ΣfEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

SFEE CODE OF ETHICS





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www.sfee.gr

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CONTENTS

DEFINITIONS

Conference Vetting System (CVS): a system used by EFPIA to assess major international events taking place in the countries within the scope of the EFPIA Code and with more than 500 HCPs coming from at least five different countries within the EFPIA scope. The platform used for this purpose is accessible via the link: https://cvs.solutions.iqvia.com/new platform CVS/e4ethics 2.0.

Conflict of Interest Disclaimer: see Article 8, Section 8.1.16.

Contribution to Costs related to Events: unrequited financial support by or on behalf of a PC covering the costs of meals, travel, accommodation and/or registration fees to support the attendance of an individual HCP or PO Representative to a Scientific Event organised by a PC and/or a HCO.

Donations and Grants: collectively, mean providing funds, assets or services to a recipient (legal entities only), for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor, or any other third party, in return.

e4ethics: a platform used for the assessment of international events by EFPIA [new_platform_ CVS/e4ethics_2.0]

E-detailing: for definition see Article 4, Section 4.3.

EFPIA: European Federation of Pharmaceutical Industries and Associations.

ELKE: Special Account for Research Funding (relevant for University hospitals/HCPs and is distinct for each University).

ELKEA: Special Account for Research and Development Funding (relevant for NHS Hospitals/ HCPs and is distinct for each Healthcare Region).

ESOMAR/EphMRA: a global organisation that sets ethical standards for healthcare market research and analytics.

European Congresses: for definition see Article 8, Section 8.2.4.

Focus groups or in-depth interviews: market research methodology, see Article 14.

Group detailing: for definition see Article 20, Section 20.2.

HCR: Healthcare Region.

Healthcare Organisation (HCO): any legal entity:

a) that is a healthcare, medical or scientific association (civil code society or union of HCPs) or healthcare organisation (irrespective of its legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for

POs within the scope of Chapter 4 hereof regarding interactions between PCs and POs) whose business address, place of incorporation or primary place of operation is in Greece; or

b) through which one or more HCPs provide services, including private providers of Primary Healthcare services.

Healthcare Professional (HCP): any natural person who is identified as a healthcare professional in the applicable legislation[1] and whose primary practice or principal professional address is in Greece and who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer medicinal products.

It is explicitly clarified that the very broad subset of Healthcare Professionals who are not legally entitled to prescribe, supply or administer medicinal products, but nevertheless belong to the category of Healthcare Professionals, are not considered as general public. In this sense, product promotions at scientific event venues where such persons may be present are no prohibited.

In the context of the national cancer policy, the specialty of pathologists is also explicitly included in this definition.

To avoid any doubt, the term "Healthcare Professional", with the exception of Chapter 1 hereof, also includes:

a) any official or employee of a government agency or other organisation (whether in the public or private sector) who may prescribe, purchase, supply, recommend or administer Medicinal Products; and

b) any employee of a Pharmaceutical Company whose primary occupation is that of a practising HCP (e.g. medical doctor, nurse, dentist, etc.).

However, the definition excludes:

(i) all other full-term personnel (whether HCPs or not) of a PC under an employment contract, professional service contract or independent work contract; and

(ii) wholesalers or distributors of Medicinal Products.

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. According to this principle, the monetary threshold set in the country where the event takes place must

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1 See Article 3(f) of Law 4213, Government Gazette A 261/9.12.2013 (Article 3 of Directive 2011/24/EU), which defines an HCP as: "a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Presidential Decree 38/2010 (GG A 75) or another professional exercising activities in the healthcare sector which are restricted to a regulated profession, as defined in Article 3(1)(a) of Presidential Decree 38/2010, or a person considered to be a healthcare professional according to the legislation of the Member State of treatment"; Article 4 of Law 4238 (Government Gazette A 38/17.02.2014), which identifies as HCP in Primary Care: family doctors, doctors of other specialties, dentists and other HCPs, such as midwives, health visitors, nurses, social workers, physiotherapists, dietitians/nutritionists, psychologists, occupational therapists, medical laboratory technologists, medical and biological laboratory assistants and medical equipment operators; and Article 32 of Law 4999 (Government Gazette A 225/07.12.2022) regarding Secondary Healthcare and professional qualifications.

prevail, unless a stricter threshold applies under a regulative provision of the home country.

http://scientific.events.sfee.gr: SFEE's digital platform used for assessing conferences; see Article 7, Section 7.14.

ICH: International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; for a reference to good clinical practice guidelines see Article 15, Section 15.2.

IFPMA: International Federation of Pharmaceutical Manufacturers and Associations.

Labelling: information on the immediate or primary packaging (e.g. on phials or outer packaging).

Medical information: the supply by a PC of any oral or written scientific information, whose contents and intended use are not associated with the promotion of medicinal products. Any scientific information containing references to off-label uses should not be forwarded to HCPs. This shall not apply to cases where the information is provided through the PCs' medical departments in response to written inquiries from HCPs.

Medical Press: scientific journals, websites and other media addressed specifically to HCPs.

Medical Sales Representative: a natural person assigned by a PC to interact with HCPs and HCOs in relation to the promotion of medicinal products, always in accordance with approved prescription information.[2]

Medicinal Product:

a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

b) any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Meet the expert session: for definition see Article 6 B.3.

NHS: Greece's National Health System.

Over-the-Counter (OTC) Medicine: any medicinal product that can be sold directly to a consumer without a prescription.

Package leaflet: a leaflet containing information for the user which accompanies the medicinal product and is approved by the competent authorities that have granted the marketing authorisation of the product concerned in accordance with the applicable legislation.

2 See Government Gazette 37/B/1985.

Patient Education and Support Programmes: for definition see Article 13.

Patient Organisation (PO): not-for-profit entity that represents and/or supports the needs of people suffering from medical conditions.

Patient Organisation Representative (POR): a natural person who is mandated to represent and express the collective views of a Patient Organisation (PO) on a specific issue or disease area.

PCs (PCs): SFEE member companies, as well as non-member companies that voluntarily adopt this Code.

Professional Congress/Conference Organiser (PCO): a private company specialising in the organisation and management of organisation and management of congresses, conferences, seminars and similar events.

Promotion/Advertising: includes any activity undertaken, organised or sponsored by a PC, or with its authority, which promotes the prescription, supply, sale, recommendation or consumption of its medicinal product(s). Any advertising of medicinal products may only be addressed to persons authorised to prescribe or supply the medicinal product concerned.

Promotional Material is any material containing exclusively scientific information and addressed to HCPs legally entitled to prescribe or supply medicinal products. Any brochures and/or digital material created by PCs for use by social security organisations, Hospital suppliers and other agencies responsible for approving procurements and/or for pricing Medicinal Products do not constitute Promotional Material.

Recipient (of Transfer of Value): any HCP or HCO whose primary practice, principal professional address or registered office is in Greece.

Research and Development Transfers of Value: transfers of value to HCPs and HCPs related to the planning or conduct of: (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice[3]); (ii) clinical trials (phase I, II, III & IV, as defined in national and EU legislation[4]); or (iii) prospective non-interventional studies that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (see also Articles 15 and 16 in Chapter 1 of this Code).

Scientific events: meetings with a scientific content, bringing together HCPs to promote scientific dialogue on medicinal products, treatments and human health in general. Depending on their thematic focus, duration and geographical scope, they may be referred to and designated as congresses, seminars, conferences, workshops, continuing education courses, webinars, or local, regional, Pan-Hellenic or international. They are held in Greece or abroad and are organised by third parties (within or outside the government sector), i.e. non-profit scientific associations, associations of health scientists, scientific societies of any legal form of a non-profit nature, or by private healthcare providers or by PCs. They are

3 OECD Principles of Good Laboratory Practice, rev. 1997.

4 Joint Ministerial Decision 59676/2016 on measures to implement Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials involving humans and repealing Directive 2001/20/EC.

governed by the regulatory framework as set from time to time by the competent Regulatory Authority in accordance with the law. If they are organised by third parties, they may be financially supported by sponsorships and/or grants from PCs, subject to the requirements of the applicable legislative and regulatory framework and the provisions of this Code.

Scientific Information: includes any activity undertaken, organised or sponsored by a PC (or on its behalf) and addressed to HCPs with a view to updating them on nosological entities, prescription-only medicinal products, active ingredients, clinical studies/trials and other scientific data.

Service and Consultancy: the term encompasses education/training (in-house for PC employees and/or externally to other HCPs), advisory boards or pharmaco-economics expert panels of any kind), expert or technical advice, speeches/lectures, planning/joint organisation of scientific events and/or general consultancy (i.e. regarding health information and/or public awareness brochures on diseases, authoring of scientific articles, translation services, etc.

SFEE Code of Conduct/Code: The Code of Conduct of the Hellenic Association of Pharmaceutical Companies, including its Annexes.

SFEE: the Hellenic Association of Pharmaceutical Companies.

Sponsorship: any support/funding provided by a PC to a legal entity for any reason or cause, in return for which the sponsor PC gains business and/or brand visibility only.

Summary of Product Characteristics (SPC): a document describing the properties and conditions for use of a medicinal product; it is addressed to HCPs and is approved by the competent authorities that have granted the marketing authorisation of the product concerned in accordance with the applicable legislation.

Transfers of Value (ToV): Any transfer of value, either as remuneration for service provided or as contribution to costs related to a training/continuing education activity,. Included in this definition are direct or indirect transfers, whether in cash or in kind or otherwise, made for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products 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 those made through a third party and where the PC knows or can identify the Recipient.

Web scientific events/congresses or virtual scientific events/congresses: for definition see Article 6 -A.7.

Web/virtual company-hosted scientific events/congresses: see Article 6 - B.2.1.

Webinars: virtual events of a three-hours' duration; see Article 6 -A.7.4. and B.2.2 for webinars organised by HCOs and (as company-hosted webinars) by PCs, respectively.

World Congresses: for definition see Article 8, Section 8.2.3.

Written form: where any provision in this Code requires a written form, this shall denote any document bearing a handwritten or electronic signature.

THE ORIGINS AND VALUE OF SELF-REGULATION

SELF-REGULATION IS AN AGILE WAY TO ENSURE HIGH STANDARDS ACROSS THE PHARMACEUTICAL INDUSTRY. HOW DOES IT WORK IN EUROPE?

Self-regulation plays a vital role in regulating how PCs promote medicines, interact with healthcare professionals and engage with the patient community. By setting and enforcing rules and standards, industry organisations (Local Associations) are at the heart of delivering on this commitment to "self-regulating", while pharmaceutical companies, in turn, ensure that they adhere to and monitor their compliance with these standards.

Ethical interactions (local codes of conduct) are at the heart of self-regulation. In fact, industry standards often go beyond what is required by law, i.e. they are stricter. This is because the aim of self-regulation in the pharmaceutical sector is to support the appropriate and legitimate use of medicines and the provision of high-quality patient care, while increasing trust and improving perceptions.

SELF-REGULATION OF EUROPE'S PHARMACEUTICAL INDUSTRY

The EFPIA Code underpins industry standards in Europe's pharmaceutical sector, building on a long history of self-regulation in various European countries. Member associations in 37 European countries apply national codes encompassing the requirements of the EFPIA Code.

The EFPIA Code sets out minimum common values and principles, while allowing Member Associations to deliver effective self-regulation through country-level rules (local codes). This creates a level playing field where companies of all sizes and maturity operate under one set of agreed standards.

Member Associations are required by EFPIA to implement the EFPIA Code, which includes arrangements for dealing with complaints, and are required to have an independent Chair. For example, Member Associations must impose sanctions when companies violate the EFPIA Code. Fines or public reprimands are common penalties for non-compliance.

Some Member Associations have set up self-regulatory bodies that are independent of the associations themselves to operate their local code. In addition to the activities of the EFPIA Member Associations, 40 PCs are direct members of EFPIA and are therefore required to adhere to the EFPIA Code.

WHAT ARE THE BENEFITS OF SELF-REGULATION?

The European pharmaceutical industry is governed by a complex combination of laws and regulation. **Self-regulation** complements legal frameworks by raising and harmonising industry standards. It helps to reduce the burden on public administrations, while providing industry with a means of enforcing Europe-wide rules to which companies must adhere. **Transparency** about the enforcement of national codes plays a crucial role, as it ensures that people see that actions are taken against non-compliant companies. For example, EFPIA requires the publication of annual reports on the code, detailing the actions taken against violators.

Self-regulatory bodies use their knowledge of how the industry works to keep codes and governance standards up to date, adapting them to reflect the ever-changing interactions between the pharmaceutical industry and healthcare systems. It is also important to reflect public expectations of how PCs should behave.

For example, EFPIA has introduced requirements for disclosure of transfers of value to healthcare professionals in order to increase transparency as a response to criticism in this area. All EFPIA Member Associations apply these rules even in the absence of local legal requirements.

The agility with which self-regulatory bodies respond to a changing environment has been illustrated through the move to digital platforms and new ways to ensure that healthcare professionals receive information about treatments.

During the Covid-19 pandemic, EFPIA, IFPMA (International Federation of Pharmaceutical Manufacturers) and PhRMA (the US national association) collaborated to produce guidance on virtual interactions, which showed how the self-regulatory process helped to ensure that interactions are conducted according to high standards. As healthcare professionals are receiving more information than ever from PCs outside their home country, it is critical to ensure that global standards are aligned as far as possible to ensure that there are consistent rules in place.

Another example of innovative self-regulation is the "Europe-wide congress vetting system" (known as e4ethics). This system reviews the compliance of large and multi-country third-party educational conferences and results in a binding decision on whether the event is compliant and appropriate for PCs to engage with. In 2021, the system merged with the equivalent system for the medical devices industry, improving consistency across the healthcare sector

THE FUTURE OF SELF-REGULATION

The way self-regulation operates is vital to public confidence in self-regulation. As with any system, self-regulation needs to be open to scrutiny and oversight to remain effective. EU law permits self-regulation, and close links with governments are critical to ensuring that it remains fit for purpose.

To be fit for purpose in the future and to maintain and increase public confidence in the industry, self-regulatory systems must continue to respond to new challenges. There are several examples from the last decade of how ethical standards have been improved via the EFPIA Code. These include the improvements in transparency through disclosure, prohibition of promotional aids that were given to healthcare professionals in the past, as well as further restrictions on the provision of samples of medicines. As a self-regulating industry, we are never complacent and will continue to drive improvements.

Self-regulation is undoubtedly a privilege that requires accountability and commitment to high standards from the organisations and companies involved, as well as significant investment. Through our proactive approach, we can continuously improve and enforce standards and integrate them throughout the sector, to deliver on our mission to help patients.

ETHICAL PRINCIPLES

- As pharmaceutical companies, we collaborate with various social partners, such as HCPs, HCOs, PAs and their representatives, with regulatory authorities, government bodies and the general public, aiming to improve people's health and quality of life.
- We continuously invest in research and development to meet existing, unmet medical needs, discovering new treatments and improving existing ones.
- 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 wellbeing depends directly or indirectly on our work.
- We aim at creating an environment in which our stakeholders and the general public recognize PCs as trusted partners.
- In addition to our compliance with a very strict and extensive institutional framework (including pharmaceutical, competition and intellectual/industrial property laws, legislation on the protection of personal data and trade secrets, as well as anti-bribery and anti-corruption legislation), we also comply with additional ethical standards and obligations, established as part of the pharmaceutical industry's self-regulation, through this Code.[5]
- For SFEE and its Members, self-regulation means being fully committed to define, through this Code, the highest possible ethical standards, where breaches are not tolerated.
- Self-regulation also includes the concept of continuous challenge for us to exceed society's expectations, while remaining open to suggestions from others on how we might strengthen trust in our industry.
- We invite stakeholders who share our values and principles to adopt these rules and guidance. The present document demonstrates our commitment to the following ethical principles:
- **PATIENTS ARE AT THE HEART OF EVERYTHING WE DO.** We aspire to ensure that everything we do will ultimately benefit patients. Our primary contribution to society is to deliver high-quality Medicinal Products and 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

5 Law 2251/1994, Article 9a: (d), "code of conduct" means an agreement or set of rules not imposed by law, regulation or administrative provision which defines the behaviour of traders who undertake to be bound by the code in relation to one or more particular commercial practices or business sectors; (e) "code owner" means any entity, including a trader or group of traders, which is responsible for the formulation and revision of a code of conduct and/or for monitoring compliance with the code by those who have undertaken to be bound by it.

communications with stakeholders are accurate, legitimate and balanced. We are accountable for our decisions, actions and interactions and we encourage other stakeholders to follow the same high ethical standards.

- We interact with all our stakeholders with **RESPECT**. We commit to approach our stakeholders with a responsive, constructive and learning attitude and mutual respect. We recognise the value of independent decision-making by stakeholders, based on evidence and with the best interests of the patient in mind. With respect for society, we listen to what is expected from us and adapt our way of working accordingly. When processing sensitive personal data, we make decisions based on the applicable legislation and our Ethical Principles.

- We aim to ensure that the principle of **TRANSPARENCY** is respected. We are open about our activities and interactions and encourage other stakeholders to act with the same openness.

INTRODUCTION

- This Code of Conduct, hereinafter referred to as the "Code", consists of six Chapters and four Annexes that form an integral part thereof. **Chapter 1** contains the substantive provisions of the Code on the Promotion of Prescription-Only Medicines; **Chapter 2** refers to interactions of PCs with HCPs, HCOs and POs; **Chapter 3** focuses on more specific types of interactions of PCs with HCPs, HCPs and POs; **Chapter 4** lays down specific requirements for interactions between PCs and POs; and **Chapter 5** concerns Disclosure of Transfers of Value from PCs to HCPs and HCOs; and **Chapter 6** describes Compliance Monitoring and Enforcement Procedures. **Annex I** specifies the limits on sponsorships, participation of HCPs, etc. in Scientific Events; **Annex II** provides an indicative calculation of fees-for-service payments from PCs to HCPs; **Annex III** refers to the registry of non-interventional clinical studies; and finally **Annex IV** contains the Disclosure template.

- SFEE actively supports free competition and a level playing field across pharmaceutical companies. The SFEE Code is not intended to restrain the promotion of medicinal products by PCs to HCPs or limit interactions with HCPs, HCOs and POs in a manner that is detrimental to fair competition. Instead, it seeks to ensure that PCs conduct such promotion and interactions in a truthful manner, avoiding deceptive practices and potential conflicts of interest with stakeholders, and in compliance with applicable laws and regulations.

- SFEE believes that interactions between PCs and HCPs have a profound and positive impact on the quality of patient treatment and the value of future research. EFPIA believes that interactions between Member Companies and HCPs have a profound and positive influence on the quality of patient treatment and the value of future research. Moreover, the integrity of the decision of a HCP to prescribe a medicinal product is one of the fundamental pillars of the healthcare system. EFPIA recognises that interactions between the industry and HCPs/HCOs can create the potential for conflicts of interest. Consequently, all professional and industry associations have adopted codes of conduct to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

- 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' perspective is 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.

SUBJECT-MATTER AND SCOPE

This Code lays down the principles and procedures to be followed in the promotion to HCPs of prescription-only medicinal products that have lawfully been granted marketing authorisation in accordance with the provisions of Ministerial Decision No. 32221 (Government Gazette B 1049/013) or through the centralised procedure under Regulation (EC) 726/2004) and are supplied on a medical prescription, as well as in the provision of information to the public on general health issues.

NON-SFEE MEMBER PHARMACEUTICAL COMPANIES

PCs that are not members of SFEE may decide to adhere to the Code if they so wish. To this end, they shall submit a declaration to the President of SFEE, also confirming their acceptance of any sanctions envisaged in the SFEE Code of Conduct for non-compliance. Such companies will be included in a separate list, which will be regularly updated and will form part of the Code. For these companies, all articles of this Code, without exception, shall apply as for SFEE members, including those regarding sanctions.

The scope of the Code encompasses:

a. **Promotion of Prescription-Only Medicines** to persons authorised to prescribe or supply medicinal products, irrespective of method or means of promotion, e.g. visits, displays, samples or sponsorship of events;

b. visits by medical sales representatives to individuals qualified to prescribe or supply medicinal products;

c. supply of medical samples;

d. sponsorship of events for the promotion of medicinal products and/or Scientific Events attended by persons authorised to prescribe or supply medicinal products, including payment for travel and accommodation in connection with such events;

e. direct or indirect information to the general public, such as health or disease information, provided that no direct or indirect reference is made to a specific medicinal product;

f. advertising in scientific journals or by mail (including email);

g. the activities of Medical Sales Representatives, as well as any material they use in the provision of hospitality at professional or scientific events and meetings for the purpose of promoting medicinal products;

h. provision of promotional materials, such as brochures, etc.; and

i. all other activities for the promotion of sales in any form whatsoever, such as participation in exhibitions, use of audiovisual material, films, disks, video recordings, electronic media, interactive systems, data, etc.

Note: Radio, television and the daily and weekly press are not mentioned herein, given that the

promotion of prescription-only medicinal products to the general public through such media is prohibited.

The following are excluded from the scope of this Code:

a. the summary of product characteristics (SPC) or the abbreviated SPC, which are subject to the relevant legislation;

b. the labelling of medicinal products and accompanying package leaflets, which are subject to the relevant legislation;

c. factual and informative announcements and reference material relating, for example, to pack changes, adverse reaction warnings in the context of pharmacovigilance, as well as trade catalogues and price lists which include no product information;

d. replies 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").

In all their activities that fall within the scope of this Code, PCs are required to comply with all the relevant provisions herein.

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 MEDICINES TO HEALTHCARE PROFESSIONALS (HCPs)

ARTICLE 1. KEY PRINCIPLES GOVERNING THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES

Section 1.1. The promotion of a Medicinal Product that has not been granted a marketing authorisation is prohibited. Also prohibited is the promotion of a medicinal product for uses outside the scope of its marketing authorisation (off-label) or for indications that have not yet been approved.

Section 1.2. Promotion must be consistent with the particulars listed in the Summary of Product Characteristics (SPC) of the Medicinal Product concerned.

Section 1.3. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the HCP to form his/her own opinion of the therapeutic value of the Medicinal Product concerned. It must be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.[6]

Section 1.4. Promotion must be capable of substantiation by way of documentation, 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. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorisation.

Section 1.5. Promotion must recognise the special nature of Medicinal Products and the professional standing of the intended audience, who must be treated with respect and protected from possible offence.

Section 1.6. Promotion must encourage the rational use of Medicinal Products by 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 property unless this can be substantiated.

Section 1.7. Promotional activities and materials must not be disguised. Indicatively, patient information or public awareness events can constitute disguised promotion, especially in cases where Article 3.4 hereof applies.

6 See also Law 2251/1994, Articles 9 and 9a(f).

ARTICLE 2. DISCREDIT TO, AND REDUCTION OF COFIDENCE IN, THE INDUSTRY

Section 2.1. Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry or any individual PC. PCs are fully aware that any inappropriate or unlawful behaviour on their part will adversely affect the industry as a whole.

Section 2.2. Examples of activities that are likely to be in breach of the preceding clause include inaccurate information, excess hospitality, inducements to prescribe, influence on government officials, inappropriate payments, promotion before official approval of drugs, improper behavior of PH employees/executives and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

ARTICLE 3. PROMOTIONAL MATERIALS

Section 3.1. Key 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[7] shall also apply to this Code.

3.1.2. The promotional material must not imitate the methods, copies, slogans or the general layout adopted by another PC in a way that is likely to mislead or confuse.

3.1.3. The medicinal products and activities of other PCs must not be disparaged.

3.1.4. The promotional material must not include any reference to the National Organisation for Medicines (EOF), the European Medicines Agency (EMA) or any committees under EOF, EMA or the Greek 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 Promotional Material, provided that they are presented intact, unabridged and without falsifications.

3.1.6. Extremes of format, size or cost of the Promotional Material must be avoided.

3.1.7. Lifelong learning programmes, clinical assessments, post-marketing monitoring, experience programmes and post-authorisation studies must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose.

3.1.8. When a pharmaceutical company pays for or otherwise secures or arranges the publication of Promotional Material in a scientific journal,[8] such material must not appear as independent, editorial content.

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7 Law 3408/2005, Code of Medical Ethics.

8 This does not apply to the medical press; see EOF/13, Q&A on Advertising, related to Article 125 of Joint Ministerial Decision 32221/2013.

3.1.9. Any promotional/informational material relating to Medicinal Products and their uses, which is sponsored by a PC, must not include misleading or inaccurate statements and must clearly indicate that it has been sponsored by that PC.

3.1.10. Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the public, contrary to Article 5 hereinbelow.

3.1.11. Any material relating to Medicinal Products and their uses which is sponsored by a PC company must clearly indicate that it has been sponsored by that PC.

3.1.12. Any text/material that at first glance appears to be of a non-promotional nature and is being used for promotional purposes is subject to the provisions of this Code.

ESection 3.2. Content of Promotional Material

Any Promotional Material relating to a Medicinal Product and addressed to persons qualified to prescribe or supply the Medicinal Product concerned, must include, as a minimum the following:

a. essential information consistent with the Summary of Product Characteristics (SPC) as set out in Article 3.3. below, specifying the date on which such essential information was generated or last revised. The Summary of Product Characteristics (SPC) may be included in all types of promotional materials in the form of a QR Code, provided that the a printed version of the SPC is available upon request and is always kept up to date;

b. the supply classification of the Medicinal Product (i.e. prescription-only);

c. the Yellow Card, as required by the applicable legislation;

d. the selling price or indicative price of the various presentations;

e. the social security reimbursement price may also be included;

f. promotion to persons qualified to prescribe or supply the Medicinal Products may include no more than the name of the Medicinal Product or its international non-proprietary name – where this exists – or the trademark, if the advertisement is intended only as a reminder;

g. all Promotional Material must bear at the bottom of the last page an code number with the initials of the Medicinal Product, the series designation, and the month and year when the material was generated or last revised, and must be approved as specified in Article 3.14 of this Code.

Section 3.3. Prescribing information

3.3.1. Prescribing information must be provided in a clear and legible manner in all Promotional Material for a Medicinal Product.

3.3.2. Prescribing information consists of the following:

a. the brand name and the non-proprietary name of the Medicinal Product;

b. qualitative and quantitative composition in active ingredients;

c. the name and address of the PC which is the Marketing Authorisation Holder (MAH), or of its representative in Greece for products authorised under the centralised procedure;

d. the approved indications;

e. side effects, warnings and contra-indications with regard to the indications being promoted;

f. any additional warning issued by the National Organisation for Medicines or the licensing authority;

g. the supply classification of the products (e.g. for hospital use, prescription-only, etc.).

η. the number of the relevant marketing authorisation;

h. (optionally) the reimbursement status of the product according to the List of Prescription-Only Medicines;

i. dosage;

j. the information specified above regarding dosage, method of use, side effects, precautions and contra-indications and any warning which is required to be included in advertisements must be presented in such a manner that its relationship to the claims and indications for the product can be appreciated by the reader.

k. the date on which the SPC was last revised.

Section 3.4. Information, claims and comparisons

3.4.1. PCs 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 properties of the Medicinal Products, as well as on an up-to-date evaluation of all the evidence. They must not be directly or indirectly misleading or distort the scientific facts.

3.4.3. Direct or indirect promotion of misleading indications of the Medicinal Product, reference to outdated scientific data, inaccurate or unsubstantiated claims, misleading comparison with other Medicinal Products and generalisation of isolated observations are all prohibited.

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

3.4.5. Substantiation of any information, claim or comparison must be promptly provided in response to reasonable requests from HCPs or appropriate administrative staff.

3.4.6. If the Promotional Material refers to published studies, clear bibliographic citations must be provided.

3.4.7. Scientific data and claims included in Promotional Material must be based on research published in scientific books, journals and/or other printed and electronic publications.

3.4.8. Eligible literature sources include articles published in scientific books and journals, mainly in the English language. Exceptionally, publications in established peer-reviewed journals in other internationally recognised languages (e.g. French, German or Spanish) may also be accepted, in which case the company should be able to provide a Greek translation of the article, upon request.

3.4.9. References to literature must be clear and sufficiently complete to enable the reader to retrieve the source. They must indicate the author(s), book or journal title, year of publication, issue/volume and page numbers. PCs are recommended to follow one of the internationally accepted referencing 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 may not be claimed that a product does not have any side effects, interactions with other Medicinal Products, toxic hazard or risk of addiction or dependency. The word "safe" must not be used.

3.4.11. Exaggerated or all-embracing claims regarding the therapeutic properties of a medicinal product (e.g. *"the key to success, "works wonders", "the only choice", "only acts where needed", "hits the problem at its heart", "only inhibits…",* etc.) must not be made, and superlatives or similar expressions (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 must 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 whereby a medicinal product is described e.g. as being "better", or having *"a better safety profile"* without stating with which it is compared are not permitted.

3.4.13. Any Promotional Material which contains claims must include at least a brief reference to significant safety aspects of the Medicinal Product and not only to its favourable properties, to ensure that the content is balanced.

3.4.14. All claims in Promotional Material must be consistent with the approved indications and other details of the product's SPC. Any claim for use of the Product outside its approved indications or other SPC details is prohibited. The use of data outside the approved indications or other SPC details is not permitted.

3.4.15. Safety and efficacy data which, according to the SPC, are subject to a 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[9] cannot justify the inclusion of indications that have not been studied for the specific Medicinal Product.

3.4.16. Comparative claims of superiority or non-inferiority are only permitted if they are supported by adequate statistical significance in head-to-head, product-specific, randomised comparative trials published in peer reviewed journals, aimed at comparing the safety/efficacy parameters and other properties of the Medicinal Product (primary or secondary end points of the trial).

3.4.17. When comparisons and/or statistical data are contained:

a. it is necessary in all cases to state the level of statistical significance (p-value or confidence intervals), and any statistically insignificant information must be identified as such;

b. no further statistical elaboration (e.g. extrapolation of data by the company) may be included when the data have not been published;

c. in cases where the clinical value is not known, this should be mentioned on the same page of the Promotional Material;

d. all the factors used for comparisons must be mentioned, with clarifications where necessary.

3.4.18. The word "new" must not be used to describe any medicinal product or packaging which has been generally available or any therapeutic indication which has been generally promoted for more than 12 months.

3.4.19. The brand name of any product marketed by other PCs must not be used without the prior approval of the MAH of that product.

Section 3.5. Use of web sources

3.5.1. When web sources are used:

a. the references provided must lead to the precise source of information;

b. the date of last access must be indicated; and

c. a printed version of the source document must be kept on record by the PC.

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9 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, antiangiogenics, 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.

3.5.2. Data from conference papers, presentations or abstracts may only be used if:

d. they have been disclosed in prestigious scientific conferences and have been approved by the scientific committee of the conference;

e. If, two (2) years after its first disclosure, the study has not been published other than partial entries in publications, announcements or abstracts/poster presentations, the underlying data must not be used in any Promotional Material;

f. the data are available in their entirety on the conference website or abstract book; and g. are accompanied by a clear reference to the website or abstract book where it is available, and not just the name of the conference.

Section 3.6. In-press articles

Articles that have been accepted for publication and are forthcoming (in press) may be used in Promotional Material, provided that they are identified as such in the relevant 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 shared and discussed with HCPs exclusively by the PC's medical department, but may not be included in Promotional Material. Only general data are acceptable, such as the total number of patients participating in clinical trial programmes investigating the Medicinal Product concerned, the total duration of the clinical trial 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 indicated in the Promotional Material.

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 used, the registry must be identified 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"*. In all cases, the following must be complied with:

3.8.1.1. Reference to safety or efficacy data using a truncated quotation from a publication or expert presentation, e.g. *"the medicinal product was effective and well tolerated"*, must 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 is not permitted, even if the data are identified as such or as *"more recent data"*. Scientific data must be faithfully reproduced without any adaptation or alteration.

3.8.1.4. Cutting a part of a sentence in a way to alter its overall meaning is not permitted. Any footnotes (e.g. using 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 is recommended; these include:

a. randomised controlled trials (RCTs) with concealed allocation, double-blind, or systematic meta-analysis review thereof;

b. well-designed non-randomised controlled trials;

c. controlled observational studies (prospective or testimonial studies);

d. uncontrolled observational studies;

e. expert opinions based on pathophysiological mechanisms or laboratory evidence, or consensus opinion without specific reference to critical review and methodology.

Section 3.9. Pharmacoeconomic studies

3.9.1. The use of pharmacoeconomic studies in Promotional Material must be limited, given that such material is intended to provide HCPs with information relevant to the treatment of patients rather than economic aspects of treatments; the latter are more of interest to those responsible for the procurement and reimbursement of 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 from studies published in reliable medical and/or pharmacoeconomic journals. The underlying methodology (assumptions) must also be stated;

c. the use of data from international studies, also published in reliable journals, must be accompanied by a disclaimer that Greek data are not available and the results should therefore be interpreted with caution;

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

e. it must be indicated that the information was drawn from published pharmacoeconomic studies (or, where appropriate, 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 what they are meant to show, and must not be included unless they are relevant to the claims or comparisons being made. Promotional Material most not feature illustrations that are irrelevant to the content thereof, misleading or suggest unspecified indications for the Medicinal Product.

3.10.2. Quotations, including tables and graphs, from medical literature must be faithfully reproduced, and the precise sources must be specified, otherwise the fact that the original has been adapted must be clearly stated.

3.10.3. The use of images, illustrations and artwork in general which distracts or misleads the readers or suggests the superiority of a medicinal product is prohibited, unless such superiority is substantiated.

3.10.4. In particular, it is prohibited:

a. to omit any 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 treatments;

d. to alter the scale in a way to overstate/understate the differences;

e. to omit the title of a table/chart, the measurement units on the x, y axes and/or any numerical data in general.

3.10.5. Changes to graphic elements from tables and figures of articles are only acceptable if:

a. the end result does not alter the meaning of the original;

b. it is clearly stated that the original material has been modified; and

c. the changes consist in deletion or omission of data on dosage, indications etc. not authorised 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 study/trial, the number of participants, statistically significant data when comparisons are made, as well as the definition of primary and secondary end points.

3.10.7. The depiction of results from several different studies in the same graph is not permitted, even if there are references to the individual studies, as this could be visually misleading.

3.10.8. In the case of competitive products, any comparison across different clinical studies (in terms of objectives, cohort characteristics, etc.) is not permitted

Section 3.11. Form of Promotional Material

3.11.1. Leavepieces

In leavepieces, the Summary of Product Characteristics (SPC) may be enclosed in a single sleeve, provided that such enclosure is explicitly stated. The SPC may also be included in the form of a QR code, provided that a printed version of the SPC is available upon request and is always kept up to date.

3.11.2. Printed material

In standard printed material, it is permitted to integrate the SPC (if extensive) into the main material (e.g. last page/pocket), provided that it is explicitly stated that the Summary of Product Characteristics (SPC) is enclosed. The SPC may also be included in the form of a QR code, provided that a printed version of the SPC is available upon request and is always kept up to date.

3.11.3. Digital material

In digital Promotional Material, it is permitted to include the SPC as a link or QR code, with clear instructions as to where to click or scan, e.g. *"For the Summary of Product Characteristics, please click here"*. The prescribing information may be included in the same or a different link, where appropriate.

3.11.4. Audio-Visual material

In cases where audio-visual material (e.g. CDs, DVDs, audio messages, etc.) or interactive data systems are used, the prescribing information may be provided:

a. in the form a document made available to all persons to whom the material is displayed or sent;

b. incorporated in the audio-visual material or interactive data system;

c. when the prescribing information is incorporated in an interactive data system, instructions on how to access it must be clearly displayed.

3.11.5. Posters

Posters must only display the name of the Medicinal Product and its international non-proprietary name. In all cases where more information is featured, a clear and prominent notice must be included: *"Before prescribing, please consult the Summary of Product Characteristics available at the company stand"*. It goes without saying that the SPC must be available at the company stand in a sufficient number of printed copies or in an electronic medium.

3.11.6. Advertisements

3.11.6.1. Advertisements may only appear in professional material, namely material sent or delivered exclusively to HCPs. This includes healthcare-specific journals and reviews, material of conferences approved by the SFEE Evaluation Committee, medical/ pharmaceutical books, etc.

3.11.6.2. A loose insert in such a publication (for instance, stand-alone leaflets distributed through the medical press) is not considered "abbreviated advertisement" (see 3.11.7 hereibelow).

3.11.6.3. Advertisements are not permitted in audio-visual material or interactive data systems or websites and/or online journals. This prohibition does not apply to systems and/or websites which cannot be accessed by HCPs without a password; in advertisements on such media that contain claims, the SPC may be included as a link where 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 advertising where the prescribing information appears overleaf, an explicit reference to where it can be found must appear on the outer edge of the first page of the advertisement.

3.11.6.5. In advertisements that continue overleaf, neither page must be misleading or untrue when read in isolation.

3.11.7. Abbreviated advertisements

3.11.7.1. Abbreviated advertisements are exempt from the requirement to include the prescribing information of the medicinal product being promoted, provided that they fulfil the conditions 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 (MAH) in Greece, for products subject to the centralised authorisation 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 licensing authority must be included in the advertisement;

f. a statement that further information is available on request by the MAH or is included 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 letters to the editor must accurately reflect the meaning of the author.

3.11.8.2. Quotations relating to Medicinal Products 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. The utmost 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. Reprints distributed on the initiative of a PC must refer to approved products, indications and elements 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 a yellow card. The copyrights of the authors must also be safeguarded.

Section 3.12. Digital communications

Subject to applicable legislation, the use of faxes, e-mails, automated calling systems, text messages and other digital communication methods for promotional purposes is prohibited, except with the prior permission, or upon the request, of the recipient.

Section 3.13. Distribution of Promotional Material

3.13.1. Promotional material must only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.

3.13.2. PCs must arrange the frequency of distribution and the volume of promotional material distributed in a manner corresponding to effective information needs.

3.13.3. Mailing lists must be kept up to date and conform with the data protection legislation. Requests by HCPs to be removed from promotional mailing lists must be complied with promptly, and no name may be restored except at the addressee's request or with their permission.

Section 3.14. Internal review and certification of Promotional Material

3.14.1. Before being printed/distributed, Promotional Material must be internally certified in accordance with the provisions of applicable legislation.

3.14.2. Every PC must have a scientific service in place, tasked to implement an appropriate internal process for the certification of any promotional/informational material, thereby ensuring compliance with applicable legislation and the Code.

3.14.3. All the personnel of the scientific service of a PC, including those in any way involved in the preparation or certification of material intended for promotion, information to HCPs and to appropriate administrative staff, or information to the general public, must fully comply with the requirements of this Code.

3.14.4. It is recommended that the scientific service in charge of certifying such material be part of the PC's medical/scientific department, depending on the organisational structure of the company. The scientific service should preferably include at least one medical practitioner or pharmacist or other appropriately qualified health scientist, as the person responsible for approving all Promotional Material before release. Such person must certify that he/she has examined the final form of the

Promotional Material and has found it to be in accordance with the requirements of the law and the Code. The person in question may not be a member of, and/or report to, the sales and marketing department, and no conflict of interest must exist.

3.14.5. Any materials prepared by PCs which relate to Medicinal Products in general but is not intended for the promotion of 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 also be certified by the PC's scientific service referred to in 3.14.4 above, in order to ensure compliance with the Code and applicable legislation.

3.14.6. Certification means that the signatories have examined the final form of the material and that, in their belief, it complies with the requirements of the law and the relevant provisions of the Code, is consistent with the marketing authorisation and SPC and/or the package leaflet, and is a fair and truthful presentation of the facts about the Medicinal Product concerned.

3.14.7. All Promotional 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 certified by the PC's scientific service.

3.14.8. Material used for a long time must be updated and recertified at intervals of no more than two years, to ensure ongoing conformity with applicable legislation and the Code.

3.14.9. PCs must preserve, for at least three (3) years, all certified material, along with the relevant accompanying documentation (e.g. literature, 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), as well as information the indicating the persons to whom it was addressed and the method of dissemination, and be ready to submit it, 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, similarly as for printed material, and produce it upon request to the competent authority in accordance with applicable provisions.

ARTICLE 4. INTERNET – DIGITAL APPLICATIONS

Section 4.1. General

4.1.1. There are various channels for delivering promotional material via the internet. The most commonly used channels are the following:

a. websites;

b. "eDetailing";

c. e-Newsletter/e-mailing to HCPs;

d. social media.

In all cases, as appropriate in view of the content and addressees of the communication and the terms of use of the relevant online platform/application, compliance is required with the applicable legislative and regulatory framework, as established by pharmaceutical laws and relevant EOF circulars, as well as with data protection and intellectual property legislation.

4.1.2. PCs are responsible for the content of any promotional/informational material which is made available on the internet on their initiative and/or sponsorship or by any third party acting on their behalf. For example, reference of a prescription-only medicine on the company's website or social media account/profile can be considered as promotion to the general public, which is prohibited. PCs are also responsible for any information which may be disclosed by their employees through their personal social media accounts/profiles if such persons (a) can be reasonably perceived as representing the company; or b) have been mandated, authorised or assisted by the company in disclosing such information.

4.1.3. PCs must have procedures in place to detect, modify and/or delete any improper comments that may appear on their social media accounts (and possibly also comments on third-party accounts), to the extent 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 name that pharmaceutical company as the sponsor. Accordingly, whenever Promotional Material is publicised on the Internet, clear reference must be made to any involvement of a PC, e.g. in defining the content to be publicised or sponsoring 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 commitment to a patient-oriented approach.

4.2.1. Company websites addressed to the public

PC websites are classified as a channel that reaches the general public, except for any areas thereof that require credentials for access. These websites therefore typically appear via a search engine, which is why keyword optimisation is very important. PCs must ensure that the use of keyword optimisation is appropriate for the intended audience.

a. The main corporate website: this can include the profile, history, news on the societal activity of the company, as well as a list of products with the respective approved package leaflets. It may also include texts informing the public on prevention and health issues, but it must not connect them with the medicinal products marketed by the PC and/or their package leaflets.

The material featured must, in the first place, have been certified according to the PC's internal processes. The same applies for any change or addition to the website. The

applicable pre-approval and notification requirements of the competent regulatory authorities must be complied with.

b. PC websites dedicated to public information on prevention and health promotion issues. The texts and visuals, as well as any significant revision thereof, must be submitted to the competent regulatory authority for pre-approval or notification, according to the provisions applying from time to time, and the following requirements must be met:

1. There must not be any direct or indirect Promotion of Medicinal Products. This precludes any references to brand names of Medicinal Products and/or names of active ingredients or to therapeutic options in terms of broad medicine groups.

2. Texts and information will be presented in a neutral and objective manner, with clear reference sources.

3. A sentence to the following effect must be included: *"The site content is provided for informational purposes only and does not intend to substitute professional medical advice"*. This disclaimer must form an integral part of the terms of use of the informational website.

4. The sources of the information included will be kept on record by the PC and be produced on request to the relevant regulatory authority and/or the SFEE Code compliance monitoring bodies (see Article 39 below).

5. For reasons of transparency and accountability, the PC responsible for providing the information must be clearly identified. No liability disclaimer from the pharmaceutical company is permitted with regard to the information included in the communication campaign.
6. The texts and visuals prepared must be signed by the HCP member of the PC's scientific service who is authorised to approve content and whose name will be notified to the First Instance SFEE Committee, upon request, as well as to the relevant regulatory authority, where this is required by applicable legislation.

4.2.2. Websites exclusively addressed to HCPs and concerning prescription-only Medicinal Products and/or other scientific issues

4.2.2.1. Measures must be in place to ensure that only HCPs have personal access, e.g. via a username and a password.

4.2.2.2. Access credentials may be provided to a specific HCP population only, under the full control of the PC; alternatively, access may be subject to registration, enabling periodic system performance checks by the PC.

4.2.2.3. In any case, the material available on such corporate websites is considered as promotional and must therefore:

a) comply with the applicable provisions on the promotion of prescription-only medicinal products (relevant legislation and Article 4 of this Chapter of the Code); and

b) be certified according to the PC's internal processes (the same applies to any change or addition to the website); and

c) be notified to the regulatory authority when first posted or subsequently revised, where required under the applicable provisions.

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 HCPs and collection of personal data, this must be done in compliance with applicable legislation and with the consent of the HCPs concerned (a relevant record must be kept by the PC).

b) In the case of accompanying questions replied using free text fields on the website and where such fields qualify as market research, approval is required under Article 14 of the present Chapter of the Code. Where interactive communication and/or free text fields are available, the PC must have procedures in place to review the data/information submitted by the HCPs, in order to ensure the effective collection of any Adverse Reactions reported therein and to fully comply with its pharmacovigilance/medical device vigilance obligations.

c) For pharmacovigilance purposes and for facilitating the timely collection and reporting of adverse effects – within the deadlines specified by law, as appropriate – through the dedicated platform and the yellow card, either in printed or in digital form, the contact details of the relevant pharmacovigilance department must be clearly indicated.

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 external websites are contained, users must be clearly warned that such third-party links may re-direct them away from the PC's website.

g) The use of website cookies is only permitted with the user's informed consent according to applicable legislation.

4.2.3. Websites of Medical Societies addressed to the public, including public information on health prevention-promotion issues and sponsored by PCs

Texts and visuals, as well as any significant revisions thereof, must be submitted to the relevant regulatory authority in accordance with applicable legislation. Medical Society websites may include references to therapeutic options, without any direct or indirect Promotion of Medicinal Products, under the following conditions:

a) All currently available treatment options must be mentioned, whether pharmaceutical or otherwise, which can be applied as alternative or supplementary

approaches (e.g. proper nutrition, exercise, surgical intervention, etc.).

b) Pharmaceutical treatment options may be referred to at up to pharmacologic class level.

c) The website must clearly indicate the name of the Medical Society and, less prominently, the name of the sponsoring PC.

In all other respects, the provisions of 4.2.B.1 to 4.2.b.4 apply.

Section 4.3. eDetailing

"eDetailing" is the presentation of digital Promotional Material (eDetails) to HCPs via electronic media (including, but not limited to, websites, CDs, video recordings, webcasts, tablets, personal computers, smartphones) in the context of Promotion and supply of information.

eDetails must only be sent and/or presented only to those categories of HCPs whose need for, or interest in, the particular information can reasonably be assumed. PCs must arrange the frequency of distribution in a manner corresponding to effective information needs.

During eDetailing activities, due consideration must be given to: (a) applicable legislation when any personal data, sensitive or otherwise, are collected; (b) pharmacovigilance, in the case of accompanying questions using free text fields; (c) copyrights when the marketing authorisation holder of the medicinal product is not the copyright owner of the content used; (d) the possibility that the eDetail might include, or qualify as, a medical technology product; (e) providing the clear contact details of the pharmacovigilance department of the MAH of the medicinal product; and (f) the possibility that the eDetail might be considered as promotional gift in the sense of Article 18 of this Code (Informational or Educational Materials and Items of Medical Utility).

4.3.1. To safeguard transparency and trust in the medical sales representative profession, the following rules must be observed:

a) The Promotional Material included in electronic devices (tablet, smartphone, etc.) must have been authorised in accordance with applicable legislation, the relevant article of the present Chapter of the SFEE Code and relevant EOF circulars.

b) The MAH must have ensured that the electronic material is locked, to prevent connection with the HCP's electronic devices and the sharing of unauthorised material.

c) The MAH must also take all necessary steps to prevent:

- free access to websites during the visit;
- downloading of unauthorised material and supply thereof to the HCP;

d) the promotional material contained in the electronic media must include, in a prominent and easily accessible part of the first/home page, the latest Summary of Product Characteristics (SPC), which can be made available to the HCP upon request;

e) if the Promotion involves the provision of gifts or software applications, these must comply with the relevant article of the present Chapter of this Code (Article 18).

f) the digital Promotional Material must be archived in accordance with the provisions of this Code or the MAH's internal archiving procedures, whichever standard is the stricter.

Section 4.4. Newsletter/e-mailing to HCPs

4.4.1. Upon request of a HCP

The sending of newsletters to HCPs upon their request must be in compliance with the provisions of Article 3 of the Code (Scientific Information).

4.4.2. Unsolicited (on the initiative of the PC)

The regular supply of information to HCPs via e-mail on the initiative of PCs is permitted subject to all the provisions laid down hereinabove with regard to digital promotional material. In addition:

a. In the case of interactive messages, i.e. where the HCP can write back in response, care must be taken to ensure appropriate collection, recording and reporting of adverse reactions. If this is not possible, a no-reply format must be used.

b. In all messages, the recipient must be clearly informed that the message is exclusively addressed to HCPs, that he/she is receiving the message because he/she has agreed to receive news and updates from the PC and that the PC is not liable for any transmission to non-HCPs. The form of dispatch must be carefully designed by the PC in advance.

c. PC must arrange the frequency of eNewsletters in a manner corresponding to the need for essential information per therapeutic class.

d. PC must with all provisions on personal data protection.

4.4.3. From the Medical Affairs Department

a) The periodic dispatch of literature update newsletters on the initiative of PCs may only be conducted by the Medical Affairs department of a PC, following internal approval by the head of that department in accordance with the PC's standard procedures.

b) Such eNewsletter may only contain data on a disease and on the respective approved medicinal products of the PC, without any data exclusively referring to competitors' products.

c) The unsolicited dispatch of literature updates regarding off-label uses of a Medicinal Product is not permitted. Such literature update is only permitted in response to a question formally submitted by an HCP and received by the PC, and may only be provided by the PC's Medical Information or Medical Affairs Department (see the preceding paragraph). HCPs may further request and obtain the full publication, subject to all relevant legislative and regulatory requirements.

d) In addition, when providing information to HCPs through their Medical Affairs departments, PCs must comply with applicable intellectual property and data protections legislation.

4.4.4. From the Marketing Department

4.4.4.1. All messages sent by the Marketing and/or Sales Department are of a promotional nature (promotional eDetailing) and must comply with all the requirements of this Chapter of the Code.

4.4.4.2. In such promotion, the Marketing/ Sales Departments must, in addition, comply with applicable intellectual property and data protections legislation.

Section 4.5. Social media

4.5.1. Use of social media – Facebook, Twitter, LinkedIn, etc.

Social media are increasingly used by consumers and HCPs alike as channels of information on health-related issues. Social media, such as Facebook, Twitter, LinkedIn etc., enable PCs to engage with a broad audience of consumers and HCPs and can be very effective information and communication tools. Nevertheless, the use of social media may not include Promotion of prescription-only medicines, except in relation to authorised vaccination campaigns. Moreover, the quality and validity of the information conveyed 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 PC, by an authorised joint team bringing together staff from all departments involved (e.g. Medical Affairs, Pharmacovigilance, Marketing, Compliance, Legal Department, E-business, Communications).

4.5.2.2. Social media engagement with consumers or HCPs on behalf of a PC is only permitted to the staff specifically authorised for this purpose by the PC's senior management (e.g. staff of the Communications Department).

4.5.2.3. Social media accounts/profiles of PCs must be created for professional and not for personal use.

4.5.2.4. For every pharmaceutical company officer authorised to manage the company's social media accounts, an alternate manager must be appointed, to ensure constant compliance with the principles, procedures and standards governing the use of social media.

4.5.2.5. Social media accounts/profiles of PCs must be regularly updated; any accounts/profiles which have not been updated for more than six months must be deactivated by the administrator.

4.5.3. Transparency assurance

4.5.3.1. All social media accounts/profiles of a PC must make clear 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 PC through its corporate social media accounts/profiles must accompany such communication with a disclaimer notice approved by the legal department of the PC 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 the PC concerned and must conform with applicable legislation.

4.5.4.2. Similarly, any communication material used in social media and aimed at informing the public on diseases must comply with applicable legislation.[10]

4.5.4.3. All corporate social media accounts/profiles, together with all their content, must be submitted to the relevant regulatory authority in accordance with applicable legislation.

4.5.4.4. All corporate social media accounts/profiles must include clear instructions on how to report Adverse Reactions, 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 PC.

4.5.5. Requirements for using social media

4.5.5.1. Each PC must have due regard to the terms of use of each social medium, follow its internal procedures and comply with the provisions of this Code and applicable legislation.

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

4.5.5.3. Notwithstanding this, PCs should remove any comments, graphic elements, videos, pictures and any other content which:

- is defamatory;
- in is breach of intellectual property legislation;

10 See EOF Circular no. 16251/13.02.2019, as correctly repeated on 26 February 2019.

- condones or promotes illegal activity;
- is misleading or deceptive;
- uses harsh, obscene, hateful or threatening language;
- is spam or intended to cause technical disruptions to the page;
- offers unauthorized medical information or advice;
- is of-topic.

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. PC must include in the terms of use of their corporate accounts/profiles a statement informing users of the obligation to 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/Checking for Violations of Terms of Use

All corporate social media accounts/profiles must be monitored at least every 24 hours, 7 days a week, enabling to detect any adverse effects reported or violation of the terms of use. In the absence of such monitoring system, a comments functionality must not be available.

Section 4.6. Personal data

When personal data are collected via social media, the consent of the persons whom the data concern is required under applicable legislation and shall be obtained using the consent tool provided by each social medium, and the purpose for which such data will be used by the PC must be clearly explained.

ARTICLE 5. ADVERTISING TO THE PUBLIC

Section 5.1. Advertising to the general public of medicinal products which are only available on medical prescription is prohibited. Information on human health or diseases is not advertising, unless reference is made to medicinal products whether directly or indirectly.

Section 5.2. This prohibition does not apply to vaccination campaigns conducted by PCs and approved by the relevant competent authority.

Section 5.3. The exception introduced in paragraph 5.2 is intended to raise public awareness and increase vaccination rates among the general population; thus, what is being advertised is not the vaccine, but rather vaccination. In this regard, the following elements of the campaign must be specified:

a) the media to be used (e.g. the daily press, the Internet, radio, television, etc.);

b) the duration of the campaign and any future repetitions at given intervals;

c) whether the vaccine is included in the National Vaccination Programme.

Section 5.4. In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer must be advised to consult a HCP.

CHAPTER 2.
INTERACTIONS WITH HCPs, HCOs AND POs

ARTICLE 6. SCIENTIFIC EVENT CATEGORIES

Section 6.1. Ethical commitment

SFEE and its members support, as a **matter of principle**, continuing medical education/information and lifelong learning in healthcare. Placing **patients at the heart** of everything we do, we see it as our duty to **promote scientific dialogue** on diseases and treatments, so as to contribute to a faster discovery of ways to heal and alleviate the burden of chronic and other serious medical conditions. To this end, we sponsor various scientific events, provide educational scholarships, sponsor medical practitioners to participate in educational programmes and promote scientific research and innovation. Our goal is to educate more and more healthcare professionals across all specialties and interact with the medical and patients communities with **integrity, respect and transparency**, building a relationship of ethical 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 guided by the value of our industry to society and are subject to strict mandatory ethical standards (scientific, economic, quantitative and communicative), underpinned by our commitment to work for people as our first and foremost priority. We disclose our transfers of value with honesty because we believe in our worth and we are proud of it. We have earned the gratitude and respect of our stakeholders because we uphold **transparency**, and we enjoy working with them in achieving this objective.

The **ethical commitment** of SFEE and its members means that, in delivering on their social responsibility, they strive to leave a **positive footprint on society and the industry** and, above all, uphold high standards of **quality**, which is ensured through a rigorous selection of activities. PCs endorse and remain dedicated to SFEE's objectives and commitments; SFEE, in turn, is the chief guardian of their principles and commitments, being fully aligned with the ethical principles of our pan-European federation, **EFPIA**. Together we safeguard our business model, an advanced production model based on ethical values and extensive interactions with society.

Section 6.2. Scientific Events are divided into two (2) broad categories: those organised by third parties (Type A) and those organized by PCs (B):

[A]. Scientific Events organised by Third Parties (Public-sector or Private HCOs)

Third parties comprise public and private Healthcare Organisations (HCOs).

In particular, public HCOs include medical schools and health science departments of Universities across the country; University hospitals of medical schools across the country; state

hospitals integrated in the NHS and hospitals supervised by the Ministry of National Defence, with all their functional units (clinics, laboratories, surgery facilities); primary healthcare centres; academic primary healthcare units; healthcare units/structures of social security funds; and non-profit scientific institutes or associations of health scientists across the country having the status of legal entities in public law.

Private HCOs include non-profit scientific associations of any legal form (legal entities in private law, civil code societies or unions, as well as private healthcare providers (clinics and hospitals). The scientific events organised by third parties which PCs may support are distinguished into the following types:

A.1. International Scientific Events held in Greece

As international scientific events are classified those organised by foreign HCOs, including jointly with domestic HCOs where foreign participation in terms of budget and speakers is at least 50%.

- For scientific events held in Greece and organised exclusively by international HCOs (i.e. not jointly with a Greek HCOs, without the participation of Greek HCPs and/or without an involvement of a domestic subsidiary), the following apply:

  1. Unlike domestic events, a request to EOF for approval is not required.

  2. The costs of such events are exclusively covered by the organising foreign HCO.

  3. If an event of this type meets the requirements for review and pre-approval by the e4ethics platform of the CVS/e4ethics 2.0 platform, SFEE member companies that are interested in sponsoring and/or supporting HCPs to attend/participate in the event must ensure that the event has been approved by the abovememntioned system before the start of the conference.[11]

- For scientific events organised in Greece exclusively by foreign HCOs, not jointly with a domestic HCO but with the participation of Greek HCPs and/or Greek sponsorship, PCs that are interested in sponsoring and/or supporting HCPs to attend/participate in the event and/or notify any sponsorships:

  1. must submit, via EOF's Online Application for Scientific Conferences, the participation of HCPs and/or sponsorships to the event, through the procedure "Request for HCP Participation" in an international scientific event in Greece and/or "Notification of Sponsorship of an International Event".

  2. For HCP participation in international scientific events held in Greece, the same provisions apply as for participation in domestic events.

  3. When entering the details of the international event into EOF's Online Application

11 These are large international conferences held in countries within the geographical scope of the EFPIA Code (European third-party organised events), with more than 500 HCPs coming from five different countries in the scope of the EFPIA Code.

for Scientific Conferences, the name of the organizing HCO must be indicated in the "organizer" field, otherwise the request for HCP participation is automatically rejected.

- For scientific events organised in Greece by international HCOs jointly with a Greek HCO, with foreign participation of at least 50% in terms of budget and speakers, provided that the Greek HCO has completed four (4) years of operation or over, the following apply:

  1. The Greek HCO, or the authorised Professional Conference Organiser (PCO), must submit a request through EOF's Online Application for Scientific Conferences.

  2. The international HCO participates with at least 50% of the budget and speakers.

  3. In the "comments" field of such request through EOF's Online Application for Scientific Conferences, the name of the co-organising international HCO must also be indicated, otherwise the request is automatically rejected.

  4. Regarding the maximum number of co-organised International Scientific Events which a PC may sponsor per year, maximum amount of sponsorship and maximum HCP registrations (only in cases of co-organised events), PCs must adhere to the limits set out in Annex I.

- 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,

- Approval by, or notification to, EOF is not required for HCP participation in scientific events and/or expert boards, domestic or foreign, where the costs of participation are exclusively covered by a company based abroad.

A.2. Pan-Hellenic Scientific Events:

- Pan-Hellenic scientific events are those organised by HCOs which correspond to the specialties and specialisations recognised by KESY (Central Health Board) and have completed four (4) years or more of operation with proven scientific and educational work. To be eligible for PC support, such events must, among other criteria, have a total programme duration of at least twenty-four (24) hours.

- Regarding the number of Pan-Hellenic events that a PF may sponsor per annum, PFs must comply with the limits set by the competent regulatory authority (see Annex I).

- The amount of sponsorship per PC must not exceed the limit specified in Annex I.

A.3. Regional Scientific Events (two-day events):

- Regional scientific events are those organised within the Administrative Region where

the organising HCO is located and are addressed to HCPs practicing in **the same Administrative Region**.[12] To be eligible for PC support, such events must, among other criteria, have a total programme duration of at least sixteen (16) hours.

- Exceptionally, regional scientific events also include events with a total programme duration of at least sixteen (16) hours, organised by HCOs which correspond to the specialties and specialisations recognised by KESY (Central Health Board), or by HCOs that have completed four (4) years or more of operation, and are addressed to HCPs practising in an Administrative Region other than that in which the HCO is based.

- For Regional events, accommodation costs are not, as a rule, applicable. Exceptionally, PCs may cover the accommodation costs of a HCP only when there is an objectively justified need for travel (to and from the venue) of more than three (3) hours and the first day of the programme has a duration of at least four (4) hours, as well as in the case of active participation of the HCP (as speaker or moderator).

- Regarding the number of regional that a PF may sponsor per annum, PFs must comply with the limit set out in Annex I)..

- The amount of sponsorship per PC must not exceed the limit specified in Annex I..

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

- Local scientific events are those organised within the Prefecture[13] where the organising HCO is located and addressed mainly to HCPs practising within the same Prefecture. To be eligible for PC support, such events must, among other criteria, have a total programme duration of at least four (4) hours.

- Exceptionally, local events also include repeated (one-day) events intended to update HCPs, which are organised in another prefecture by a HCO corresponding to the specialties and specialisations recognised by KESY or by a HCO that has completed four (4) years or over of operation and are addressed to HCPs of a Prefecture, provided that the main focus is on updating the local medical community.

- For local events, accommodation costs are not, as a rule, applicable, given their local character.

- Exceptionally, PCs may cover the accommodation costs of a HCP only when there is an objectively justified need for travel (to and from the venue) of more than three (3) hours, as well as in the case of active participation of the HCP (as speaker or moderator).

- The maximum number of local scientific events a PC may support per HCP/HCO and the amount of sponsorship per PC must not exceed the limits specified in Annex I.

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12 It is clarified that, according to Article 3 of Law 3852/2010, the Administrative Regions of Greece are thirteen (13); they are self-governed legal entities in public law and form the second tier of local government: 1) Eastern Macedonia-Thrace, 2) Central Macedonia, 3) Western Macedonia, 4) Epirus, 5) Thessaly, 6) Ionian Islands, 7) Western Greece, 8) Central Greece, 9) Attica, 10) Peloponnese, 11) North Aegean, 12) South Aegean and 13) Crete.

13 See Article 1 of Law 3852/2010. Greece is administratively divided into 51 prefectures..

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

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

a. participation of HCPs is free;

b. the events are preferably held in the Hospital auditorium or close to the city/town where the Hospital is located; and

c. there are no display booths, in accordance with applicable laws and regulations.

Exceptionally, PCs may sponsor such events and display booths may be present if the events are held in a venue external to the Hospital, with access provided to HCPs only and not the general public. Regarding the maximum number of events a PC may support per year, PCs must comply with the regulatory limits (see Annex I).

- Such events are addressed to HCPs who:

1. practise within the same Administrative Region, if the event is organised by a University clinic. PCs may cover the accommodation costs of HCPs in connection with their participation in such events, provided that only when there is an objectively justified need for travel (to and from the venue) of more than three (3) hours.

2. practise within the same Prefecture, if the event is organised by an NHS clinic and/or a private hospital/clinic in the same Prefecture. No accommodation costs may be covered by PCs in this connection.

- HCPs actively participating in the event (speakers or moderators) are excluded from the restrictions laid down in the two preceding paragraphs.

- The total duration of these events may not exceed sixteen (16) hours, with a programme of at least 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 "Training Course" (or Seminar) is defined as an educational event that is held domestically, in live, virtual or hybrid format, and is organised by Higher Education Institutions, hospitals and HCOs, as a series of lessons aimed to expand participants' knowledge and skills in a holistic manner. It can be addressed to medical specialists or interns/trainee specialists, postgraduate, doctoral and postdoctoral students, professional nurses and other healthcare professionals.**

2. **Conditions for a positive opinion from the SFEE Evaluation Committee: Learning Cycles** may be sponsored by PCs when all of the following conditions are met:

i. **Single EOF Approval for the entire programme of the course (not individual lessons or sessions).**

ii. Submission for evaluation on the **SFEE platform**, accompanied by the EOF approval for the entire programme of the course and by the respective sponsorship package.

iii. **Clear identification of the audience to which it is addressed (i.e. HCPs, specialists, interns/trainee specialists, students and professional nurses).**

iv. Minimum duration of **four (4) hours** per day.

v. With regard to **accommodation** in the context of in-person participation, the restrictions provided for regional scientific events apply.

vi. Obtaining a Certificate of Medical Education **(CME)** upon completion of the course is not necessary, although it is positively considered in the evaluation.

vii. The maximum number of Learning Cycles that a PC may sponsor per year must not exceed the limit specified in Annex I.

3. Limit on sponsorships

The maximum number of registrations and the maximum number of sponsorships per PC must not exceed the limits specified in Annex I.

It should be noted that, in case the Pharma Companies choose to participate in a training course only online, there is no registration cost and the maximum amount of sponsorships per PC is that specified in Annex I, under 2. "ONLINE PARTICIPATION IN SCIENTIFIC EVENTS OF HCOs AND ONLINE SCIENTIFIC EVENTS & PRESENTATIONS OF HCOs".

4. Interpretation problems (Guidelines)

Any interpretation problems that may arise relating to the evaluation of a "Training Course" must always be resolved in the light of the Ethical Commitment of SFEE members (Article 6.1.), the experience gained by the SFEE Evaluation Committee in evaluating domestic events, the letter of the regulatory framework (EOF circulars), and the overall perception, and always in favour of a stricter interpretation.

5. Product/Company promotion

The general terms and conditions governing promotion apply, depending on the targeted audience. It is clarified that undergraduate students are not HCPs.

A.7. WEB/VIRTUAL HCO-HOSTED EVENTS

1. In all the types of scientific events referred to in A.1 to A.6 above, the organising HCO may provide live streaming. After the end of the event, the whole or part of the programme may be posted on the HCO's website so that more HCPs can watch it as video on demand.

The fact that the programme will be live streamed must mandatorily be mentioned in the initial request of the organising HCO.

PCs may sponsor HCPs by covering any applicable access code/registration costs for individual HCP participants. If a registration cost applies, the prospective sponsor (PC) must submit a request to EOF through EOF's online platform, with the indication Web Scientific Events (mentioning "registration cost"). In the case of group attendance of web/virtual events, approval from EOF is not required (except for covering the participation costs of individual HCPs, where applicable), while only coffee/refreshmentsmay be offered. The costs for the venue, installations and coffee/refreshmentsmay be covered by PCs.

The maximum number of sponsored HCP participations and the maximum sponsorship limit per PC in these cases are those set out in Annex I, depending on the type of event (A1. - A6.).

It should be noted that, if PCs choose to only sponsor **online attendance** of scientific events under A.1.-A.6. above, i.e. without covering the costs for in-person participants, and/or without any promotional display of the PC at the physical venue, the registration and sponsorship limits of category 2 below apply (see Annex I, Table 2).

2. Web-only/Virtual scientific events/congresses organised DOMESTICALLY (live streaming or video on demand)

HCOs may organise scientific events conducted exclusively online, i.e. without the physical presence of participating HCPs, in live streaming with or without the possibility of interaction between the Speakers and the HCPs, which may be posted after the end of the event on the host's website with controlled access only for HCPs, so as to give HCPs the opportunity to watch at a time of their choice (on demand). Such events have a duration corresponding to that of the events described in A.1.-A.6 above.

To host such an event, the organising HCO is required to obtain approval from EOF, by submitting a request on EOF's platform with the indication "Web Scientific Event".

PCs may sponsor HCPs by covering any applicable access code/registration costs for individual HCP participants. If a registration cost applies, the prospective sponsor (PC) must submit a request to EOF through EOF's online platform, with the indication Web Scientific Events (mentioning "registration cost"). In the case of group attendance of web/virtual events, approval from EOF is not required (except for covering the participation costs of individual HCPs, where applicable), while only coffee/refreshments may be offered. The costs for the venue, installations and coffee/refreshments may be covered by PCs.

The maximum amount of registration/participation grant for a HCO, the maximum limit of sponsorships per HCO in the above-mentioned online scientific events, as well as the maximum number of such events per HCO that a PC may sponsor are those specified in Annex I.

The maximum number of sponsored HCP participations, the maximum sponsorship amount per PC and the maximum number of such events that a PC may sponsor per HCO are those specified in Annex I.

PCs may sponsor web-only events of HCOs only if the organising HCOs provide them with the possibility to monitor actual attendance in real time.

For sponsoring the online participation of a HCP in such events, PCs must have the appropriate technical tools to ensure the actual attendance of HCPs, which will be a prerequisite for the issuance of the relevant certificate of attendance.

3. Scientific Events organised ABROAD by HCOs and conducted in hybrid format (in-person and virtual participation) or as web-only scientific events/congresses

PCs may sponsor HCPs by covering any applicable access code/registration costs for individual HCP participants. If a registration cost applies, the prospective sponsor (PC) must submit a request to EOF through EOF's online platform, with the indication Web Scientific Events (mentioning "registration cost"). In the case of group attendance of web/virtual events, approval from EOF is not required (except for covering the participation costs of individual HCPs, where applicable), while only coffee/refreshments may be offered. The costs for the venue, installations and coffee/refreshments may be covered by PCs.

Companies within EOF's remit may sponsor the online participation of HCPs in virtual and hybrid events held abroad (covering the costs of registration fee and certificate of medical education) beyond the limits specified in Annex I, Table 2A.

4. Webinars

HCOs may organize scientific presentations (Webinars) conducted exclusively online, i.e. without the possibility of in-person participation of HCPs, and attended only online, in live streaming with or without the possibility of interaction between the Speakers and the HCPs, which may be posted after the end of the event on the host's website with controlled access only for HCPs, so as to give the HCPs the opportunity to watch at a time of their choice (on demand). Such events have a duration of up to three hours.

The maximum amount of sponsorship per PC in such events is that specified in Annex I.

HCOs intending to host such events must submit a relevant request to EOF with the indication "Web", provided that the event has a duration of up to three (3) hours and there is an organisation cost. These requests are submitted, but do not count towards the limits. No request is required for organising or participating in webinars, i.e. online scientific events with a maximum programme duration of three (3) hours, where there is no participation cost and no sponsorship to HCPs to attend.

A.8. Patient information events

- Patient information events focus on matters related to health, diagnosis, therapy, disease management, hospitalisation and care in general, the social aspects of diseases and improvement of patients' quality of life. These events are organised either by POs or by HCOs. The organisation of patient information/public awareness events by PCs is subject to EOF approval, for which a request must be submitted through EOF's Online Platform for Scientific Conferences. It is clarified that, under pharmaceutical legislation, PCs are not permitted to organise patient information events particularly concerning products within EOF's remit.

a) Events organised by POs

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

b) Events organised by HCOs

- Patient information events and, more generally, public awareness events on disease prevention matters, organized by HCOs may be sponsored by PCs up to an amount of 3,500 euro (VAT inclusive) per PC/per event and are subject to approval by EOF.
- 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, PCs must establish that the organising HCOs comply with all applicable laws and regulations.[14]

c) Events organised by PCs:

- Companies of products within EOF's remit may hold patient and civilians in general, information events, thus building public awareness about the prevention, diagnosis, and treatment of diseases, following a request through the EOF's Online Platform for Scientific Conferences.

A.9. Health/pharmaceutical policy events organised by advertising companies or other service providers:

- These events do not constitute scientific events within the meaning of the law (EOF/Ministry of Health). However, they are events that can be supported by PCs.
- They are organised in Greece by advertising companies or other service providers, mainly communication service providers. They are not promotional in nature; rather, through the participation of different stakeholders (e.g. HCPs, patients, pharmaceutical companies, government officials, journalists), they are aimed to provide the public with general information and foster an exchange of views on topical health and pharmaceutical policy issues. These events are normally characterised as "conferences" and are of a broader (not purely scientific) scope.
- PCs may only have business promotion, as part of their corporate communication. According

14 See Ministry of Health Circular no. 19814/2018.

to the law, product promotion/speeches by PCs are not permitted, as such events are addressed to the general public. Similarly, any sponsorship of HCP participation in such events is prohibited by Article 8 of this Code and the relevant provisions of legislation.

- Member companies are recommended to carefully evaluate the programme and the nature of the event and calculate the amount of their sponsorships taking into account the market fair prices, as these apply to scientific events organised by HCOs (see Annex I) and, in all cases, the duration of the event.

Conferences of this type are not subject to evaluation by the SFEE's Conference Evaluation Committee.

[B] Scientific events organised by PCs

I. Greece

B.1. General

PCs may **themselves** organise scientific events of purely scientific or promotional content, in accordance with the terms of the applicable legislation. These events are organised and financed by PCs themselves and take place at PC facilities or other venues arranged by PCs, or in virtual format. PCs **are not permitted** to organise and hold events ***at University or Hospital facilities***, as this is prohibited by relevant legislation.

Depending on the context, the content and the programme involved, events organised by PCs are classified as:

a) Promotional events: scientific events aimed at providing information on medicinal products. These events are managed by the Sales/Marketing Department of PCs. The participation of HCPs from the NHS and Universities in any way whatsoever is not permitted. 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 a non-promotional nature, exclusively serving educational or research purposes. These events are managed by the Medical Affairs/Scientific Department of PCs. NHS and University physicians working in units of NHS hospitals or University hospitals may participate in these events, while HCPs in the broad sense of the term (see definition above) are permitted to participate as speakers.

Any PCs interested in organising and hosting scientific events themselves, must submit a request to that effect to the competent Regulatory Authority, in accordance with applicable legislation.

- PCs **may not** submit **requests to organise** scientific events **abroad** or requests to co-organise scientific events jointly with HCOs, whether in Greece or abroad.

- Regarding the maximum amount a company may pay as contribution to the cost of meals and accommodation to support the participation of individual HCPs in scientific events organised by PCs, the same provisions apply as for hospitality offered to HCPs participating

in scientific events organised by HCOs.

- After the end of the scientific event, the organising PC must submit to the competent Regulatory Authority an ex post report on the event, in accordance with the provisions of applicable legislation.

B.2 WEB SCIENTIFIC EVENTS & PRESENTATIONS ORGANISED BY PCs

1. Web/virtual company-hosted scientific events/congresses

PCs may organise scientific events of promotional or non-promotional nature exclusively via the internet, i.e. without the physical presence of participating HCPs, who will attend the event virtually, either (a) in live streaming, with or without the possibility of interaction between the Speakers, or (b) as video recording posted on the organising PC's website with controlled access only for HCPs, so as to give HCPs the opportunity to watch at a time of their choice (on demand).

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

- the cost of use of venue and technical facilities; and
- the participation of HCPs as speakers, moderators, etc. and their honorary fees.

These events count towards the maximum number of scientific events that can be organised by each PC per year, as such number is defined by EOF. In any case, care must be taken to ensure that the number of participant HCPs does not compromise the quality of live transmission and the ability of HCPs to interact with the speakers and moderators. If the event is attended by a group of participants gathered in a given space, only coffee/refreshments can be offered.

2. Company-hosted webinars

PCs may organise scientific presentations (webinars) exclusively via the internet, without the physical presence of HCPs, who will attend the webinars virtually, either (a) either (a) in live streaming, with or without the possibility of interaction between the Speakers, or (b) as video recording posted on the organising PC's website with controlled access only for HCPs, so as to give HCPs the opportunity to watch at a time of their choice (on demand). Webinars may have a total duration up to three hours.

These events do not count towards the maximum number of scientific events that each PC can organise annually, as such number is defined by EOF. To organise web events of this type, PCs must submit to EOF a request to that effect, stating: the cost of use of venue and technical facilities: and the participation of HCPs as speakers, moderators, etc. and their honorary fees.

Attendance of such webinars by HCPs does not count towards the limits on HCP participation in company-hosted scientific events, and no request to EOF is required. The number of HCPs that may attend these events is unlimited. If the event is attended by a group of participants gathered in a given space, only coffee/refreshments can be offered.

B.3. Company-hosted events in the context of conferences held in Greece

Scientific events organised by PCs in the context of conferences organised by HCOs, in Greece, are non-promotional, scientific in nature and supervised and/or organised by the relevant medical affairs/scientific departments of the PCs. The content of these presentations is not reflected in product templates. Such company-hosted events take the form of **"satellite symposia"** and/or **"meet the expert sessions"** or other forms and may also be addressed to specific HCP groups (upon invitation). These events are included in the conference programme and are not subject to separate approval from EOF. The programme of these events, the speakers, the content of presentations/speeches as well as invitations to HCPs are approved by the Medical Affairs/Scientific Department of the PC concerned and by the organising committee of the event in the context of which they take place.

For these events, the following apply:

a) participants do not earn Continued Medical Education (CME) credits, and attendance is not monitored;

b) references to brand names of medicinal products are not permitted;

c) total duration should not exceed 20% of the total duration of the scientific programme of the main event;

d) they may not be organised in the context of the scientific events referred to in A.6. 4. (HCO-hosted webinars);

(e) each HCP may participate as remunerated speaker/chair in up to three (3) satellite symposia/lectures.

II. Abroad

C1. Scientific events organised abroad by foreign PCs

HCPs working in Greece (private practitioners or University/military NHS employees, specialists or interns/trainee specialists) may, within the framework of their employment status in Greece, actively participate in or attend company-hosted events that constitute specialised foreign seminars of high scientific interest and international scope, with the participation of speakers from various countries, organised by PCs based outside Greece, subject to the following ethical requirements:

1. The event is organized by the foreign company's Medical Affairs/Scientific Department – unless it is addressed to private practitioners only – and the programme must have scientific content.

2. The affiliate or representative in Greece undertakes to coordinate the sponsorship to the HCP and verify the legitimacy of both the participation of the HCP according to his/her employment status under Greek law and of the event under the law of the foreign company's home country. It also keeps a record of all relevant documents/files and communications.

3. The invitation to the HCP is sent directly by the foreign company.

4. The event is held abroad by an organising company within the same Group to which the Greek affiliate or representative belongs, and the venue and other terms are in conformity with the SFEE Code and Greek and local legislation .

5. In the case of active participation, a written contract must be signed between the Greek-based HCP and the foreign company according to the HCP's employment status. The HCP's remuneration amount is subject to the limits specified in the SFEE Code. The same applies to travel and hospitality costs (meals and accommodation), unless the host country has lower limits. For meals and accommodation, the limits specified in Tables D and E of Annex I of this Code apply.

6. Remuneration in the case of active participation may be paid by the foreign company to the Greek-based HCP, according to his/her employment status.

7. It is explicitly clarified that such events are foreign company-hosted events and not international.

8. The disclosure of any transfer of value is made in the country where the HCP is based (i.e. in Greece) by the domestic affiliated or representative company), as a cross-border transaction.

9. Sponsorship to HCPs to participate in foreign company-hosted events organised by PCs based in countries outside the EFPIA scope should be avoided. If this is not possible, the same requirements should be complied with, as jurisdictions outside Europe come under the regulatory ethical scope of IFPMA, of which EFPIA is a member. The principles of our industry (legitimacy, transparency, integrity, respect and trust) must also be observed in these events, as they govern all our activities.

10. The number of participants per event and per PC is up to 5 HCPs. The total number of events per calendar year per PC must not exceed two (2) events. These events are only covered if they take place in Europe.

11. Compliance with all of the above requirements is monitored by the relevant department of the domestic PC, which also keeps a record of all related documentation.

C.2. Scientific events organised in Greece by foreign PCs

Greek subsidiaries interested in sponsoring the participation of Healthcare Professionals (HCPs) in scientific events organised in Greece exclusively by a company within the remit of EOF based abroad, with the participation of Greek HCPs, must submit the relevant HCP participations to EOF's Online Platform, by the procedure "HCP Participation Request" for a foreign-organised scientific event.

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

Section 7.1. Location and venue

PCs must not sponsor events organised by third parties, or themselves organise scientific events in locations and venues that are renowned for their entertainment facilities and/or are extravagant or special-purpose, not commonly perceived as intended for educational/professional uses (including, but not limited to, spas, casinos, religious places). Events taking place in museums may only be sponsored if a separate appropriate room is available. When an extravagant or special-purpose venue is chosen, the entertaining/recreational character is presumed to prevail, far from the educational/professional purpose and nature of the event (which is what PCs aim for), thereby harming the public image of the industry as a whole. The locations and venues of HCO-hosted events are evaluated by SFEE's Conference Evaluation Committee in a comprehensive manner, on the basis of our ethical commitment (see paragraph 6.1. above) and in conjunction the programme and participations, guided by common sense and the average prudent man's perception of pharmaceutical industry as a whole.

7.1.1. **VENUE:** The venue must be of a strictly professional nature, and a **conference hall** appropriate for the event must be available at the facilities.

- Eligible for PC sponsorship are events taking place at hotels up to 4 stars having a conference hall with a price per room in line with the current seasonal price and meeting the cost-per-night requirements of this Code, and subject to applicable provisions on seasonality (see paragraph 7.1.2. a-b below).

- PCs are not permitted to sponsor domestic scientific events at 5-star hotels and the accommodation of HCPs in such hotels.

Exceptionally, PCs may sponsor conferences taking place in:

- 5-star hotels located in the capital city of the Prefecture and having a conference hall, provided that the cost-per-night requirements laid down in this Code are met, subject to applicable provisions on seasonality (see paragraph 7.1.2. a-b below).

7.1.2. PLACE and TIME of EVENTS

a) PCs may not sponsor scientific events taking place at locations which may be considered as "tourist destinations", during the relevant tourist seasons (i.e. summer season from 1 July to 31 August; winter season from 15 December to 15 January), or ski destinations (from 15 December to 15 March).

b) PCs may not sponsor scientific events taking place during a long weekend.

Section 7.2. PCs may not sponsor entertaining/leisure activities or the participation of HCPs in such activities (e.g. excursions and tourist activities in general).

Section 7.3. The provisions of paragraphs 7.1. to 7.2. also apply to events organised by PCs themselves.

Section 7.4. Content of sponsorship package – limits

The sponsorship package of a scientific event delivered to PCs must not include the participation and hospitality costs of participant HCPs and speakers (air or other travel, registration fee, accommodation), nor any honoraria to persons invited to speak or chair meetings. Also, the sponsorship package may not include: bags, notebooks, pens, badges, lanyards, CDs/USBs, etc., as the coverage of such costs by PCs is prohibited by the provisions of Article 18 hereinbelow.

Section 7.5. Sponsorships should be deposited in an account held by the beneficiary HCO with the Special Account for Research and Development Funding (ELKEA) of the relevant Healthcare Region (HCR), in the case of clinics and laboratories of state hospitals, or in the Special Account for Research Funding (ELKE) in the case of universities and higher education institutions, against a receipt issued in the name of the sponsor. If the organising HCO has legal personality and capacity to issue receipts and invoices, the invoicing of the full range of services related to the sponsorship package of the conference to the PC will be exclusively undertaken by the HCO.

If the HCO has no legal personality or capacity to issue receipts and invoices, it may assign the entire financial management of the conference (collection of sponsorships, invoicing of sponsors, issuance of tax documents to sponsors) to the Professional Conference Organiser (PCO), under a written agreement with the latter. In this case, the invoicing of all services related to the sponsorship package for the conference to the PC will be exclusively undertaken by the PCO.

Section 7.6. In all cases of financial support by PCs to scientific events of any permitted type, the funds must be deposited into an account with a duly authorised bank, opened by the Organising Committee of the conference or by the managing body of the Scientific Society or HCO in general – as appropriate according to its statute, in the name of the HCO. Any assignment to a Professional Conference Organiser should be notified to the sponsoring PCs, so that the funds can be transferred to the assignee by a deposit into the PCO's account.

Section 7.7. Any MAHs of prescription-only medicines or their Representatives who wish to promote both prescription-only and OTC products in a scientific event must ensure that each of the two categories of products is promoted in a distinct manner, easily distinguishable by HCPs and in conformity with the promotional/information rules applying to each category

In particular:

- Promotion areas for prescription-only and OTC must be distinct.
- Promotional messages and material, by category of medicines, must comply with applicable legislative and regulatory provisions.

- All informative and advertising material and reminders must be distributed at an appropriate spot in the promotion area, with the relevant designation (e.g. "OTC medicines promotion area").
- If the event includes sessions with patients and/or the public, all spaces and materials used must be conforming to applicable legislative and regulatory provisions.

Section 7.8. The upper limits on PC sponsorships apply to any support to scientific events/ conferences via display booths, satellite symposia, lectures, advertising, etc. and combinations thereof as decided by PCs.

Section 7.9. All entities involved in organising scientific events should apply due prudence in budgeting processes, to reflect fair market value.

Section 7.10. Accompanying persons are not allowed to scientific events organised or sponsored by PCs, 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 PC may not demand to be the sole sponsor of a HCO or any activities of a HCO.

Section 7.12. In order to ensure adherence to the ethical commitments of its members, SFEE may engage external associates to conduct inspections at events organised by HCOs, for the purpose of verifying compliance by PCs with the provisions of this Code. The outcomes of such inspections will be notified to SFEE's Ethics & Transparency Committee and to its Board of Directors, for assessment and adoption of decisions and measures as appropriate, where breaches are identified. This mechanism ensures the effective enforcement of the provisions of this Code and is a best practice recommended by EFPIA.

Section 7.13. SFEE auspices
SFEE may grant its auspices to any scientific event, provided that it meets the requirements of this Code, is aligned with the ethical values of the industry and promotes better healthcare provision to citizens, continued education of HCPs and the dialogue with social partners and other stakeholders on health and prevention issues. In this regard, SFEE may also consult the Conference Evaluation Committee. In case of doubt, the decision will be made by the SFEE Board of Directors of SFEE.

Section 7.14. Evaluation of third-party events
Scientific events organised by third parties (state or private HCOs in Greece or abroad) and taking place in Greece are subject to evaluation by **SFEE's Conference Evaluation Committee** and are posted on SFEE's online platform (https://scientific.events.sfee.gr). The Committee is mandated 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 is composed of PCs' Compliance Officers nominated by SFEE members and is supported, when necessary, by a SFEE Lawyer, participating without the right to vote. The committee and its decisions are supervised by SFEE Board of Directors. PCs should take into account the SFEE committee's evaluation of an event before they decide to provide any kind of financial support, and should consult the files posted on the platform.

Section 7.15. Scientific events should be uploaded by the organising HCOs or their authorised PCOs on SFEE's platform for evaluation, **at least 45 days before the start of the event,** to enable the timely engagement of PCs with the organisers.

7.15.1. The **following information** must mandatorily be uploaded on SFEE's online platform:

a. A printscreen from the platform of the competent regulatory authority (currently EOF) including the HCO's request to EOF, its reference number and EOF's approval.

b. The assignment of the event by the HCO to a PCO.

c. The programme of the event, without mentioning the names of any PCs sponsoring satellite symposia, lectures, etc.

d. The sponsorship package, with a detailed breakdown of costs for the services to be provided and the benefit expected by the sponsor in return.

e. The registration fees and the costs of accommodation/meals, if applicable.

f. The HCO's Statute as last revised.

7.15.2. In addition to the above, the HCO and/or PCO must fill out the following declaration:

"I hereby declare that all data/information submitted for evaluation are accurate, true and in accordance with SFEE's Code of Conduct, as applicable. I am also aware that personal data concerning natural persons (name, title, home address, tax registration number, etc.) are included in some of the documents uploaded and are thereby transmitted to SFEE, and I declare that I have notified the data subjects (HCPs, legal representatives etc.) of such transmission, pursuant to Article 13 of the General Data Protection Regulation (Regulation (EU) no. 2016/679)".

7.15.3. **It should be noted that** any change to the data/information submitted (e.g. a shorter duration of the programme, addition of recreational activities, different dates inconsistent with seasonality-related provisions, addition of management/ communication costs, inclusion of accompanying persons, etc.) that takes place following the opinion of SFEE's Conference Evaluating Committee, will be deemed a breach of this Code. In the case of any change occurring following the **final evaluation** of a scientific event by SFEE's Conference Evaluating Committee but prior to the date of the event, the Evaluating Committee will immediately turn the colour status of the event to orange ("in breach of one or more provisions of the Code"). Moreover, a change to the organising HCO is not permitted after SFEE's evaluation. Re-evaluation is only permitted in the case of unexpected and unforeseeable changes and following a relevant decision by SFEE Board of Directors.

Section 7.16. The SFEE Conference Evaluation Committee, in line with the EFPIA standards, evaluates scientific events against the criteria of this Code and posts its findings and assessments on the online platform, using the following colour code:

GREEN: Complies with the provisions of the SFEE Code.

ORANGE: In breach of one or more provisions of the Code.

BLUE: Missing information, cannot be evaluated.

YELLOW: Not within the scope 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 Conference Evaluation Committee takes into account the relevant EFPIA assessment, where available.

Section 7.17. The SFEE Conference Evaluation Committee is not mandated to assess, approve or reject the scientific programmes or the overall content and materials of scientific and promotional events of any type. HCOs bear sole responsibility for the content of the event, the oral dissemination and the materials they use, hence also the burden of proof in demonstrating the lawfulness of the use of such materials and, more generally, of their event-related activity (Article 130 of Joint Ministerial Decision 32221/2013).

Section 7.18. The scientific service of the PC is responsible for the medical information regarding the medicinal products the PC makes available on the market. It ensures that information on, and promotion or advertising of, medicinal products by the PC is in compliance with the provisions of applicable legislation and that the medical sales representatives engaged by the PC are appropriately trained and follow the authorisation procedures by EOF, in accordance with the provisions of applicable legislation. The promotion of a medicinal product by a PC or jointly by more PCs is subject to notification to EOF. The responsibility for Promotion and for ensuring compliance with all the requirements of the legislation (training of medical sales representatives, as well as their professional ethics) remains exclusively with the PC. In any case and for any breach of pharmaceutical legislation, the PC bears objective liability towards EOF. SFEE does not exercise substantive control, and in the event of a complaint being filed against a PC, the PC concerned bears the burden of proof in demonstrating that it has acted lawfully (Article 130 of Joint Ministerial Decision 32221/2013).

Section 7.19. With particular regard to for scientific events of any type, member PCs must ensure that their involvement and role is clearly recognisable and visible right from the start. Activities must have a fair, balanced and objective content, designed to enable the presentation of diverse scientific evidence and answer meet unmet educational needs in healthcare. The purpose of this guideline is to ensure that lifelong learning provided by PCs does not constitute promotion and adheres to high ethical standards and strong educational principles with the ultimate common goal to benefit patients. In conclusion, the members agree that the SFEE Code seeks to ensure that PCs, in all their activities of scientific information, lifelong learning and promotion of their products, act with honesty and ethical principles, avoiding practices of conflict of interest with other stakeholders and complying with applicable legislation.

ARTICLE 8. PROVISIONS ON SPONSORING HCP PARTICIPATION IN SCIENTIFIC EVENTS HELD IN GREECE OR ABROAD AND OTHER PROVISIONS

Section 8.1. General principles

8.1.1. PCs may sponsor the participation of HCPs in scientific events organised either by third parties (HCOs) or by themselves and may offer hospitality, subject to the provisions of the law and of this Code.

8.1.2. The area of expertise or practice of HCPs must be relevant to the topic of the event.

8.1.3. An essential requirement for sponsoring HCP participation in scientific events/conferences/Expert Committees in Greece or abroad is the submission of a request to EOF and obtaining EOF's approval, where required, in accordance with applicable legislative and regulatory provisions. In particular for scientific events/conferences taking place abroad and fall under the scope of assessment and pre-approval through the e4ethics platform, SFEE member companies that are interested in supporting the participation/attendance of HCPs in such a scientific event must make sure that the event has been pre-approved by the above system, prior to the start of the conference.[15]

8.1.4. PCs are reminded that, according to applicable legislation in effect, [16] NHS physicians or other NHS scientific or nursing staff, as well as university physicians working in clinics within NHS hospitals or University hospitals, are not permitted to participate in any conferences or seminars in Greece or abroad, which are organised by domestic or foreign PCs for the purpose of promoting their products.

8.1.5. For HCPs employed in clinics of NHS hospitals or hospitals or clinics supervised by the Ministry of Education and/or the Ministry of National Defence, eligibility to participate in events is regulated by the legislation applicable from time to time and by this Code.

8.1.6. HCPs should take care to obtain the relevant educational leave from their employer, as and where required under applicable legislation. HCPs are exclusively responsible for the accuracy of the underlying information of such leave and for compliance with its terms.

8.1.7. The maximum number of PC-sponsored participations in third-party events per HCP annually and the maximum amount of sponsorship per PC and per HCP are those specified by applicable legislation (see Annex I).

8.1.8. Annual limits on participations must be complied with in terms of a calendar year. Any unused participations may not be carried forward to the next year. In cases of cancellation and/or replacement of an HCP's participation, the provisions of the Competent Regulatory Authority shall apply.

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15 See relevant training presentation by CVS Team (September 2024) https://www.ethicalmedtech.eu/wpcontent/uploads/2024/10/CVS-2.0-Training_Slides_deck-v2.0-to-upload-1.pdf

16 See Article 36 of Law 4272/2014.

8.1.9. The following cases are exempt from the restriction on the maximum number of annual participations of HCPs in conferences held in Greece and abroad: HCPs in the capacity of "speaker", "chairperson" or "member" of the organising committee or "author" of a paper (first, second or last name credited in the paper or poster presentation) that has already been approved and is to be announced during the event. If the speech or announcement is a result of collaboration of more than one clinic or laboratory, then the above exemption applies also to the third author and the second to last (1st, 2nd, 3rd, second to last, last). HCPs must have provided the PC with all necessary evidence to prove their active role in the event.

8.1.10. For the sponsoring of a HCP's participation in scientific events, it is recommended that the requesting HCP fill out a relevant form addressed to the PC, taking into account the restrictions arising from Data Protection legislation.

8.1.11. After the end of the event, PC should request from the sponsored HCP a copy of the participation certificate.

8.1.12. An ex post report on HCP participations in Scientific Events & Advisory Boards held in Greece and or abroad must be submitted to EOF after the end of the event, as specified in applicable legislation.

8.1.13. In scientific events organised by PCs, the number of participants can be unlimited, subject only to the maximum annual limit per HCP specified in applicable legislation (see Annex I). Active participations of a HCP do not count towards such limit.

8.1.14. PCs may offer remuneration (honorarium) to HCPs invited to speak or play an active role at scientific events, in conformity with applicable legislation and up to the limits specified in Annex II.

8.1.15. In particular, any honorarium to HCPs working in the NHS or Universities (employed by clinics within NHS or University hospitals) will be paid via the entities provided for by legislation (ELKEA or ELKE), which will transfer the amount to the beneficiary net of applicable taxes and other 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. PCs must contractually oblige any HCPs who receive honoraria for a speech in an event to acknowledge this fact in a conflict-of-interest statement (a) at the start of their speech; and (b) for two years thereafter, 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 organise business lunches or dinners outside the scientific scope of an event, in places offering a business setting rather than a social one. In any case, the cost per meal, per person and per day may not exceed 70 euros, VAT inclusive.

Section 8.2. Scientific Events held abroad

8.2.1. SFEE supports and encourages participation in conferences held in Europe only, except for international conferences held outside Europe that have been recognised 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 applicable legislation.[17]

8.2.3. International Scientific Events are events organised by, and not just under the auspices of, an international scientific organisation.

8.2.4. Pan-European scientific events organised by, and not just under the auspices of, a scientific organization.

8.2.5. Events, specialised seminars in foreign countries of particular scientific interest, organised by a scientific body or a company within EOF's remit.

8.2.6. Events on rare diseases, as defined in Article 24 of Law 4213/13 (Government Gazette A 261/9.12.2013), organised by, and not just under the auspices of, a HCO.

8.2.7. The maximum number of PC-sponsored participations annually per company and per conference and the share of interns/trainee specialists may not exceed the limits specified in applicable legislation (see Annex I).

8.2.8. Retired HCPs may not be sponsored PCs to participate in scientific events held abroad, unless their active role in these events can be proved.

8.2.9. When sponsoring HCP participation in scientific events held abroad, PCs must comply with this Code of Conduct, which is harmonised with the respective EFPIA Code of Ethics, and the local Code of the host country, whichever is stricter.

8.2.10. HCPs may participate in conferences of their specialty and/or similar specialties and/or other specialties (justification is required in the latter case), with a view to keeping abreast of scientific developments in matters relevant to their field of expertise.

8.2.11. HCPs may not be offered accommodation in 5-star hotels in the context of conferences held abroad. Exceptionally, this can be permitted under certain conditions, if the choice of the 5-star hotel is justified by objective criteria:

A. for events falling within the scope of the Conference Vetting System (CVS), when the hotel has been approved before the start of the conference by the e4ethics platform; and

B. the Accommodation & Meals limit specified in the SFEE Code of Conduct is complied with, or the corresponding limit applying in the host country, whichever is the stricter;

C. all other requirements of the SFEE Code of Conduct, as applicable, are met;

D. 5-star hotel accommodation is permitted under the rules of the host country

17 See Article 11, paragraph 18 of Law 2889/2001; Article 36 of Law 4272/2014; Article 31 of Law 2889/2001; and EOF Circular 45560/2025.

Section 8.3. Terms regarding hospitality offered to HCPs at scientific events held in Greece or abroad

8.3.1. PCs may cover the costs of travel, registration, accommodation and meals of HCPs, subject to approval by the competent regulatory authority and provided that the HCP's employer has granted an educational leave.

8.3.2. Hospitality costs include only registration fees, cost of accommodation and meals, and the cost of travel from the HCP's place of practice to the venue of the event and back. Hospitality must be reasonable in level and cost, in line with market prices and the main scientific purpose of the event.

8.3.3. Hospitality for HCPs in scientific events must be strictly limited to the main scientific purpose of the event, which prevails over any socialising purposes.

8.3.4. The limits applying to participation costs and the number of sponsored HCP participations in scientific events per HCP per year in Greece and abroad are those specified by the competent regulatory authority (see Annex I).

8.3.5. For air travel, economy class tickets should be issued; business class tickets may be issued only for flights more than four hours long, where this is possible.

8.3.6. The cost of meals and accommodation per HCP should not exceed the limits specified in Annex I. Any additional taxes (e.g. accommodation tax) will not be covered by PCs. The same limits on the cost of meals and accommodation also apply to foreign HCPs participating in scientific events held in Greece, unless the limits of their home country are lower, in which case the stricter limits apply.

8.3.7. Moreover, the registration fees for domestic events may not exceed the limit specified in Annex I. Any registration fees in excess of this limit, if adequately substantiated (corpse preparations, live surgery broadcasts, etc.) is subject to evaluation by the SFEE Conference 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, conference programme, badges, conference minutes, lanyards, etc.).

Section 8.4. Expenses for the promotion of medicinal products

8.4.1. According to applicable legislation,[18] eligible recipients of promotional actions funded out of the promotional budgets of PCs are only the persons qualified to prescribe or supply medicinal products. Indicatively, the following apply:

8.4.2. The promotional expenses of PCs include sponsorships for HCO-hosted events

18 Article 123 of Ministerial Decision 32221 (Government Gazette B 1049/29.4.2013), as currently in force, in conjunction with Ministerial Decisions 28403/2001 and 116328/2002, as currently in force.

the subject-matter of which, exclusively or predominantly, relates to the supply or promotion of medicinal products. These expenses must concern the promotion of specific products through events, exhibitions, printed material, display booths, etc.

8.4.3. Promotional expenses also include costs for hosting the events (rental of venue, conference material, audiovisual equipment, hospitality for organising entities and guests, catering), as well as travel, hospitality and registration of HCPs.

8.4.4. Sponsorships for events organised by entities whose activity is not related to the promotion or supply of medicinal products are not considered promotional expenses.

ARTICLE 9. SERVICES AND CONSULTANCY BY HCPS

Section 9.1. Subject to the relevant provisions that apply to NHS- and University-employed doctors, and also subject to the provisions of the Code of Medical Ethics,[19] PCs may engage medical specialists to provide consultancy or other services directly related to their specialty.

More specifically, PCs may contract HCPs as consultants, whether individually or in groups, for services such as speaking at an/or chairing scientific meetings, involvement in medical/ scientific studies, clinical trials or training services, participation in advisory board meetings, and participation in market research (see Article 14) where such participation involves remuneration and/or coverage of travel expenses.

Section 9.2. Advisory Boards in Greece and abroad

9.2.1. Subject to the requirements of applicable legislation,[20] PCs may set up working groups in Greece or abroad, comprising a small number of HCPs, whether against a remuneration or otherwise, and tasked to provide expert input on strictly scientific matters relating to medicinal products or treatments **("Advisory Boards")**.

9.2.2. The maximum number of Advisory Boards that may be set up by each PC per therapeutic class (up to ATC 3), the maximum number of HCPs per Advisory Board and the number of HCP participations per year are those laid down in applicable legislation (see Annex I).

9.2.3. According to the law, physicians and other scientific and nursing staff employed by the NHS, as well as University physicians employed at clinics established in NHS or University hospitals may participate in "Advisory Boards", of purely scientific content relevant to medicinal products and treatments, in order to provide expert opinion on scientific matters, against a fee or otherwise, provided that they have obtained permission to that effect by the relevant supervisory body.

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19 See Article 6(4) of Law 3418/2005 (Government Gazette A 287/2005).

20 See Law 2889/2012, Article 11, as amended with Article 36 of Law 4272/2014.

9.2.4. Military physicians are subject to the restrictions applicable to NHS/University physicians, except for the method of remuneration: they are remunerated against the issuance of a fee-for-service invoice, as they are allowed by the law to operate a private practice.

9.2.5. For the setting up of an Advisory Board in Greece and participation of HCPs therein, a relevant request must be submitted through EOF's Online Application for Scientific Conferences. The details of the HCPs who will participate must also be indicated in the request. 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-employed HCPs (working in clinics within NHS or University Hospitals) for their participation in Advisory Boards are disbursed through the entities provided for in the law, i.e. ELKE or ELKEA, respectively.

9.2.7. An ex post cost report is required, submitted by PCs to EOF's Online Platform and disclosing the final cost incurred in relation to Advisory Boards (along with the cost of other services provided by HCPs).

9.2.8. The participation of HCPs in Advisory Boards in Greece or abroad, for which the costs of participation of Greek HCPs are covered exclusively by a foreign company, do not require notification to/approval by EOF.

Section 9.3. The provision of services by HCPs to PCs must not jeopardise the clinical independence of the consulting/collaborating HCP, who must always be bound by the ethical obligation to make independent medical decisions and exercise his/her profession for the benefit of patients. The services provided by the HCP must meet an identified scientific/research need of the PC.

Section 9.4. Any service shall be provided on the basis of a written contract between the PC and the collaborating HCP. In their written contracts with experts/HCPs (as well as when they employ HCPs on a part-time basis), PCs are strongly encouraged to include provisions regarding the obligation of experts/HCPs to declare their contractual relationship with the PC whenever they write or speak in public about a matter that is the subject of the contract or any other matter relating to that PC (conflict of interest disclaimer)

Section 9.5. PCs must establish a contractual obligation of HCPs/consultants to the effect that, whenever they present views or results to third parties concerning the medical/pharmaceutical part of their consultancy services, this is accompanied by a declaration of interest/conflict of interest statement, in order to ensure transparency towards all parties.

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

Section 9.7. The provision of consultancy services by HCPs to PCs companies must meet the following criteria cumulatively:

(a) before entering into any contractual arrangements with experts, a legitimate need for the services must have been clearly identified;

(b) prior to the commencement of the services, a written contract must have been agreed, specifying the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;

(c) the criteria for selecting experts must be directly related to the identified need, and the persons responsible for selecting the experts must have the experience necessary to evaluate whether the particular HCP meets those criteria;

(d) HCPs must be selected on the basis of their qualifications and capacity to provide the services. The criteria for selecting a HCP can include:

- clinical experience in the treatment, in the product and/or in the relevant scientific matter;
- scientific reputation;
- academic work;
- publications.

(e) the number of experts per mission must not exceed ten (10), and each expert may participate up to two (2) times per year and per company within EOF's remit, with regard to services provided in Greece;

(f) the contracting PC must maintain records concerning the services provided by HCPs;

(g) the remunerated engagement of the HCP to provide the relevant service must not be an inducement to prescribe, supply or administer a particular medicinal product;

(h) the remuneration for the services must be reasonable and reflect the fair market value of the services provided (see Annex II for an indicative calculation of HCPs' remuneration for services provided to PCs). PCs are called on to internally establish scales of fair market values applicable to remuneration for typical services and HCP categories, considering the experience of the HCP, the time of engagement (preparation and participation) and the kind of service provided (see Annex II).

(i) The maximum annual remuneration (per calendar year) paid to a HCP by a PC for activities carried out in Greece and/or Europe (in aggregate) must not exceed EUR 5,000, excluding VAT and other deductions. This limit does not apply to HCPs with international experience who, during the reference calendar year, have in-person provided services outside Europe (or both inside and outside Europe), in which case the recommended maximum annual remuneration per calendar year is seven thousand (7,000) euros (in aggregate for services provided in Greece and within Europe, and/or in-person outside Europe), excluding VAT and other deductions. Any amounts concerning remuneration for the conduct of clinical trials do not count towards this limit.

Section 9.8. Also, medical practitioners 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 their expertise on scientific matters, elaboration of epidemiological facts, i.e. diseases and therapeutic approaches, etc. (consultant meetings).

Section 9.9. Ex post financial reporting: With regard to requests for the organisation of a scientific event or an Advisory Board, sponsorships, as well as participation of HCPs in a scientific event or expert committee (including any honoraria), an ex post financial report is required after the end of the scientific event/committee, during the year when the activity takes place and until 30 June of the following year. This is submitted by the requesting party, exclusively through the EOF Online Application for Scientific Conferences, with the full details of all transfers of value and costs.

Section 9.10. Breach of regulatory obligations: Inaccurate reporting or failure to submit the ex post financial report referred to in the preceding clause incurs suspension from organising scientific events or Advisory Boards or providing sponsorships within the scope of EOF Circular for a period of one (1) year and, in the case of repeated breach, two (2) years.

A relevant table and the related notes are provided in Annex II attached to the end hereof.

ARTICLE 10. PROHIBITION OF GIFTS

Section 10.1. SFEE recommends PCs to ensure that any Transfers of Value they make to HCPs and HCOs comply with the terms and restrictions applicable under the law.[21] According to applicable legislation, PCs are prohibited from providing, offering or promising any gifts, cash or benefits in kind relevant to the medical or pharmacist profession to persons qualified to prescribe or supply medicinal products, except for items of negligible value (i.e. up to EUR 15.00 per item, VAT inclusive, according to 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, HCO members or PO 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.

21 In particular, Article 16 of Legislative Decree 96/1976; Articles 126-127 of Joint Ministerial Decision 32221/2013; the Code of Medical Ethics (Law 3418/2005); and, more generally, any specific prohibitory provision.

Section 10.4. Promotional aids to HCPs, HCO members and PO Representatives are strictly prohibited. A promotional aid is a non-monetary item given by PCs to HCPs, HCO members of and PO Representatives for a promotional purpose (which does not include promotional materials as defined in Article 3 of this Code).

ARTICLE 11. DONATIONS AND GRANTS

Section 11.1. Donations and Grants by PCs to HCOs staffed by 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/grantor; and (c) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific Medicinal Products.

Section 11.2. Donations and grants are allowed to:

a) Hospitals established as legal entities in public law, NHS Health Centres and Hospital Institutions in general which belong to the public sector and are supervised by the Ministry of Health or another Ministry as appropriate, where the donations/grants directly relate to the provision of health services, medical and educational goods and services that improve patient care and benefit patients and the National Health System, according to applicable legislation.

b) Medical societies/institutes/organisations/associations/unions and non-profit civil code societies established by HCPs as non-profit legal entities in private law;

c) Patient Organisations (POs), established as civil code societies, non-profit associations, subject to the provisions of Chapter 4 of this Code on POs.

Section 11.3. Requests by such entities to PCs for donations to third parties, shall not be accepted or considered.

Section 11.4. Donations or grants directly to individuals (a HCP or a third party indicated thereby) are not permitted.

Section 11.5. Donations may be in kind or in cash and must always be consistent with the applicable legislation on donations. A donation in cash 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 concern medical equipment (instruments, devices), consumables and laboratory kits, but not fixed equipment whereby the Donee becomes dependent on the Donor (i.e. permanent support or lasting contractual commitment to procure goods and services from the Donor). For donations of computers and peripherals, a detailed description and documentation shall be required, evidencing that the Donation is intended to meet the needs of a hospital/organisation and in no circumstances of a natural person. Donations for the construction/renovation of building facilities are not permitted. Donations in cash may not be made for the general purpose of supporting the Recipient's objectives.

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

Section 11.7. Donations are also permitted when they are aimed to finance awards and scholarships to and HCPs and scholars or to financially support independent educational scientific programmes (educational grants) or to financially support research programmes (research grants) conducted by Hospital and University Institutions and other eligible Donnees under Article 11.2 hereof.

Section 11.8. Donations must not be made in a way to constitute an inducement to prescribe, supply, approve, price or reimburse a medicinal product. The name of the donor PC may be featured on the items donated to hospital institutions, but not the name of any medicinal product.

Implementation of this section requires compliance with to all procedures as appropriate from time to time, in a context of full openness and transparency, as well as with the relevant applicable rules and provisions of tax legislation.

Section 11.9. Donations may not be offered to Hospital Institutions established as legal entities in private law, nor to medical firms 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 documenting the need, purpose and intended use of the donation/grant, including the value/cost in the case of donations in kind.

Section 11.11. The PC will examine the request and reply in writing or orally to the requesting party.

In the case of a positive response, the following are required:

a. **A written agreement (mandatory):** an agreement must be prepared and signed by both parties, as legally represented.

b. **Extract from the minutes of the meeting of the Board of Directors or other management body** of the donee (e.g. Medical Society, Hospital institution, NHS, or of the Board of Rectors/ Department in the case of a University) in which the decision to accept the donation was taken.

c. The donation/grant must be followed up **by a confirmation on the part of the donee/ grantee** of the **delivery/purchase/procurement of the goods or services** or, where the donation/grant concerns a research programme, **a progress report** on the programme, and, more generally, a confirmation that the donation/grant has been or is being used for the agreed purpose, an activity report and a thank you letter.

Section 11.12. Donations/grants may be made by PCs up to 1% of their total annual turnover. Any donations/grants made on the initiative of the parent company of a multinational group count as expenses of the domestic affiliate, subject to written approval from its Managing Director (legal representative).

Section 11.13. All the above apply also to any Donations in the context of Corporate Social Responsibility.

Section 11.14. Donations consisting exclusively in medicinal products, made in the context of corporate social responsibility or for charity purposes by PCs whether individually or through SFEE are exempt from the donation procedure described herein; they must, in all cases, comply with the procedure for approval by EOF and with applicable legislation and do not fall within the scope of this article.

ARTICLE 12. FEES-FOR-SERVICE TO HCOS AND USE OF HCO LOGOS AND PROPRIETARY MATERIAL BY PCS

Section 12.1. Contracts between PCs and institutions, organisations or HCP associations (HCOs) under which HCOs provide any kind of services to PCs or any funding from PCs to HCOs not covered by Article 11 or other clauses of this Code, are only permitted if such services (or other funding): (a) are provided for the purpose of supporting healthcare or research; and (b) do not constitute an inducement for the counterparty to prescribe or supply specific medicinal products.

Section 12.2. The public use by a PC of the logo and/or proprietary material of a HCO or PO requires written permission from the Board of Directors or management body of the HCO or CO, upon a request of the PC, clearly indicating the specific purpose and the manner and time of use of the logo/and or proprietary material.

CHAPTER 3.
SPECIFIC TYPES OF INTERACTIONS WITH HCPS AND HCOS AND OTHER PROVISIONS

ARTICLE 13. PATIENT EDUCATION AND SUPPORT PROGRAMMES

Section 13.1. Purpose - Background

13.1.1. In their journey through disease and treatment, patients can contribute to a deeper understanding of therapeutic needs and provide input to the design of treatments. Their experience and ideas are crucial for the pharmaceutical industry, which always aims to develop treatments and solutions that benefit people.

A Patient Education and Support Programme is a patient-centered solution that addresses a need emerging during the treatment phase or a gap of the public health system at the treatment and/or diagnosis level. It is always based on the instructions of the treating physician and aims to inform, educate and support patients and/or their caregivers in receiving and complying with the treatment, with the ultimate goal of alleviating the disease burden and improving their life quality.

Patient Education and Support programmes are not Clinical Trials, nor are they promotional actions aimed to encourage HCPs to prescribe, supply, sale or administer medicinal products to the general public, including patients. They are of a purely educational and supportive character. These Programmes are mainly applicable to **special medicinal products** warranting a special approach, use of accompanying medical devices or special instructions during use, management of any Adverse Effects and, more generally, in cases where it is important to ensure patient compliance with treatment. They may or may not be linked to a particular medicinal product, but in all cases they must be linked to the pharmaceutical company's therapeutic area of disease management.

In the context of such programmes, PCs do not collect any personal data of patients, other than the minimum information required to comply with pharmacovigilance legislation

Patient Education and Support Programmes are in particular aimed to:

- educate and support patients and/or their caregivers in the appropriate use of medicinal products, in line with the SPC and the package leaflet;
- educate and support patients and/or their caregivers in following instructions on the daily management of their disease;

- provide materials and services, including informational such as leaflets or reminder programmes for taking the medicine, with a view to promoting compliance with the treatment;

- continuous supply of the medicinal product, either through a reminder or by facilitating its delivery. Patients are entitled to request and authorise a third party (healthcare provider) to carry out this procedure;

- inform patients about their disease or treatment through call centres and hotlines;

- provide home care services to patients;

- if not already available from by the national healthcare system, provide diagnostic test kits and/or services, helping to identify undiagnosed or underdiagnosed diseases;

- support patients in the management of aspects/manifestations of the disease, including complications such as potential effects on the patient's mental health, nutrition and physical activity;

- provide any service related to the above, in the context of compliance with the treatment, including the transfer of the patient to a HCO or a state healthcare provider.

13. 1.2. As part of Patient Education and Support Programmes, **digital applications** may be made available to patients, which are identified as **Class I medical devices**, according in accordance with the classification rules of EU legislation and which enable them to not forget taking their medication, monitor their symptoms, access educational material about their disease and treatment, as well as to communicate with their treating physician in relation to the above, while also ensuring that the treating physician is informed accordingly. If such digital applications appear on the PC's website, it must be ensured that the PC does not have access to the patients' personal data..

13.1.3. Patient support programmes **do not interfere with the HCP-patient relationship** and do not compromise the independent therapeutic choices or medical decisions of treating HCPs. If the proposed therapeutic solution is related to the instructions for use of a medicinal product that has already been prescribed, the final decision on whether the patient should be included in the programme is made by the HCP and not directly by the patient.

13.1.4. For the inclusion of a patient in a Patient Education/Support Program, the written consent of the patient or his/her legal representative is required. The written consent is signed either manually or by electronic signature (via gov.gr).

13.1.5. Patient Education/Support Programs may not implemented by companies involved in the marketing/distribution/promotion of medicinal products for human use.

13.1.6. Patient Education and Support Programmes are implemented **by third-party independent healthcare companies**, with funding from a PC, on the basis of

a written agreement. In this agreement, the PF is referred to as the "sponsor" of the Programme. These providers must meet the conditions and comply with the procedures specified by healthcare legislation and the applicable Personal Data Protection legislation, in order to ensure the independent and appropriate provision of educational and support services.

13.1.7. The provision of support by healthcare companies serves a social need and at the same time contributes to the appropriate and, as far as possible, safe treatment of patients, without substituting the need for permanent healthcare support from HCPs.

13.1.8. In the context of Patient Education and Support programmes, any direct or indirect communication between a patient or his family and the PC involeved in the marketing/supply/promotion of a medicinal programme is forbidden, except for cases of reporting adverse effects as required by pharmacovigilance legislation. Any spontaneous queries on the part of patients, requesting from the PC information on services related to Patient Education and Support Programmes, must only be responded by the Med Info and/or pharmacovigilance department of the company.

13.1.9. Sponsoring PCs may communicate the existence and purpose of the patient support programme to HCPs. Any further information concerning the Programme may exclusively be provided to patients by the healthcare company implementing the Programme.

Section 13.2. Conditions – Methodology – Transparency

13.2.1. Goods and services of scientific, educational and supportive nature delivered to the patient and intended to ensure the appropriate and/or the safest possible use of a medicinal product must bear the brand name of the sponsoring PC.

13.2.2. The link of a PC to Patient Education and Support Programme must be **transparent**. Patient availability and eligibility to participate in a Patient Education and Support Programme and the role of a PC in its activation must be made known to interested parties and to the administrative staff that implements the programme. The PC must ensure the existence of clear, **objective and documented** criteria for patient inclusion in such programmes. These criteria must be communicated to HCPs and interested parties throughout the duration of support.

13.2.3. Patients must be fully informed. This is confirmed by consent form, signed manually or electronically, as described in paragraph 13.1.4. above, acknowledging and accepting the PC's support to the services provided to them.

13.2.4. The consent is collected by the company implementing the Programme at the first visit and onboarding of the patient.

13.2.5. The **scope** and **duration** of data collection are specified in line with the context and as justified by the explicitly stated purpose of the programme. Patient data collection should be limited to the minimum necessary data required for the successful operation of the programme and should not be extended to other purposes (e.g. non-interventional studies, market research, etc.). Patient Support

Programmes are not intended to collect data relating to the efficacy or safety of a medicinal product, 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 provider are communicated to the PC, in line with the requirements of applicable legislation. The sponsoring PC must train the service provider on pharmacovigilance matters.

13.2.6. Consent forms and patient data should be retained by the support service provider in a manner conforming with applicable data protection legislation. A patient consent may be revoked at any time, without stating reasons, on the initiative of the patient or his/her legal representative.

13.2.6. HCPs and healthcare service providers, in particular patient support/patient education service providers, must ensure compliance with applicable data protection legislation. Clauses relating to protection of personal data and specific categories of personal data, as well as to pharmacovigilance, must be included in the agreement between the provider and the PC.

13.2.7. In agreements between PCs and healthcare service providers, care must be taken to protect the personal data of patients should the Programme be permanently terminated or the provider is replaced. This is because, especially in the latter case, it is necessary to ensure, for the benefit of the patients, that the patient data already collected remain available for use by the successor healthcare service provider (data **portability**). In any case, and for the benefit of patients, an **exit policy** is recommended to be included in the agreement and implemented so that patients can exit the programme without harm to their health.

13.2.8. The sponsoring PC and its staff may not have access to data and files which could enable to identify, or be associated with, individual patients, except for the case of reporting adverse effects. However, the provider should be able to inform the pharmaceutical company about the progress of the documents or perhaps other qualitative and quantitative data regarding the implementation of the programme, ensuring the anonymity of such data in accordance with applicable legislation.

13.2.9. The total cost of such programmes should be reasonable, appropriate and reflect the **fair market value** of the support provided. Patient support should be transparent and include information about the support provided by a PC to the patient.

13.2.10. Treating physicians who recommend a patient's participation in the programme do not receive and remuneration or any other indirect financial advantage for doing so. The staff of the provider (e.g. nurses, dieticians, pharmacists, etc.) may not be involved in the promotion of medicinal products.

13.2.11. All printed and digital materials that have been designed to be used for patient education purposes must not be used for promotional purposes. In particular, these materials may not promote the prescription, supply, sale or administration of the medicinal products of the sponsoring company. Also, such materials may not criticise competitive products, as this could be considered Promotion. All relevant materials to be delivered to the patients participating in the programme must be approved by the PC's Medical Affairs/Scientific Department.

Section 13.3. Competences

13.3.1. HCPs acting on behalf of an institution/healthcare service provider, which is sponsored by a PC are competent to implement these Programmes.

13.3.2. Patient participation in the programme may not involve or be substituted by financial remuneration or other reward in kind and may not cover routine costs or patients or HPCs and permanent healthcare needs. Participation in these programmes is voluntary and is not a prerequisite for, or related to the level of, social security coverage of their treatment or reimbursement for the medicinal products they use for coping with their disease. If these programmes form part of terms of the marketing authorisation and are included in the risk management plan of the medicinal product, they are subject to approval by EOF's Adverse Effects Department, along with all the relevant supporting documentation of the programmes.

13.3.3. In all other cases, EOF approval is not required.

13.3.4. The healthcare service companies providing these services, based on their articles of association, staff organisation and training and availability of a quality assurance department, must hold any relevant accreditation (i.e. ISO 9001, ISO 27001). Moreover, their staff must comprise HCPs or other qualified professionals as relevant to the nature of the programme (nurses, health visitors, nutritionists, psychologists, etc.).

13.3.5. Before the commencement of the programme, the sponsoring PC must compile a dossier containing the following documents:

1. a detailed description of the programme, accompanied with the relevant scientific documentation, drawn from the SPC or the disease literature, demonstrating the technical/social need;

2. an agreement with the company providing the programme services (provider), describing in detail each party's tasks, obligations and responsibilities;

3. a statement confirming the provider's compliance with applicable data protection legislation;

4. any other supporting documents that will be used in implementing the programme according to the PC's internal procedure.

13.3.6. In addition to the ethical commitments and principles established by this article of the SFEE Code, SFEE member companies, during the implementation of such programmes, must comply with pharmaceutical legislation, including rules on medical devices, competition law, intellectual property law, personal data protection, anti-bribery and corruption legislation and environmental, social and governance (ESG) reporting requirements.

ARTICLE 14. MARKET RESEARCH

Section 14.1. Market research is the systematic collection and analysis of views and attitudes of individuals or organisations using methods of applied social sciences and aiming to support business decision-making.

Section 14.2. Market research is a well-established method for recording facts and characteristics of the pharmaceutical market. Market research is different from non-interventional studies (see Annex III, Table 5), has a commercial purpose and are intended for use within the company.

Section 14.3. Market research can be conducted:

(a) through questionnaires, collecting responses from a representative sample of the target population (quantitative research); or

(b) through focus groups or in-depth interviews in a representative sample of the target population, in order to obtain a synthesis of views (qualitative research).

Section 14.4. Market research must be impartial, not focused on promoting sales, not seek to influence the views of participants and be conducted for exclusively commercial purposes.

Section 14.5.

(a) Market research in the healthcare sector may only be conducted by certified Market Research Companies, which are bound to the principles of ESOMAR/ EphMRA (htpp:www.esomar.org., http://www.ephmra.org), as well as to the relevant provisions of personal data protection legislation and pharmaceutical legislation in general, in particular pharmacovigilance provisions. In every instance of market research, care should be taken to ensure a random but representative selection of participants.

(b) If, for market research purposes, the PC and the market research company are considered as joint Data Controllers, both parties must transparently specify their respective responsibilities for complying with the requirements of applicable data protection legislation, and each Controller's responsibility must be disclosed to the persons participating in the research.

(c) To ensure the impartiality and objectivity of market research, and given the requirement under data protection legislation to inform participants of the identity of the PC as joint Data Controller, such information will be disclosed only after the market research has been completed and all responses have been collected and only to participants who, in the initial information by the market research company, had indicated that they wish to know the identity of the PC..

Section 14.6. Data collection must take place in accordance with applicable data protection legislation. Any patient data collected from HCPs may not include clinical data and must be delivered fully anonymised and only in aggregate form.

Section 14.7. PCs are not entitled or permitted to keep lists of patient names.

Section 14.8. Market Research captures a snapshot in time, even if it may refer to past experiences or future intentions of a 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 the collection of data in the context of market research is carried out by a PC without the involvement of a Market Research Company, the principles of ESOMAR/EphMRA must be observed. In this case, no fee is envisaged for HCPs participating in the research. Medical Sales Representatives may not be involved in the conduct of market research. The sales departments of PCs may not be involved in market research, but only in its design.

Section 14.12. When PCs enter into agreements with market research companies, they may stipulate a reasonable compensation to be given to the HCPs who participate in the research, where this is permitted under applicable legislation, depending on the time of their work for the research; such time is recommended to not exceed two (2) hours.

ARTICLE 15. INTERVENTIONAL CLINICAL TRIALS

Section 15.1. Collaboration between PCs and physicians in carrying out interventional clinical trials is vital to 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 observed:

a) all persons participating must follow 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 to improve therapeutic and/or diagnostic methods and/or expand medical knowledge in the best interest of patients;

c) the objective of the interventional trial must be stated in advance. Trial protocols must be compiled in a way to ensure the achievement of that objective and valid conclusions;

d) interventional clinical trials are carried out only upon approval by the competent regulatory and supervisory authorities (the National Organisation for Medicines and the National Ethics Committee);

e) the sponsor company must be made known to patients participating in the trial;

f) the physician must not receive any remuneration or other benefit for simply recruiting patients to participate in interventional clinical trials;

g) the physician may receive remuneration for his/her work in the interventional trial. Remuneration of any kind must be proportionate to 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 paid through ELKE or ELKEA accounts or, as appropriate, against the issuance of a fee-for-service invoice, where applicable;

h) all efficacy and safety data in relation to medicinal products must honestly be publicised via the internet – at least in summary form – irrespective of the outcome of the trial, within one year of completion of the trial. Other clinically significant results must also be publicised in a similar way;

i) in publications, speeches and other presentations, the identity of the sponsor must be made known;

j) the physician may receive remuneration for speeches relating to the interventional clinical trial and its results;

k) when presenting interventional clinical trials, the physician must make known his connections to all PCs in the therapeutic area covered by his/her speech.

Section 15.3. A necessary condition for the recognition of any clinical trial or investigation is documentation through relevant scientific results or evidence.[22]

ARTICLE 16. NON-INTERVENTIONAL CLINICAL TRIALS

Section 16.1. A non-interventional trial on a medicinal product that is already available on the market is a study in which the medicinal product is prescribed in the usual manner way in accordance with the terms of the marketing authorisation, and the diagnostic or monitoring procedures are those of current clinical practice. The assignment of a patient to a particular therapeutic strategy is not decided in advance by the trial protocol, but falls within current practice. The prescription of the medicine is clearly separated from the decision to include the patient in the study. Epidemiological methods are used for the analysis of data, collected in accordance with the principles of Vol. 9A of the pharmacovigilance rules applicable to medicinal products for human use (https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-9_en?prefLang=el). Non-interventional trials must be

22 In all other respects, see also Chapters I-IV of Ministerial Decision 36809/2019 (Government Gazette B 2015/03.06.2019).

conducted in compliance with Good Pharmacoepidemiological Practices (GPP)[23] and Good Pharmacovigilance Practices (GVP).[24]

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 who take it; or to collect data on the evolution and monitoring of a disease; or to evaluate the pharmaco-economic impact of a therapy; or to identify the prevalence or impact of a disease;

b) the medicinal product being studied is administered to participating patients in accordance with 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 PC, the principal investigator, the legal representative of the hospital, or, in the case of a public hospital, the ELKE/ELKEA administrator, specifying, among other things, the nature of the services to be provided and the basis for compensation of such services, in accordance with 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 PC, which will also undertake to supervise the conduct of the trial, either directly or via a CRO, assigned by the local or centralised procedure;

g) once approval under point (f) 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) prior to the commencement of the trial, its key characteristics and the key information included in the Protocol must be recorded in the relevant, publicly accessible, registry maintained by SFEE on its webpage https://www.dilon.sfee.gr/ ;

i) all applicable provisions of data protection legislation must be complied with;

j) trial results must be analysed by the contracting PC or under its authorisation, and the summaries of such analysis must be reported to the PC's medical affairs/scientific

23 https://www.pharmacoepi.org/resources/policies/guidelines-08027/

24 https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/goodpharmacovigilance-practices

department within a reasonable period of time (Article 19 of the Code), which in turn must keep record of this report for a reasonable period of time. The PC company must send the summary report to all HCPs participating in the trial and must record it (or the relevant publication) in the registry of non-interventional trials/pharmaco-epidemiological studies maintained by SFEE. If any results that are significant for the benefit-risk assessment arise from the trial, the summary report must be promptly forwarded to the National Organisation for Medicines (EOF);

k) medical sales representatives may not be involved in the conduct of the study.

Section 16.3. The only type of non-interventional trials that are subject to approval by EOF before their commencement are non-interventional post-authorisation safety/efficacy studies required by the Competent Authority when it granted the marketing authorisation or any time thereafter.

Section 16.4. Meetings with a small number of physicians in order for them to: a) contribute to the design of clinical trials; or b) be updated on new data regarding clinical trials in which they have participated as investigators (investigator meetings) and are organised by the medical affairs department of a PC are not subject to approval by EOF.

Section 16.5. To the extent practicable, PCs are encouraged to comply with Article 16.2 for all other types of studies within the scope of Article 16.1 of the present Chapter of the Code, including epidemiological studies and registries and other studies that are retrospective in nature.

Section 16.6. Further details on the registry of non-interventional trials, on the applicable criteria and requirements, as well as on the disclosure of transfers of value in connection with non-interventional clinical trials are provided in Annex III of the present Code.

ARTICLE 17. MEDICAL SAMPLES

Section 17.1. The production, import and distribution free of charge of medical samples to medical and dental practitioners aimed to familiarize them with a new medicinal product is permitted only **after approval from the National Organisation for Medicines (EOF).** The approval, granted in exceptional cases, specifies the packaging (the smallest presentation available on the market), the total quantity, the time, the method of distribution and any other necessary details. The number of medical samples provided to each HCP must be limited. Without prejudice to an EOF approval to the contrary (national deviation), EFPIA's guideline is that each HCP should receive, per year, no more than four (4) medical samples of a particular Medicinal Product he/she is qualified to prescribe for two (2) years after its first circulation, i.e. after the issuance of the first sales invoice by the PF for each approved Medicinal Product (i.e. the "4x2" standard). It is recommended that every effort be made to comply with this rule in the absence of specific national legislation.

Medical samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific Medicinal Products and must not be given for the sole purpose of treating patients.

Medical Samples are given to HCPs so that they may familiarise themselves with a new Medicinal Product and acquire experience in dealing with them. In this context, a **"new Medicinal Product"** is a product for which a new marketing authorisation has been granted, either following an initial marketing authorisation application or following an extension application for new strengths/dosage forms that include a new indication. Extensions of the marketing authorisation to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) **cannot be considered as new Medicinal Product.**

Medical Samples can only be given in response to a written request from HCPs qualified to prescribe that particular Medicinal Product. Such written requests must be signed and dated by the HCPs requesting the Medical Samples.

Section 17.2. PCs must have adequate systems of control and accountability for Medical Samples which they distribute and for all Medicinal Products handled by their Medical Sales Representatives.

Section 17.3. Each Medical Sample must be no larger than the smallest presentation available on the market.

Section 17.4. Each Medical Sample must be marked "free medical sample – not for sale" or words to that effect and must be accompanied by a copy of the Summary of Product Characteristics (SPC).

Section 17.5. Medical sampling is prohibited for the following Medicinal Products: (a) Medicinal Products containing substances which are defined as psychotropic or narcotic by an international convention, such as the 1961 and 1971 United Nations Conventions; and (b) any other Medicinal Product for which medical sampling is appropriate, as determined by the competent authorities.

ARTICLE 18. INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

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

Section 18.2. Exceptionally, it is permitted to offer HCP devices/applications of insignificant value, up to EUR 15.00 (per item) VAT inclusive, directly relevant to the practice of the HCP, such as:

a. Applications for mobile phones/computers which, due to their nature, are not identified as medical devices of Class II and subsequent classes according to the EU Classification Rules[25] (e.g. they do not serve diagnostic or dosing purposes, etc.).

25 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,

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 (to be provided via the HCP) intended as aid, e.g. nutrition/exercise advice, or in the context of a disease awareness campaign approved by the competent authorities;

e. printed or digital publications with guidelines from Scientific Societies, provided that they do not mention uses outside the approved indications and dosage;

f. printed or digital publications containing therapeutic protocols.

Section 18.3. The above items may not use the product brand name and/or include a direct or indirect advertising message, but only the company's logo.

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

- Antiseptic fluids
- Surgical gloves/scrub caps/clothes
- Catheters
- Syringes/needles/tourniquets
- Ultrasound gel
- CPR pocket masks
- Mp3
- Stethoscopes
- Prescription pads
- ECG paper
- Personal objects of any kind
- Organisers, notebooks, etc.
- Stationery items of any kind
- PC accessories, etc.

Section 18.5. The provision of promotional gifts bearing the logo of a PC or of a product, such as bags, notepads, pens, memory sticks, stationery, mouse pads, PC mouses, etc., is not permitted.

Chapter III.

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

Section 19.1. PCs are required to have a scientific service (Medical Info Department) in charge of information on the medicinal products they market. This service will be responsible for responding to all spontaneous queries from patients/consumers, HCPs (physicians, pharmacists etc.), Medical Sales Representatives or other sources (e.g. government agencies, HCOs, 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 each PC, depending on its organisational structure. Preferably, it should include a medical doctor or a pharmacist or other HCP.

Section 19.3. The scientific service must be trained and have access to those records that will enable it to provide a scientifically substantiated response. Moreover, it must be informed of any relevant change in the records. Finally, the scientific service must be trained in the field of pharmacovigilance and Medical Devices Vigilance, so that any safety issues and pharmacotechnical complaints can be referred to the competent company departments.

Section 19.4. PCs must 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 should 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. HCPs working in PCs 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 should belong and report to the medical affairs/scientific departments of PCs and not to the sales/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 to the same category of HCPs; as a scientist of the health sector, the Medical Science Liaison, may not report, even indirectly, to any departments other than the medical affairs department and may not have visit-frequency or volume-sales targets. PCs may also have appropriately trained staff to respond to inquiries concerning specialised products (e.g. medical devices).

Section 19.7. PCs must have an organised system to receive, log, process, respond to and keep record of requests for medical information. Such system must be in compliance with applicable legislation on the prohibition of advertising to the public and on the handling of personal data. It is recommended that such system record, as a minimum, the following information:

a. the inquiry and the product concerned;

b. contact details of the inquirer;

c. date of receipt of the inquiry;

d. the member of staff responsible for handling the inquiry and the response given, with clear indication of the reference source;

e. date of response.

Section 19.8. PCs are required to notify callers of the existence of a logging and archiving system and the purpose thereof, as well as of their right to access, and object to, the contact details they have provided.

Section 19.9. Answers 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. Responses 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 only be given in response to specific unsolicited inquiries and be limited to the scope of such inquiries.

19.9.2. Answers may be based on varying sources, depending on the capacity of the inquirer:

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

Answers to inquiries from patients and their family, patient organisations 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 duly approved.

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

Exceptionally, 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), as approved by the Pharmacovigilance Department of EOF.

For inquiries concerning off-label use, the patient must be advised to consult 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 consult the literature, published articles, online information and any available conference summaries. In all these cases, 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 at the company concerned and be readily available upon request.

In exceptional cases, and where permitted by applicable legislation, answers can be based on the product Risk Management Plan (RMP) and the respective training material.

For inquiries concerning off-label use, the answer must make clear that the specific use is not envisaged in the approved product characteristics, and the answer 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 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 (reactively) rather than unsolicited for promotional purposes, aimed exclusively to substantiate the answer and enhance the HCP's scientific knowledge. Scientific literature must only be sent to the HCP who made the inquiry, be faithfully reproduced and the source must be precisely indicated.

Any literature material used on the PC's initiative for promotional purposes falls within the scope of Article 3 of this Code (see 3.11.8. Reprints).

If a HCP requests to obtain scientific literature containing information on off-label use, it must be made clear that the specific use is not envisaged in the approved product characteristics, and the answer must be accompanied by the SPC (see also 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 properly trained 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's consent to the use of his/her work must be clear, specifying how the material is to be used, for how long and on which medium.

Section 19.10. Presentations by the Medical Affairs Departments of PCs companies at Hospital clinics

The Medical/Scientific Departments of PCs may organise presentations of scientific content on products at Hospital clinics, in response to a justified request of the clinic Director. These presentations do not constitute scientific events as defined by EOF. PCs may not offer coffee/snacks/refreshments, etc. inside the Hospital. PCs must 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 applicable legislation. PCs are responsible for ensuring such compliance.

20.1.1. During each visit to HCPs, medical sales representatives must give the persons visited, or have available for them, a 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 transmit to the PC's scientific service referred to in Article 19 of this Code, any information they receive from the persons visited in relation to the use of the medicinal products they promote, particularly reports of side effects, which must be promptly notified to the company's Pharmacovigilance Officer so that the appropriate procedures can be activated, where necessary.

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 whom representatives ask to visit, as well as the regulations or time and place restrictions set by each Hospital Institution must be respected at all times.

20.1.4. In 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 PC they represent.

20.1.5. PCs are liable for any activities performed by their medical sales representatives within the scope of their engagement.

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

20.1.7. Medical sales representatives must, under the responsibility of the PC they work for, be taught the Code during their training and periodically receive systematic training on the products promoted.

Section 20.2. Group Detailing

PCs may organize small group meetings with HCPs regarding their products (Group Detailing). These meetings have a scientific content regarding the properties of the products. Participation can be in-person or virtual. They are addressed to private practitioners (HCPs) or to full-time or part-time HCPs working in the public sector. Such meetings are not subject to EOF's approval and are in compliance with the SFEE Code if they meet all of the following requirements:

a) For meetings with private practitioners:

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

b) For meetings with public-sector HCPs:

1. they concern prescription-only medicinal products;
2. are attended exclusively by HCPs (public sector employees) of the Hospital;
3. they take place inside the Hospital;
4. the speaker is an internal Medical Information/Medical Sales Representative of the PC;
5. they have been approved by the Clinic Director (not by EOF);
6. PCs do not offer coffee/snacks/refreshments or other meals inside the Hospital

CHAPTER 4.
SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs

ARTICLE 21. GENERAL PRINCIPLES

Any forms of interactions of PCs with POs as well as any support from PCs to 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 PCs and POs must be based on mutual respect, with the views and decisions of each partner having equal value;
- PCs may not ask POs to promote any prescription-only medicinal products;
- the objectives and scope of any collaboration between PCs and POs must be transparent. Financial and non-financial support provided by PCs must be clearly acknowledged;
- PCs welcome the funding of POs from multiple sources.

ARTICLE 22. PROMOTION OF MEDICINAL PRODUCTS

In the implementation of this chapter, the provisions of national and EU legislation prohibiting promotion of prescription-only medicines (POM) to the general public apply.

ARTICLE 23. WRITTEN AGREEMENT

Any financial support from PCs to POs requires a prior written agreement, specifying the amount of funding and also the purpose (e.g. donation or grant for a specific meeting or publication, etc.); the agreement must also include a description of significant indirect support (e.g. donation of public relations agency's time and the nature of its involvement) and significant non-financial support. Companies must have an approval procedure in place for agreements of this type.

ARTICLE 24. USE OF LOGOS AND PROPRIETARY MATERIAL

The public use by a PC of the logo and/or proprietary material of a PO requires written permission from the PO concerned, upon a request of the PC, clearly indicating the specific purpose and the manner and time of use of the logo/and or proprietary material.

ARTICLE 25. PUBLICATIONS

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

ARTICLE 26. CONTRACTED SERVICES

Section 26.1. Contracts between PCs and PO 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 contract PO Representatives as consultants, e.g. in advisory meetings, or as speakers. The arrangements that cover these consultancy and/or other services must meet all 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 extent of the services provided is not greater than reasonably necessary to meet the identified need;

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 for the services is reasonable and reflects the fair market value of the services provided. In this regard, remuneration of PO Representatives for services provided may not exceed seventy euros (EUR 70.00) per hour, subject to a total ceiling of five hundred and sixty euros (EUR 560.00) per service. Such remuneration will be deposited in an account held by the PO;

h) in their written contracts with PO Representatives, PCs are strongly encouraged to include provisions regarding the obligation of the PO 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 PC.

ARTICLE 27. SINGLE-COMPANY FUNDING

A PC may not be the exclusive sponsor or a PO or any of its activities during a year, except when no other funding is available. This does not apply to POs in the field of Rare Diseases.

ARTICLE 28. EVENTS AND HOSPITALITY

Section 28.1. All events organised by POs and sponsored by a PC or on its behalf, 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 Chapter 2, Article 7.1. above.

Section 28.2. All forms of hospitality offered by PCs to PO Representatives must be "reasonable" and strictly limited to the main purpose of the event, irrespective of whether the event is organised by the PO or the PC, in accordance with the terms of Article 8.3. above and with the same limits applying as in the case of hospitality to HCPs (see Annex I).

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 PO Representatives. In exceptional cases of established health needs (e.g. disability), the travel, meals, accommodation and registration fee costs of an accompanying person (considered as caregiver) can be reimbursed within the same parameters.

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

Section 28.6. PCs may not 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 certain facilities[26] that are relevant to the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

28.7. For the approval of PO events, see Chapter 2, Article 6, Section A.8.

ARTICLE 29. TRANSPARENCY

a) Each PC must, on an annual basis, post on its website under the title "Annual transfers of value to POs" a publicly accessible list of POs to which it offers financial support and/or

26 E.g. research laboratories, manufacturing plants, etc.

significant indirect non-financial support, as well as POs contracted to provide services to the PC, communicating the relevant link to SFEE at www.sfee@sfee.gr.

The list must include a brief description of the nature of the support, which must be adequate to enable the average reader to understand the nature of the support or contractual relationship, without disclosing confidential information. If significant non-financial support is provided the financial value of which cannot be precisely defined, the description must specify the non-financial benefit obtained by the PO. This information can be provided and updated at least once a year, not later than 30 June of the year following the reporting period (calendar year).

b) If financial and/or indirect non-financial support is provided, in addition to the name of the PO, the following must also be disclosed:

- the monetary value/amount of financial support and verified expenses;
- the non-financial benefit obtained by the PO where the value of the indirect non-financial support cannot be precisely defined;
- for contracted services, the total amount paid to the PO during the reporting period.

c) METHODOLOGY: Each PC must publish a note summarising the methodology used by it in preparing the disclosure and identifying Transfers of Value for each category of support and/ or services provided.

d) It is recommended that each PC designate a person from among its staff, depending on its corporate structure but not associated with its promotion/sales/marketing departments, as its the key contact person in any communications with POs. The name of the contact person will be notified to SFEE upon request.

CHAPTER 5.
DISCLOSURE OF TRANSFERS OF VALUE BY PCS TO HCPs AND HCOs

1. DISCLOSURE OF TRANSFERS OF VALUE TO HCPs and HCOs

A. SCOPE

This Chapter of the Code governs the disclosure of transfers of value by PCs to HCPs and HCOs resident in Greece.

ARTICLE 30. DISCLOSURE OBLIGATION

Section 30.1. ***General Obligation.*** Subject to the terms of this article and in line with applicable legislation[27], each PC must disclose on its website the Transfers of Value it makes, directly or indirectly to or for the benefit of a Recipient, on an individual Recipient named basis, within six months of the end of each calendar year, i.e. **not later than 30 June** of the year following the reporting period. The information disclosed must be posted on the PC's website for a period of three (3) years.

Section 30.2. ***Exemptions from the disclosure obligation.*** The obligation laid down in paragraph 30.1. does not apply to Transfers of Value that

(a) are solely related to over-the-counter medicines;

(b) are not included in Article 32 of this Code, namely meals and beverages (see Article 8); medical samples (see Article 17); and inexpensive items of medical utility referred to in Article 18.1 of this Code;

(b) are part of ordinary commercial transactions between a PC and a HCP professionally engaged in sales of Medicinal Products (such as a pharmacist, a wholesaler) and/or a HCO, i.e. transactions within the pharmaceutical supply chain.

ARTICLE 31. FORM OF DISCLOSURE

Section 31.1. ***Annual Disclosure Cycle.*** Disclosures must be made on an annual basis and each Reporting Period must cover a full calendar year.

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

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27 See Article 66, paragraph 7 of Law 4316/2014 (Government Gazette A 270/24.12.2014).

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

A) Company website: Disclosures are made on each PC's website, in accordance with paragraph 31.4, with free public access to the information disclosed.

B) EOF Platform: Disclosures on EOF website are made in accordance with the rules, time frame and standards specified by EOF.

Section 31.4. ***Applicable National Code and National Law:*** Disclosures for all HCPs and HCOs whose place of activity or professional address is in Greece shall be made in accordance with the present Chapter of the Code.

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

Section 31.6. ***Documentation and retention of records:*** Each PC must document all Transfers of Value required to be disclosed pursuant to paragraph 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 required by the law or the Data Protection Authority.

ARTICLE 32. INDIVIDUAL AND AGGREGATE DISCLOSURE

Section 32.1. ***Individual Disclosure.*** Except as explicitly provided by this Chapter of the Code, transfers of value must be disclosed on an individual basis. Each PC must disclose, on an individual basis for each clearly identifiable Recipient (full name and specialty), the amounts of transfers of value it made, directly or indirectly, to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below.

32.1.1. Transfers of value to HCOs related to:

a. Donations and grants: Donations to HCOs (in cash or in kind, governed by Article 11, Chapter 2 of this Code).

b. Sponsorship of Events. Contribution to costs related to events organised by HCOs, as such costs arise from contracts with HCOs, or third parties appointed by HCOs to manage an Event, and do not concern a HCP individually.

Note: Any costs related to the participation of a HCP in a conference in an active role (speaker, moderator, etc.) and included in the sponsoring contract between the PC and the entity organising the event/conference, must be disclosed on an individual basis by the sponsor PC (after the signing of the relevant contract), taking into account the applicable restrictions.

c. Fees for service and consultancy. Transfers of Value resulting from or related to contracts between PCs and HCOs, under which HCOs provide any type of services to a PC, or any other type of funding not covered in the previous categories (e.g. personal fees for services payable directly to a HCP). Fees, on the one hand, and all other expenses agreed in the written contract, on the other, will be disclosed as two separate amounts.

32.1.2. ***Transfers of value to HCPs related to:***

a. Events:

1. Registration fees

2. Travel and accommodation.

b. Fees for service and consultancy. Transfers of Value resulting from or related to contracts between PCs and HCPs, under which HPCs provide any type of services to a PC, or any other type of funding not covered in the previous categories. Fees, on the one hand, and all other expenses agreed in the written contract, 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 to a HCO relating to services provided by HCPs, PCs must, where possible, identify and disclose at the individual final Recipient (HCP) rather than HCO, as long as this can be achieved with accuracy, consistency and in compliance with applicable laws and regulations.

Section 32.2. ***Aggregate Disclosure***

32.2.1. Transfers of value within the scope of Article 32.1. that cannot be disclosed on an individual basis for legal reasons, are disclosed on an aggregate basis. Such aggregate disclosure must identify: (i) the number of Recipients covered by the disclosure, in absolute terms and as a percentage of all Recipients; and (ii) the aggregate amount of Transfers of Value to such Recipients.

32.2.2. ***Research and Development Transfers of Value.*** Transfers of Value concerning Research and Development activities in each Reporting Period must be disclosed by each PC on an aggregate basis. Costs related to events that are auxiliary to activities covered by this paragraph (e.g. investigator meetings) are disclosed on an aggregate basis.

32.2.3. ***Non-Duplication.*** Where a transfer of value required to be disclosed pursuant to paragraph 32.1. or 32.2. is made to an individual HCP indirectly via a HCO, such transfer of value must only be disclosed once. Such disclosure must be made on an individual HCP named basis in accordance with paragraph 32.1.2.c.

32.2.4. ***Methodology.*** Each PC must publish a note summarising the methodology used by it in preparing the disclosures and identifying Transfers of Value for each category. The note, including a general summary, must describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amounts of Transfers of Value for the purposes of the present Chapter of the Code.

Section 32.3. Disclosure of indirect transfers of value 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) pursuant to the provisions of Article 7.11. of this Code, the relevant Transfers of Value must be disclosed under the name of the HCO hosting the event.

CHAPTER 6.
COMPLIANCE MONITORING AND ENFORCEMENT PROCEDURE

ARTICLE 33. BODIES MONITORING COMPLIANCE WITH THE CODE

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

Section 33.1. The First Instance Committee for Code Compliance, hereinafter referred to as the First Instance Committee, which examines the complaints filed; this involves two mandatory steps, as follows:

(a) a mediation procedure, in which the First Instance Committee is represented by its Chair and Secretary, acting in the context of this step as mediators for an amicable settlement of the dispute between the opposed parties; and, if the mediation procedure fails:

(b) a hearing 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 in a second degree of jurisdiction, following an appeal from a PC sanctioned by the First Instance Committee.

Section 33.3. The Disciplinary Board of SFEE, provided for in Article 19 of the SFEE Statute, which addresses cases of PCs referred to it by the Second Instance Committee with the request to consider expulsion from membership.

ARTICLE 34. FIRST INSTANCE COMMITTEE: COMPOSITION, COMPETENCES, PROCEDURE OF SUBMISSION AND HEARING OF COMPLAINTS

Section 34.1. Monitoring of compliance with the Code is entrusted to the First Instance Committee, which is competent to examine and decide on complaints about Code violations. It is also competent to conduct any compromises or other settlements in the context of compliance with the Code.

34.1.1. The First Instance Committee is assisted in its work by SFEE's Ethics and Transparency Committee, which is responsible for providing advice, guidance and training on the stipulations of the Code. In addition, it provides technical support both to the First Instance and the Second Instance Committees.

34.1.2. The Ethics and Transparency Committee consists of nine (9) members and their alternates, is set up by decision of the Board of Directors, and its term of office expires with the end of the tenure of that Board of Directors.

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 recognized standing, as Chair;
- SFEE's Legal Counsel, as Secretary;
- two (2) former CEOs of member companies;
- one (1) expert as Scientific Officer (external consultant);
- and the respective alternates of regular members.

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

Section 34.4. Entitled to file a complaint are the following (locus standi):

34.4.1. Any natural or legal person affected by any breach of the provisions of this Code is entitled to file a complaint before the First Instance Committee by post, in person or by email at www.complaints@sfee.gr. In response, the First Instance Committee convenes and decides on the matter. Complaints can be named or anonymous. A named complaint in which the complainant requests to remain anonymous is not considered an anonymous complaint.

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

34.4.3. The First Instance Committee may take action on its own initiative, when any any breach of the Code is brought to its attention.

34.4.4. It is also 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 alleged breach.

Section 34.6. As soon as a complaint filed, it 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 Chair of the First Instance Committee, who performs a preliminary review as to whether the complaint is sufficiently precise or not. No further action is taken where a complaint is found to be vague, which archived as a non-case. The complaint is also notified by the Secretary of the Committee to the PC against which it is filed.

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 record them on the same day in the complaints registry. The Secretary of the First Instance Committee then notifies without undue delay, by fax or email, the Chair of the First Instance Committee of the receipt of the complaint, whereupon the Chair activates the procedure before the First Instance Committee as provided for in this Chapter 6.

Section 34.8. If the complaint is sufficiently precise, the Chair of the First Instance Committee starts the evidence collection process, in which the defendant PC may be invited to assist. Once this process is over, the Chairman initiates the mediation procedure as described above.

Section 34.9. The hearing of a complaint before the bodies monitoring compliance with the Code is not suspended where a case with the same subject matter is pending before the National Organisation for Medicines (EOF) or the civil courts having jurisdiction.

Section 34.10. During the mediation procedure, an amicable settlement of the dispute is attempted. If an amicable settlement is achieved, this is documented and signed by both parties.

Section 34.11. If the mediation procedure fails, the complaint is brought before the Plenum of the First Instance Committee by a letter from the Chair addressed to the other Committee members and to the disputing parties. The Committee meets in plenary session within thirty (30) business days of dispatch of the letter send by the Chair and including all documentation and evidence provided by the parties. This deadline may only be extended in the case of an objective impediment.

Section 34.12. The First Instance Committee is in quorum if at least four of its members are present. Decisions are taken by majority vote. If majority is not reached, the vote is repeated. If again a majority is not reached, the Chair of the Committee has a casting vote. At the conclusion of the meeting the First Instance Committee, the Secretary of the Committee, jointly with the Chair and the other members, prepare the text of the decision, which is recorded in the decision book of the First Instance Committee, duly signed by the Chair and the other members. Thereafter, the Secretary of the Committee notifies the decision to the defendant PC and the complainant (natural or legal person).

Section 34.13. The Chair of the First Instance Committee may, during the meeting, invite any person whose input might, in the Chair's judgment, be useful in making a decision on the complaint at hand. The Chair may consult expert advisors on any issue within the scope of the First Instance Committee. Expert advisors may be invited to participate in 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 a complaint against a PC before the Committee or has in the past worked for the complainant PC or the defendant PC, that member is excluded from the meeting discussing the specific complaint. The place of the excluded member in the relevant meeting is taken by the respective alternate member..

ARTICLE 35. REFERRAL PROCEDURE AND HEARING OF COMPLAINTS BEFORE THE SECOND INSTANCE COMMITTEE

Section 35.1. A PC that is subject to a First Instance Committee decision imposing sanctions reserves the right to appeal the decision before the Second Instance Committee, within thirty (30) business days of notification of the First Instance Committee's decision.

Section 35.2. The appeal must be filed with SFEE's Legal Department, which must communicate it without undue delay by e-mail or fax to the Chair, the Secretary and the other members of the Second Instance Committee.

Section 35.3. The Second Instance Committee is appointed by the Board of Directors of SFEE. Its term of office 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 recognised standing, as Chair;
- a legal expert, presumably familiar with medical and pharmaceutical matters, as Secretary;
- two (2) former CEOs of member companies;
- one expert as Scientific Officer (external consultant);
- and the respective alternates of regular members.

The regular 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 of notification by SFEE's Legal Department of the appeal. After examining the case, the Committee issues a decision, which is binding on the disputing parties.

Section 35.6. The Second Instance Committee is in quorum when at least four (4) of its members are present. However, all the categories set out in Section 35.4 must be represented by at least one person in the meeting. Decisions are taken by majority vote.

Section 35.7. The Chair of the Second Instance Committee schedules a hearing of the case within two (2) months of the appointment of the Second-Instance Committee and invites to the hearing the complainant and the defendant, who may attend in person or submit written pleas instead. The presence of both disputing parties is preferable. In all other respects, Articles 34.8, 34.9. and 34.12. of the Code apply by analogy.

Section 35.8. The Chair of the Second Instance Committee may invite to the meeting of the Committee any person whose input, in the Chair's judgement, might be useful in establishing the facts of the case.

Section 35.9. Expert advisors may be invited to participate in 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 a complaint against a PC before the First Instance Committee or has in the past worked for the complainant PC or the defendant PC, that member is excluded from the meeting discussing the specific complaint. The place of the excluded member in the relevant meeting is taken by an alternate from the same category of members.

Section 35.11. Similar cases of complaints are treated in a consistent manner. If a complaint has as its subject matter an issue that has recently been addressed by the Second Instance Committee, the Chair of the Committee may accelerate the procedure, e.g. by requesting the defendant PC to promptly provide evidence 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, are compensated by SFEE for participation in Committee meetings. The amount of compensation is determined by agreement between Committee members and the SFEE Board of Directors.

ARTICLE 36. SANCTIONS

Section 36.1 If the **First Instance Committee,** after examining the complaint, determines the existence of a breach of any articles of the Code, it may impose on the non-compliant PC, with due regard to type and severity of the breach, the number of breaches and any repeated breaches by the same PC, the following sanctions, which are executed after the expiry of the deadline for appeal before the Second Instance Committee:

(a) a financial penalty of up to twenty-five thousand euros (EUR 25,000); and

(b) if the breach relates to Promotional materials, an obligation of the PC concerned to correct the non-compliant promotional material and send the corrected material to the same addressees, along with a letter stating the corrections made;

Section 36.2 The Second Instance Committee may uphold, modify or annul the decision of the First Instance Committee, but without worsening the position of the appellant PC.

Section 36.3. If the deadline for appeal before the Second Instance Committee has expired and the PC refuses to comply with the First Instance Committee's decision, the Second Instance Committee may impose on that PC the following sanctions:

(a) a financial penalty of up to twenty-five thousand euros (EUR 25,000);

(b) referral of the matter to the SFEE Disciplinary Board, with the request to consider expulsion from membership.

Section 36.4. A PC that is subject to a decision of the Second Instance Committee, must comply with such decision as soon as possible. If it fails to fulfill the obligations imposed by the decision of the Second Instance Committee, whether these require from the PC an action, including the payment of a financial penalty, or omission, the Second Instance Committee, at the request of the complainant, convenes again and decides to impose further sanctions, up to three times the sanction initially imposed, considering the matter 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 matter to the SFEE Disciplinary Board with the request to consider expulsion from membership.

Section 36.6. All decisions of the First and Second Instance Committees for SFEE Code Compliance (acquitting, sanctioning or resolving the dispute by compromise), following their notification to the parties concerned, are promptly posted on the SFEE website in the relevant locked field and will remain posted for a period of three (3) months.

Section 36.7. A SFEE member that fails to comply with a sanctioning decision of the Second Instance Committee will be excluded from participation in any working group of SFEE. Moreover, the dispatch of any communication material to that member will be suspended for a period of one (1) year.

Section 36.8. For as long as a case is pending before the First or Second Instance Committee for SFEE Code Compliance, neither party may participate in SFEE Committees that may have a material influence on the case (e.g. 9-member Ethics and Transparency Committee, Conference Evaluation Committee, Medical Directors Committee, or any other relevant committee that may be established in the future).

ARTICLE 37. ANNUAL REPORT TO EFPIA

The Secretary of the First Instance Committee must 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 any case of conflict between the provisions of this Code and relevant provisions of applicable national legislation, the stricter rule will apply.

Section 38.2. Acts which are deemed formally lawful, due to the tacit lapse of the deadline for necessary action to be taken by EOF or other competent authority, may be.

Section 38.3. Any formal procedures before public authorities included in the Code will automatically cease to apply or be amended accordingly in the event of a new relevant decision of the Competent Authority.

ANNEXES

I) Table of limits

II) Indicative calculation of HCP remuneration for services provided to PCs

III) Registry of non-interventional clinical trials

IV) Disclosure template

V) Indicative list of most representative HCOs/Specialisations and Medical Specialties

ANNEX I*

1.LIMITS ON PC SPONSORSHIPS OF HCO SCIENTIFIC EVENTS PER YEAR

A. HCO

1. IN-PERSON SCIENTIFIC EVENTS									
DEFINITIONS		**MINIMUM DURATION**		**MAXIMUM SPONSORSHIP AMOUNT** PER PC**		**MAXIMUM REGISTRATION FEE** (EOF)/ SPONSORSHIP OF PARTICIPATIONS (SFEE CODE)**		**MAXIMUM NUMBER PER YEAR**	
EOF	**SFEE**	**EOF**	**SFEE**	**EOF**	**SFEE**	**EOF**	**SFEE**	**EOF**	**SFEE**
INTERNATIONAL HELD IN GREECE (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 terms of budget and Speakers. Events organised by Greek HCOs under the auspices of a foreign entity are not considered international events		N/A		N/A	Organised by foreign HCOs: ≤€30,000 (Incl. VAT)*	N/A	N/A	N/A	N/A
				≤€25,000 (incl. VAT)	Jointly organised by a foreign HCO and a Greek HCOs: EUR ≤14,000 (incl. VAT)	N/A	€≤140.00 (excl. VAT) ONLY IF JOINTLY ORGANISED by a foreign HCO and a Greek HCO	N/A	1 ONLY IF JOINTLY ORGANISED by a foreign HCO and a Greek HCO
PAN-HELLENIC		Maximum duration up to 5 days and up to 4 night stays	At least 24 programme hours	≤ €25,000 (incl. VAT)	≤ €14,000 (incl. VAT)	N/A	≤€140.00 (VAT excluded)	1	1
TWO-DAY EVENTS	**REGIONAL**	Up to 3 Days	At least 16 programme hours	≤ €5,000 (incl. VAT)	≤ €5,000 (incl. VAT)	N/A	≤€140.00 (VAT excluded)	Up to 3 (excluding Learning Cycles)	TOTAL (A.3, A.4 and A.6) Up to 3
ONE-DAY EVENT	**LOCAL EVENTS**	1 Day	At least 4 hours	≤ €5,000 (incl. VAT)	≤ €3,500 (Incl. VAT)	N/A	≤€140.00 (VAT excluded)		
LEARNING CYCLES	At least 4 hours/day			≤€3,500 (incl. VAT)		≤€150.00 (VAT included)		Up to 10	

** International congresses evaluated by EFPIA according to the Conference Vetting System (CVS) are excluded from the limit.*
*** The table shows the maximum possible.*

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/PC		MAXIMUM NUMBER OF SPONSORSHIPS/YEAR	
EOF	**SFEE**	**EOF**	**SFEE**	**EOF**	**SFEE**	**EOF**	**SFEE**	**EOF**	**SFEE**
WEB SCIENTIFIC EVENTS	**WEB/ VIRTUAL SCIENTIFIC EVENTS/ CONGRESSES**	Not defined	As in A1, A.2, A.3, A.4 or A.5) Scientific Events	Not defined	SEs of equal duration as: A.1 ≤50 € (VAT excluded) only in jointly organised by a foreign HCO and a Greek HCO 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 ≤€25,000 (incl. VAT) in joint organisation A.2 ≤ €25,000 (incl. VAT) A.3. ≤€5,000 (incl. VAT) A.4 ≤€5,000 (incl. VAT) A.5. ≤ €2,500 (incl. VAT)	Depending on the duration of the event (as in A.1, A.2, A.3, A.4 or purely web events organised by the HCOs referred to in A.5) A.1 ≤€15,000 only in JOINTLY ORGANISED by foreign and Greek HCOs: ≤€7,000 (incl. VAT) A.2. ≤€7,000 (incl. VAT) A.3. ≤€3,500 (incl. VAT) A.4. ≤€1,750 (incl. VAT) A.5. ≤ €1,500 (incl. VAT)	Depending on the type of the event (A1, A.2, A.3, A.4. or A.5), is subject to the limits applying to in-person events and count towards such limits-cumulatively	Is subject to the limits applying to in-person events and count towards such limits-cumulatively
LEARNING CYCLES		At least 4 hours/ day	Not defined.	≤€150.00 (VAT included)	No registration fee	≤ €3,500 (incl. VAT)	≤ €1,750 (VAT included)	Up to 10	
WEBINARS	**ONLINE PRESENTATIONS (WEBINARS)**	Up to 3 hours	Up to 3 hours	Not defined	No registration fee	-	≤ €1,000 (incl. VAT)	Unlimited	Unlimited

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 3 days	≤€2,500/PC ≤€20,000 in total	Up to 3

C. EVENTS ORGANISED BY PCs (FORMER TYPE B)

	DURATION	NUMBER/YEAR/COMPANY
Promotional and Non-Promotional Events (EOF AND SFEE) In-person and/or virtual attendance of HCPs.	At least 4 hours/day Up to 3 days (up to 2 overnight stays)	≤40
WEBINARS	Up to 3 hours	Unlimited, not counting towards the limit of 40/year/PC

D. DAILY LIMITS ON COST OF MEALS[1] (FOR PARTICIPATION IN HCO- AND PC[2]-ORGANISED SCIENTIFIC EVENTS)

	EOF	SFEE
IN GREECE[3]	≤€100.00 (incl. VAT)	≤€70.00 (incl. VAT)
ABROAD[4]	≤€150.00 (incl. VAT)	≤€150.00 (incl. VAT)

Clarifications:

1. *IMPORTANT NOTE: SFEE's limits are in certain cases stricter than the limits specified in the EOF Circular.*
2. *Companies of products within EOF's remit may not submit requests to organise scientific events abroad or to co-organize scientific events jointly with other entities (government organizations, non-profit scientific bodies, private Universities or Hospitals, etc.) in Greece or abroad.*
3. *The limit applicable in Greece also applies to foreign HCPs attending/participating in a scientific event held in Greece (host country principle).*
4. *In cases where the relevant limits applying in the country where the event takes place are lower than the above, the stricter limits apply (host country principle). In cases where the relevant limits of the country where the event takes place are higher than the above, the SFEE/EOF Circular limits apply.*

E. DAILY LIMITS ON ACCOMMODATION[1] (FOR PARTICIPATION IN HCO- AND PC[2]-ORGANISED SCIENTIFIC EVENTS)

	EOF	SFEE
IN GREECE[3]	≤ €270 (incl. VAT)	≤ €150 (incl. VAT)
IN GREECE ATHENS METROPOLITAN AREA[28] AND THESSALONIKI METROPOLITAN AREA[29]	≤ €270 (incl. VAT)	≤ €180 (incl. VAT)
ABROAD[4]	≤ €400 (incl. VAT)	≤ €400 (incl. VAT)

Clarifications:

1. *IMPORTANT NOTE: SFEE's limits are in certain cases stricter than the limits specified in the EOF Circular.*
2. *Companies of products within EOF's remit may not submit requests to organise scientific events abroad or to co-organize scientific events jointly with other entities (government organizations, non-profit scientific bodies, private Universities or Hospitals, etc.) in Greece or abroad.*
3. *The limit applicable in Greece also applies to foreign HCPs attending/participating in a scientific event held in Greece.*
4. *In cases where the relevant limits applying in the country where the event takes place are lower than the above, the stricter limits apply. In cases where the relevant limits of the country where the event takes place are higher than the above, the SFEE Code limits apply.*

28 https://en.wikipedia.org/wiki/Athens_metropolitan_area Includes 40 municipalities.

29 https://en.wikipedia.org/wiki/Thessaloniki_metropolitan_area Includes 11 municipalities.

2. MAXIMUM LIMIT OF PC SPONSORSHIP FOR HCP IN-PERSON[30] PARTICIPATION IN SCIENTIFIC EVENTS

A. PER SPONSOR PC:

Organised by entities based in:

GREECE	**UNLIMITED -20% Interns**
EUROPE	**≤ 10 HCPS/EVENT - 20% Interns**
REST OF THE WORLD	**≤ 5 HCPS/EVENT - 20% Interns**

B. PER HCP/YEAR:

IN GREECE	**≤4**
ABROAD**	**≤3**

C. SPONSORSHIP AMOUNT PER PC/HCP/CALENDAR YEAR:

IN GREECE HOSTED BY HCOs+HOSPITALS	**≤2**
IN GREECE PCs (former Type B)	**≤2**
ABROAD	**≤2**
WEBINARS in Greece + abroad	**Unlimited**
DOCUMENTED ACTIVE PARTICIPATIONS	**Unlimited**

D. SATELLITE SYMPOSIA/LECTURES

In the context of a scientific event, each HCP may participate as remunerated speaker or chair at meetings in up to three (3) satellite symposia or satellite lectures.

***Retired HCPs may not be sponsored by PCs for their participation in scientific events held abroad, unless they have provably active participation in these events.*

30 Virtual participation in events taking place abroad is subject to guidelines issued by EOF as applicable at the time of event.

3. MAXIMUM LIMITS ON THE ORGANISATION OF, AND ON HCP PARTICIPATIONS IN, ADVISORY BOARDS/CALENDAR YEAR

NUMBER/PC/YEAR IN GREECE	Up to **5/PHARMACOLOGICAL CATEGORY** (ATC3 level) and **20 MAXIMUM/YEAR** (in-person or virtual)
NUMBER OF ADVISORY BOARD PARTICIPANTS	Up to **10**
PARTICIPATIONS/HCP	**IN GREECE:** Up to **2/YEAR/PC**
	ABROAD: UNLIMITED

- *IF THE APPLICABLE LIMITS ARE LOWERED BY THE COMPETENT REGULATORY AUTHORITY, ANNEX I WILL BE AMENDED/UPDATED ACCORDINGLY BY DECISION OF THE SFEE BOARD OF DIRECTORS.*

- *IF THE APPLICABLE LIMITS ARE ABOLISHED BY THE COMPETENT REGULATORY AUTHORITY, THEY WILL REMAIN IN PLACE UNTIL THE NEXT SFEE GENERAL ASSEMBLY MEETING.*

ANNEX II*

CALCULATION OF HCP FEES

Below are instructions regarding the indicative limits on fees that are recommended to be paid by PCs to HCPs, as the latter are defined in this SFEE Code of Conduct, for services provided to PCs, having due regard to the relevant European standards, Ministerial Decision no. 72944 (Government Gazette B 1958/12.08.2013), Article 36 of Law 4272/2014, the provisions of Law 4009/2011, as currently in force, and the relevant decisions of the Athens University Senate (Government Gazette B 826/1996 and B 2163/2012):

Indicative calculation of HCP fees for services provided to PCs, depending on status/rank:

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

1. International experience: (meeting at least 3 of the following criteria)

- Chair at 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 member of the steering committee and/or principal investigator (PI) 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.
- Chair or member of the Board of Directors of an international scientific organisation/ society in the last 3 years.

2. Experience at national level: (meeting at least 3 of the following criteria)

- Chair at scientific events in Pan-Hellenic conferences (as the latter are defined in the relevant EOF Circular), held in the last 3 years (excluding satellite symposia)
- Speaker at Pan-Hellenic conferences (as the latter are defined in the relevant EOF Vircular), held in the last 3 years (excluding satellite symposia)
- 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 chair or member of the Board of Directors of national scientific organisations/ societies.

3. Experience and other expertise: (meeting 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 elsewhere classified.

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

Hourly Fees

- Hourly fees paid to a HCP for services provided to a PC must not exceed the following levels that reflect the fair market value of the services:

A. For HCPs with international experience and for services provided in-person outside Europe: up to €375* (subject to a total cap per service of: 8 hours X €375 = €3,000*);**

B. For HCPs with international experience and for services provided in Greece and within Europe: up to €190* (subject to a total cap per service of: 8 hours X €190 = €1,520*);**

C. For HCPs with experience at national level: up to €170* (subject to a total cap per service of: 8 hours X €170 = €1,360*);

E. Experienced and other experts: up to €130* (subject to a total cap per service of: 8 hours X €130 = €1,040*);

F. For Scientists/ HCPs: up to €100 (subject to a total cap per service of: 8 hours X € 100 = €800*).

* HOURLY FEES INCLUDE TRAVEL TIME, WHICH IS NOT SPECIFICALLY COMPENSATED. The amounts of hourly fees do not include any withholding in favour of ELKE/ELKEA or VAT. Such withholding charges are calculated on top of the fee amounts indicated above.

**** EXCEPTIONS:**

It is explicitly clarified that any amounts concerning remuneration for the conduct of clinical trials are not included in the above limits.

- Services provided by HCPs include:
  - – Speeches at scientific events, conferences, symposia.
  - – Consultancy, participation in Advisory Boards
  - – Staff training seminars
  - – Development of educational materials and/or presentations for educational purposes
  - – Services such as writing protocols, literature reviews, other services that require significant presence and/or preparation time, if documented, are calculated taking into account the HCP's experience and the hourly compensation, as described above, while they are excluded from the limits on preparation hours (see below) and on total time of employment (see hourly compensation).
  - – Excluded: HCPs services related to legal cases are excluded from the present method of calculation of fees, as they do not fall within the scope of this Code.
- The preparation time for coordination of a domestic event, speech, staff training or participation in Advisory Boards are determined based on the content, scope and duration of the service and may not exceed four (4) hours. In the 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 two (2) hours.
- The presence time is determined according to the scientific programme of the event, based on the total time of presence in the conference/event, rather than solely on the speaking time, thus providing for the time needed for the speaker to make additional comments or answer questions until the end of the session.
- The total recommended fee per HCP per calendar year may not exceed €5,000 for services provided in Greece and/or within Europe (cumulatively), excluding VAT and other withholding charges (see Article 9.7.(i)), except for HCPs with international experience where the HCP providing services in-person outside Europe, in which case the maximum recommended fee per HCP per calendar year is seven thousand euros (€7,000) for services provided in Greece and within Europe and in presence out of Europe (cumulatıvely), excluding VAT and other withholding charges (see NEW Table in Annex II).
- The abovementioned fee limits are indicative and represent SFEE members' common understanding of what can be a fair and reasonable fee to HCPs for the services described herein. SFEE members are recommended to observe these limits for the reasons stated in Article 2 of this Code.

Fair market value remuneration*
According to the common understanding of SFEE members, the fair and reasonable value of fees for services provided by HCPs to PCs are shown in the table below

	Experience of HCP and hourly fee	Maximum limit on fee# per service and per PC (maximum duration per service: 8 hours)§	Maximum limit on fee# per calendar year and per PC for services§ (cumulatively, services in Greece + Europe + in-person outside Greece, as applicable)
A.	International experience, only in person/services outside Europe (hourly fee – up to €375)	Up to €3,000 (8hr x €375)	Up to €7,000
B.	International experience/ services in Greece and/or within Europe (hourly fee – up to €190)	Up to €1,520 (8hr x €190)	Up to €5,000
C.	Experience at national level/services within and outside Greece (hourly compensation – up to €170)	Up to €1,360 (8hr x €170)	Up to €5,000
D.	Experienced and Experts/ services within and outside Greece (hourly fee – up to €130)	Up to €1,040 (8hr x €130)	Up to €5,000
E.	Scientists/HCP/services within and outside Greece (hourly fee –up to €100)	Up to €800 (8hr x €100)	Up to €5,000

* It is expressly stated that the above table only shows a methodology for analogous calculations of a fair and reasonable fee.

HOURLY FEEs ALSO COVER TRAVEL TIME, WHICH IS NOT SPECIFICALLY COMPENSATED. The above amounts do not include VAT and other withholding charges.

§ Services such as writing protocols, literature reviews, other services that require significant presence and/or preparation time, provided that they are documented, are calculated taking into account the experience and hourly compensation as described in this guidance, while they are excluded from the limits on preparation hours and total employment time. HCP services related to legal cases are excluded from this method of calculating fees, as they do not fall within the scope of this Code. With regard to the remuneration of HCPs for their participation in market research, the provisions of Article 14 of this Code apply. Finally, amounts relating to remuneration for the conduct of clinical studies do not count towards the above limits.

ANNEX III

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 PC, with a description of the design, targets and time schedules.
- Recording of the details of research centres and of envisaged fees
- Recording of the number of participating patients
- Each trial is posted by the sponsor PC/SFEE member using a unique identifier for each sponsor and trial, enabling follow-up
- Posting of the relevant details and approvals of the Scientific Board of non-interventional trials, as well as the results of trials when concluded
- A relevant manual by the SFEE's Medical Directors Committee will be available as soon as the online registry is posted and becomes operative.

2. Statistical design of Non-Interventional Trials

- Based on the primary objective 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 envisaged in EU guidelines and the EMA algorithm, Annex 1, March 2011, must be followed.
- 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 objective and according to a robust sampling methodology.

4. Remuneration in the context of Non-Interventional Trials

- Fair market value. Hourly fees for researchers are calculated within a reasonable range of fees that would be charged by a private practitioner, depending on his/her specialty and therapeutic field.

	Indicative rates
Gross remuneration of a researcher per hour	**€50 – 90**
Gross remuneration of a study coordinator per hour	**€20 – 40**
Training on online CRF (one-off)	**€190 – 290**
Preparation and review of files (one-off)	**€270 – 430**

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

	Non-interventional studies involving medicinal product administration	Non-interventional studies not involving medicinal product administration – Epidemiological studies	Market research among HCPs	Clinical Trials
Collection of patients' personal data	Yes	Yes	All data from HCPs concerning patients are collected and delivered fully anonymized 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

	Non-interventional studies involving medicinal product administration	Non-interventional studies not involving medicinal product administration – Epidemiological studies	Market research among HCPs	Clinical Trials
Selection of patients	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
Patients are randomised in treatments	No	No	No	Usually
Retrospective/ prospective	Retrospective or prospective	Retrospective or prospective	Snapshot – synchronic	Prospective
Requires supervision	Possibly – depending on the design	Possibly – depending on the design	No	Yes
Requires approval from the National Organisation for Medicinal products (EOF)	No (apart from exceptions, see Article 16.3)	No	No	Yes
Requires approval from the Ethics Committee/ Scientific Committee	Yes	Yes	No	Yes

	Non-interventional studies involving medicinal product administration	Non-interventional studies not involving medicinal product administration – Epidemiological studies	Market research among HCPs	Clinical Trials
Requires written consent of patient	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
Adverse effects may be monitored	Yes	N/A - they do not involve any medicinal product. The HCPs report any adverse effects	The HCPs report any adverse effects Special care should be taken by the Pharmaceutical Company	Yes
Comparison with competitive medicinal products is allowed	Yes, but with reduced reliability due to increased risk of systematic errors (bias)	N/A - they do not involve any medicinal product.	No	Yes
The main features are published before commencement	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/

	Non-interventional studies involving medicinal product administration	Non-interventional studies not involving medicinal product administration – Epidemiological studies	Market research among HCPs	Clinical Trials
Results may be published	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
Participation of medical sales representatives in the conduct	Only in a supportive role, under the supervision of the Company's Scientific Department and without being related to any form of promotion	Only in 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 [NEW ADDITION FROM THE EFPIA CODE]

Aggregate disclosure of Transfers of Value to HCPs and HCOs relating to non-interventional studies (NIS) is limited to NIS that are prospective in nature. By contrast, Transfers of Value to HCPs and HCOs in the contest 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, Transfers of Value are disclosed on an aggregate basis.

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

Prospective and retrospective non-interventional studies are distinguished as follows:

PROSPECTIVE NIS	RETROSPECTIVE NIS
▪ Prospective cohort studies in which the prescription of medicinal products is done independently of the patient's inclusion in the study. ▪ Prospective studies which also have a retrospective section. ▪ 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.	▪ Review and/or research of data deriving purely from an observation database. ▪ Retrospective review of files where all events of interest have already taken place. e.g. case - control, and purely retrospective cohort studies ▪ 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

PCs 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	Donations & Grants to HCOs	Contribution to the cost of events			Fees for service and consultancy		TOTAL
							Sponsorship agreements with HCOs/ third parties appointed by HCOs to organise the event	Registration Fee	Travel Accommodation Expenses	Fees	Relevant expenses stipulated as part of the fee payable for the services or in the consultancy agreement, including travel and accommodation relevant to the agreement	
INDIVIDUAL	HCP	*INDIVIDUAL DISCLOSURE- one line per HCP, i.e. all payments made during the year to a HCP will be summed up (a detailed recording of each payment must be available to each Recipient or to the public authorities, where necessary)*										
		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*	
		OTHER AMOUNTS NOT INCLUDED ABOVE - if the information may not be disclosed for legal reasons										
		Total amount of Transfers of Value to HCPs				N/A	N/A	*HCO aggregate*	*HCO aggregate*	*HCO aggregate*	*HCO aggregate*	*Optional*
		Number of Recipients included in the aggregate disclosure				N/A	N/A	*number*	*number*	*number*	*number*	*Optional*
		Percentage of the number of Recipients included in the aggregate disclosure over the total number of Recipients disclosed				N/A	N/A	%	%	%	%	N/A
	HCO	*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)*										
		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*
		OTHER AMOUNTS NOT INCLUDED ABOVE - if the information cannot be disclosed for legal reasons										
		Total Transfers of Value to HCOs				*HCO aggregate*	*HCO aggregate*	*HCO aggregate*	*HCO aggregate*	*HCO aggregate*	*HCO aggregate*	*Optional*
		Number of Recipients included in the aggregate disclosure				*number*	*number*	*number*	*number*	*number*	*number*	*Optional*
		Percentage of the number of Recipients included in the aggregate disclosure over the total number of Recipients disclosed				%	%	%	%	%	%	N/A

RESEARCH & DEVELOPMENT	*AGGREGATE DISCLOSURE (RESEARCH & DEVELOPMENT TRANSFERS OF VALUE)*	
	RESEARCH & DEVELOPMENT TRANSFERS OF VALUE	TOTAL AMOUNT

Non-Binding Template for the Disclosure of Transfers of Value to Patient Organisations (POs)						
Registered name	**Registered address**	**Kind of support or services**	**Description of the Support or Services[1]**	**Monetary value of financial support and of invoiced charges**	**Non-monetary Support to POs[2]**	**Fee for services provided**
		Financial support		In euro		
		Significant indirect support		In euro		
		Non-financial support			In euro	
		Provision of services				In euro

1. Please insert a clear description of the purpose of the support or services.

2. For example, PC staff work hours or use of PC facilities to support a PO activit

ΣfEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

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