs. The SFEE Code is not intended to limit the Promotion of Medicinal Products by PCs to HCPs or impose restrictions on the relations between PCs and HCPs, HCOs and POs thus impairing competition. On the contrary, the Code is intended to ensure that, in promoting their Products, PCs are acting with honesty and ethics, avoid misleading practices and conflicts of interest with other stakeholders and comply with the applicable laws.
- SFEE believes that PC - HCP relations have a considerably positive impact on the quality of therapies and add significantly to the value of future research. Besides, HCP integrity when prescribing Medicinal Products is one of the cornerstones of the healthcare system. SFEE acknowledges that PC relations with HCPs/HCOs may give rise to conflicts of interest. Therefore, all representative professional bodies involved in this process have adopted Codes of Conduct to ensure that these relations meet high integrity standards as well as the reasonable expectations of the patients, the Government and other stakeholders.
- PCs also interact with POs in order to benefit from the latter’s knowledge and experience on diseases, given that POs can present a realistic picture of what it is like for a person to live with a particular disease/medical condition/disability. POs are also important in terms of how healthcare services are provided; how this affects patients and their professional and family life and how medicines can improve their quality of life. PCs publicise their transfers of value to POs in the context of such interaction.

## \* SCOPE

This Code lays down the principles and procedures that must be complied with during the promotion to HCPs of prescription-only medicines granted marketing authorisation as per the provisions of Ministerial Decision Δ.ΥΓ3α/Γ.Π. 32221 (GG 1049/B/2013) or through the centralised procedure laid down in the Regulation (Reg. EC 726/2004) as well as in the provision of information to the public on general health issues.

### NON-MEMBER PHARMACEUTICAL COMPANIES

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 declaration shall essentially include a statement of acceptance of any sanctions described in the SFEE Code of Ethics for potential infringements. Such companies will be set out in a separate list, which shall be regularly updated and shall form part of the Code. These companies shall be subject to all articles of this Code, including to those providing for the imposition of sanctions.

#### The Code's scope of application includes the following:

- a. **Promotion of prescription-only Medicinal Products** directed at persons authorised to prescribe or administer medicinal products, irrespective of how or by what means they are prescribed, e.g. patient visits, exhibitions, samples, event sponsorships;
- b. Medical sales representatives' visits to persons authorised to prescribe or administer Medicinal Products;
- c. Supply of samples;
- d. Sponsorship of meetings for the Promotion of Medicinal Products and/or Scientific Events attended by persons authorised to prescribe or administer Medicinal Products, including payment of travel and accommodation in connection therewith;
- e. Direct or indirect supply of information to the general public, e.g. health or disease information, provided that no direct or indirect reference is made to a certain Medicinal Product;
- f. Advertising in scientific journals, by post or email;
- g. 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.;
- h. 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 systems, data 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.

**The following are excluded from the scope of application of this Code:**

- a. the Summary of Product Characteristics (SPC) or the abbreviated Summary of Product Characteristics, for which the relevant provisions apply;
- b. the Labelling and the package leaflet of Medicinal Products, for which the relevant provisions apply;
- c. factual and informative announcements and reference material relating, for example, to pack changes, adverse reaction warnings in the context of pharmaco-vigilance, as well as trade catalogues and price lists which include no product information;
- d. replies in response to individual enquiries from HCPs or to specific questions or comments;
- e. replies to letters published in scientific journals, provided these relate solely to the subject matter of the letter or enquiry, are accurate and not misleading and are not promotional in nature;
- f. promotion of non-prescription medicines, as this is governed by the relevant Code of the Association of Self-Medication Industry ("EFEX").

**Pharmaceutical Companies are liable to ensure compliance with the terms of this Code when conducting any activities that lie within the scope hereof.**

**"EFPIA member companies and anyone acting on their behalf must comply directly with applicable national codes of member associations where such codes exist" (following the "Host Country Principle").**

**"IFPMA member companies and anyone acting on their behalf must comply directly with applicable national codes of member associations where such codes exist" (following the "Host Country Principle").**

# \* CHAPTER 1. PROMOTION OF PRESCRIPTION-ONLY MEDICINAL PRODUCTS TO HEALTHCARE PROFESSIONALS (HCPS)

## ARTICLE 1. BASIC PRINCIPLES OF SCIENTIFIC INFORMATION/PROMOTION OF PRESCRIPTION-ONLY MEDICINAL PRODUCTS

**Section 1.1.** It is prohibited to promote any Medicinal Products for which a marketing authorisation has not been granted. It is also prohibited to promote indications which are not covered by the marketing authorisation (off-label products) or have not yet been approved.

**Section 1.2.** All Scientific Information/Promotion concerning a Medicinal Product must be consistent with the information included in the product's SPC.

**Section 1.3.** Scientific Information/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.

**Section 1.4.** Scientific Information/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.

**Section 1.5.** Scientific Information/Promotion must acknowledge the special nature of Medicinal Products and the professional standing of the addressees, who must be respected and protected from any offence.

**Section 1.6.** Scientific Information/Promotion must promote 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.

**Section 1.7.** Scientific Information/Promotion material and activities must not be disguised. By way of indication, patient and public awareness campaigns/events may constitute disguised promotion, especially if the conditions set out under Article 3.4 of this Code are met.

## ARTICLE 2. DISCREDIT TO AND REDUCTION OF CONFIDENCE IN THE INDUSTRY

**Section 2.1.** Scientific Information/Promotion material and activities must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry in general or any specific pharmaceutical company. Pharma companies must bear in mind that any unlawful conduct on their part is bound to have a detrimental effect upon the entire industry.

**Section 2.2.** Examples of infringing conduct, according to the above, may indicatively consist in supply of inaccurate information, excessive hospitality, unfair incentives for prescribing, exerting influence on government officials, improper payments, Promotion prior to formal approval of the medicines, misconduct of Pharma Companies staff/managers and multiple/cumulative violations of a similar and serious nature in the same therapeutic class within a short period of time.

## ARTICLE 3. SCIENTIFIC INFORMATION/PROMOTIONAL MATERIAL

### Section 3.1. Basic Principles

- 3.1.1.** The name or photograph of an HCP must not be used in any way that is contrary to the ethics of his/her profession. The principles of the Code of Medical Ethics shall also apply to this Code<sup>5</sup>
- 3.1.2.** The Medical Information material must not imitate the methods, copies, slogans or the general layout adopted by another Pharma Company in a way that is likely to mislead or confuse.
- 3.1.3.** The Medicinal Products and activities of other pharmaceutical companies must not be disparaged.
- 3.1.4.** 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.
- 3.1.5.** Reproductions of official documents may be used in the context of Medical Information, provided they are presented intact, unabridged and without falsifications.
- 3.1.6.** Extremes of format, size and cost of the Scientific Information/Promotional material must be avoided.

- 3.1.7.** Lifelong learning in healthcare (LLH), clinical assessments, post-marketing surveillance, experience programmes and post-authorisation studies must not be disguised promotion. Such assessments, lifelong learning programmes and studies should be carried out with a primarily scientific or educational purpose.
- 3.1.8.** When a pharmaceutical company pays for or otherwise secures or arranges the publication of Scientific Information/Promotion Material in a scientific journal, such material must not appear that constitute independent editorial material.
- 3.1.9.** Any promotional/informational material relating to Medicinal Products and their uses, 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.
- 3.1.10.** 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 5 herein below.
- 3.1.11.** Any material relating to Medicinal Products and their uses, which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that pharmaceutical company.
- 3.1.12.** Any text/material which is non-promotional at first site and is being used for Promotion is subject to the provisions of this Code.

### **Section 3.2. Material Content**

Any Scientific Information / Promotion addressed to persons authorised to prescribe or administer the Medicinal Product, must include:

- a. essential information consistent with the summary of product characteristics (SPC) as per Article 3.3. above, and the date such information was drafted or last revised; In case the product's SPC is modified, any material bearing its previous version may only be available for a period of six (6) months from the date the SPC was last revised, save for any Urgent Safety Restriction situations and/or other serious restrictions.
- b. the supply classification of the Medicinal Product (i.e. prescription-only);
- c. the Yellow Card, as per the applicable legislation;
- d. the selling price or indicative price of the various presentations;
- e. In addition, the reimbursement rate by social security funds may also be included.



- f. Scientific Information / Promotion with respect to a medicinal product addressed to persons authorised to prescribe or administer 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.
- g. All Scientific Information / Promotion material 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 3.14 of the Code.

### **Section 3.3. Prescribing Information**

**3.3.1.** Prescribing information must be included in a clear and legible manner in all Scientific Information / Promotion material.

**3.3.2.** Prescribing information shall essentially include the following:

- a. the brand name and the common name of the Medicinal Product;
- b. the qualitative and quantitative composition in active substances;
- c. the trade name and the registered office of the pharmaceutical company which is the marketing authorisation holder (MAH) or those of its Representative in Greece, in respect of products subject to the Centralised Procedure;
- d. the approved indications;
- e. the side-effects, warnings and contra-indications related to the indications promoted;
- f. any warnings approved or additionally imposed by the National Organisation for Medicines or the authority that issued the marketing authorisation;
- g. the method in which the Medicinal Product is distributed (i.e. for hospital use, under medical prescription, etc.);
- h. the marketing authorisation number;
- i. the registration data of the product in the List of Prescribed Medicinal Products (optional);
- j. dosage;
- k. Information provided with respect to the dosage, method of administration, adverse effects, 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.
- l. the date the SPC was last revised.

## Section 3.4. Information, Claims and Comparisons

- 3.4.1.** Pharmaceutical companies must provide to HCPs and appropriate administrative staff, upon request, accurate information on the medicinal products they market.
- 3.4.2.** 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 evidence. They must not be directly or indirectly misleading and they must not distort the scientific facts.
- 3.4.3.** 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.
- 3.4.4.** Any information, claims or comparisons must be capable of scientific substantiation.
- 3.4.5.** The substantiation of any information claim or comparison must be provided without delay, upon request, to an HCP or appropriate administrative staff of the healthcare system.
- 3.4.6.** If the Scientific Information/Promotion material refers to published studies, clear references to literature must be provided.
- 3.4.7.** 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.
- 3.4.8.** 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.
- 3.4.9.** 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 Pharma Companies follow the internationally accepted citation styles (e.g. Vancouver style, Harvard system).

- 3.4.10.** 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, toxic hazards or addiction hazards. The word “safe” must not be used.
- 3.4.11.** Exaggerated or all-embracing claims (e.g. *“the key to success, “works wonders”, “the only choice”, “only acts where needed”, “hits the heart of the problem”, “it only inhibits...”* etc.) must not be made and superlatives (e.g. *“the best”, “the strongest”, “THE analgetic”, “unique”* etc.) 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.
- 3.4.12.** Hanging comparisons such as “it is better”, “better safety profile”, etc. without stating what the medicinal product is compared with are not allowed.
- 3.4.13.** 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.
- 3.4.14.** All claims in promotional material must be consistent with the approved indications and other SPC information of the product. Any claim for use of the Product other than its approved indication and other SPC information is prohibited. The use of data outside the approved indications and other SPC information is not allowed.
- 3.4.15.** 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<sup>6</sup> cannot justify the inclusion of indications not having been tested for the specific medicinal product.
- 3.4.16.** 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).

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6 – The “class effect” definition of Medicinal Products is based on three factors: Similar chemical composition (e.g. the dihydropyridine ring in certain calcium channel blockers), similar action mechanism (beta-adrenergic blocking agents) or similar pharmaceutical properties (antihypertensives, anti-angiogenics, etc.) “Class effect” refers to similar effects, therapeutic effects and similar side effects between two or more pharmaceutical products. All products of a certain class are considered to be closely related to the above three concepts: similar chemical composition, similar pharmacological properties and similar action mechanism.

- 3.4.17.** Along with comparisons and/or statistical data, the following must always be stated:
- a. the statistical significance level (P/P value or confidence intervals) must be stated for data that are statistically non-significant;
  - b. further statistical data analysis, when such data have not been published (i.e. extrapolation of results by the company), is not allowed.
  - c. In case of unknown clinical significance, this must be stated on the same page.
  - d. All factors under comparison must be stated, along with all necessary clarifications.
- 3.4.18.** 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.
- 3.4.19.** The trade names of Products of other Pharma Companies should not be used without the prior approval of the CCP of the other Product.

### **Section 3.5. Use of web sources**

- 3.5.1.** If web sources are used:
- a. the respective reference must accurately lead to the source of information;
  - b. the date of last access must be indicated;
  - c. the relevant print-out must be kept on record by the pharmaceutical company.
- 3.5.2.** Data from conference papers, poster presentations or abstracts may be used only if:
- d. they have been presented in prestigious scientific conferences and have been approved by the scientific committee of the conference;
  - e. the period elapsed from the first presentation of the data in a conference does not exceed two years; If, two (2) years after the disclosure of the study, the 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 Scientific Information/Promotion material anymore;
  - f. they are available in their entirety on the website or the abstract book of the conference;
  - g. 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.

## Section 3.6. In press articles

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.

## Section 3.7. Data on file

The use of unpublished data regarding the efficacy and safety of Medicinal Products (data on file) for promotional purposes is prohibited. Such data may constitute the subject-matter of discussions between HCPs and the scientific department 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.

## Section 3.8. Patient Registries

- 3.8.1.** 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”*. The following must be complied with at all times:
- 3.8.1.1.** 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.
  - 3.8.1.2.** Generalisation of isolated remarks, e.g. data from case reports, is not permitted.
  - 3.8.1.3.** The use of off label data and other SPC information 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.
  - 3.8.1.4.** 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.

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

- a. randomised controlled trials (RCTs) (with concealed allocation, double-blind) or systematic post-review thereof (post-analysis);
- b. properly designed non-randomised controlled trials;
- c. controlled observational studies (prospective or studies in patients-witnesses);
- d. uncontrolled observational studies;
- e. expert opinion based on pathophysiological mechanisms, or laboratory evidence, or consensus opinion without specific reference to critical evaluation and methodology.

### **Section 3.9. Pharmacoeconomic Studies**

**3.9.1.** The use of pharmacoeconomic studies in Scientific Information/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 HCPs with 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.

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

- a. the studies do not concern safety and efficacy issues;
- b. 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.
- c. 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;
- d. 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;
- e. It must be pointed out that the information was drawn from published pharmacoeconomic studies (or, respectively, experimental studies).

## Section 3.10. Tables / Graphs

- 3.10.1.** 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.
- 3.10.2.** 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, otherwise clear reference must be made to the fact that the original has been adapted.
- 3.10.3.** 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.
- 3.10.4.** In particular, it is prohibited:
- a. to delete a part of a graph or table in a way that the remaining part provides misleading information;
  - b. to remove parts of a study or the results in other treatment sub-groups;
  - c. to remove the results of other therapeutic treatments;
  - d. to alter the scale, so that the differences appear smaller or higher than they actually are;
  - e. to omit the title, measurement units on the x/y axes and/or numbers in general.
- 3.10.5.** Changes in graphic elements from tables and figures of articles are only acceptable if:
- a. the end result does not change the initial meaning of the original;
  - b. clear reference is made to the fact that the original has been adapted; and
  - c. changes concern erasure or omission of dosage, indications etc. which are not approved and/or not marketed in Greece.

- 3.10.6.** 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.
- 3.10.7.** 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.
- 3.10.8.** In the case of competitive products, comparison between different clinical studies is not allowed (in terms of targets, patients' characteristics, etc.).

## **Section 3.11. Form of Material**

### **3.11.1. Cards**

Leave pieces 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.

### **3.11.2. Printed Material**

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.

### **3.11.3. Digital Material**

In digital Scientific Information/Promotion 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". The prescribing information may be included in the same or a different link, where necessary.

### **3.11.4. Audio-Visual Material**

In the case of audio-visual material, such as CDs, DVDs, audio messages etc. and in the case of interactive data systems, the prescribing information may be provided:

- a. by way of a document which is made available to all persons to whom the material is shown or sent; or
- b. by inclusion in the audio-visual recording or in the interactive data system;
- c. When the prescribing information is included in an interactive data system, instructions for accessing it must be clearly displayed.



### 3.11.5. Posters

Only the name of the medicinal product and its international common name must be displayed. In case more information is displayed, the following indication must be included legibly: *“Prior to prescription, please consult the Summary of Product Characteristics available on the stand”*. It is understood that the SPC must be available on the stand in a sufficient number of copies or in an electronic medium.

### 3.11.6. Advertisements

- 3.11.6.1.** Advertisements may only appear in professional publications, namely publications sent or delivered exclusively to HCPs. Scientific journals and publications of the health sector, printed material of conferences positively evaluated by the SFEE Evaluation Committee, medical/ pharmaceutical books, etc. fall under this category.
- 3.11.6.2.** A loose insert in such a publication (for instance, separate leaflets distributed through the medical press) is not considered “Abbreviated Advertisement”.
- 3.11.6.3.** Advertisements are not permitted in audio-visual 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: *“For the Summary of Product Characteristics, please click here”*.
- 3.11.6.4.** 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.
- 3.11.6.5.** If two pages of an advertisement are not facing, neither of them must be misleading or false when read in isolation.

### 3.11.7. Abbreviated advertisements

- 3.11.7.1.** 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.
- 3.11.7.2.** Abbreviated advertisements must include the following information:
  - a. the name of the medicinal product, which may be either a brand name or a non-proprietary name;
  - b. the name and address of the marketing authorisation holder in Greece, for products subject to the centralised procedure;

- c. the qualitative and quantitative composition in active ingredients;
- d. where additional information or claims are included, the contra-indications, warnings and adverse reactions must necessarily be stated;
- e. any warning issued by the National Organisation for Medicines (EOF) or the authority which issued the marketing authorisation, must be included in the advertisement;
- f. 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.

### **3.11.8. Reprints**

- 3.11.8.1.** Reprints and quotations from medical and scientific literature or from personal communications (letters to the editor) must accurately reflect the meaning of the author.
- 3.11.8.2.** 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.
- 3.11.8.3.** 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.
- 3.11.8.4.** Unsolicited reprints distributed on the initiative of the pharmaceutical company must refer to approved products, indications and information of the approved SPC; they 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.

### **Section 3.12. Electronic Communications**

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.

### **Section 3.13. Distribution of Scientific Information/Promotion Material**

- 3.13.1.** Scientific Information/Promotion Material must only be sent or distributed to those categories of HCPs who need or are interested in the particular information or are reasonably deemed to be the recipients of such information.
- 3.13.2.** Pharmaceutical companies must exercise restraint on the frequency of distribution and the volume of Scientific Information/Promotion material in a way to respond to the need for effective information.
- 3.13.3.** 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, save upon request or with the consent of the recipient.

### **Internal Control/Authorisation Procedure for Scientific Information/Promotion material**

- 3.14.1.** Before printing/distribution, Scientific Information/Promotion material must be certified in accordance with the provisions of the legislation in force.
- 3.14.2.** Pharmaceutical companies must have a scientific department which shall ensure the appropriate internal procedures for the certification of promotional material, thereby ensuring compliance with the legislation in force and the Code.
- 3.14.3.** The scientific department personnel of the pharmaceutical company, including the members of staff involved in any way in the preparation or approval of medical information 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.
- 3.14.4.** It is recommended that the scientific department in charge of certifying the printed material is integrated into the medical/scientific department of each Pharma Company, depending on the organisational structure of each Pharma Company. The scientific department should preferably include a medical doctor or a pharmacist or other properly qualified healthcare scientist who shall be responsible for approving all Scientific Information/Promotion material before release. Such person must certify that he/she has examined the final form of the Scientific Information/Promotion 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 sales and marketing department and no conflict of interest must exist.

- 3.14.5.** Materials prepared by pharmaceutical companies which relates to medicinal products in general but is not intended to Promote any particular medicinal products, such as corporate advertising, press releases, market research material, financial information to shareholders, stock value information, educational/ information material for patients, etc., must be certified by the Company's scientific service as above (see paragraph 3.14.4.), in order to ensure compliance with the Code and the legislation in force.
- 3.14.6.** 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) and/or the package leaflet, and is a fair and truthful presentation of the facts about the medicinal product.
- 3.14.7.** All Scientific Information / Promotion material 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 or its last revision was originally approved by the pharmaceutical company's scientific service.
- 3.14.8.** 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 from time to time and the Code.
- 3.14.9.** Pharmaceutical companies must preserve all certified material, along with the relevant accompanying information (e.g. bibliography, dated printouts of online publications etc.) in the form certified (i.e. non only in .pdf form but also in hard copy or digital form) 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 First Instance and Second Instance Committees for Code Compliance.
- 3.14.10.** It is very important to keep record of audio-visual and digital material as well, which shall be submitted to the competent authority as per the applicable regulations, as is the case with printed material.

## ARTICLE 4. INTERNET-DIGITAL APPLICATIONS

### Section 4.1. General

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

- a. Websites
- b. Digital presentation of «eDetailing» Scientific Information / Promotion Forms
- c. e-Newsletter/E-mailing to HCPs
- d. Social Media

In any case, depending on the content of the communication, its recipients and the terms of use of the relevant internet platform/application, 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.

**4.1.2.** Pharmaceutical companies are responsible for the content of any promotional and informational material which is posted on the internet at their initiative and/or is sponsored by them or by any third parties acting on their account. For example, reference of a prescription-only medicine to the company's Website or to the account/profile of PCs on the social media may be considered as promotion addressed to the general public, which is prohibited. Pharmaceutical companies are also responsible for any information which may be disclosed by their employees through their personal social media accounts/profiles if (a) it can be reasonably inferred that these persons represent the company; or b) these persons have been mandated, authorised or assisted by the company in disclosing such information.

**4.1.3.** Pharmaceutical companies are liable to have proper procedures in place to timely check, modify and erase any improper comments which may appear on their social media accounts (as well as on third-party social media accounts), insofar as this is permitted under the data protection legislation and the applicable laws.

**4.1.4.** According to Article 3.1.9. above, any promotional/informational material relating to Medicinal Products and their uses, which is sponsored by a pharmaceutical company, must clearly indicate that it has been sponsored by that pharmaceutical company. Accordingly, whenever Scientific Information/Promotion material is publicised on the Internet, clear reference must be made to any involvement a pharmaceutical company may had in it, e.g. if it has been involved in defining the content to be publicised or if it has sponsored the publication in whole or in part.

## Section 4.2.Websites – Website Types

Pharmaceutical company websites must abide by the principles of objectivity, truthfulness, seriousness, accountability and must adopt a patient-oriented approach.

### 4.2.1. Company Websites addressed to the public

The websites of pharmaceutical companies fall under the category of Internet media which are addressed to the general public, save for those accessed only through use of access credentials. Access to these websites is therefore normally gained through Internet search engines, which is why using the correct keywords is extremely important. Pharmaceutical companies must ensure that the keywords they use are appropriate, depending on the target group.

- a. The main corporate website:** 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. All applicable regulations of the competent regulatory authorities shall apply with respect to pre-approval and notification requirements.

- 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 the competent regulatory authority from time to time for pre-approval or notification, as per the applicable regulations, while the following conditions must also be met:

1. 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.
2. Texts and information will be quoted in a neutral and objective manner with precise reference sources.
3. A phrase to the following effect will be included: *“This is intended for general information purposes and is no substitute for advice from a physician or another competent HCP”*. This phrase must form an integral part of the terms of use of each informational website/web page.
4. The sources of the information included will be kept on record by each pharmaceutical company and be made available to the competent regulatory authority from time to time and/or the competent SFEE Code Compliance Monitoring Bodies (see Art. 39 below), upon request.

5. 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.
6. The texts and graphs prepared will be signed by the HCP of the pharmaceutical company's scientific service, whose name will be notified to the First Instance SFEE Committee, upon request, as well as to the competent authority from time to time, where this is required under the law.

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

**4.2.2.1.** Measures must be adopted in order to ensure that only HCPs will have personal access via a username and a password.

**4.2.2.2.** 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.

**4.2.2.3.** In any case, the material included in such corporate websites is considered as promotional and must therefore:

- a) comply with the respective provisions on the promotion of prescription-only medicinal products (effective legislation and Article 4 of the present Chapter of the Code), and
- b) be certified as per the company's internal procedures (the same applies to any changes or additions to the website), and
- c) be notified to the competent authority from time to time, after it is originally posted or whenever subsequently revised, as per the applicable regulations.

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

**4.2.2.5.** 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 Article 14 of the present Chapter of the Code. Where interactive

communication and/or free text fields are available, the company is liable to apply effective control procedures for any texts/information submitted by the HCPs, to ensure effective collection of reported Adverse Reactions and compliance with the applicable pharmacovigilance / Medical Devices Vigilance requirements.

- 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 website operator.
- 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.

#### **4.2.3. Websites of Medical Companies addressed to the public, including texts for public information on health prevention-promotion issues and financially supported by pharmaceutical companies.**

Texts and pictures, as well as any substantial updating thereof, must be submitted to the competent regulatory authority from time to time as per the applicable legislation. Medical Companies websites may include references to therapeutic options – but not any direct or indirect Promotion of medicinal products – under the following conditions:

- a) All currently available therapeutic options, pharmaceutical or not, applied alternatively or supplementary, must be mentioned (e.g. proper nutrition, exercise, surgical intervention, etc.).
- b) Pharmaceutical options references must extend up to the level of the pharmacological group.
- c) The name of the Medical Company 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 4.2.b.1. through 4.2.b.4. shall apply.



### **Section 4.3. Digital presentation of Scientific Information/Promotional Material “eDetailing”**

“eDetailing” is the presentation of digital Scientific Information/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 supply of information.

eDetails must be sent and/or presented 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.

During the conduct of eDetailing activities, care must be taken: (a) to collect any personal data, sensitive or otherwise, 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 the content used; (d) to consider the case that the eDetail might include or 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 18 of this Code (Informational and Educational Material and Medical Use Material).

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

- a) The approval of the promotional material included in the electronic media (tablet, smartphone, etc.) must comply with the applicable legislation, the respective article of the present Chapter of the SFEE Code of Ethics and the relevant circulars of EOF.
- b) 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.
- c) 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;
- d) 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;

- e) ensure, if the Scientific Information/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 (Article 18).
- f) keep record of the electronic Scientific Information/Promotion material in accordance with the provisions of this Code and the internal archiving procedures of the Marketing Authorisation Holder. The highest standard rule will apply in this regard.

#### **Section 4.4. Newsletter/e-mailing to HCPs**

**4.2.1. Upon request of the HCP** Newsletters shall be sent out to HCPs upon their request, essentially in accordance with the provisions of Article 3 of the Code (Scientific Information).

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

The regular supply of information to HCPs via e-mail on the initiative of pharmaceutical companies is permitted subject to the regulations on digital promotional material, as same are laid down herein above. Furthermore:

- a. 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 adverse reactions. If this is not possible, the dispatch must be performed in a manner that prevents replies (no reply).
- b. 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.
- c. Pharmaceutical companies are required to regulate the frequency of eNewsletters in a manner corresponding to the need for essential information per therapeutic category.
- d. Pharmaceutical companies are liable to comply with all applicable data protection regulations.

#### **4.4.3. From the Scientific/Medical Affairs Department**

- a) 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.
- b) 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.

- c) 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). HCPs may further request and obtain the full publication, subject to all relevant legislative and regulatory requirements.
- d) When providing information to HCPs through their medical affairs/scientific departments, pharmaceutical companies are liable to comply with the applicable copyright legislation.

#### **4.4.4. From the Marketing Department**

- 4.4.4.1.** All messages sent by the Marketing and/or Sales Department constitute promotion (scientific information eDetailing) and the provisions of this Chapter of the Code shall apply.
- 4.4.4.2.** Medical information messages may be sent by the Marketing/Sales Department, provided that all copyright and data protection regulations are fully observed.

### **Section 4.5. Social Media**

#### **4.5.1. Using social media – Facebook, Twitter & LinkedIn.**

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, Twitter, LinkedIn etc. enable pharmaceutical companies to establish interactive communication with a broad section of the consumers and HCPs and can prove very effective information and communication tools. Nevertheless, the use of social media may not include Promotion of prescription-only medicines, save for authorised vaccination campaigns. Moreover, the quality and validity of the information transmitted and its objectives must be ensured at all times.

#### **4.5.2. Social media management:**

- 4.5.2.1.** The decision to create corporate accounts/profiles on social media 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).

- 4.5.2.2. Only the staff authorised by the management of each company to that effect (e.g. members of the Communications Department) may contact consumers or HCPs on behalf of the company through the social media.
- 4.5.2.3. Social Media accounts of pharmaceutical companies must be created for professional and not for personal use.
- 4.5.2.4. An alternate “administrator” must be appointed for every pharmaceutical company officer authorised to manage the company’s social media accounts, so as to ensure constant compliance with the principles, procedures and standards governing the use of Social Media.
- 4.5.2.5. Corporate social media accounts must be regularly updated. Any accounts of pharmaceutical companies which have not been updated for a period exceeding 6 months must be deactivated by the main administrator.

#### **4.5.3. Transparency assurance:**

- 4.5.3.1. All corporate social media accounts/profiles must clearly state their association with the respective company via the name of the account/profile or the use of a brand/corporate logo.
- 4.5.3.2. Third parties who may communicate on behalf of a company through that company’s Social Media accounts/profiles must include a disclaimer notice in their communications, approved by the legal department of the company concerned.

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

- 4.5.4.1. Any communication material used in social media must be approved through the standard approval procedures of each company and must conform with the applicable regulations.
- 4.5.4.2. Accordingly, any communication material used in social media aimed at informing the public on diseases must comply with the effective legislation.<sup>7</sup>
- 4.5.4.3. All corporate social media accounts/profiles must be submitted along with their content to the competent regulatory authority as per the applicable legislation.

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7 – See EOF Circular Ref. 44787/12.05.2017.

**4.5.4.4.** All corporate social media accounts/profiles must include clear instructions explaining the manner in which Adverse Reactions can be reported, as well as the contact details of the respective Pharmacovigilance Department of the Marketing Authorisation Holder of the medicinal product concerned.

**4.5.4.5.** All corporate social media accounts/profiles must include a “Terms of Use” statement, approved by the Legal Department of the respective company.

#### **4.5.5. Social Media Terms of Use**

**4.5.5.1.** Each pharmaceutical company must have due regard to the terms of use of each social medium and must follow its internal procedures, the terms of this Code and the applicable legislation.

**4.5.5.2.** The company is not responsible for the validity of any views, information, advice or comments displayed on its corporate account/profile, unless they have been directly communicated by the company itself.

**4.5.5.3.** Pharmaceutical companies, however, are liable to remove any 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 the page;
- Provides non-approved medical information;
- Is irrelevant with the subject matter.

**4.5.5.4.** Each pharmaceutical company reserves the right to restrict access to its corporate account/profile to any person who repeatedly makes comments that fall into the above categories.

**4.5.5.5.** Pharmaceutical companies are liable to include in the terms of use of their corporate accounts/profiles a statement informing users that they must report to the MAH and/or their attending physicians any adverse effects identified when using the medicinal product concerned.

#### 4.5.6. Reporting Adverse Effects / Compliance with Terms of Use

All corporate social media accounts/profiles 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.

#### Section 4.6. 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 the social medium, as per the applicable laws, and the manner in which such data will be used by the company must be clearly explained.

### ARTICLE 5. PROMOTION ADDRESSED TO THE PUBLIC

**Section 5.1.** It is prohibited to address promotions to the public for medicinal products supplied with medical prescription only. Information on human health or diseases is not promotion, unless reference is made to medicinal products whether directly or indirectly.

**Section 5.2.** This prohibition does not apply to vaccination campaigns conducted by pharmaceutical companies and approved by the competent authorities.

**Section 5.3.** The exception introduced in paragraph 5.2 is intended to promote public awareness and increase vaccination rates in the general population. Therefore, the main scope of the promotion is not the vaccine, but vaccination. For this purpose, the following must be defined:

- a) the means to be used (e.g. the daily press, the Internet, radio, television etc.);
- b) the duration of the campaign and any future repetitions at specified intervals;
- c) whether the vaccine is integrated in the National Vaccination Programme.

**Section 5.4.** If individual members of the general public ask for advice on personal medical issues, they must be advised to consult an HCP.

## \* CHAPTER 2. INTERACTIONS WITH HCPs, HCOs AND POs

### ARTICLE 6. SCIENTIFIC EVENT CATEGORIES ΕΚΔΗΛΩΣΕΩΝ

#### Section 6.1. Moral Commitment

SFEE and its members support continuing medical education, information and lifelong learning, as a **stance of principle**. Placing the **patient at the centre** of all our activities, we believe it is our duty to **promote scientific dialogue** on diseases and therapies, as a means to speed up the process of finding treatments and less painful solutions to chronic and other serious medical conditions. To that end, we sponsor various scientific events, provide educational scholarships, sponsor doctors' educational expenses and promote scientific research and innovation. Our goal is to educate more and more physicians of all specialties and to interact with the community of doctors and patients with **integrity, respect and transparency**, establishing relationships of mutual moral cooperation and honest exchange of views.

However, the practical manifestation of our social contribution to patients and science should not tarnish the image of our industry. All our sponsorship activities are therefore based on the value our industry has in the community and are subjected to strict mandatory ethical standards (scientific, economic, quantitative and communicative), as we realise above all that we care for "human beings", as a value. We disclose our transfers of value with honesty because we believe in our worth and we are proud of it. We receive gratitude and respect from our partners because we support **transparency** and enjoy working with them in achieving this objective.

The **moral commitment** of SFEE and its members consists in contributing to the community with **social** and **sectoral reciprocity** and above all **quality**, which is ensured through a **high-standard selection of activities**. Pharmaceutical companies are committed to SFEE's objectives and commitments, and SFEE is the main custodian of their principles and commitments, fully endorsing the ethical principles of our pan-European organisation, **EFPIA**. Together we safeguard our business model, an advanced production model armoured with ethical values and strong social interaction.

**Section 6.2.** Scientific Events are divided into two (2) major general categories: those organised by third parties (A) and those organized by Pharma Companies (B):

#### [A]. Scientific Events organised by Third Parties (Government or Private HCOs)

Third parties include both public and private Healthcare Organisations (HCOs).

In particular, public HCOs include medical schools and health science departments of universities across the country, University hospitals throughout the country, state hospitals integrated in the NHS and hospitals supervised by the Ministry of National Defence, including all their functional units (clinics, laboratories, operating rooms), primary healthcare centres, Academic Units of Primary Health Care<sup>8</sup>, Social Security healthcare units/structures and non-profit scientific institutions or associations of health scientists across the country, operating in the form of Legal Entities of Public Law.

Private HCOs include non-profit scientific associations of any legal form, operating in the form of Legal Entities of Private Law, corporations or unions, as well as private clinics and hospitals.

The scientific events organised by third parties which pharmaceutical companies may support are divided in the following categories:

### ***A.1. International Scientific Events held in Greece***

- International scientific events are events organised by foreign HCOs either independently or jointly with Greek HCOs, where the former participate by at least 50% in terms of budget and Speakers.
  - a) International scientific events are events organised by foreign HCOs either independently or jointly with Greek HCOs, where the former participate by at least 50% in terms of budget and Speakers and the Greek HCOs have completed an operation period of four (4) years and above.
  - b) As regards the maximum number of International Scientific Events a pharmaceutical company may support every year, only in the case of co-organization, pharmaceutical companies are aligned with the limit set out in Annex I (i.e. one -1- per year).
- It is pointed out that the following are considered to be “Domestic Events with International Participation” rather than “International Events”:
  - a) Events organised in Greece by HCOs based in Greece under the auspices of HCOs based abroad;
  - b) Events held by HCOs based in Greece with the participation of foreign speakers,

Where the sponsorship value is proportional to the duration of the event, according to the above.

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8 – See Article 24 of Law 4486/2017 on PHC transformation.



- The following apply to scientific events organised in Greece exclusively by international scientific bodies without involvement of a Greek scientific body:
  1. No application needs to be filed to EOF for validation, as is the case with domestic scientific events.
  2. Any pharmaceutical companies interested in declaring to EOF sponsorships in International conferences in Greece, organised exclusively by foreign scientific entities, shall subject their sponsorships to the “International Event Sponsorship Notification” procedure.
  3. No actuarial data needs to be submitted in respect of these sponsorships.

### **A.2. Panhellenic Scientific Events:**

- Panhellenic scientific events are those organised by HCOs corresponding to the recognized specialties and specializations of KESY and any HCOs that have completed an operation period of four (4) years and above, with proven scientific and educational work. The amount of sponsorships per pharmaceutical company must not exceed the limits specified in Annex I. Such events must have a minimum total duration of twenty-four (24) hours, in order to be eligible to receive financial support from pharmaceutical companies- provided of course that all other applicable criteria are met.
- As regards the number of Panhellenic scientific events a pharmaceutical company may support every year, pharmaceutical companies shall to observe the limit set by the competent regulatory authority to that effect (see Annex I).
- The limits of sponsorships per pharmaceutical company must not exceed the limits specified in Annex I.

### **A.3. Regional Scientific Events (Two-day events):**

- Regional scientific events are those organised within the Administrative Region of the HCO’s registered seat and addressed to HCPs practicing within **the same Administrative Region**<sup>9</sup>. Such events must have a minimum total duration of sixteen (16) hours, in order to be eligible to receive financial support from pharmaceutical companies - provided of course that all other applicable criteria are met.
- Exceptionally, Regional scientific events may also be considered the scientific events, with minimum total duration of sixteen (16) hours, that are organised by HCOs corresponding to the recognized specialties and specializations of KESY and any HCOs that have completed an operation period of four (4) years and above and are addressed to HCPs in an Administrative Region other than that of the entity’s registered seat.

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9 – It is noted that, according to Article 3 of Law 3852/2010, Greece comprises the following thirteen (13) Administrative Regions, which are Legal Entities of Public Law and 2nd degree self-government organisations: 1) Eastern Macedonia - Thrace; 2) Central Macedonia; 3) Western Macedonia; 4) Hesperus; 5) Thessalia; 6) Ionian Islands; 7) Western Greece; 8) Sterea Ellada; 9) Attica; 10) Peloponnese; 11) Northern Aegean; 12) Southern Aegean; and 13) Crete.

- For Regional events accommodation costs are not, in principle, justified. Exceptionally, pharmaceutical companies may pay for the accommodation costs of HCPs where there is a confirmed need of more than three (3) hours transport (to and from the location) and the duration of the Program on the 1<sup>st</sup> day is, at least, four (4) hours, as well as if the HCP concerned is actively involved in the event (as a speaker or coordinator).
- As regards the number of Regional scientific events a pharmaceutical company can support every year, pharmaceutical companies are liable to observe the limit set by the competent regulatory authority to that effect (see Annex I).
- The limits of sponsorships per pharmaceutical company must not exceed the limits specified in Annex I.

#### **A.4. Local Scientific Events (One-day events):**

- Local scientific events are those organised within the District<sup>10</sup> of the registered seat of the HCO and addressed mainly to HCPs practicing within **the same District**. Such events must have a minimum total duration of twenty-four (4) hours, in order to be eligible to receive financial support from pharmaceutical companies- provided of course that all other applicable criteria are met.
- Exceptionally, local events are also repetitive (one day) scientific events, intended to inform HCPs, organised, outside their registered seat, by HCOs corresponding to the recognized specialties and specializations of KESY and any HCOs that have completed an operation period of four (4) years and above and are addressed to HCPs of one District, provided that the element of information of the local medical community prevails.
- In local events, accommodation costs are not, in principle, justified, due to locality.
- Exceptionally, accommodation costs may be justified if there is a confirmed need of more than three (3) hours transport (to and from the location). Actively involved HCPs (speakers or coordinators) are excluded from the above restriction.
- The maximum number of local scientific events a pharmaceutical company may support per HCO and the limits of sponsorships per pharmaceutical company must not exceed the limits specified in Annex I.

#### **A.5. Events organised by State Hospitals, University clinics, laboratories, NHS clinics and Private Clinics/Hospitals:**

Pharmaceutical companies may sponsor scientific events organised by hospital institutions in general, provided that:

- a. they involve free participation of HCPs;

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10 – See Article 1 of Law 3852/2010. Greece is divided into 51 administrative Districts.

- b. they are preferably held in the Hospital amphitheatre or near the city, where the Hospital is located and
- c. they are carried out without the presence of exhibition stands, in accordance with the applicable laws and regulations.

By exception, pharmaceutical companies may sponsor such events, even when there are exhibition stands involved, if the events are held in another independent space outside the Hospital, accessible only to HCPs and not to the general public. As regards the maximum number of events a pharmaceutical company may support per year, pharmaceutical companies shall observe the limits set by the Competent Regulatory Authority to that effect (see Annex I)

- Such events are addressed to HCPs:
  1. practising within the same Administrative Region, if the event is organised by a University clinic. Pharmaceutical companies may cover the accommodation costs of HCPs for his/her participation in such events, provided that there is a confirmed need of more than three (3) hours transport in total (to and from the HCP's workplace).
  2. practising within the same District, if the event is organised by an NHS clinic and/or a private hospital/clinic in the same District. Any accommodation expenses incurred by such HCPs to attend the event shall not be covered by the pharmaceutical companies.
- HCPs actively involved in the event (speakers or moderators) are excluded from the restrictions laid down in the above paragraphs.
- The total duration of these events may not exceed sixteen (16) hours, based on a schedule of minimum 4 hours per day.
- In scientific events organised by Hospitals, University clinics, laboratories, NHS clinics, private clinics and hospitals, sponsorships must not exceed the limits specified in Annex I.

## **A.6. LEARNING CYCLES**

**1. Definition: a 'Learning Cycle' (or Seminar) is an educational event, organised by Scientific Healthcare Organisations (HCO) and/or hospitals as a training cycle with an educational curriculum, that takes place in Greece, either by physical attendance, web attendance or hybrid. It may be addressed to Healthcare Professionals (HCP), qualified or interns, undergraduate medical students and professional nurses.**

**2. Conditions for a positive evaluation by SFEE Evaluation Committee:**

**"Learning Cycles"** are sponsored by the Pharmaceutical Companies under the following conditions which must be met simultaneously:

- i. **A single approval by the National Organization for Medicines (EOF) for the entire cycle (not per course).**
- ii. **Submission** for evaluation at **SFEE platform**, by uploading EOF's approval for the entire cycle and the corresponding sponsorship package.
- iii. **Identification of the participants** (i.e., HCPs, qualified or interns, undergraduate students, professional nurses).
- iv. Minimum duration of **four (4) hours** per day.
- v. With respect to overnight **accommodations** in case of physical attendance, the restrictions of regional scientific events apply.
- vi. Receipt of **CMEs** upon completion of attendance of the cycle, is not a prerequisite, however it would be evaluated positively by SFEE Evaluation Committee.
- vii. The maximum number of events to be supported by a Pharma Company per HCO are set forth in Annex I.

### 3. Sponsorship Limit

The maximum amount of registration fee and sponsorship per pharmaceutical company must not exceed the limits specified in Annex I.

It is noted that, in case the Pharma Companies choose to participate in learning cycles scientific events **exclusively through Web**, there is no registration fee and the maximum amount of sponsorship per Pharma Company is that set out in ANNEX I, in category 2 below (web/virtual - scientific events/congresses ) shall apply.

### 4. Interpretation Guidelines

Problems that may arise during the evaluation of a «Cycle» should be interpreted in light of the Ethical Commitment of SFEE members (Article 6.1.), taking into account the previous experience on internal events of SFEE Evaluation Committee, the literal interpretation of the regulatory framework (EOF circular), the overall perception and always under the principle that *"the strictest rule applies"*.

### 5. Product promotion or corporate (brand) promotion:

Depending on the audience of the cycle, the respective applicable requirements should be met. It is hereby clarified that undergraduate students are not HCPs.

#### A.7. WEB/VIRTUAL, HYBRID SCIENTIFIC EVENTS & WEBINARS of HCOs

1. **(Domestic) Scientific Events referred to in paragraphs A1, A2, A3, A4 and A5 carried out with physical presence (f2f) of part of the speakers and participants (and not just the speakers) and simultaneous webcast (hybrid events).**

The HCO may arrange for the simultaneous online transmission of an event, irrespective of the event category (categories A.1. through A.5 above). Once the event is completed, all or part of the program may be posted on the website of the host HCO, so as to enable more HCPs to attend the programme at their convenience (on demand).

The simultaneous online transmission of the event must be stated in the original application of the organising entity.

Pharmaceutical companies may financially support HCPs, by sponsoring the purchase of any access/registration codes necessary for attendance, individually for each HCP, when applicable. For the sponsoring of the online attendance of an HCP to such events, the sponsoring pharmaceutical company must file an application to EOF to that effect, if there is a registration fee involved, through the EOF database, with the indication “Web Scientific Events” and a reference to the registration fees involved. In case the above internet transmissions are attended by groups of participants, no special approval is required from EOF (except for the sponsoring of the participation of each HCP individually), and participants may only be offered coffee and soft drinks. The costs of use of the space, installations and the cost of supply of coffee/soft drinks may be covered by pharmaceutical companies.

The maximum registration fee and the maximum sponsorship limit per Pharma Company in these situations are defined in ANNEX I, depending on the type of scientific event involved (A1., A.2., A.3., A.4. or A.5.).

It is noted that, in case the Pharma Companies choose to participate in the scientific events referred to in categories A.1.through A.5.**exclusively through the Internet**, i.e. without sponsoring the physical attendance of the participants and/or without promoting themselves at the space where participants are physically present, the registration and sponsorship limits referred to in category 2 below (web/virtual - scientific events/congresses) shall apply.

## **2. Scientific Events (of HCOs established in Greece) carried out exclusively via the Internet, (through live transmission or video recording (web/virtual scientific events/congresses))**

HCOs may organise scientific events conducted exclusively via the Internet, i.e. without the face to face attendance of the participating HCPs, through live transmission, enabling interaction between the Speakers and the HCPs or otherwise. Once ended, these events may be posted on the organising entity’s controlled-access website, only for HCPs, to enable HCPs to attend the programme at their convenience (on demand). These scientific events shall have a duration equivalent to that of the events referred to in points A.1.-A.5.

These events are subject to approval by EOF (as “Web Scientific Events”), which is obtained by care of the organising entity.

Pharmaceutical companies may financially support HCPs, by sponsoring the purchase of any access/registration codes necessary for attendance, individually for each HCP. For the sponsoring of the online participation of an HCP in such scientific events, a request must

be submitted by the sponsoring company to EOF, if there is a registration fee involved, through the EOF database, with the indication “Web Scientific Events” and a reference to the registration fees involved. In case the above scientific events are attended by groups of participants, no special approval is required from EOF (except for the sponsoring of the participation of each HCP individually), and participants may only be offered coffee and soft drinks. The costs of use of the space, installations and the cost of supply of coffee/soft drinks may be covered by pharmaceutical companies.

The maximum amount of sponsorship for registration/participation of HCPs, the maximum amount of sponsorship per Pharma Company in the web events mentioned above and the maximum number of events to be supported by a Pharma Company per HCO are set forth in Annex I.

Pharma Companies may only support web events organised by HCOs, under the condition that the HCOs allow them to monitor real-time the number of participants (HCPs).

Pharma Companies may sponsor the online participation of HCPs in web events only if the HCOs possess appropriate technical equipment to ensure real participation of the HCPs - which shall constitute the condition for the issuance of the relevant CME.

### **3. Scientific Events organized ABROAD by scientific bodies and carried out with physical presence and simultaneous online transmission (hybrid events) or conducted exclusively via the Internet (virtual/web - scientific events/congresses)**

Pharmaceutical companies can financially support HCPs, by sponsoring the purchase of any access/registration codes necessary for attendance.

For the sponsorship of an online participation of HCPs in these scientific events, a request must be submitted by the sponsoring (pharma) company to EOF, if there is a registration fee involved, through the EOF database, with the indication “Web Scientific Events” and an indication of the registration fees involved.

In case the above internet transmissions are attended by groups of participants, no special approval is required from EOF (except to cover the participation of each HCP), and participants will only be offered coffee and soft drinks. The costs of use of the space, installations and the cost of supply of coffee/soft drinks may be covered by pharmaceutical companies.

### **4. Online Scientific Presentations (webinars)**

HCOs may organise scientific events (webinars) conducted exclusively via the Internet, i.e. without the physical presence of the participating HCPs, exclusively through live transmission, enabling interaction between the Speakers and the HCPs or otherwise. Once ended, these events may be posted on the organising entity’s controlled-access website, only for HCPs, to enable HCPs to attend the programme at their convenience (on demand). Such events may have a total duration up to 3 hours.

The maximum amount of sponsorship per pharmaceutical company for these webinars is the one laid down in Annex I.

Webinars may be organised after a request to that effect is filed to EOF with the indication “Web”.

#### **A.8. Patient Awareness Events**

- Patient awareness events are held in relation to health/diagnosis/therapy - related matters, special treatments, hospitalisation/healthcare matters, social aspects of diseases and the improvement of the quality of life of patients. These events are organised either by POs or by HCOs. Pharmaceutical companies are not allowed under the Greek legislation, to organise patient or public awareness events.

##### a) Events organised by POs

Events organised by POs on disease prevention matters are not subject to approval by EOF and may be sponsored by pharmaceutical companies in accordance with the provisions of Chapter 4 of this Code.

##### b) Events organised by HCOs

- The financing of patients and public awareness events on disease prevention matters organised by HCOs are subject to approval by EOF and may be sponsored by pharmaceutical companies.
- If any preventive medical examination programmes, interventions and/or actions are taking place at Primary Healthcare level as part of these events for the general public or for special groups of the population, then, in order to support these events in any manner, pharmaceutical companies must establish that the organising HCOs comply with all applicable laws and regulations.<sup>11</sup>

#### **A.9. Conferences on Health/Medicinal Policies organised by advertising companies or other services providers.**

- These events do not constitute scientific events within the meaning of the law (EOF/ Ministry of Health). They do, however, constitute events which may be supported by pharmaceutical companies.
- They are organised in Greece by advertising companies or other service providers, mainly communication service providers; they are not promotional in nature, but rather, intended to provide the public with general information, through the participation of different stakeholders (i.e. HCPs, patients, members of pharmaceutical companies, government officials, journalists), and to promote the exchange of views on health and medicine-related issues. These events are normally characterised as “congresses” and they are of broader (not purely scientific) scope.

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11 – See Circular no. Γ1γ/Γ.Φ.13,18/Γ.Π.οικ.19814 of the Ministry of Health.

- Since these events are addressed to the wide public, pharmaceutical companies may participate only by means of a business sponsorship (corporate brand-name), in the context of their corporate communication. According to relevant legislation, product promotion or speech with regard to a product is not allowed to these events. Accordingly, Pharma Companies are not allowed to sponsor the participation of HCPs, in accordance with Article 8 of this Code and the relevant laws and regulations.
- SFEE Member companies are advised to carefully examine the programme and the character of such events and to calculate the amount of their sponsorship taking under consideration fair market values and the duration of the event.

Scientific Events of this type do not fall under the scope of evaluation of SFEE's Evaluating Committee.

## **[B] Scientific events organised by Pharma Companies**

### ***B.1. General***

Pharma Companies may organise ***themselves*** scientific events of purely scientific or promotional content, in accordance with the terms of the applicable legislation. These events are organised and financed by the Pharma Companies themselves and they are conducted either on the Pharma Companies' premises or at other locations as the Pharma Companies may choose for that purpose or even online. **Pharma Companies are not allowed** to organise and hold events ***in University or Hospital premises***, as this is prohibited under the relevant legislation.

Depending on the context, the content and the programme involved, events organised by Pharma Companies are distinguished as follows:

- a) Promotional events: scientific events aimed at providing information on medicinal products. These events are managed by the Commercial Department of the Pharma Companies. NHS HCPs are not allowed to participate in these events in any manner. All relevant material e.g. invitations, agendas, presentations etc. is considered to be promotional material.
- b) Non-promotional events (scientific fora, educational events, etc.): These are scientific events of non-promotional purpose, serving educational or research purposes exclusively. These events are managed by the Medical Affairs/Scientific Department of the Pharma Companies. NHS and University physicians working for clinics established within NHS hospitals or Universities are allowed to participate in these scientific events, while HCPs in the broad sense of the term (see definition above) are permitted to participate as speakers.

Any Pharma Companies interested in organising scientific events themselves, as organising bodies, must submit a request to that effect to the competent Regulatory Authority, in accordance with the applicable legislation.



- Pharma Companies **are not allowed** to file **requests** regarding the organisation of scientific events **abroad** or requests to **jointly organise** scientific events with HCOs, whether in Greece or abroad.
- As regards to the limits of sponsorships for meals and accommodation expenses relating to the participation of HCPs in scientific events organised by pharmaceutical companies, the provisions regulating the sponsoring of hospitality for the participation of HCPs in scientific events organised by HCOs shall apply in this case as well.
- After the end of the scientific event, the organising (Pharma) Company submits to the competent Regulatory Authority a report on the event, in accordance with the provisions of the applicable legislation.

## **B.2 WEB SCIENTIFIC EVENTS & PRESENTATIONS ORGANISED BY PHARMA COMPANIES**

### **1. Scientific Events organized by Pharma Companies exclusively via the Internet without the physical presence of participants (web/ virtual - company hosted scientific events/congresses)**

Pharma Companies may organise scientific events or promotional or non-promotional nature conducted exclusively via the Internet, i.e. without the physical presence of the participating HCPs, who may only attend via the Internet, either (a) through live transmission, enabling interaction between the Speakers and the HCPs or otherwise, and/or b) through video recording. The videos are then posted on the Pharma Companies' controlled-access website, only for HCPs, to enable HCPs to attend the programme at their convenience (on demand).

To organise web events of this type, Pharma Companies must submit to EOF a request to that effect, stating essentially:

- the cost of use of the space & technical transmission equipment and
- the participation of HCPs as Speakers, Presidents of HCP associations, etc. and their honoraria.

These events are included in the maximum number of scientific events that can be organised by each Pharma Company per year, as such number is defined by EOF. However, care must be taken to ensure that the number of participant HCPs does not compromise the quality of the live transmission and the ability of HCPs to interact with the speakers and Presidents.

In case the event is attended by groups of participants, only coffee/soft drinks can be offered.

### **2. Company hosted webinars**

Pharma Companies can organise scientific presentations (webinars) exclusively via the internet, without the physical presence of HCPs, who will attend the webinars exclusively

via the Internet, either (a) through live transmission or b) through video recording. The videos are then posted on the Pharma Companies' controlled-access website, only for HCPs, to enable HCPs to attend the programme at their convenience (on demand). Webinars may have a total duration up to 3 hours.

These presentations are not included in the maximum number of scientific events that each PC can organise annually, such number is defined by EOF. To organise webinars of this type, Pharma Companies must submit to EOF a request to that effect, stating essentially the participation of HCPs as Speakers, Presidents of HCP associations, etc. and their honoraria.

Attendance of these webinars by HCPs is not considered when calculating the maximum participation limits of HCPs in company-hosted scientific events and no application needs to be filed to EOF to that effect. The number of HCPs that may attend these events is unlimited.

In case the event is attended by groups of participants, only coffee/soft drinks can be offered.

### ***B.3. Company-hosted events in the context of HCOs' conferences held in Greece.***

Scientific events organised by Pharma Companies in the context of conferences organised by HCOs, in Greece, are non-promotional, scientific in nature and supervised and/or organised by the competent medical affairs/scientific departments of the Pharma Companies. The content of these presentations is not presented in product templates. Such company-hosted events are held in the form of "satellite symposia" and/or as "meet the expert sessions" or in other forms and may also be addressed to specific HCP groups (by prior invitation). These events are included in the conference program and they are not subject to separate authorisation from EOF. It is recommended that the programme of these events, the speakers, the content of the presentations / speeches as well as the invitations to HCPs are approved by the Medical Affairs/ Scientific Department of the Pharmaceutical Company concerned.

These events:

- a) do not entail credits;
- b) may not make reference to brand names of medicinal products;
- c) the total duration/duration per conference should not exceed 20% of the total duration of the scientific programme of the scientific event;
- d) are not organised in the context of the scientific events referred to in point A.6. 4. (webinars) organised by HCOs.

## ARTICLE 7. PROVISIONS ON THE PERFORMANCE AND SPONSORSHIP OF SCIENTIFIC EVENTS HELD DOMESTICALLY/ABROAD

### Section 7.1. Locations and venues of events

Pharma Companies must not sponsor events organised by third-party entities, or organize themselves scientific events that take place in venues that are renowned for their entertainment facilities and/or are extravagant or special-purpose and generally considered to be intended for uses other than educational/business purposes (e.g. spas, casinos, places/venues of religious observance etc.). Events organised in museums may only be sponsored if there is a separate appropriate room. The choice of extravagant or special-purpose venues raises a presumption of prevalence of the entertaining nature of the event, alienates the educational/professional purposes and character of the event (which is what Pharma Companies should mainly emphasize) and eventually disparages the image of the entire industry. The locations and venues of HCO-held events are evaluated by the Conference Evaluation Committee in total, in the context of our moral commitment (see para. 6.1. above), in conjunction with the programme and the participations and based on common sense and the perception of the average prudent man of the pharmaceutical industry as a whole.

**7.1.1. VENUE:** Scientific events must be held in strictly professional venues comprising appropriate **conference rooms**.

- Scientific events can be held at hotels up to 4 stars with a price per room proportionate to the amount of costs provided for in this Code, provided that the hotel comprises a conference room and subject essentially to any applicable regulations on seasonality (see paragraph 7.9 below).
- Domestic scientific events at 5-star hotels and accommodation costs incurred by HCPs in such hotels may not be sponsored by pharmaceutical companies

Exceptionally, the following conferences can be sponsored by Pharma Companies:

- Conferences held in 5-star hotels located in the capital city of the District and comprising a conference room, provided that the cost-per-night requirements laid down in this Code are met, subject essentially to any applicable regulations on seasonality (see paragraph 7.9 . below).

### 7.1.2. PLACE and TIME of EVENTS

- a) Scientific events held at locations which may be considered as “tourist destinations”, during the corresponding tourist seasons, e.g. during the summer tourist season (1/7 - 31/8) or the winter season (15/12 - 15/1) or at winter ski destinations during the period 15/12 - 15/3 may not be sponsored.
- b) Scientific events taking place during any 3-day holiday period/long weekends (public holidays preceding or succeeding weekends) must not be sponsored by Pharma Companies.

**Section 7.2.** Pharmaceutical companies are not allowed to sponsor entertaining events or the participation of HCPs therein (e.g. excursions and tourist activities in general).

**Section 7.3.** The provisions of paragraphs 7.1. Through 7.2. shall also apply to any events organised by pharmaceutical companies.

#### **Section 7.4. Content of the sponsorship package - limits**

The sponsorship package of a scientific event delivered to 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, CDs/USBs etc. Pharma Companies may not pay for any such expenditures according to the provisions of Article 18 herein below.

**Section 7.5.** Sponsorships shall be deposited in an account held by the beneficiary scientific entity with 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 institutions, and a receipt shall be issued in the name of the sponsor. If the scientific organising entity is competent or it is by nature of its legal form able to issue receipts and invoices, the invoicing of the full range of services related to the sponsorship package of the conference to the pharmaceutical company shall be done solely by the scientific organising entity.

If the scientific organising entity is not competent or if it is unable, due to the nature of its legal form, to issue such receipts, it is entitled - under a valid contract signed with the Professional Conference Organiser - 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 to the sponsors). In this case, the invoicing of all services related to the sponsorship package for the conference to the pharmaceutical company will only be performed by the Professional Conference Organiser (PCO).

**Section 7.6.** Financing of scientific events of any eligible form by pharmaceutical companies must take the form of a deposit in an account held with an accredited bank. This account must be opened by the Conference Hosting Committee or by the BoD of the Scientific Society or by another institution – where applicable – in accordance with its statute, where the entity shall be designated as account holder. If there is written assignment to a Professional Conference Organiser, it should be notified to the financing pharmaceutical companies, so that the deposit can be made to the account of the PCO.

**Section 7.7.** Any MAHs of prescription-only medicines and their Representatives who wish to also promote non-prescription medicines in a scientific event must ensure that such promotion is distinct, easily identifiable by the HCPs and must follow the applicable promotional / information rules per product category.

In particular:

- Information / promotion areas for prescription and non-prescription medicines must be clearly distinguished.
- Information messages and supporting material, by category of medicines, must be conforming to the applicable laws and regulations.
- All informative and advertising material and reminders must be distributed at an appropriate position in the promotion area, which will be properly marked (e.g. “non-prescription medicines promotion area”).
- In case an event includes sessions with patients and/or the public, all spaces and materials used must be conforming to the relevant legislation and the applicable regulatory framework.

**Section 7.8.** The maximum financing amount per pharmaceutical apply to sponsorship of scientific events/conferences by pharmaceutical companies with stands, satellite symposia, lectures, advertisements etc.

**Section 7.9.** All entities involved in hosting scientific events are recommended to prepare the relevant budgets with due prudence.

**Section 7.10.** The participation of accompanying persons in scientific events organised or sponsored by pharmaceutical companies is not allowed, even if they pay for their own costs. “Accompanying person” means any person other than HCPs who qualify as participants in their own right.

**Section 7.11.** A pharmaceutical company may not demand to be the sole sponsor of an HCO or any activities of the latter.

**Section 7.12.** EOF is entitled to conduct inspections through external associates during events organised by scientific entities, for the purpose of establishing the level of compliance by the Pharma Companies with the regulations of this Code. The results of such inspections shall be notified to SFEE’s Ethics & Transparency Committee and to its Board of Directors, for evaluation and for the adoption of resolutions and appropriate measures, where this is considered imperative. This mechanism ensures the effective enforcement of the regulations of this Code and it is recommended by EFPIA as the most expedient practice.

### **Section 7.13. SFEE Auspices**

SFEE may offer their auspices to any scientific event of whatever nature, as long as it fulfils the code harmonisation requirement and the specific scientific event is generally consistent with the ethical standards prevailing in the industry and promotes the improvement of healthcare services offered to the public, the scientific education of HCPs and the dialogue between social partners and other stakeholders on health- and prevention-related matters. To that effect, SFEE may request an opinion from the Conference Evaluation Committee. In cases of doubt, the SFEE Board of Directors will make the final decision.

#### **Section 7.14. Evaluation of scientific events organised by third-party entities.**

Scientific events organised by Third-Party Entities (State or Private HCOs in Greece or abroad) and carried out in Greece are subject to evaluation by **SFEE's Conference Evaluation Committee** and are posted on SFEE's electronic platform (<https://scientific.events.sfee.gr>). The Committee's main task is to evaluate the programme of each event, with a view to safeguarding the image of the industry, in line with our ethical commitments (see paragraph 6.1. above). The committee shall comprise the Compliance Officers of member companies proposed by SFEE members and is supported, when needed, by SFEE's Lawyer, 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 shall take into account the SFEE committee's evaluation for each conference before they decide to participate by offering any kind of financial support and consult the files posted on the platform.

**Section 7.15.** Scientific events are uploaded to SFEE's platform for evaluation, **at least 45 days before the date of the event**, to enable the timely commitment of companies with the organising entities.

**7.15.1. The following data/information** shall be uploaded in SFEE's e-platform:

- a. A print screen of the platform of the competent regulatory authority (now EOF) including the HCO's application addressed to EOF, its reference number and EOF's clearance.
- b. The assignment of the event by the organising entity (HCO) to the PCO.
- c. The Program of the Event, without reference to the names of the pharmaceutical companies that sponsor satellite symposia, lectures etc.
- d. The Sponsorship Package, with thorough description of the costs of the services rendered and the compensatory benefit involved.
- e. The registration fees and accommodation/bard costs, if applicable.
- f. The entity's latest Statutes.

**7.15.2.** Further to the above, the scientific body and/or PCO shall fill up the following declaration:

*"I hereby declare that all data/information submitted to be evaluated are accurate, true, in accordance with SFEE's Code of Ethics as in force. I also know that some of the above documents include personal data of natural persons (name and surname, title, residential address, tax registration number etc.) and that such data are forwarded to SFEE. I state that I have notified the data subjects (HCPs, legal representatives etc.) of such forwarding, pursuant to Article 13 of the General Data Protection Regulation (Regulation (EU) no. 2016/679)".*

**7.15.3. Note:** Any alteration of data/information submitted (e.g. reduction of the duration of the Programme, entertaining events, change of the date in a manner

inconsistent with seasonality, addition of handling/communication fees, financial offer for the participation of accompanying members etc.) that takes place following the opinion of SFEE's Evaluating Committee, shall be construed as violations of this Code. In case such alterations take place following the **final evaluation** of a scientific event by SFEE's Evaluating Committee and prior to the date of the event, the Evaluating Committee shall immediately indicate such event with orange colour (inconsistent with one or more provisions of the Code). Moreover, no change of the organising entity shall be possible after SFEE's evaluation. Re-evaluation is only possible if the changes were due to sudden and unforeseeable situations and following a relevant decision by SFEE's Board of Directors.

**Section 7.16.** The SFEE Evaluation Committee evaluates the conferences in line with the EFPIA standards, having first applied the criteria of the Code, and presents its findings and conclusions on the platform with the following colour distinction:

**CAUTION: CHANGE OF COLOUR INDICATIONS AS PER e4thics.**

**GREEN:** In compliance with the SFEE Code.

**ORANGE:** Infringes on one or more of the Code provisions.

**BLUE:** Missing elements, cannot be evaluated.

**YELLOW:** Lies outside the scope of competence of the SFEE Conference Evaluation Committee.

**PURPLE:** At the discretion of each Pharma Company.

When evaluating international conferences which take place in Greece, the SFEE Evaluation Committee takes into account the relevant EFPIA evaluation, where available.

**Section 7.17.** SFEE Evaluation Committee does not evaluate, approve or reject scientific programs and the general content and materials of scientific and promotional events of any type. Pharmaceutical Companies are solely responsible for the content of the manner of organization, oral presentations and materials used. As a result, the Member Companies bear the burden of proving the lawful use of such materials and, in general, the legitimacy of their actions (Article 130 of Joint Ministerial Decision No. 32221/2013).

**Section 7.18.** The scientific service of the Pharmaceutical Company (P.C.) is in charge of providing medical information on the medicines available on the market. It shall ensure that the information, promotion or advertising of medicines it carries out is in accordance with the provisions of the legislation in force. It ensures that the medical visitors working on its behalf are adequately trained and follow the procedures for approval by the EOF, in accordance with the legislation in force. The co-promotion of a medicinal product by one or more Pharmaceutical Companies is subject to notification to the EOF. The responsibility for medical information and the responsibility for ensuring that all the requirements of the legislation (the training of medical visitors, the ethics of their work) remain the sole

responsibility of the P.C. In any case and for any breach of pharmaceutical legislation, the P.C. is objectively liable to the EOF. SfEE does not exercise substantive control and in the event of a complaint, the P.C. itself bears the burden of proof that it has acted appropriately ((Article 130 of Joint Ministerial Decision No. 32221/2013).

**Section 7.19.** Especially for scientific events, of any type, Member Companies should ensure that their participation and role is clearly acknowledged and visible from the outset. Activities must have content that is fair, balanced and objective, designed to allow for the expression of diverse scientific evidence and to meet unmet educational needs in health care. The purpose of the guideline is to ensure that lifelong learning from Pharmaceutical Industries does not constitute promotion and adheres to high ethical standards and strong educational principles with the ultimate common goal of benefiting patients. In conclusion, member companies agree that the SfEE Code of Ethics seeks to ensure that P.C., when providing scientific information, lifelong learning and promoting their products, act with honesty and ethical principles, avoiding practices of conflict of interest with other partners and complying with existing legislation.

## **ARTICLE 8. PROVISIONS WITH REGARD TO SPONSORSHIPS OF HCP PARTICIPATIONS IN SCIENTIFIC EVENTS HELD DOMESTICALLY OR ABROAD AND OTHER PROVISIONS**

### **Section 8.1. General Principles**

- 8.1.1.** Pharmaceutical companies may sponsor the participation of HCPs in scientific events organised either by third parties (HCOs) or by themselves and may offer hospitality, in line with the law and the provisions of this Code.
- 8.1.2.** The area of expertise or scope of work of the HCPs must be relevant to the topic of the event.
- 8.1.3.** An essential prerequisite for the sponsoring of HCP participation in scientific events/conferences/Expert Committees in Greece or abroad is the submission of an application to EOF and authorisation by EOF, where necessary, as per the applicable regulations.
- 8.1.4.** Pharmaceutical companies are reminded that, according to the relevant legislation in effect,<sup>12</sup> NHS physicians or other NHS scientific or nursing staff, as well as university doctors working in clinics established in NHS hospitals or University hospitals, are not allowed to participate in any promotional scientific events held in Greece or abroad, which are organised by pharmaceutical companies (based in Greece or abroad). (NEW ADDITION- ARTICLE 36 of Law 4272/2014).



- 8.1.5.** Eligibility of HCPs employed in clinics of NHS hospitals or hospitals or clinics supervised by the Ministry of Education and/or the Ministry of National Defence, to participate in events is regulated by the legislation applicable from time to time and by this Code.
- 8.1.6.** Physicians are liable to obtain the relevant “training leave” permits, where necessary, as per the applicable legislation. HCPs are exclusively responsible for the accuracy of the information of such permit and for compliance with its terms.
- 8.1.7.** The maximum limit of sponsored, by pharmaceutical companies, participations in scientific events organised by third parties, per HCP per year, and the maximum limit of HCPs participations a pharmaceutical company may sponsor per scientific event, are those defined in the applicable legislation (see Annex I).
- 8.1.8.** In establishing compliance with the applicable limits, participations shall be counted every calendar year. Unredeemed participations shall not be transferred to the next year. In case of cancellation and/or replacement of an HCP’s participation, the provisions of the Competent Regulatory Authority shall apply.
- 8.1.9.** 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: 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. If the speech or the announcement is a product of collaboration of more than one clinic or more than one laboratory, then the exemption in above also includes the third and the one before last author (1st -2nd -3rd one before last and last author). HCPs are liable to present to the pharmaceutical company all necessary evidence to prove active participation in the event.
- 8.1.10.** As a prerequisite of the sponsoring of an HCP’s participation in scientific events, the HCP must fill in a special application form addressed to the pharmaceutical company, taking into account all applicable Data Protection restrictions.
- 8.1.11.** Upon completion of the event, pharmaceutical companies must request from the sponsored HCP a copy of the participation certificate.
- 8.1.12.** All HCP participations in Scientific Events & Advisory Boards held in Greece and/or abroad, shall be reported ex post at EOF, as per the applicable legislation.
- 8.1.13.** With respect to scientific events organised by pharmaceutical companies themselves, the number of participants may be unlimited, subject to the maximum annual limit of HCP participations prescribed in the applicable legislation (see Annex I). HCP being actively involved in the event are not considered in calculating such limit.

- 8.1.14.** Pharmaceutical companies may offer remuneration (honorarium) to HCPs invited to speak or play an active role at scientific events, as per the applicable legislation.
- 8.1.15.** In particular, any honorarium payable to HCPs of the NHS or Universities (employed by clinics established in NHS or University hospitals) shall be deposited to the entities foreseen by the legislation in force ("ELKEA" or "ELKE"), which shall transfer it to the beneficiary after the appropriate deductions and, at the end of the year, will issue a relevant income certificate to be used by the beneficiary for tax purposes.
- 8.1.16.** Pharmaceutical companies must require any HCPs who receive honoraria for a speech in an event to state this fact in a conflict-of-interest statement, which is submitted, 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.
- 8.1.17.** It is permitted to organize business meals outside the scope of scientific events in places whose business character supersedes the social one. In any case, the cost per meal, per person and per day may not exceed 70 Euros, VAT included.

## **Section 8.2. Scientific Events held Abroad**

- 8.2.1.** 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).
- 8.2.2.** HCPs participate in Scientific Events held Abroad in accordance with the applicable legislation.<sup>13</sup>
- 8.2.3.** World Congresses: World congresses are congresses of medical content held in the US and Canada.
- 8.2.4.** European Congresses.
- 8.2.5.** Events/specialised seminars held in Europe or in the US, of high scientific interest and international range, with participants from various countries.
- 8.2.6.** Events on rare diseases, as same are defined in Article 24 of Law 4213/13 (Government Gazette 261A/9.12.2013), organised by scientific entities (not merely under their auspices).

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13 – See Article 11(18) of Law 2889/2001 & Article 36 of Law 4272/2014.

- 8.2.7.** The maximum number of company-sponsored participations annually per company and per conference and the percentage of second last- and last-year interns and interns who have to present research work on account of Physicians may not exceed the limits prescribed in the applicable legislation (see Annex I).
- 8.2.8.** Pensioner HCPs may not be sponsored by pharmaceutical companies for their participation in scientific events held abroad, unless they have provably active participation in these events.
- 8.2.9.** In order to support HCP participation in scientific events held abroad, pharmaceutical companies must follow this Code of Ethics, which is harmonised with the corresponding EFPIA Code of Ethics and the Code of Ethics of the country in which the scientific event is held, taking into account the strictest restriction rule.
- 8.2.10.** HCPs may participate in conferences of their own discipline and/or similar disciplines and/or conferences of other disciplines, in the context of their briefing on matters that are relevant to their own discipline (participation in these events needs to be justified).
- 8.2.11.** HCPs may not be offered accommodation in 5-star hotels in the context of conferences held abroad.

### **Section 8.3. Terms governing HCP accommodation in scientific events held in Greece or abroad**

- 8.3.1.** Pharmaceutical companies are allowed to sponsor the costs of transportation, registration, board and accommodation of HCPs, subject to approval by the competent regulatory/supervisory Authority, provided that the employer has granted an educational permit.
- 8.3.2.** 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 and back. Hospitality must be reasonable in terms of level and cost, in view of market prices and the main scientific objective of the event.
- 8.3.3.** Hospitality for HCPs in scientific events must be strictly limited to the main scientific objective of the event, which supersedes the social one.
- 8.3.4.** Limits to participation costs and to the number of sponsored HCP participations in scientific events per HCP per year in both Greece and abroad are prescribed by the competent regulatory Authority from time to time (see Annex I).
- 8.3.5.** 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.
- 8.3.6.** The cost of meals and hospitality per HCP should not exceed the limits laid down in the applicable legislation (see Annex I). Any additional taxes (e.g.

accommodation tax) accruing on these limits shall not be covered by the pharmaceutical companies. These board and accommodation limits shall also apply to foreign HCPs participating in scientific events held in Greece, provided they do not exceed the limits applicable in their country of origin.

- 8.3.7.** Moreover, the registration fees for domestic events may not exceed the limit prescribed in Annex I. Any excessive registration fees, if adequately substantiated (corpse preparations, live transmission of surgical operations etc.) shall be subject to evaluation by the competent SFEE evaluation committee. The registration fee limit shall not apply to International (world/European) congresses which are held in Greece and organised exclusively by foreign HCOs.
- 8.3.8.** The registration fee must include at least: admission, certificate of attendance and conference material (e.g. bags, notebooks, pens, CDs, DVDs, USBs, books, programme, badges, conference minutes, lanyards etc.).
- 8.3.9.** Pharmaceutical companies are not allowed to cover any registration fees for webinars.

#### **Section 8.4. Expenses for the promotion of medicinal products**

- 8.4.1.** According to relevant legislation,<sup>14</sup> recipients of promotional actions funded financed by the promotional budgets of pharmaceutical companies may only be the persons authorized to prescribe or supply medicinal products.
- 8.4.2.** For instance, based on the relevant legal framework, the following apply:
  - Promotional expenses of pharmaceutical companies include sponsorships for hosting events by scientific agencies the subject matter
  - Expenses for the promotion of medicinal products
  - According to 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 frame- work, the following apply:
  - The promotional expenses of pharmaceutical compa- nies include sponsorships for hosting events by scien- tific agencies the subject-matter of which exclusively or predominantly – relates to the supply or promo- tion of medicines. These expenses must concern the promotion of specific products through events, exhibi- tions, print material, stands, etc.

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14 – Article 123 of Ministerial Decision ΔΥΓ3α/ Γ.Π 32221 (Government Gazette B 1049/29.4.2013), as currently in force, in con- junction with Ministerial Decisions Y6a28403/2001 and Y6a116328/2002 as currently in force.

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

## ARTICLE 9. PROVISION OF CONSULTING AND SIMILAR SERVICES BY HCPs

**Section 9.1.** Subject to the relevant provisions that apply to NHS physicians and university physicians, and also subject to the provisions of the Code of Medical Ethics<sup>15</sup>, pharmaceutical companies may request from physicians the provision of Advisory or other services that are directly related with their specialty.

More specifically, pharmaceutical companies may engage HCPs as experts or scientific / technical advisors either individually, for services such as lectures and chairmanship at scientific meetings, or in groups, for employment in medical/scientific studies, clinical trials or educational services, participation in meetings of advisory bodies and participation in market research (see Article 14), where such participation includes remuneration and/or coverage of travel expenses.

### Section 9.2. Advisory Boards in Greece and abroad

- 9.2.1.** Subject to the requirements of the applicable legislation, <sup>16</sup>, pharmaceutical companies are allowed to set up themselves expert advisory boards comprised of a small number of HCPs to opine on medicines or therapies of strictly scientific content in Greece or abroad, in which HCPs participate against remuneration or otherwise. These boards are called “**Expert Advisory Boards**” or, as they are internationally known, “**Advisory Boards**”.
- 9.2.2.** The maximum number of Advisory Boards that can be set up by each pharmaceutical company, the maximum number of HCPs participating in each Advisory Board and the number of HCP participations per year are those laid down in the applicable legislation (see Annex I).
- 9.2.3.** According to the relevant legislation, NHS physicians and other scientific and nursing staff, as well as University physicians employed at clinics established in NHS or University hospitals are allowed to participate in “Advisory Boards”, of purely scientific in content, with regard to medicines and therapies, in order to opine on scientific matters, against remuneration or otherwise, provided that they have obtained permission to that effect by their supervisory body.

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15 – See Article 6(4) of Law 3418/2005 (GG 287/A/2005)

16 – See Law 2889/2001, Article 11, as amended by Article 36 of Law 4272/2014.

- 9.2.4.** Military physicians are subject to the restrictions applicable to NHS/University physicians, save for the method of remuneration (they are remunerated upon issue of invoices for services rendered), as they may be operating a private practice, as per the applicable legislation.
- 9.2.5.** For the participation of an HCP in “Advisory Boards” in Greece or abroad and only if the relevant expenditures are covered by pharmaceutical companies based in Greece, a relevant application shall be submitted to the competent Regulatory Authority, under the procedure prescribed in the applicable legislation. Each HCP is exclusively responsible for the accuracy of the information and for obtaining an educational leave.
- 9.2.6.** Any fees payable to NHS or University HCPs (employed by clinics established in NHS or University Hospitals) for their participation in Advisory Boards shall be paid through the entities provided for in the law about ELKE or ELKEA.
- 9.2.7.** Advisory Boards shall be reported to EOF. Pharmaceutical companies shall submit to the EOF platform all costs relating to Advisory Boards.

**Section 9.3.** The provision of services by HCPs to pharmaceutical companies must not jeopardise the clinical independence of the advisor or of the collaborating HCP, who must always be bound by the ethical obligation to make independent medical decisions and exercise the medical profession to the benefit of the patients. The service provided by the HCP must cover a verified scientific/research need for the pharmaceutical company.

**Section 9.4.** Services shall be provided on the basis of a special agreement signed between the pharmaceutical company and the collaborating HCP. Pharmaceutical companies are strongly encouraged to include in their written contracts with experts (including in contracts entered with HCPs for part-time employment), provisions with regard to the expert’s/HCP’s obligation to declare that he has signed a service agreement with the pharmaceutical company, whenever he is the author or speaks publicly about an issue which is the subject-matter of the agreement with the pharmaceutical company, or about any other issue relating to the latter.

**Section 9.5.** 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.

**Section 9.6.** With regard to any fees payable to HCPs for participation in market research, the provisions of Article 14 of this Code shall apply.

**Section 9.7.** The supply of consulting services by HCP to pharmaceutical companies must meet the following criteria cumulatively:

- (a) Before any agreements are entered with experts, a legitimate need for those services must have been clearly identified.
- (b) 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 concerning the basis for payment of those services.
- (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) HCPs must be selected on the basis of their qualifications and capacity to provide the service re-quired. 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
- (e) The number of HCPs who will provide services must not be greater than the number that is reasonably necessary to achieve the identified need.
- (f) The contracting pharmaceutical company must keep records of the services provided by the HCPs.
- (g) 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.
- (h) The compensation for the services must be reasonable and correspond to the level that is usual for those services (see Annex II concerning the indicative calculation of HCPs' remuneration for services provided to pharmaceutical companies). 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 experience of the HCP, the time of engagement (preparation and participation) and the type of service provided. (see Annex II).
- (i) The maximum annual fee (per calendar year) per HCP by a pharmaceutical company may not exceed EUR 5,000, excluding VAT and further deductions. The above limit does not include fees for services rendered by HCPs with international experience, who were actively involved in scientific events during the year and have provided services outside of Europe (or both inside and outside of Europe). In these situations, the recommended maximum annual fee per calendar year is seven thousand (7,000) Euros, excluding VAT and further deductions. Any amounts concerning payments for the conduct of clinical research are not included.

**Section 9.8.** Moreover, physicians and other scientific and nursing staff who have obtained relevant permission from their supervisory body, are allowed to participate in meetings organised by the Medical Affairs/scientific departments of pharmaceutical companies, in order to become informed on recent developments or contribute with their acknowledged experience on scientific issues, elaborate epidemiological facts, i.e. diseases and therapeutic approaches etc. (consultant meetings)

## **ARTICLE 10. PROHIBITION OF GIFTS**

**Section 10.1.** SFEE recommends pharmaceutical companies to make any Transfers of Value to HCPs and HCOs taking under consideration all terms and restrictions applicable under the law.<sup>17</sup> According to the relevant legislation, providing, offering or promising any gifts, moneys or benefits in kind relevant to the profession of a physician or pharmacist to persons authorised to prescribe or administer medicines is prohibited, save where the items offered are of immaterial value (i.e. not exceeding EUR 15.00 per piece, VAT included, in accordance with Article 17.1 hereof).

**Section 10.2.** Gifts for the personal benefit (such as sporting or entertainment tickets, and/or social courtesy gifts) of HCPs, HCOs' members or POs' Representatives (either directly or indirectly) are prohibited.

**Section 10.3.** Providing or offering cash, cash equivalents or personal services to HCPs, HCO members and POs' Representatives is also prohibited. For these purposes "Personal services" are any type of services unrelated to the profession and that confer a personal benefit to the Recipient.

**Section 10.4.** A promotional aid is anon-monetary item given for a promotional purpose (which does not include promotional materials as defined in Article 3 of the Code). Providing or offering them to HCPs, HCOs' members and POs' Representatives in relation to the promotion of POM is prohibited. For the purposes of this paragraph, "promotional aid" means any non-monetary item given by a pharmaceutical company to a HCP, HCO member or PAR for promotion purposes.

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17 – In particular, see Article 16 of Legislative Decree 96/1976, Articles 126 and 127 of Joint Ministerial Decision 32221/2013, the provisions of the Code of Medical Ethics (Law 3418/2005) and any special restrictions which may generally apply.



## ARTICLE 11. DONATIONS AND GRANTS

**Section 11.1.** Donations and grants by pharmaceutical companies to HCOs that are comprised of HCPs and/or POs are only allowed if: (a) they are made for the purpose of supporting healthcare, research, education, or the provision of better health services; (b) they are documented and kept on record by the donor; and (c) they do not constitute an inducement to the donation Recipients to prescribe, sell or purchase specific medicinal products.

**Section 11.2. Donations and grants** are allowed to:

- a) Hospitals established as legal entities of 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 applicable legislation.
- b) Medical societies/institutions/associations/organisations/unions and non-profit civil societies established by HCPs and operating in the form of non-profit legal entities of private law;
- c) POs, organised as civil society associations, non-profit associations and in accordance with the provisions of Chapter 4 of this Code.

**Section 11.3.** Requests for donations to third parties, submitted to pharmaceutical companies by the aforementioned organisations, shall not be accepted or considered.

**Section 11.4.** Donations or grants that are offered directly to a HCP (natural person) or to a third party designated by a HCP are not allowed.

**Section 11.5.** Donations may be in kind or in money and must always be consistent with the applicable legislation on donations. 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), consumables and reagents but it may not involve products/establishments that create a relationship of dependency (i.e. an ongoing contractual relationship for the supply of goods or services from the Donor to the Donee). For donations of computers and peripherals, detailed description and documentation shall be required, evidencing that the Donation is intended to meet the needs of a hospital/organisation, rather than a natural person. 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".

**Section 11.6.** This category includes various medical or diagnostic instruments, scientific textbooks, electronic aids (mainly electronic connections to databases, supportive software and computers, books) exceeding EUR 15.00 in value (VAT included).

**Section 11.7.** Donations are also permitted to provide grants for awards and scholarships to HCPs and other beneficiaries; to support the economic development of independent educational scientific programmes (educational grants); and to financially support research programmes (research grants) conducted by Hospital and University Institutions and other organisations which may be eligible as Donees according to Article 11.2 hereof.

**Section 11.8.** Donations 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 applicable from time to time depending on the situation, in the context of full disclosure and transparency, as well as to the relevant applicable rules and the tax legislation.

**Section 11.9.** Donations may not be offered to Hospital Institutions established as legal entities of private law, as well as medical companies providing primary care services under Article 11 of Presidential Decree 84/2001.

**Section 11.10.** Donation/grant requests must be submitted by the requesting organisation/medical society/university department/hospital department/PO, etc., along with a detailed description substantiating the need, purpose and method in which the donation will be used, including the requested amount/cost (applicable to donations in kind).

**Section 11.11. 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:

- a. **An agreement in writing:** an agreement must be prepared and signed by both parties, as same are legally represented.
- b. **Extract from a decision of the Board of Directors or other governing body:** of the Donee/Recipient of the Donation (e.g. Medical Society, Hospital Institution, NHS, or of the Rector's Council or Faculty (for Universities), etc., indicating the acceptance of the donation by the Recipient.
- c. 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**, (where the donation relates to research work) and, more generally, prove the use of the Donation for the agreed purpose. Moreover, the

Recipient is liable to submit a **report of actions taken to that effect** and a thank you letter.

**Section 11.12.** Donations/grants by pharmaceutical companies must not exceed 1% of their total annual turnover. 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.

**Section 11.13.** The above shall also apply to any Donations that are made in the context of Corporate Social Responsibility.

**Section 11.14.** Donations of exclusively medicinal products (and not other types of donations) in the context of corporate social responsibility and charity activities of the FIs, either individually or through the SFEE, are excluded from this donation procedure and in any case follow the approval procedures of the EOF and the applicable legislation and are not subject to this article.

## **ARTICLE 12. FEES TO HCOs FOR SERVICES RENDERED TO PHARMA COMPANIES & USE OF HCO LOGOS AND PROPRIETARY MATERIAL**

**Section 12.1.** Contracts between pharmaceutical companies and institutions, organisations or HCP associations (HCOs) under which HCOs provide to pharmaceutical companies any kind of services or sponsoring not covered by Article 11 or otherwise by the present Code, are permitted only if such services (or sponsorship): (a) are provided with the aim to support healthcare or research; and (b) do not constitute an inducement for the parties involved to prescribe or supply specific medicinal products.

**Section 12.2.** The public use of an HCO or PO 's logo and/or proprietary material by a Pharmaceutical Company requires written permission from that organisation.

## \* CHAPTER 3.

# SPECIFIC INTERACTIONS WITH HCPs & HCOs AND OTHER PROVISIONS

### ARTICLE 13. PATIENT EDUCATION & SUPPORT PROGRAMMES

#### Section 13.1. Purpose - Framework

**13.1.1.** A Patient Education and Support programme aims to support the patients and their caregivers, where necessary, under the directions of the treating doctor. These programmes aim at enhancing patient information and education on their diseases and compliance with their prescribed therapies, having as a final objective the reduction of difficulties related to the implementation procedure of the therapy. Patient Education and Support programmes are not Clinical Trials; have a purely educational and supportive role; and no collection of patients' personal data is collected by the pharmaceutical companies, further to any information necessary for compliance with the legislative framework on pharmacovigilance.

Patient Education and Support programmes are mainly intended to:

- Educate and support patients and/or their caregivers in using their medicines, in the context of the approved and updated information of the SPC and the package leaflet.
- Educate and support patients and/or their caregivers in implementing regular instructions on how to deal with their condition.
- Provide materials and services in the context of compliance with treatment, such as Leaflets or reminder programmes for taking the medicine,
- Replenishment of the medicine, whether through a reminder or by facilitating its delivery. The patient has the right to request and authorise a third party (health care provider) to carry out this procedure.
- Informing patients about their disease or treatment through use of call centres.

**13.1.2.** In the context of Patient Education and Support Programmes, the companies implementing the Programmes may provide digital applications to patients (sponsored by a pharmaceutical company), which are classified as medical devices classified in Class I under the EU classification rules 18 and enable the patients to be reminded to take their treatment, monitor their symptoms, access

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18 – See footnote 9 above

educational material about their disease and treatment and inform their treating physician in relation to the above. In case such digital applications appear on the company's website, the pharmaceutical company must also ensure that it does not have access to any patients' personal data.

- 13.1.3.** All the above shall be implemented in accordance with the recommendation of the treating physician.
- 13.1.4.** To include a patient in a Patient Education and Support Programme, the written consent of his/her legal representative is required.
- 13.1.5.** Patient Education and Support Programmes are not allowed to be applied by companies dealing with the trade/ allocation/ Promotion of drugs for human use. These programs are mainly applicable to special medicines which entail the need for specific handling either during the setting title procedure, the use of accompanying medical devices, or special instructions for use and generally in situations where patient compliance to their therapy is necessary.
- 13.1.6.** Such Programmes are implemented exclusively by companies providing health services, which are contracted with the sponsoring pharmaceutical company of the program and observe the procedures prescribed in the relevant legislation and the applicable Data Protection laws, in order to ensure independent and correct provision of support and/or education services. (see in particular Chapter 5.2., Article 36.3. below).
- 13.1.7.** Provision of support services by healthcare service providers serves a social need and at the same time contributes to the correct and as safe as possible therapy of the patients, without meeting the standard need for healthcare support by HCPs.
- 13.1.8.** Any direct or indirect communication between a patient and his familiars and the pharmaceutical company dealing with the trade/ allocation/ promotion of a drug, is forbidden in the context of Patient Education and Support programmes, save in cases of reporting side effects in line with the relevant provisions of the law. If patients spontaneously ask the pharmaceutical company to provide information related to Patient Education and Support Programmes, the Med Info and/or pharmacovigilance department of the company may address these requests.
- 13.1.9.** Sponsoring companies can communicate the existence and purpose of the patient support programme to HCPs. Any further information concerning the Programme may be provided to patients by the healthcare service provider exclusively.

## **Section 13.2. Conditions - Methodology**

- 13.2.1.** Goods and services of scientific, educative and supportive nature delivered to the patient and intended to ensure proper and/or as safe as possible use of a medicine, must bear the company name of the sponsoring pharmaceutical company.

- 13.2.2.** Availability and patient eligibility to participate in a Patient Education and Support Programme and the role of a pharmaceutical company to its activation shall be made available to the interested parties and to the administrative staff that implements the programme.
- 13.2.3.** In addition, patients may also be fully informed of the support of the pharmaceutical company on the services provided to them, through their written signed consent, as same is described in paragraph 12.1.4. above.
- 13.2.4.** The consent is collected by the company implementing the Programme during the first visit and activation of the patient's participation.
- 13.2.5.** Patient Support Programmes are not intended to collect data relating to the effectiveness or safety of a medicine, nor are designed to serve that purpose. However, it must be ensured that the pharmacovigilance data disclosed by the patient via the treating physician or healthcare service provide are only disclosed to the pharmaceutical company insofar as this is essentially required to comply with the applicable legislation. The pharmaceutical company sponsoring the programme must train the service provider on Pharmacovigilance matters.
- 13.2.6.** Consent forms and patient data may be retained by the company providing the support service in accordance with the applicable data protection legislation. The consent form may be retired at any given time and unconditionally, on the initiative of the patient or his/her legal representative.
- 13.2.7.** HCPs and healthcare service providers, in particular patient support/patient education service providers must ensure compliance with the applicable data protection legislation. The contract between the provider and the pharmaceutical company should contain the provisions of the laws about the protection of sensitive personal data and pharmacovigilance.
- 13.2.8.** In contracts between pharmaceutical companies and healthcare service providers, care must be taken to protect the personal data of the patients in case the Programme is permanently terminated or the provider is replaced. This is because, especially in the latter case, it is imperative to ensure, for the benefit of the patients, that the patient data already collected remain available for use by the healthcare service provider to succeed the previous one in providing the relevant healthcare services.
- 13.2.9.** The pharmaceutical companies and their employees may not have access to data and files which may lead to disclosure of the identity of specific patients or be associated with specific patients, apart from the case of reporting side effects. However, the provider should be able to inform the pharmaceutical company about the progress of the documents or possibly about other qualitative and quantitative elements of the implementation of the programme, ensuring the anonymity of these data in accordance with the applicable regulations.

- 13.2.10.** Treating physicians who recommend a patient's participation in the programme are not remunerated nor receive any other indirect sponsorship for this action.
- 13.2.11.** The provider's staff (e.g. nurses, nutritionists, pharmacists, etc.) are not allowed to engage in promotion of medicinal products.
- 13.2.12.** All printed materials drafted to be used for education purposes should not be used for promotional reasons. In particular, these materials may not promote the prescription, supply, sale or administration of the medicines of the sponsoring company. Nor is it acceptable that these materials make critical judgments about competitive products, as this might be deemed as a promotional activity. All pertinent materials to be delivered to the patients participating in the programme must be approved by the company's Medical Affairs/Scientific Department and notified to the competent regulatory authority, in accordance with the provisions of the applicable legislation.

### **Section 13.3. Competences**

- 13.3.1.** HCPs acting on behalf of an institution/healthcare service provider, which is financed by a pharmaceutical company are competent to implement these Programmes.
- 13.3.2.** Patient participation in the programme may not include or be substituted by financial remuneration or other reward in kind. Participation in these programs is not obligatory for the patients nor a prerequisite for the patients' social security coverage or relevant to the level of the coverage care and the drugs for the confrontation of the disease. If these programmes form part of the medicine's marketing authorisation terms and are included in the risk management program of the product, they are subject to authorisation by the EOF Adverse Effects Department, along with all other supportive documentation.
- 13.3.3.** In no other circumstances are they subject to EOF approval.
- 13.3.4.** The healthcare service providers providing these services according to their articles of association, the organization of their personnel, their training and their quality control procedures should hold accreditation of any kind (i.e. ISO 9001, ISO 27001). Moreover, their personnel must comprise HCPs or individuals with relative to the program specialties (nurses, health visitors, nutritionists, psychologists etc.). Before setting off any of such programmes, the grantor company must keep a file containing the following documents:
- 1.** In depth description of the programme with the relevant scientific documentation, either from the SPC or from the disease and bibliography, or by the technical/social need.
  - 2.** Cooperation contract with the company providing the programme services, including an analytical description of each party's obligations and responsibilities.

3. A document confirming the provider's compliance with the applicable data protection legislation.
4. Any other supportive documents that will be used in implementing the programme as per the pharmaceutical company's internal procedure.

## ARTICLE 14. MARKET RESEARCH

**Section 14.1.** Market research refers to any systematic data collection and analysis of opinions or positions of persons or organisations with the application of the methods of the applied social sciences aiming to support people or bodies in making a decision.

**Section 14.2.** Market research is a valid method for recording the data and characteristics of the pharmaceutical market. Market research is different from the non-interventional studies (see Annex III, Schedule 5), have a commercial purpose and are intended for internal use.

**Section 14.3.** Market research can be conducted:

- (a) either through questionnaires to which subjective answers are given by a sample that is representative of the reference population (quantitative research);
- (b) or through a discussion guide (focus groups or in-depth interviews) to groups or personal interviews constituted by a representative sample of the population under examination, in order to obtain a synthesis of opinions (qualitative research).

**Section 14.4.** Market research must be unbiased, must not be focused on promoting sales, and must not aim at influencing the opinion of the participants and is conducted for exclusively commercial purposes.

**Section 14.5.**

- (a) Each market research must be conducted through certified "Market Research" companies, which must abide by the principles of ESOMAR/ EphMRA (<http://www.esomar.org>., <http://www.ephmra.org>), as well as by the relevant provisions of the personal data protection legislation and of the pharmaceutical legislation in general and especially the provisions regarding pharmacovigilance. In each market research care should be taken to ensure the random but representative choice of participants.
- (b) If, for market research purposes, the pharmaceutical company and the market research company are considered as joint Data Controllers, each must clearly determine their responsibility for complying with the requirements of the applicable data protection legislation, and each Controller's responsibility must be disclosed to the persons participating in the research.



(c) In order to ensure the impartiality and objectivity of the market research, where participants have a right to be informed of the identity of the pharmaceutical company as joint Data Controller according to the applicable data protection legislation, the relevant information will be provided. After the market research is thoroughly completed and answers have been collected from all participants, provided that the participant has declared, at the time he/she was initially informed by the market research company, that he/she wishes to know the identity of the pharmaceutical company.

**Section 14.6.** Data shall be collected in accordance with the applicable data protection legislation. Patient data collected from HCPs, must not refer to clinical data and shall be delivered exclusively anonymized and in aggregate form.

**Section 14.7.** Pharmaceutical companies are not entitled nor have any legal right under the law to keep lists of patient names.

**Section 14.8.** Market Research shall be a snapshot, even if it refers to past or future intentions, always to random/representative sample of population.

**Section 14.9.** Aggregate information and statistical results of market research may be used for commercial purposes, provided that the identity of the research (who, when, where, which sample) is clearly stated. In any case, the collection and use of research data must be clearly distinct processes.

**Section 14.10.** Market research must be conducted in a manner that does not affect the credibility and reputation of the pharmaceutical industry.

**Section 14.11.** If collection of data in the context of market research is conducted by a pharmaceutical company, without the involvement of a Market Research company, the principles of ESOMAR/EphMRA must be observed. In this case, no fee is provided for HCPs participating in the research. Medical Sales Representatives may not become involved in the conduct of market research. The commercial departments of pharmaceutical companies may not become involved in market research, save in its planning.

**Section 14.12.** When pharmaceutical companies enter into contracts with market research companies, they may stipulate a reasonable compensation to be given to the HCPs that participate in the research, where this is permitted under the applicable legislation, taking under consideration the working time spent by the HCPs, which may under no circumstances exceed two hours.

## ARTICLE 15. INTERVENTIONAL CLINICAL TRIALS

**Section 15.1.** Collaboration between pharmaceutical companies and physicians in carrying out interventional clinical 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.

**Section 15.2.** 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 and the National Ethics Committee).
- e) The sponsor company 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 of any kind 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.

**Section 15.3.** A necessary condition for the acknowledgement of any clinical trial or investigation is documentation through corresponding scientific results or findings.<sup>19</sup>

## ARTICLE 16. NON-INTERVENTIONAL CLINICAL TRIALS

**Section 16.1.** A non-interventional 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 diagnostic and patient monitoring methodologies fall under the regular clinical practice. Allocation of patients to a particular therapeutic strategy is not determined in advance based on the trial protocol, but rather, falls under the current practice. The prescription of the medicinal product is clearly distinguished from the decision to include a patient in the study. Epidemiological methods will be used to analyse the data collected according to the principles of Vol 9A of the pharmacovigilance rules applicable to medicinal products for human use ([https://ec.europa.eu/health/documents/eudralex/vol-9\\_e/](https://ec.europa.eu/health/documents/eudralex/vol-9_e/)). Non-interventional trials are carried out as per the GPP (Good Pharmacoepidemiological Practices)<sup>20</sup> and the GVP (Good Pharmacovigilance Practices)<sup>21</sup>.

**Section 16.2.** Non-interventional trials for medicinal products of prospective or retrospective nature and trials intended to monitor the course of a disease under a particular treatment which a patient may receive as part of the daily clinical practice (medicine-free observational trials), 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, e.g. to assess the safety or efficacy of the medicine concerned in the daily clinical practice or its effects on the quality of life of the patients that take it; to collect data on the evolution and the monitoring of a disease; to evaluate the pharmaco-economic effects of a therapy or to identify the prevalence or the effects of a disease.

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19 – As for the rest, see also Chapters I-IV of Ministerial Decision no. Δ3(α) οικ. 36809/2019 (GG 2015/B/3.6.2019)

20 – <https://www.pharmacoepi.org/resources/policies/guidelines-08027/>

21 – <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices>

- b) The medicine concerned is administered to the participants as per the therapeutic protocol (where available) of the disease for which it is taken, the terms of the marketing authorisation and the approved indications.
- c) A contract is signed between the sponsoring company, the principal investigator, the legal representative of the hospital institution, or, if a public hospital is involved, the ELKE/ELKEA administrator defining, among others, the nature of the services to be provided and the basis for compensation of such services under point (e) below.
- d) Any compensation provided must correspond to the value of the service offered.
- e) The trial must not constitute an inducement to prescribe, sell or supply a specific medicinal product.
- f) The trial protocol must be approved by the medical affairs/scientific department of the pharmaceutical company, which will be responsible for supervising the trial process either itself or through a CRO, the local or centralised procedure.
- g) Once approval as per point (g) is obtained, the trial protocol must be submitted for evaluation to the competent Committees (scientific or ethics committees) of the bodies conducting the trial.
- h) Before the beginning of a trial, its basic characteristics and the information included in the Protocol must be recorded in a special registry freely accessible by the public through SFEE's website (<https://www.dilon.sfee.gr/>).
- i) All applicable data protection laws and regulations must be observed.
- j) 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 medical affairs/scientific department within a reasonable time period (Article 19 of the Code). This department must keep record of these reports for a reasonable period of time. The pharmaceutical company must send such brief report to all HCPs participating in the trial and must record it (or the relevant publication) in the special registry of non-interventional / pharmaco-epidemiological studies, which is kept at SFEE. 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).
- k) Medical Sales Representatives may not become involved in the conduct of the trial.

**Section 16.3.** The only type of non-interventional trials which are subject to approval by EOF before their commencement are non-interventional post-approval safety/efficacy studies dictated by the Competent Authority at the time marketing authorisation is granted or subsequently.

**Section 16.4.** Meetings between a small number of doctors in order for them to: a) contribute to the planning of clinical trials or b) be informed about new data with regard to clinical trials in which they have participated as investigators (investigator meetings) and are organised by the medical department of a company, are not subject to approval by EOF.

**Section 16.5.** To the extent practicable, pharmaceutical companies are encouraged to comply with Article 16.2 for all other types of trials covered by Article 16.1 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.

**Section 16.6.** Further details on the special registry where non-interventional trials shall be recorded, as well as on the criteria and conditions that must be fulfilled by the non-interventional trials and how transfers of value are publicised in the context of Non-Interventional Clinical Trials are provided in Annex III of the present Code.

## **ARTICLE 17. MEDICAL SAMPLES**

**Section 17.1.** The production, importation 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<sup>22</sup>. The permission, which is granted in exceptional cases, determines the packaging, the overall quantity, the time and mode of distribution and any other information necessary.

**Section 17.2.** Pharmaceutical companies must have suitable control and calculation systems for the samples they distribute and for all medicinal products they handle through their representatives.

**Section 17.3.** A sample cannot be larger than the smallest presentation of the medicinal product on the market.

**Section 17.4.** 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).

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22 – See Article 128 of Decision no. Δ.ΥΓ3α/Γ.Π. 32221/2013 (GG/17785/B/2013)

**Section 17.5.** The provision of samples 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 18. INFORMATIONAL AND EDUCATIONAL MATERIAL AND MEDICAL USE MATERIAL**

**Section 18.1.** The supply of Educational Material to HCPs is prohibited. The supply of educational material is only permitted by way of donation to legal entities (see Article 11).

**Section 18.2.** By exception, it is permitted to offer HCP devices/applications of insignificant value, up to EUR15.00 (per item) VAT included, closely associated with daily HCP practice such as:

- a. 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.), and fall under Category II or any subsequent categories<sup>23</sup> according to the EU Classification Rules;
- b. Anatomy and/or physiology models (physical or electronic, e.g. CD/DVD/ locked USB);
- c. anatomy maps (physical or electronic, e.g. CD/DVD/ locked USB);
- d. 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;
- e. Printed or digital publications including guidelines from Scientific Societies – provided they do not describe outside the approved indications and dosage;
- f. Printed or digital publications of therapeutic protocols.

**Section 18.3.** Such material must not use the product brand name and / or include a direct or indirect advertising message, but only the company's logo.

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23 – Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Annex VIII, CHAPTER III.

**Section 18.4.** Any other donation, sponsorship or benefit in kind to HCPs is prohibited.

#### INDICATIVE LIST OF **UNACCEPTABLE** MEDICAL/EDUCATIONAL USE OBJECTS

- Antiseptic fluids
- Surgical gloves/scrub hats/clothes
- Catheters
- Syringes/needles/tourniquets
- Ultrasound gel
- CPRs
- Mp3
- Stethoscopes
- Prescription pads
- ECG paper
- Any personal objects
- Organisers, notebooks, etc.
- Stationery items of any kind
- PC accessories

**Section 18.5.** 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 mice, etc. is not permitted.

### **ARTICLE 19. MEDICAL AFFAIRS / SCIENTIFIC DEPARTMENT AND SCIENTIFIC SERVICE RESPONSIBLE FOR MEDICAL INFORMATION (MEDICAL INFO)**

**Section 19.1.** Pharmaceutical companies are required to have a scientific service (Medical Info 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).

**Section 19.2.** It is recommended that the scientific service in charge of processing and responding to requests for medical information be integrated into the medical affairs / scientific department of the pharmaceutical companies, depending on the organisational structure of each company. Preferably, it should include a physician or pharmacist or other HCP.

**Section 19.3.** 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.

**Section 19.4.** Pharmaceutical companies are required to be prepared to receive queries by phone, post, e-mail 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 liable to check such media on a daily basis for any incoming inquiries (incoming calls, electronic/printed mail). The staff in charge of receiving such messages (e.g. reception staff) must be trained to recognise requests for medical information and promptly forward them to the relevant scientific service for processing and response.

**Section 19.5.** Health scientists working in pharmaceutical companies and assigned with 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 and development, the staffing of non-promotional medical stands in scientific conferences and communication of scientific information to the competent authorities shall belong and report to the medical affairs / 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.

**Section 19.6.** A Medical Science Liaison belongs also to the same category of HCPs who, as scientists of the health sector, may not report, even indirectly, to any departments other than the medical affairs department and may not have visit-frequency or volume-sales based targets. Pharmaceutical companies may also have specially trained staff to respond to inquiries concerning specialised products (e.g. medical devices).

**Section 19.7.** 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 personal data. It is recommended that such system records essentially the following information:

- a. The inquiry and the product concerned;
- b. The contact details of the person making the inquiry;
- c. The date the inquiry is received;
- d. The person responsible for processing the inquiry and the response that was given, with clear indication of the reference source;
- e. The date a response was given to the inquiry.



**Section 19.8.** Pharmaceutical 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.

**Section 19.9.** Replies to medical inquiries 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.

**19.9.1.** Answers must concern specific unsolicited inquiries and be limited to the scope of such inquiries.

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

**A) *Patients – Patients Organizations – General Public***

Answers to inquiries from patients and their relatives, POs 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 properly 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 inquiries concerning use outside indications, the patient must be referred to his/her treating physician and it must be made clear that the specific use is not envisaged in the approved product characteristics.

Finally, the answers, whether in writing or oral, must make clear that the information provided in response to the relevant inquiry 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 inquiries from HCPs must be based on the SPCs of the products. Standard answers to FAQs must also be based on the SPCs.

If these are not sufficient to fully answer the inquiry, the department in charge may refer to literature, published articles, online information and any available announcement summaries. In all these situations, the source of information must be indicated and the copyrights to use such publications must be taken into account (see Article 3.11.8.).

If the inquiry 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, insofar as this is permitted under the law, answers can be based on the product RMP and the respective training material.

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

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

Answers to inquiries from a company's Medical Sales Representatives to its Medical Affairs department (where applicable) must be exclusively based on the SPCs.

**19.9.3. Scientific Literature Update**

This refers to the provision of scientific literature (in printed or electronic format) in reply to an incoming question from a HCP<sup>24</sup>, (rather than inquiries made on the initiative of the pharmaceutical company to serve promotional activities), aimed exclusively to substantiate the answer and enhance his/her scientific knowledge. Scientific literature must only be sent to the HCP who made the inquiry, be a precise quotation and include a clear indication of its exact source.

Scientific literature must be sent exclusively to the HCP who made the inquiry, be a precise quotation and include a clear indication of its exact source.

The use of literature on the company' initiative for promotional purposes is subject to the provisions of Article 3 of the Code (see Article 3.11.8. - Reprints)

If an HCP requests to obtain scientific literature information containing information on use outside indications, it must be made clear that the use in question is not envisaged in the approved product characteristics and the answer must be accompanied by the SPC (see also Article 19.9.2. B).

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.

### ***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 provably 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 copyright owner must grant clear consent to the use of his/ her work, the time period of such use and the medium by which his/her work will be used.

**Section 19.10.** Presentations of the Medical Affairs Departments of pharmaceutical companies to Hospital clinics

The Medical/Scientific Departments of pharmaceutical companies may organise presentations of scientific content on products to Hospital clinics, upon a documented request of the clinic Director. These presentations do not constitute scientific events, as the latter are defined by EOF. Pharmaceutical companies are not allowed to offer coffee/snacks/soft drinks etc. inside the Hospital. Pharmaceutical companies shall fully respect the operating regulations of the hospital and the relevant legislation.

## ARTICLE 20. MEDICAL SALES REPRESENTATIVES

**Section 20.1.** Medical sales representatives must comply with the Code and legislative provisions in force. Pharmaceutical companies shall ensure the compliance of medical sales representatives.

- 20.1.1.** 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 the information referred to in Article 3.2 of the Code, regarding price and reimbursement by social security.
- 20.1.2.** Medical sales representatives must report to the pharmaceutical company's scientific service, which is provided for in Article 18 of the Code, any information concerning the use of the medicinal products they promote, in particular, reports of side effects from persons they have visited, which must be promptly notified to the company's Pharmacovigilance Officer so that the appropriate legal steps can be taken, where required.
- 20.1.3.** 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 Institution must be observed at all times.
- 20.1.4.** 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.
- 20.1.5.** Pharmaceutical companies are responsible for the activities of their representatives, when such activities are performed within the scope of their employment.
- 20.1.6.** Medical sales representatives must not employ any inducement or subterfuge to gain an interview with any HCP.
- 20.1.7.** 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.

## Section 20.2. Meetings for products (Group Detailing)

Pharmaceutical companies may organize small group meetings with HCPs regarding their products (Group Detailing). These meetings have a scientific content regarding the properties of the products; they may take place either with the physical presence of participants or via the Internet and shall be addressed either to private practitioners (HCPs) or to full-time or part-time HCPs of the public sector. Such meetings are not subject to EOF's approval and are in compliance with the SFEE Code, provided that the following conditions are cumulatively met:

### a) Meetings with private sector HCPs:

1. The meeting concerns prescription-only medicinal products.
2. The meeting comprises a small number of private HCPs. "Small number" means no more than ten (10) persons.
3. The meeting has a short duration (up to 1.5 hour) and no accommodation expenses are covered by the pharmaceutical company.
4. The speaker is an internal Medical Information Officer/Medical Sales Representative of the company.
5. The scientific character of the meeting prevails over its social one.

### b) Meetings with public sector HCPs:

1. The meeting concerns prescription-only medicinal products.
2. The meeting is attended exclusively by HCPs (public officials) of the Hospital
3. The meeting takes place inside the Hospital.
4. The speaker is an internal Medical Information/Medical Sales Representative of the company.
5. The meeting was approved by the Clinic Director (not by EOF).
6. Pharmaceutical companies do not offer coffee/snacks/soft drinks or other sweets or snacks inside the Hospital.

## ✧ CHAPTER 4.

# SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs

### ARTICLE 21. GENERAL PRINCIPLES

Pharmaceutical Companies and POs must comply with the following principles:

- The independence of POs, in terms of their political judgement, policies and activities, must be assured.
- All interactions between POs and pharmaceutical companies must be based on mutual respect, with the views and decisions of each partner having equal value.
- Pharmaceutical Companies must not request POs to undertake, the Promotion of a particular prescription-only medicinal product.
- The objectives and scope of any collaboration between pharmaceutical companies and POs must be transparent. Financial and non-financial support provided by pharmaceutical companies must always be clearly acknowledged.
- Pharmaceutical companies welcome broad funding of POs from multiple sources.

### ARTICLE 22. MEDICINAL PRODUCTS PROMOTION

In the implementation of this chapter, the provisions of national and EU law prohibiting promotion of POM to the general public shall apply.

### ARTICLE 23. WRITTEN AGREEMENT

When pharmaceutical companies provide financial support to POs, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. donation or grant for a specific meeting or publication, etc.). It must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support. Companies must have an authorisation procedure in place for the agreements of this kind.

## ARTICLE 24. USE OF LOGOS AND MATERIAL OF EXCLUSIVE USE

Use by pharmaceutical companies of logos and materials intended for exclusive use by POs requires written permission from the PO concerned. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

## ARTICLE 25. PUBLICATIONS

Companies offering financial support of any kind to POs must not influence the text of PA's material they sponsor in a manner favourable to their own commercial interests. This does not preclude companies from correcting any inaccuracies identified in such texts. In addition, at the request of POs, pharmaceutical companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

## APΘPO 26. CONTRACTED SERVICES

**Section 26.1.** Contracts between pharmaceutical companies and POs' Representatives under which the latter provide any type of services to the former are only allowed if such services are provided for the purpose of supporting healthcare or research.

**Section 26.2.** It is permitted to POs' Representatives to provide services as consultants, e.g. in consultancy meetings or as speakers. The arrangements that cover these Consultancy and/or other services must, meet all of the following conditions:

- a) a written contract is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
- b) a legitimate need for the services has been clearly identified and documented by the company in advance of requesting the services and entering into arrangements;
- c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular consultants and experts meet those criteria;
- d) the services are provided to a degree proportionate to what is reasonably required to meet the identified needs;
- e) the contracting company maintains records concerning the services and makes appropriate use thereof;
- f) the engagement of POs Representatives is not an inducement to promote a POM;

- g) the remuneration provided for the services is reasonable and reflects the fair market value of the services provided. In this context, the maximum fee payable to POs' Representatives for services rendered may not exceed seventy Euros (EUR 70.00) per hour, subject to a total maximum fee of five hundred and sixty Euros (EUR 560.00) per service. Such fees shall be deposited to the PO.
- h) In their written contracts with POs' Representatives, companies are strongly encouraged to include provisions regarding the obligation of the POs' Representatives to declare that they have offered remunerated consultancy services to the company concerned, whenever they write or speak in public about a matter that is the subject of the agreement or any other matter relating to that company.

## ARTICLE 27. SINGLE (PHARMA) COMPANY FUNDING

A single pharmaceutical company may not be the only sponsor of a PO and all actions which the latter may organised over a year, save for in relation to any diseases for which no other funding is available. This shall not apply to any POs engaged in Rare Diseases.

## ARTICLE 28. EVENTS AND HOSPITALITY

**Section 28.1.** All events organised by POs and funded by or on behalf of a pharmaceutical company, including scientific, business or industry meetings, must be held in "appropriate" locations and venues that are conducive to the main purpose of the event, avoiding those that are "renowned" for their entertainment facilities or are "extravagant", according to the terms of the CHAPTER 2, Article 7.1. in above.

**Section 28.2.** All forms of hospitality offered to POs' Representatives by pharmaceutical companies must be "reasonable" and strictly limited to the main purpose of the event, irrespective of whether the events is organised by the PO or the company, in accordance with the terms of the Article 8.3. in above. All hospitality limits laid down in Annex I, are applicable in this case as well.

**Section 28.3.** Hospitality offered in the context of events must be limited to travel, meals, accommodation and registration fees.

**Section 28.4.** Hospitality may only be extended to the POs' Representatives . In exceptional cases of established health needs (e.g. disability), the travel, accommodation and registration fee costs of an accompanying person, who will be considered as caregiver, can be reimbursed within the same parameters.

**Section 28.5.** Pharmaceutical companies are not allowed to financially support entertaining events (e.g. excursions and tourist activities in general).



**Section 28.6.** Pharmaceutical companies are not allowed to organise or sponsor a PA event that takes place outside its home country unless:

- a) most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
- b) given the location of the installations <sup>25</sup> that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

## ARTICLE 29. TRANSPARENCY

- a) Each pharmaceutical company shall post on its website a publicly accessible list of POs to which it offers financial support and/or significant indirect non-financial support, as well as POs with which it has entered into a service agreement.

The list should include a brief description of the nature of the support, which should be thorough enough to allow the average reader to understand the nature of the support or contractual relationship, without disclosing confidential information. In case significant non-financial support is provided, whose financial value cannot be precisely defined, the description must specify the non-financial benefit obtained by the PA. This information can be provided and updated at least once a year, not later than June 30<sup>th</sup>, (Reporting Period/Calendar Year).

- b) In case financial and/or indirect non-financial support is provided, in addition to the name of the PA, the relevant disclosure should include the following information:
  - The monetary value/amount of financial support and certified expenses;
  - The non-financial benefit obtained by the PA in case it is impossible to accurately identify the value of the indirect non-financial support;
  - For contracted services: The total amount paid to the PA during the Reporting Period.
- c) **METHODOLOGY:** Each pharmaceutical company will issue a memo summarising the methodology applied for the above disclosure and identifying any form of support and/or services provided.
- d) It is recommended that each pharmaceutical company designate one person as its the main contact person in any communications with the PA. Such designation shall be made in line with the company's corporate structure. The designated person must not be associated with the company's Promotion/sales/marketing departments. Each company shall notify to SFEE of the name of the person designated as above, upon request.

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25 – e.g. Research laboratories, production plants etc.

# ✧ CHAPTER 5.

## DISCLOSURE OF TRANSFERS OF VALUE BY PHARMACEUTICAL COMPANIES TO HCPs AND HCOs

### 1. DISCLOSURE OF TRANSFERS OF VALUE TO HCPs and HCOs

#### A. SCOPE

The present Chapter of the Code governs the disclosure of transfers of value effected by pharmaceutical companies to HCPs and HCOs resident in Greece.

#### ΑΡΘΡΟ 30. ΥΠΟΧΡΕΩΣΗ ΔΗΜΟΣΙΟΠΟΙΗΣΗΣ

**Section 30.1. General Disclosure Obligation.** Subject to the above, each Member Company is liable to disclose on their website,<sup>26</sup> within six months' from the end of each calendar year at the latest, i.e. **no later than June 30<sup>th</sup>**, individually by name, all Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient, in line with the applicable legislation. Such data shall remain posted on the company's website for a period of three (3) years.

**Section 30.2. Exclusion from the Disclosure Obligation.** Excluded from the scope of Article 30.1. of this Chapter are transfers of value which:

- a. are solely related to over-the-counter medicines;
- b. are not listed in Article 32 of this Code, such as meals and drinks (see Article 8), medical samples (see Article 17) and medical utility items of insignificant value set out in Article 18.1 of the Code;
- c. 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.

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26 – See Article 66 (7) of Law 4316/2014 (GG 270/A/24.12.2014).

## ΑΡΘΡΟ 31. FORM OF DISCLOSURE

**Section 31.1. *EAnnual Disclosure Cycle.*** Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (**the “Reporting Period”**).

**Section 31.2. *Disclosure Template.*** Disclosures shall be made using a standardised template (see Annex IV) which is consistent with the provisions of the present Chapter of the Code.

**Section 31.3. *Platform of Disclosure.***

- A) *Company website:* Disclosures shall be made on each company’s website, in accordance with Article 31.4. The disclosed information shall be freely and publicly available.
- B) *EOF Platform:* Disclosures shall be made on EOF website, as per EOF’s rules, time schedule and standards.

**Section 31.4. *Applicable National Code and National Law.*** Disclosures for all HCPs and HCOs resident or carrying out activities in Greece shall be made pursuant to the present Chapter of the Code.

**Section 31.5. *Language of Disclosure:*** Disclosures shall be made essentially in the Greek language.

**Section 31.6. *Documentation and Retention of Records:*** Each Member Company shall document all Transfers of Value required to be disclosed pursuant to Article 30.1. and maintain the relevant records of the disclosures made under this Code for a minimum period of three (3) years after the end of the relevant Reporting Period, unless a longer or shorter retention period is designated by the law or the Data Protection Authority.

## ARTICLE 32. INDIVIDUAL AND AGGREGATE DISCLOSURE

**Section 32.1. *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, and speciality), the amounts of transfers of value that were made directly or indirectly to such Recipient in each Reporting Period which may be reasonably allocated to one of the following categories.

### **32.1.1. *Transfers of value to HCOs related to:***

- a. *Donations and grants:*** Any kind of donation or grant to HCOs (either in cash or benefits in kind *governed by Article 11, Chapter 2 of the Code.*

**b. Sponsorship of Events.** Sponsorships of events organised by HCOs, as the relevant costs derive from the contracts entered with the HCOs or with third parties appointed by the HCOs to manage an Event, and do not concern an HCP individually.

**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/conference, 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 fees not covered in other categories (e.g. personal fees for services rendered, payable directly to a HCP). Fees, on the one hand, and all other expenses included in the agreement, on the other, will be disclosed as two separate amounts.

### **32.1.2. Transfers of value to HCOs related to**

#### **a. Events:**

1. Registration fees
2. Travel and accommodation expenses.

**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 all other expenses included in the agreement, on the other, will be disclosed as two separate amounts.

**c.** The Disclosure obligation applies both to direct and indirect transfers of value to HCPs and HCOs. When deciding how to disclose a Transfer of Value that was made to a HCO relating to services rendered by HCPs, companies must, where possible, disclose the transfer of value individually per final Recipient (HCP) (not per HCO), provided that this can be done in an adequate and accurate manner in compliance with the applicable laws and regulations.

## **Section 32.2. Aggregate Disclosure**

**32.2.1.** Transfers of value lying within the scope of Article 32.1. that may not be disclosed individually due to legal reasons, shall be disclosed on an aggregated basis. This type of disclosure (aggregate) must include: (i) the number of Recipients concerned, indicated both in figures and as a percentage of the total Recipients; and (ii) the total Value of Transfers made to the relevant Recipients.

**32.2.2. Transfers of Value concerning Research and Development activities.** Transfers of Value concerning Research and Development activities in each Reporting Period shall be disclosed by each company on an aggregated basis. Costs relating to events that are auxiliary to activities lying within the scope of this paragraph (e.g. Investigator meetings) shall be disclosed on an aggregated basis.

**32.2.3. Non Duplication.** Where a transfer of value required to be disclosed pursuant to paragraph 3.1. or 3.2. is made to an individual HCP indirectly via an HCO, such transfer of value shall only be disclosed once. Such disclosure shall be made on an individual basis, indicating the name of the HCP in accordance with paragraph 32.1.2.c.

**32.2.4. Methodology.** Each Member Company shall publish a note summarising the methodology applied for the disclosure and identification of Transfers of Value for each category of disclosed transfers of value. 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.

### **Section 32.3. Disclosure of indirect transfers of value made through third parties**

#### **SUPPORT / SPONSORSHIP OF SCIENTIFIC EVENTS THROUGH PCOs**

If the financial management of a scientific event is assigned to a Professional Conference Organiser (PCO), as per the provisions of Article 7.11. of the Code, the relevant Transfers of Value shall be disclosed in the name of the HCO organising the event.

## \* CHAPTER 6.

# COMPLIANCE MONITORING PROCEDURE

### ARTICLE 33. COMPLIANCE MONITORING BODIES

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

**Section 33.1.** The First Instance Committee for Code Compliance, hereinafter referred to as the First Instance Committee, which examines complaints filed essentially on two levels, as follows:

- (a) A mediation procedure, where the First Instance Committee is represented by its Chairman and Secretary, acting at this stage as mediators for the amicable settlement of the dispute arising between the opposed parties. If this procedure turns out unfruitful:
- (b) A procedure before the First Instance Committee in plenary session (discussion and decision on the complaint).

**Section 33.2.** The Second Instance Committee for Code Compliance, hereinafter referred to as the Second Instance Committee, which reviews complaints on second instance following an application for referral by the company that was sanctioned by the First Instance Committee.

**Section 33.3.** The Disciplinary Board of SFEE, stipulated in Article 19 of the Statutes of SFEE, which addresses cases of pharmaceutical companies referred to it upon request of the Second Instance Committee and can consider expulsion of the member company from SFEE.

### ARTICLE 34. FIRST INSTANCE COMMITTEE: STRUCTURE, RESPONSIBILITIES AND COMPLAINTS PROCEDURE

**Section 34.1.** Monitoring of compliance with the Code is entrusted to the First Instance Committee, which shall be competent to investigate and rule on complaints about Code violations. In addition, it shall be responsible for any settlements or other arrangements in the context of compliance with the Code.

- 34.1.1.** 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. In addition, it provides support both to the First Instance and the Second Instance Committee for Code Compliance with regard to technical issues.

**34.1.2.** The Code of Ethics and Transparency Committee consists of nine members and their alternates and is set up by decision of the Board of Directors. Its term of office expires upon expiry of the tenure of the Directors that set the Committee up.

**Section 34.2.** The First Instance Committee is set up by the Board of Directors of SFEE. The terms of office of its members is three (3) years and may be renewed by decision of the Board of Directors.

The First Instance Committee comprises:

- A member of the judiciary or a person of broad recognition, to act as Chairman;
- The Legal Advisor of SFEE, to act as Secretary;
- two (2) former General Managers of Pharmaceutical Companies;
- A specialised Scientific Officer (external advisor);
- The respective alternates of regular members.

**Section 34.3.** Pharmaceutical companies shall make every possible effort to settle disputes before filing a complaint to the First Instance Committee.

**Section 34.4.** A complaint may be made by the following:

**34.4.1.** Any natural or legal person affected by the violation of the provisions of this Code is entitled to file a complaint before the First Instance Committee by post, in person or by email (complaints@sfee.gr). The First Instance Committee shall convene *ad hoc* and decide on the matter. Complaints may be named or anonymous. A complaint filed by a person stating his/her identity and requesting to retain anonymity is not deemed to be anonymous.

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

**34.4.3.** The First Instance Committee may act *ex officio*, if a violation of the Code is brought to its attention.

**34.4.4.** Furthermore, it is possible to file a complaint directly at EFPIA offices in Brussels.

**34.4.5.** A complaint may also be filed by an EFPIA member Association of Pharmaceutical Companies.

**Section 34.5.** Complaints shall be filed within a reasonable period of time, which may not exceed six (6) months from the occurrence of the reported action.

**Section 34.6.** As soon as filed, a complaint is forwarded to the Secretariat of the First Instance Committee and recorded in the relevant registry of complaints on the same day. The Secretary of the First Instance Committee then forwards the complaint without undue delay to the Chairman 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. The complaint is also notified to the reported company by the Secretary of the Committee.

**Section 34.7.** Complaints filed with EFPIA and concerning activities of SFEE member companies shall be forwarded by EFPIA to the Secretary of the First Instance Committee, who shall register them on the same day in the complaints registry. The Secretary of the First Instance Committee then notifies without undue delay the Chairman of the First Instance Committee of the receipt of the complaint, by fax or email. Following the above, the procedure laid down in this Chapter 6 before the First Instance Committee is applied.

**Section 34.8.** If the complaint is sufficiently precise, the Chairman of the First Instance Committee shall gather the necessary factual evidence. The company concerned may also be invited in order to assist in the evidence collection process. Following the above, the Chairman shall initiate the mediation procedure as described above.

**Section 34.9.** The discussion of the 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 the competent civil courts.

**Section 34.10.** During the Mediation Procedure, an amicable settlement of the dispute is attempted. If an amicable settlement is achieved, settlement Minutes are drafted to that effect.

**Section 34.11.** In the event that the Mediation Procedure fails, the complaint shall be referred to the First Instance Committee in Plenary Session by letter of the Chairman of such Committee, addressed to the other members and to the disputing parties. The Committee shall meet in plenary session within thirty (30) business days following the date of the letter sent by the Chairman, which shall include all documentation presented by the parties. The above deadline may only be extended in case of objective impediment.



**Section 34.12.** 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 Chairman of the Committee shall prevail. At the conclusion of the meeting the First Instance Committee, the Secretary of the Committee, jointly with the Chairman 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 Chairman and the members thereof. The decision shall be thereafter notified by the Secretary of the Committee to the pharmaceutical company concerned and to the complainant (natural person or legal entity).

**Section 34.13.** The Chairman 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 complaint filed before the Committee. The Chairman 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.

**Section 34.14.** If a member of the First Instance Committee has filed before the Committee a complaint against a company or worked for a pharmaceutical company which has filed a 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 worked for a company against whom a 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.

## **APŌPO 35. REFERRAL PROCEDURE AND HEARING OF COMPLAINTS BEFORE THE SECOND INSTANCE COMMITTEE**

**Section 35.1.** A company sanctioned by the First Instance Committee has the right to file an application for referral of the matter to the Second Instance Committee, within thirty (30) business days from the date it is notified of the First Instance Committee's decision.

**Section 35.2.** The application for referral must be filed with the Legal Department of SFEE, which shall communicate it without undue delay by e-mail or fax to the Chairman, the Secretary and the members of the Second Instance Committee.

**Section 35.3.** The Second Instance Committee is set up by the Board of Directors of SFEE. The terms of office of its members is three (3) years and may be renewed by decision of the Board of Directors.

**Section 35.4.** The Second Instance Committee comprises:

- A member of the judiciary or a person of broad recognition, to act as Chairman;
- A Lawyer, presumed to be familiar with medical and pharmaceutical matters, to act as Secretary;
- two (2) former General Managers of Pharmaceutical Companies;
- A specialised Scientific Officer (external advisor);
- The respective alternates of regular members.

The regular and alternate members of the Second Instance Committee may not participate in the First Instance Committee.

**Section 35.5.** The Second Instance Committee convenes within twenty (20) working days at the latest after being notified by the SFEE Legal Department of the application for referral of the complaint. After examining the case, the Committee shall issue a decision, which is binding on the disputing parties.

**Section 35.6.** The Second Instance Committee shall be in quorum when at least four (4) of its members attend. However, there must always be one representative from each of the categories described in Article 35.4. Decisions shall be taken by majority vote.

**Section 35.7.** The Chairman of the Second Instance Committee shall set a hearing of the case within two (2) months from the constitution of the Secondary Committee and invite the complainant and the complainant, who may also appear by way of a memorandum, to a hearing. Discussion in the presence of the parties is preferred. Otherwise, Articles 34.8, 34.9 and 34.12 of the Code shall apply *mutatis mutandis*.

**Section 35.8.** The Chairman 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 establishing the facts of the case.

**Section 35.9.** Expert advisors may be asked to attend the proceedings of the Second Instance Committee, without the right to vote.

**Section 35.10.** If a member of the Second Instance Committee has filed before the First Instance Committee a complaint against a pharmaceutical company or worked for a pharmaceutical company that has filed a 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 worked for a pharmaceutical company against which a complaint was filed before the First Instance Committee, which is under discussion in the Second Instance Committee.

**Section 35.11.** Similar issues of complaints shall be addressed in the same manner. If a complaint concerns an issue which has recently been addressed by the Second Instance Committee, the Chairman 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.

**Section 35.12.** 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.

## **ARTICLE 36. SANCTIONS**

**Section 36.1.** If the **First Instance Committee**, considers, after examining the complaint, that there is a violation of any articles of the Code, it may impose the following sanctions, taking into account the type of the violation, the number of violations, the gravity and the relapse. Any sanctions imposed shall be executed after the deadline for filing an appeal before the Second Instance Committee has elapsed:

- (a) A financial penalty of up to twenty-five thousand Euros (EUR 25,000) and
- (b) If the identified violations relates to Scientific Information/Promotion material, correction of the non-compliant promotional material and obligation of the pharmaceutical company concerned to send the corrected material to its addressees, along with a letter stating the corrections;

**Section 36.2. The Second Instance Committee** may ratify the decision of the First Instance Committee, without amending it, or repeal it, but without worsening the position of the appellant (pharmaceutical company).

**Section 36.3.** In case the deadline for an appeal before the Second Instance Committee has elapsed and the company refuses to comply with the First Instance Committee's decision, the Second Instance Committee may impose on the company the following sanctions:

- (a) A financial penalty of up to twenty-five thousand Euros (EUR 25,000);
- (b) Refer the matter to the SFEE Disciplinary Board, which may, among others, decide on the expulsion of the member concerned.

**Section 36.4.** The company concerned must comply with the Second Instance Committee's decision as soon as possible. If the company concerned fails to comply with the sanction imposed on it by the Second Instance Committee, whether the sanction consists in performance of an action, including payment of a fine, or omission of an action, 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. This shall be deemed as a new, independent case.

**Section 36.5.** 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.

**Section 36.6.** Any final decision<sup>27</sup>, which is not subject to further review, imposing any of the sanctions in above shall be promptly publicized on SFEE's locked website. The publication shall remain posted for a period of three (3) months.

**Section 36.7.** In any event, failure to comply, or to properly comply, with the decision shall be notified to the National Organisation for Medicines (EOF).

## **ARTICLE 37. 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 complaints handled during the past year by SFEE's First Instance and Second Instance Committees.

## **ARTICLE 38. GENERAL PROVISIONS**

**Section 38.1.** In case of conflict between the provisions of this Code and the provisions of the applicable national legislation, the stricter rule applies.

**Section 38.2.** Acts deemed as formally lawful, due to EOF's or other competent Authority's tacit approval may be challenged in terms of ethical compliance of their content under the provisions of this Code.

**Section 38.3.** Any typical proceedings (formalities) before public authorities included in the Code, automatically cease to be valid, or are amended accordingly, in case of a new relevant decision of the Competent Authority.

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27 – For the purposes of this Code, "final decision" means a decision rendered by the First Instance Committee, if the deadline for referral to the Second Instance Committee has elapsed or a decision rendered on a matter which has been heard on both first and second instance.



- I) Table of Limits
- II) Indicative calculation of HCP remuneration for Services provided to pharmaceutical companies
- III) Non-interventional clinical trials registry
- IV) Disclosure Template
- V) Indicative List of most representative HCOs/Specialty and Medical Specialisation



## 1. LIMITS ON CORPORATE SPONSORSHIPS OF HCO SCIENTIFIC EVENTS PER YEAR

### A. HCO

1. FACE 2 FACE SCIENTIFIC EVENTS								
DEFINITIONS		MINIMUM DURATION		MAXIMUM SPONSORSHIP AMOUNT/COMPANY		MAXIMUM REGISTRATION FEE (EOF)/ SPONSORSHIP OF PARTICIPATIONS (SFEE CODE)		MAXIMUM NUMBER/ YEAR
EOF	SFEE	EOF	SFEE	EOF	SFEE	EOF	SFEE	
<b>INTERNATIONAL EVENTS HELD DOMESTICALLY</b> (by foreign HCOs or jointly with Greek HCOs) If the event is jointly organised by foreign and Greek HCOs: at least 50% participation of the foreign HCO in the budget and in the Speakers. Events organized by Greek HCOs under the auspices of a foreign body are not considered international events		N/A		EUR 30,000 (VAT included)	Organised by foreign HCOs:  EUR 30,000 (VAT included)*  Jointly organised by foreign and Greek HCOs: EUR 14,000 (VAT included) from 01.09.2024	N/A	EUR 140.00 (VAT excluded) only in case of jointly organised - from 01.09.2024.	1 Only in case of jointly organised - from 01.09.2024
<b>PAN-HELLENIC EVENTS</b>		At least 2 days	At least 24 programme hours	EUR 30,000 (VAT included)	EUR 14,000 (VAT included)	N/A	EUR 140.00 (VAT excluded)	1
<b>TWO-DAY EVENTS</b>	<b>REGIONAL</b>	Over 8 hours	At least 16 programme hours	EUR 15,000 (VAT included)	EUR 7,000 (VAT included)	N/A	EUR 140.00 (VAT excluded)	<b>TOTAL (A.3, A.4 and A.6)</b>  <b>up to 3</b>
<b>ONE-DAY EVENT</b>	<b>LOCAL EVENTS</b>	1 Day	At least 4 hours	EUR 5,000 (VAT included)	EUR 3,500 (VAT included)	N/A	EUR 140.00 (VAT excluded)	
<b>LEARNING CYCLES</b>	-	-	-		EUR 3,500 (VAT included)	N/A	EUR 140.00 (VAT excluded)	

\*international congresses evaluated by EFPIA according to the Conference Vetting System (CVS) are excluded from the limit.

## 2. WEB/VIRTUAL ATTENDANCE OF HCO SCIENTIFIC EVENTS, HCO WEB/VIRTUAL SCIENTIFIC EVENTS & WEBINARS

2. WEB/VIRTUAL ATTENDANCE OF HCO SCIENTIFIC EVENTS, HCO WEB/VIRTUAL SCIENTIFIC EVENTS & WEBINARS									
DEFINITIONS		DURATION		MAXIMUM REGISTRATION FEE (EOF)/ SPONSORSHIP OF PARTICIPATIONS (SFEE CODE)		MAXIMUM SPONSORSHIP AMOUNT/COMPANY		MAXIMUM NUMBER/ YEAR	
EOF	SFEE	EOF	SFEE	EOF	SFEE	EOF	SFEE	EOF	SFEE
<b>WEB SCIENTIFIC EVENTS</b>	<b>WEB/ VIRTUAL SCIENTIFIC EVENTS/ CONGRESSES</b>	Not defined	As in points A1., A.2., A.3., A.4. or A.5.) Scientific events	Not defined	SEs of equal duration as:  A.1: 50.00 € (VAT excluded) only in case of jointly organised - from 01.09.2024  and  A.2: 50.00 € (VAT excluded) Pan-Hellenic SEs.  SEs of shorter duration: No sponsorship for registration fees	Depending on the type of the event  A.1. <€ 30,000  A.2. <€ 30,000  A.3. <€ 15,000  A.4. <€ 5,000  A.5. <€ 2,500 (Vat included)	Depending on the duration of the event (as in points A1., A.2., A.3., A.4. or purely web events organised by the bodies referred to in point A.5)  A.1. <€ 10,000 only in case of jointly organised by foreign and Greek HCOs: 7,000 € (VAT included) - from 01.09.2024  A.2. <€ 7,000  A.3. <€ 3,500  A.4. <€ 1,750  A.5. <€ 1,500 (vat included)	Depending on the type of the event (A1., A.2., A.3., A.4. or A.5.) The limits applicable to scientific events requiring the physical presence of the participants shall apply and are included (i.e. apply cumulatively)	The limits applicable to scientific events requiring the physical presence of the participants and hybrid events shall apply and are included (i.E. Apply cumulatively)
<b>LEARNING CYCLES</b>			-		No registration fee		<EUR 1,750 (vat included)		
<b>WEBINARS</b>	<b>ONLINE PRESENTATIONS (WEBINARS)</b>	Up to 3 hours	Up to 3 hours	Not defined	No registration fee		<EUR 1,000 (vat included)	No limit applies	No limit applies

**B. EVENTS ORGANISED BY STATE HOSPITALS, UNIVERSITY CLINICS,  
LABORATORIES, NHS CLINICS AND PRIVATE CLINICS/HOSPITALS (EOF AND SFEE)**

DURATION	SPONSORSHIP AMOUNT	NUMBER/YEAR
Up to 2 days	EUR 2,500/COMPANY EUR 10,000 in total	3

**C. PHARMACEUTICAL COMPANIES (EX TYPE B)**

	DURATION	NUMBER/YEAR/COMPANY
PROMOTIONAL and NON-PROMOTIONAL EVENTS (EOF AND SFEE) with the physical presence and/or online attendance of HCPs.	at least 4 hours/day Up to 3 days (Including 2 overnight stays)	48
WEBINARS	Up to 3 hours	No limit applies

**D. BOARD/ACCOMODATION LIMITS (EOF AND SFEE)  
(FOR PARTICIPATION IN HCO- AND COMPANY-ORGANISED SCIENTIFIC EVENTS)**

	MEALS	ACCOMMODATION
DOMESTICALLY	EUR 70.00 (VAT included)	EUR 150.00 (VAT included)
ABROAD	EUR 150.00 (VAT included)	EUR 400.00 (VAT included)



## 2. MAXIMUM LIMIT OF SPONSORSHIP FOR HCP PARTICIPATION IN SCIENTIFIC EVENTS

### A. PER SPONSOR:

Only for PHYSICIANS: at least 10%, for participation in events organised by scientific bodies in Greece or abroad (only in Europe), provided that the physician is in his/her second last or last year of internship, including interns liable to present research work.

<b>EUROPE</b>	<b>10 HCPs/EVENT (9+1 Interns)</b>
<b>NORTH AMERICA</b>	<b>5 HCPs/EVENT</b>
<b>OTHER COUNTRIES</b>	<b>5 HCPs/EVENT</b>

### B. PER HCP/YEAR:

<b>DOMESTIC EVENTS</b>	<b>4</b>
<b>ABROAD**</b>	<b>3</b>

### C. SPONSORSHIP AMOUNT PER (PHARMA) COMPANY/SAME HCP/YEAR:

<b>DOMESTIC EVENTS SCIENT. EVENTS HCOs+HOSPITALS</b>	<b>2</b>
<b>DOMESTIC EVENTS PHARMA COMPANIES (ex Type B)</b>	<b>2</b>
<b>ABROAD*</b>	<b>2</b>
<b>WEBINARS domestically + abroad</b>	<b>No limit applies</b>
<b>DOCUMENTED ACTIVE PARTICIPATIONS</b>	<b>No limit applies</b>

\*\*Pensioner HCP cannot not be sponsored by pharmaceutical companies for their participation in scientific events held abroad, unless they have provably active participation in these events.

### 3. MAXIMUM ORGANISATION LIMITS AND LIMITS TO HCP PARTICIPATIONS IN ADVISORY BOARDS/CALENDAR YEAR

<b>NUMBER / COMPANY / DOMESTICALLY</b>	<b>2/THERAPEUTIC CATEGORY</b> (ATC3 level) and <b>20 MAXIMUM</b>
<b>NUMBER OF PARTICIPATIONS</b>	Up to <b>10</b>
<b>PARTICIPATIONS/HCP</b>	<b>DOMESTIC EVENTS: 2/YEAR/COMPANY</b>
	<b>ABROAD: NO LIMIT APPLIES</b>

- \*- *IN CASE THE APPLICABLE LIMITS ARE REDUCED BY THE COMPETENT REGULATORY AUTHORITY, ANNEX I WILL BE AMENDED/UPDATED ACCORDINGLY BY DECISION OF THE BOARD OF DIRECTORS.*
- *IN CASE THE APPLICABLE LIMITS ARE ABOLISHED BY THE COMPETENT REGULATORY AUTHORITY, SUCH LIMITS SHALL REMAIN IN FORCE AS IN FORCE RIGHT BEFORE THEIR ABOLISHMENT UNTIL THE NEXT SFEE GENERAL ASSEMBLY MEETING.*



## **CALCULATION OF HCP FEES**

Below are instructions regarding the indicative limits of fees that are recommended to be paid by pharmaceutical companies to HCPs, as the latter are defined in this SFEE Code of Ethics, for services provided to pharmaceutical companies, having due regard to the relevant European data, Ministerial Decision no. οικ. 72944 (Government Gazette 1958/B/12.8.2013), Article 36 of Law 4272/2014, the provisions of Law 4009/2011 as in force, and the relevant resolutions of the Athens University Senate (GG 826/B/1996 and GG 2163/B/2012):

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

The following categories are used to rank all HCPs (NHS, Academics, private physicians) and take into account the experience of HCPs which also establishes (documents) the participation and remuneration for such services.

The evaluation sheet is included in the file of this cooperation.

#### **1. Experience at international level: (to meet at least 3 of the following criteria)**

- Chairman of scientific events in international conferences held in the last 3 years
- Speaker in international conferences held in the last 3 years.
- Participation in international clinical trials as a member of the steering committee of the study and/or principal investigator (PI at his/her centre) in the last 5 years
- Active member of the editorial board or author of at least 5 publications in international peer-reviewed journals in the last 5 years
- Author of international guidelines in the last 5 years.
- Chairman or member of the Board of Directors of an international scientific organisation, in the last 3 years.

#### **2. Experience at national level: (to meet at least 3 of the following criteria)**

- Chairman of scientific events in Pan-Hellenic conferences (as the latter are defined in the relevant EOF circular), held in the last 3 years (excluding satellite conferences)
- Speaker in Pan-Hellenic conferences (as the latter are defined in the relevant EOF circular), held in the last 3 years (excluding for satellite conferences)
- Participation in interventional clinical trials as Primary Investigator (PI) in the last 5 years

- Author of at least 5 publications in Greek or foreign peer-reviewed journals in the last 5 years
- Author of national guidelines in the last 5 years.
- Active chairman or member of the Board of Directors of national scientific organisations.

### **3. Experience and other expertise: (to meet at least 3 of the following criteria)**

- Speaker in local conferences held in the last 3 years.
- Participant in clinical studies \* in the last 5 years.
- Author of publications in Greek peer-reviewed journals in the last 5 years.
- 5 years of clinical experience after the end of internship

### **4. HCPs: This category includes indicatively the following: nurses, pharmacists, dentists, non-specialised physicians, interns and physicians not falling under any of the above categories.**

\* In case of non-interventional clinical trials, these must be included in the electronic register of non-interventional clinical trials on SFEE's website.

#### **Hourly Fees**

- Hourly fees are determined as follows:
- Experience at international level: Up to EUR 190.00\* (subject to a EUR 1,520.00 total fee cap\*)\*\*
- Experience at national level: Up to EUR 170.00\* (subject to a EUR 1,360.00 total fee cap\*)
- Experience and other expertise: Up to EUR 130.00\* (subject to a EUR 1,040.00 total fee cap\*)
- Scientists / HCPs up to EUR 100.00\* (subject to a EUR 800.00 total fee cap\*).

\* Hourly fees include transportation time. ELKE/ELKEA withholdings and VAT not included.

## **\*\* EXCEPTIONS:**

**The above total remuneration cap and the preparation and presentation time limits do not apply to HCPs with experience at international level who are actively involved in scientific events and provide services outside of Europe.**

**The total attendance time and the topics must be presumed by the programme/agenda/subject and the content of the activity.**

**The hourly fee remains unchanged.**

**In the above situations, the total fee limit per activity/service is EUR 3,000 (excluding VAT & other withholdings). The limit of the annual (calendar year) total remuneration provided by a pharmaceutical company to a HCP having international experience, in case the HCP has actively participated in the SE within the year or has provided services inside Europe (or even outside Europe), may not exceed seven thousand Euros (EUR 7,000), excluding VAT and other withholdings. Any amounts concerning payments for the conduct of clinical research are not included.**

- The services provided by HCPs include:
  - Lectures at scientific events, conferences, symposia
  - Consulting services, participation in Advisory Boards
  - Staff training seminars
  - Configuration of educational material and/or presentations for educational purposes
  - Services such as protocol writing, bibliography review, other services that require considerable time of involvement and/or preparation, if documented, are calculated taking into account experience and the hourly remuneration rate, as same are laid down herein, and are excluded from the preparation hours (see below) and the total involvement hours (see hourly fees).
  - HCP services related to legal cases are exempted by this HCP fees calculation methodology, as the lie outside the scope of this Code.
- Preparation hours for coordination of a domestic event, lecture, staff training or participation in Advisory Boards are defined based on the content, scope and duration of the service and may not exceed 4 hours. In case of a presentation, the content of which has been presented in the past in whole or in part, the preparation time is determined accordingly and may not exceed 2 hours.
- The involvement time is defined by the scientific programme of the event, based on the total time of presence in the conference/event, rather than based solely on the speaking time, so that the speaker can make comments or give answers to questions by the end of the conference/event.

- The total recommended fee per HCP per calendar year (cap) may not exceed EUR 5,000, excluding VAT and other withholdings (see Article 9.7.) (i) Save for the cases where the HCP is actively involved in the scientific event and provides services outside of Europe. Applicable to HCPs with international experience, where the maximum recommended fee per HCP per calendar year is seven thousand Euros (EUR 7,000), excluding VAT and other withholdings.
- The aforementioned fee limits are merely indicative and represent all SFEE members' perception of a fair and reasonable fee for the services defined herein. SFEE members are recommended to observe these limits for the reasons stated in Article 2 of this Code.



## REGISTRY OF NON-INTERVENTIONAL CLINICAL TRIALS - ON-LINE REGISTRY OF NON-INTERVENTIONAL TRIALS POSTED ON SFEE WEBSITE

### 1. Description

- Recording of all non-interventional trials conducted by the sponsor company, with a description of the planning, targets and time schedules.
- Recording of the details of research centres and of the applicable fees
- Recording of the number of patients to participate
- Each trial is posted by the sponsor company/SFEE member 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 is posted and 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, ENcePP standards & guidelines.
- Based on Directive 28/2005, envisaging specific types of trials.

### 3. Types of Non-Interventional Trials

- The types provided for in EU guidelines and the EMA algorithm, Annex 1, March 2011, must be observed.
- ANNEX: DECISION TREE TO ESTABLISH WHETHER A TRIAL IS A "CLINICAL TRIAL"

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 a researcher per hour	EUR 50 – 90
Gross remuneration of a study coordinator per hour	EUR 20 – 40
Training on the filling in of electronic CRF (one-off)	EUR 190 – 290
Preparation and review of files (one-off)	EUR 270 – 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 studies	Market research among HCPs	Clinical Trials
Collection of patients' personal data	Yes	Yes	All data from HCPs concerning patients shall be collected and delivered fully anonymised and aggregated.	Yes
Requires statistical calculation of the number of patients and epidemiological analysis	Yes	Yes	No, but the persons asked must be a random and representative sample from the reference population	Yes



	<b>Non-interventional studies involving medicine administration</b>	<b>Non-interventional studies not involving medicine administration – Epidemiological studies</b>	<b>Market research among HCPs</b>	<b>Clinical Trials</b>
<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 dis-qualification 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	Possibly – depending on the design	No	Yes
<b>Requires approval from the National Organisation for Medicines (EOF)</b>	No (apart from exceptions, see Article 16.3)	No	No	Yes
<b>Requires approval from the Ethics Committee/ Scientific Committee</b>	Yes	Yes	No	Yes

	<b>Non-interventional studies involving medicine administration</b>	<b>Non-interventional studies not involving medicine administration – Epidemiological studies</b>	<b>Market research among HCPs</b>	<b>Clinical Trials</b>
<b>Requires written consent of patient</b>	Yes, in prospective trials, unless the Ethics Committee/ the Supervising Board of the Hospital decides otherwise No, in properly documented retrospective trials	Yes, in prospective trials, unless the Ethics Committee/ the Supervising Board of the Hospital decides otherwise. No, in properly documented retrospective trials	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 Special care should be taken by the Pharmaceutical Company	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 commencement</b>	Yes, in SFEE's Registry of non-interventional trials	Yes, in SFEE's Registry of non-interventional trials	No	Yes, at clinical trials. gov and clinicaltrials register.eu/

	<b>Non-interventional studies involving medicine administration</b>	<b>Non-interventional studies not involving medicine administration – Epidemiological studies</b>	<b>Market research among HCPs</b>	<b>Clinical Trials</b>
<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	Medical sales representatives may not be involved in market research	Not allowed

## 6. Disclosure of non-interventional clinical trials

Aggregate disclosure of ToVs to HCPs and HCOs relating to non-interventional studies (NIS) is limited to NIS that are prospective in nature. By contrast, ToVs to HCPs and HCOs in the context of retrospective NIS must be reported on an individual names basis. If a distinction between prospective and retrospective non-interventional clinical trials is not possible, ToVs are disclosed on an aggregated basis.

Below is **guidance for distinguishing between prospective versus retrospective NIS**

The distinction between prospective and retrospective non-interventional studies is made as follows:

PROSPECTIVE NIS	RETROSPECTIVE NIS
<ul style="list-style-type: none"><li>▪ Prospective cohort studies in which the prescription of medicinal products is done independently of the patient's inclusion in the study.</li><li>▪ Prospective studies which also have a retrospective section.</li><li>▪ Extension of long-term studies to monitor patients beyond the study Protocol, where patients are observed for a certain period of time and additional data is collected immediately.</li></ul>	<ul style="list-style-type: none"><li>▪ Review and/or research of data deriving purely from an observation database.</li><li>▪ Retrospective review of files where all events of interest have already taken place. e.g. case - control, and purely retrospective cohort studies</li><li>▪ Studies in which the prescribing HCP later becomes a researcher but the prescription has already taken place e.g. retrospective collection of data from individual medical records from the researcher's archive</li></ul>

Pharmaceutical companies are recommended to include a relevant comment in their Methodological Note, as the case may be.



# ANNEX IV Disclosure Template

TEMPLATE												
										Disclosure Date: .....		
	Full Name (Name & Surname)	HCP: City of practice HCO: Registered address	Country of practice / Country of registered address	Registered address/ Headquarters	Contribution to cost of events			Fee for service and consultancy		TOTAL		
					Donations & Grants to HCOs	Sponsorships agreements with HCOs/ Third parties organising the event by designation of the HCOs	Registration Fee	Travel Accommodation Expenses	Fees		Relevant expenses stipulated as part of the fee payable for the services or in the consulting services agreement, including travel and accommodation expenses relevant to the agreement	
INDIVIDUAL	<b>INDIVIDUAL DISCLOSURE- one line per HCP, i.e. all payments made during the year to an HCP will be summed up (a detailed recording of each payment must be available to each Recipient or to the public authorities, where necessary)</b>											
	HCP A				N/A	N/A	Annual Amount	Annual Amount	Annual Amount	Annual Amount		
	HCP B				N/A	N/A	Annual Amount	Annual Amount	Annual Amount	Annual Amount		
	etc.				N/A	N/A	Annual Amount	Annual Amount	Annual Amount	Annual Amount		
	HCP	<b>OTHER AMOUNTS NOT INCLUDED ABOVE - if the information may not be disclosed for legal reasons</b>										
		<b>Total amount of fees to HCPs</b>				N/A	N/A	HCO aggregate	HCO aggregate	HCO aggregate	HCO aggregate	Optional
		<b>Number of Recipients included in the aggregate disclosure</b>				N/A	N/A	number	number	number	number	Optional
		<b>Rate (%) of the number of Recipients included in the aggregate disclosure over the total number of Recipients disclosed</b>				N/A	N/A	%	%	%	%	N/A
	HCO	<b>HCO NAMES TO BE DISCLOSED - one line per HCO, i.e. all payments made to each HCO in one year (a thorough description of each payment must be available to each Recipient or to the public authorities (where necessary))</b>										
	HCO 1					Annual Amount	Annual Amount	Annual Amount	Annual Amount	Annual Amount	Annual Amount	Optional
	HCO 2					Annual Amount	Annual Amount	Annual Amount	Annual Amount	Annual Amount	Annual Amount	Optional
	etc.					Annual Amount	Annual Amount	Annual Amount	Annual Amount	Annual Amount	Annual Amount	Optional
	HCO	<b>OTHER AMOUNTS NOT INCLUDED ABOVE - if the information may not be disclosed for legal reasons</b>										
		<b>Total amount of fees paid to HCOs</b>				HCO aggregate	HCO aggregate	HCO aggregate	HCO aggregate	HCO aggregate	HCO aggregate	Optional
		<b>Number of Recipients included in the aggregate disclose</b>				number	number	number	number	number	number	Optional
	<b>Rate (%) of the number of Recipients included in the aggregate disclosure over the total number of Recipients disclosed</b>				%	%	%	%	%	%	N/A	
Research & Development	<b>AGGREGATE DISCLOSURE (FEES FOR RESEARCH &amp; DEVELOPMENT)</b>											
	<b>FEES FOR RESEARCH &amp; DEVELOPMENT</b>										TOTAL AMOUNT	

# ΣφEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES



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