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LIFE SCIENCES & HEALTHCARE PRACTICE

Final Version of SFEE's Code of Ethics

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Underlined references indicate amendments.

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Very recently, the Hellenic Association of Pharmaceutical Companies ("SFEE") published on its website the new, updated, version of the SFEE's Code of Ethics, entering into force from **01.08.2020**[1]. This industry self-regulation Code incorporates the provisions and the format of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice 2019 as well as circulars of the National Organization for Medicines (EOF), regarding the Promotion of Medicinal Products to HCPs and the interactions with Healthcare Professionals ("HCPs"), Healthcare Organisations ("HCOs"), and Patient Organizations ("POs"), on the basis of ethical rules and the principles of professional responsibility and transparency. More specifically, the new version of the SFEE's Code of Ethics:

1) Covers, inter alia, the promotion of prescription-only medicinal products and the disclosure of transfers of value by pharmaceutical companies to HCPs and HCOs, but also the relationship between pharmaceutical companies and POs.

2) Amends the definition of HCPs in order to include every HCP in Greece as defined by law, namely even those HCPs not authorized to prescribe medicinal products. It should be noted, however, that in the chapter for promotion of prescription-only medicines, the definition of HCPs remains as narrow as the definition provided in the MD DYG3a G.P. 3221/2013 and the previous version of the SFEE's Code of Ethics, including only the members of the medical, dental, pharmaceutical or nursing professions, as well as any other person authorized to prescribe, supply or administer medicinal products.

3) Exemplifies instances of "discredit to and reduction of confidence in the industry".

4) Incorporates the ethical principles of the EFPIA Code of Practice.

5) Includes posters as promotional materials for the promotion of prescribing medicinal product to HCPs.

6) Introduces new categories of scientific events, namely:
   a) Scientific events organized by State Hospitals, University Clinics,

[1] With the exception of the new maximum financing amounts for web / virtual scientific events (see below).

laboratories, NHS clinics, Private Hospitals and Clinics.

b) Hybrid Scientific Events.
c) Virtual/ Web Scientific Events/Congresses.
d) Webinars.

7. Clarifies that scientific events, such as satellite symposiums and/or "meet the expert sessions", organized by HCOs in the context of conferences in Greece, are classified as non-promotional scientific events organized by the Medical-Scientific Department of pharmaceutical companies.

8. Establishes another restriction to the support of scientific events during festive days (holidays preceding or following weekends).

9. Prohibits pharmaceutical companies from requesting to be the sole sponsor of HCOs, or any of their activities.

10. Changes the events pre-assessment colour codes in accordance with the colors on the EFPIA e4ethics platform.

11. Clarifies that the provisions regarding the participation of HCPs, practicing in University Clinics/NHS clinics, in Advisory Boards are also applicable to military HCPs, with the exception of the payment method.

12. Introduces a new article on the prohibition of gifts in compliance with the EPFIA Code of Practice.

13. Establishes pharmaceutical companies' obligation to submit a request to the HCO in order to use of the HCO's logo or the material of exclusive use of the HCO.

14. Foresees the possibility to supply patients participating in Patient Education and Support Programs with Class I medical devices / digital apps that remind them to receive their treatment and enable them to monitor their symptoms, access educational materials for their disease and treatment as well as to inform their treating physician in relation to the above.

15. Furthermore, the prohibition of systematic performance of medical/ nursery actions, pursuant to the implementation of the patient's treatment, including the medicines' allowance at home, is removed.

16. Allows pharmaceutical companies sponsoring Patient Education and Support Programs to communicate the existence and the purpose of those programs to HCPs. However, any other information shall be provided exclusively by Health Services' companies.

17. Recommends that the agreements between pharmaceutical companies and Health Services' companies for the conduct of Patient Education and Support Programs shall include data protection clauses.

18. Introduces additional provisions in relation to data protection in Market Researches. In particular, (a) in case both pharmaceutical companies and market research companies are data controllers, they shall distinguish their liabilities, (b) the participants will be informed about the identity of the pharmaceutical company, jointly responsible as data controller with the

market research company, after the completion of the market research and after the answers have been received from all participants, as long as they have declared to the market research company that they want to know the identity of the pharmaceutical company and (c) pharmaceutical companies are not entitled or authorized to have lists with patients' names.

19. Clarifies that presentations of scientific content on products organized by the Medical/Scientific Department of pharmaceutical companies in Hospitals' clinics, upon a documented request of the clinic's Director, are not considered scientific events. Pharmaceutical companies shall not offer coffee/ meals / soft drinks etc. inside the Hospital.

20. Establishes the conditions under which HCPs working in the public sector may participate to Group Detailing Meetings.

21. Incorporates the General Principles of the EFPIA Code of Practice in relation to the interaction between pharmaceutical companies and POs.

22. Establishes the amount of reasonable hourly compensation for the Patient Organisation Representative services up to 70 € and a maximum possible fee of 560€. The amount of compensation shall be deposited to the PO.

23. Foresees the possibility of aggregate disclosure of transfer of values in cases where, due to a legal impediment, individual disclosure is not possible.

24. Incorporates the provision of EFPIA Code of Practice, according to which aggregate disclosure applies only to prospective non-interventional studies; hence retrospective non-interventional studies are still disclosed on an individual basis.

25. Establishes new maximum financing amounts per pharmaceutical company for scientific events with physical presence organized by HCOs. More specifically, those maximum amounts shall not exceed:

(a) the amount of 30.000 € (VAT included) for International/ Worldwide Scientific Events that take place in Greece organized by foreign HCOs.

(b) the amount of 20.000 € (VAT included) for International/ Worldwide Scientific Events that take place in Greece jointly organized by foreign and Greek HCOs.

(c) the amount of 20.000 € (VAT included) for PanHellenic Scientific Events.

(d) the amount of 10.000 € (VAT included) for Regional Scientific Events.

26. Establishes the new maximum financing amounts per pharmaceutical company for web / virtual scientific events / congresses organized by HCOs, **applicable from 29.06.2020.** In particular those maximum amounts shall not exceed:

(a) the amount of 10.000 € (VAT included) for International/ Worldwide Scientific Events that take place in Greece organized by a foreign scientific institution/ association or co-organized with a

Greek scientific institution/ association and for PanHellenic Scientific Events.

(b) the amount of 5.000 € (VAT included) for Regional Scientific Events.

(c) the amount of 2.500 € (VAT included) for Local/One-day Scientific Events.

(d) the amount of 1.500 € (VAT included) for Scientific events held by State Hospitals, University Clinics, laboratories, NHS clinics, Private Hospitals and Clinics.

(e) the amount of 1.000 € (VAT included) for webinars (of up to 3 hours).

27. Determines new limits of hourly compensation of up to 3.000 € (excluding VAT & other withholdings) and total maximum possible fee of 7.000 € (excluding VAT & other withholdings) for HCPs experienced at international level, who participate actively in scientific events and provide services outside Europe.

In light of the above, it is apparent that the amendments and the additional provisions of the new SFEE's Code of Ethics respond to the need for clarifications on the interaction between Pharmaceutical Companies and HCPs, HCOs, and POs.

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