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NEW

SFEE CODE OF ETHICS

SFEE CODE OF ETHICS

(FOR THE)

PROMOTION OF PERSCRIPTION ONLY MEDICINAL PRODUCTS

+

DISCLOSURE OF ToVs to HCPs & HCOs

+

NEW

INTERACTIONS WITH POs

NEW CHAPTERS-ARTICLES LAY OUT

FOLLOWING EFPIA'S CODE LAY OUT

DEFINITIONS
ETHICAL PRINCIPLES
PREAMBLE
SCOPE

CHAPTER 1 PROMOTION OF PRESCRIPTION ONLY MEDICINES TO HCPs
CHAPTER 2 INTERACTIONS WITH HCPs, HCOs & POs
CHAPTER 3 SPECIFIC INTERACTIONS WITH HCPs & HCOs AND OTHER PROVISIONS
CHAPTER 4 PROVISIONS ON INTERACTIONS WITH POs
CHAPTER 5 DISCLOSURE OF ToVs to HCPs & HCOs
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ANNEXES
ANNEX I. LIMITS
ANNEX II. INDICATIVE FAIR MARKET VALUE FOR HCP FEES
ANNEX III. REGISTRY OF NON-INTERVENTIONAL STUDIES
ANNEX IV. DISCLOSURE TEMPLATE

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AMENDMENTS PER CHAPTER
DEFINITIONS

A. HARMONIZATION WITH EFPIA CODE DEFINITIONS

- ✓ *«Donation»:* **Amended – exact translation of EFPIA's Code definition**
- ✓ *«Patient Organization Representative Εκπρόσωπος»: a person who is mandated to represent and express the collective views of a PO on a specific disease area.* ***NEW*** – Exact translation of EFPIA's CODE definition
- ✓ *« Healthcare Professional(HCP)»:* ***Amended***: The HCP definition was not the same in (previous) Chapter A and Chapter B. Broader definition chosen with the EXCEPTION of Chapter 1 (Promotion of prescription only medicines to HCPs) where HCP's definition is narrower and pursuant to the provisions of the CMD ΔΥΓ3α Γ.Π. 32221/2013 and includes HCPs who have a legal right to prescribe. (Exception was added further to EFPIA's Code Committee relevant recommendation)

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AMENDMENTS PER CHAPTER

B. SFEE's CODE OF ETHICS & TRANSAPRENCY COMMITTEE SUGGESTIONS

- ✓ *«Scientific Events»:* Amended-Updated.
- ✓ *Scientific Information/Promotion»*: **Introduction of Definition.**
- ✓ *«Medical Sales Representative»: the person delegated by a Member Company to promote its medicinal products to HCPs and HCOs (by in person visits or any other way), according to the approved prescription information.*
- ✓ *« Pharmaceutical Company/ies».*– SFEE Member Companies and any other non-SfEE members pharmaceutical companies adhering to this Code.
- ✓ *«SFEE»* : The Hellenic Association of Pharmaceutical Companies
- ✓ *«EFPIA»*: European Federation of Pharmaceutical Industries and Associations

+ Definitions from Chapter 5 (Disclosure).

OUR OVERARCHING ETHICAL PRINCIPLES

PATIENTS FIRST

We aspire to ensure that everything we do will ultimately benefit patients.
Our primary contribution to society is to make high quality Medicinal Products and to encourage their appropriate and rational use in the care pathway.

INTEGRITY

- All interactions take place in a responsible manner and aim to ensure that our communications with stakeholders are accurate, legitimate and balanced.
- We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.

RESPECT

- Interactions take place in an open manner, with a responsive, constructive and learning attitude and mutual respect.
- We value the importance of independent decision-making by stakeholders, based on evidence and including patient interest.
- With respect to society, we listen to what is expected from us and adapt our way of working accordingly.
- We follow applicable laws and make ethical judgements when processing Personal Health Data.

TRANSPARENCY

We are committed to ensure that transparency is respected.
We are open about our activities and interactions and encourage stakeholders to act with the same openness

CHAPTER 1 PROMOTION OF PERSCRIPTION-ONLY MEDICINAL PRODUCTS TO HCPs

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

ADDITION of examples of defamation

Examples of such activities may include inaccurate information, excessive hospitality, provision of motives to prescribe, influence to State agents and officials, inappropriate payments, promotion of pharmaceutical products prior to the official marketing authorization granting, inappropriate behavior of employees/ executives of Member Companies and multiple/cumulative infringements of such type in the same therapeutic category within a short period of time.

ARTICLE 3 PROMOTIONAL-SCIENTIFIC INFORMATION MATERIAL NEW ARGTICLE /TITLE - CODIFICATION OF SCATTERED PROVISIONS IN THE PREVIOUS EDITION. **NEW ADDITIONS:**

3.9. Pharmacoeconomic Studies: *The use of pharmacoeconomic studies in promotional material must be limited and is permitted under specified conditions.*

3.11.5. Posters: reference of only the name and the international name of the medicinal product. Otherwise, a statement to *consult the, available in the promotional booth, SPC before prescribing,* should be included.

ARTICLE 4. INTERNET– DIGITAL APPLICATIONS (old art. 27) UPDATED (due to the amendment of relevant regulatory framework/procedures by EOF)+HARMONISATION WITH EFPIA PRINCIPLES FOR THE USE OF DIGITAL CHANNELS

ARTICLE 5 PROMOTION ADDRESSED TO THE PUBLIC

(OLD ART. 20) ENHACEMENT OF THE CONTECT OF THE PROVISION WITH THE INCLUSION OF EXEMPTION WITH REGARD TO VACCINATION CAMPAINGS

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CHAPTER 2
INTERACTIONS WITH HCPs, HCOs & POs

ARTICLE 6 TYPES OF SCIENTIFIC EVENTS (old 17.3.)

NEW TYPE «Scientific Events organized by Public Hospitals, University Clinics, laboratories, ESY clinics and private clinics/hospitals - (from EOF's Circular)

NEW TYPE «*Hybrid +Web/Virtual-Scientific Events & Webinars*»

"Hybrid": Scientific Events with "face2face" attendance of some participants and live streaming in parallel

"Web/Virtual-Scientific Events": Scientific events held only virtually –categorized as the respective scientific events with "in person" attendance, based on their duration-same applicable limits with the EXEMPTION of sponsorship limits and registration cost.

"Webinars": Scientific events held only virtually with maximum duration of 3h

MEMBER COMPANIES SCIENTIFIC EVENTS:

- DISTINCTION BETWEEN PROMOTIONAL AND NON-PROMOTIONAL SCIENTIFIC EVENTS ORGANISED BY MEMBER COMPANIES
- **Satellite symposia, meet the experts sessions**: They don't provide CME credits- Reference to brand names of medicinal products is not allowed- Total duration/scientific event shall not supersede 20% of the total duration of the scientific program.
- Member Companies may not organize satellite symposia and/or meet the expert sessions within the framework of an HCO's webinar.

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ARTICLE 7 PROVISIONS WITH REGARD TO THE ORGANISATION AND SPONSORSHIP OF SCIENTIFIC EVENTS HELD IN GREECE AND ABROAD (OLD ART 18 & PART OF ART. 19)

Member-Companies must not support Sc. Events taking place **during long w/e** (public holidays before or after w/e)

* No Member Company may require that it be the sole funder or sponsor of a PO or HCO or any of its programmes.

* EVALUATION OF INTERNATIONAL SCIENTIFIC EVENTS HELD IN GREECE by SFEE's SCIENTIFIC EVENT EVALUATING COMMITTEE

* CHANGE OF COLORS IN EVALUATION – harmonization with EFPIA's e4ethics platform

GREEN: In full compliance with the Code's provisions

ORANGE: Infringes one or more of the Code's provisions

BLUE: Missing elements, cannot be evaluated

YELLOW: Outside the scope/competence of SFEE's Scientific Events Evaluating Committee

PURPLE: Member-Companies may participate at their own responsibility

ARTICLE 8 PROVISIONS WITH REGARD TO THE SUPPORT OF THE HCPs' PARTICIPATION TO SCIENTIFIC EVENTS HELD IN GREECE AND ABROAD (OLD ART. 19)

-

BUSINESS MEALS (taking place outside the context of Scientific Events): REDUCTION OF COST/HCP:
(From 70Euro ⇨ 50 Euro)

ARTICLE 10 PROHIBITION OF GIFTS (to HCPs, member of HCOs and PO Representatives)

NEW ADDITION - HARMONIZATION WITH EFPIA CODE

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

10.3. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the Recipient.

10.4. A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Article3). Providing or offering them to HCPs, HCOs'members or POs' Representatives in relation to the promotion of POM is prohibited.

ARTICLE 11 DONATIONS

REMOVAL OF OBLIGATION OF DONATIONS DISCLOSURE at SFEE's WWEBSITE as:

a) all donations to HCOs are disclosed by virtue of chapter 5 (disclosure) and
b) art. 29 (exact translation of art. 24 of EFPIA code) provides for the disclosure of support and services to POs

ARTICLE 12 FEES FOR SERVICE AND USE OF HCOs' (OLD ART. 21+NEW ADDITION)

The public use of an HCO or PO ś logo and/or proprietary material by a Member Company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

CHAPTER 3
SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HCPs & HCOs AND OTHER PROVISIONS

ARTICLE 13 PATIENTS SUPPORT PROGRAMS NEW ADDITIONS:

13.1.2. *Healthcare provider companies implementing PSPs may provide to patients digital applications financed by Member Companies, which are classified as medical devices of Class I, according to the Classification Rules of the European Legislation for Medical Devices, which function as a treatment reminder, provide access to educational material for their disease and informational material to HCPs with regard to the above. In case such digital applications are included at a Member-Company's web site, Member Companies should ensure that they don't have access to patients' personal data.*

13.1.5. DELETED: *"The systematic performance of medical/ nursery actions, pursuant to the implementation of the patient's treatment, including the medicines' allowance at home, is not allowed under the scope of this present provision."*

13.1.9. *Member Companies financing a PSP may communicate the existence and scope of the PSP to HCPs. Any further information with regard to the Program shall be communicated to the patients through the healthcare provider.*

13.2.8. *Member companies are advised to include in their agreements with the healthcare providers a provision regulating the" fate" of patients' personal data in case of termination of the Program or incase of replacement of the healthcare provider as, especially in the latter case, it is important, for the benefit of the patients that any personal data have already been collected, continue to be available for use by the successor healthcare provider.*

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CHAPTER 3

ARTICLE 14. MARKET RESEARCH (Old Art. 24)

NEW ADDITIONS:

14.5. *b) In case a Member Company and the Market Research Company are considered for the purposes of a market research are considered "joined controllers", they should define in a transparent manner their respective responsibilities for compliance with their obligation under the relevant legislation in force and the responsibilities of each party shall be communicated to the participants in the market research.*

c) In order to ensure impartiality and objectivity of the market research, in case according to the applicable legislation with regard to the protection of personal data, the participants of the market research shall be informed on the name of the pharmaceutical company that is a joint controller, the participants shall be so informed after the market research is concluded and all answers of the participants have been received and only if the participant has expressed his/her interest to be informed about the pharmaceutical company's name.

14.7. **DELETED:** *"Market research does not include any patient enrolment and/or randomization."*

ADDED: *"Member Companies are not allowed to keep records with patients' names".*

CHAPTER 3

ARTICLE 19 MEDICAL/SCIENTIFIC DEPARTMENT & SCIENTIFIC DEPARTMENT RESPONSIBLE FOR MEDICAL INFORMATION (OLD ART. 15 SCIENTIFIC SERVICE RESPONSIBLE FOR INFORMATION)

NEW ADDITION Member Companies Medical Department Presentations in Hospitals

19.1.10. *Tthe Medical/Scientific Department of Member Companies may organize presentations of scientific content, about medicinal products, in Hospitals, following a substantiated request of the Head/Director of the Hospital. Such presentations do not fall under the definition of scientific events, as defined by EOF. Member companies must not offer coffee/snack/soft drinks etc. inside the hospital. Member companies shall abide by the Hospital's Rules and Procedures and relevant legislation.*

ARTICLE 20 MEDICAL SALES REPRESENTATIVES (OLD Art. 12)

Group Detailing: (OLD 17.3. D.)

NEW ADDITION

- GD may take place either in person or virtually

- b) GD with public sector HCPs :

1. Shall concern medicinal products

2. Only HCPs of the Hospital may participate

3. Shall be held within the Hospital

4. The Speaker/Presenter shall be an internal Medical Sales Representative of the Member Company

5. The Head/Director of the Hospital approval is necessary (not EOF's).

6. Member companies must not offer coffee/snack/soft drinks etc. inside the hospital.

CHAPTER 4
SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs
(OLD CODE OF PRACTICE ON THE RELATIONSHIP BETWEEN PHARMACEUTICAL COMPANIES AND PATIENT ORGANISATIONS

ARTICLE 21 GENEREAL PRINCIPLES NEW ADDITION– (EXACT TRANSLATION FROM EFPIA CODE OF ETHICS)

ARTICLES 22 – 29 (OLD ART. 1-8 of POs CODE)

NEW ADDITION

FAIR MARKET VALUE FOR PO REPRESENTATIVE FEES: 70 €/hour

MAXIMUM FEES/SERVICE: 560€

PAYMENT OF THE FEES SHALL BE MADE TO THE PO

* MEMBER COMPANIES SHALL PROVIDE HOSPITALITY TO PO REPRESENTATIVES (NOT JUST MEMBERS OF POs)- HARMONIZATION WITH EFPIA CODE OF ETHICS

CHAPTER 5
DISCLOSURE OF ToVs TO HCPs AND HCOs

- REMOVAL OF PREAMBLE – NOT NECESSARY IN VIEW OF THE RELEVANT LEGAL PROVISION

ARTICLE 32. INDIVIDUAL AND AGGREGATE DISLOSURE (OLD ART. 3 CHAPT. B)

- INTRODUCTION OF A CLAUSE PROVIDING FOR AGGREGATE DISLOSURE FOR ToVs THAT SHOULD BE DISCLOSED ON AN INDIVIDUAL BASIS, WHEN SUCH DISCLOSURE (ON AN INDIVIDUAL BASIS) IS NOT POSSIBLE FOR LEGAL REASONS

- DISCLOSURE OF PROSPECTIVE AND RETROSPECTIVE NON-INTERVENTIONAL STUDIES

CHAPTER 6
ENFORCEMENT

- Amendment of Composition of the 2nd Instance Committee – Same Composition with the 1st Instance Committee (Members and alternates of the 1st Instance Committee may not be members of the 2nd Instance Committee.)
- Term of Office: 3 years with possibility of renewal by virtue of a BoD decision (same amendment on the 1st Instance Committee)
- Right to Refer to 2nd Instance Committee only the Member Company to which sanction have been imposed by the 1nd Instance Committee.
- 2nd Instance Committee may not impose stricter sanctions than the ones imposed by the 1st Instance Committee

ANNEXES

ANNEX I: LIMITS (SPONSORSHIPS etc.)

NEW

* In case of reduction of limits by the EOF : Annex Update by virtue of a BoD decision
* In case of abolition of limits by EOF – limits remain as is prior to their abolition until next GA

REDUCTION OF SPONSORSHIP LIMITS ON SCIENTIFIC EVENTS:

1. INTERNATIONAL SC. EVENTS HELD IN GREECE:

Organized by Greek HCO : 20.000 € (from 30.000 €)

Organized by foreign HCO or jointly with Greek HCOs : 30.000 € (not amended)

2. NATIONAL : 20.000 € (from 30.000 €)

3. REGIONAL : 10.000 € (from 15.000 €)

SPONSORSHIP & REGITRATION COST LIMITS ON WEB/VIRTUAL SCIENTIFIC EVENTS/CONGRESSES:

A. SPONSORSHIP LIMIT/MEMBER-COMPANY: Web/virtual scientific events/congresses with same duration as;

- National: 10.000 €
- Regional: 5.000 €
- Local : 2.500 € and
- Web/virtual sc. Events organized by hospital etc.: 1.500 €
- WEBINARS (up to 3 h): 1.000 € & Member Companies may not cover registration costs may not

B. REGISTRATION COST SUPPORT LIMITS: 50 € for respective web/virtual sc. Events (of same duration) with National f2f Sc. Events. Member Companies may not support registration costs to web/virtual sc. events of a shorter duration.

ANNEX II: Indicative calculation of HCP fees for services provided to Member Companies
(Old Annex. I)

Amendment/Raise of fees for experienced at International level HCPs in case of:

1. Active participation to World Congresses (International Scientific Events held outside Europe) and for services provided in countries outside Europe

- Maximum possible Fee/Service up to 3.000 € -instead of 1.520 €- (VAT and other taxes excluded)
- Maximum possible Fee/Year up to 7.000 € -instead of 5.000 €- (VAT and other taxes excluded)

ANNEX III:REGISTRY OF NON-INTERVENTIONAL STUDIES
ON-LINE REGISTRY OF NON-INTERVENTIONAL TRIALS POSTED ON SFEE WEBSITE

NEW ADDITION (FROM EFPIA CODE OF ETHICS) Disclosure of Prospective and Retrospective International Studies

ANNEX IV: DISCLOSURE TEMPLATE

NEW ADDITION (FROM EFPIA CODE OF ETHICS)

- For ToVs TO HCPs and HCOs
- For ToVs to Pos (non-binding)


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