CODE OF PRACTICE

for the Promotion of Prescription only Medicinal Products

'08-'09

ΣfEE
HELLENIC ASSOCIATION
OF PHARMACEUTICAL COMPANIES

www.sfee.gr

01. Hellenic Association of Pharmaceutical Companies

The Hellenic Association of Pharmaceutical Companies was founded in 1982 and in 1983 it became a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the voice of the pharmaceutical industry in the European Union.

The vision and mission of SFEE are encompassed in the formation and support of cogent and well documented positions that contribute decisively to the enhancement of public health.

SFEE's vision is elaborated in five key positions:

- **Patients' direct access to new medicines and advanced treatments**
- **Ensuring the highest quality of medicines,** meaning that only branded medicines, branded original medicines and branded essentially similar medicines guarantee quality, safety and therapeutic efficacy.
- **The technological streamlining of the IT infrastructure of social insurance funds and hospitals** is the only effective way to completely and definitely eliminate overspending across the whole range of health expenditure.
- **The adherence** of those involved in the promotion of medicinal products to the Code of Practice.
- **The flawless operation of the Distribution Network** in order to ensure the adequate supply of medicinal products in the Greek market.

02. SFEE Code of Practice

In the framework of its activities, SFEE adopted the Code of Practice being aware of the importance of providing substantiated, fair and objective information regarding medicinal products leading to taking rational decisions regarding their use.

The SFEE Code of Practice **determines** the regulatory framework for the promotion of medicinal products based on professional responsibility, ethics and transparency.

The Code of Practice took effect in March 2002 and was last revised in March 2008 in order to be harmonized with EFPIA's respective Code of Practice.

Its implementation **aims** at ensuring that medicinal products are prescribed based on their benefits and the specific health needs of the patient.

03. To whom is addressed SFEE's Code of Practice & its Contents

SFEE's Code of Practice is addressed to **all pharmaceutical companies**, members of SFEE and **the broader scientific community of healthcare professionals**.

As far as its content is concerned, the Code of Practice includes two chapters and one annex.

- Chapter A includes **the key provisions of the Code**
- Chapter B covers the **Procedure for the control of its implementation**
- The Annex includes **guidelines for the contents of the member – companies' web sites**

- In general, the Code includes the principles and procedures that must be implemented for the promotion of prescription only medicinal products to healthcare professionals (doctors, pharmacists, nurses, etc.) as well as the information addressed to the public on healthcare issues.

04. Key provisions of the Code

Scientific Information addressed to healthcare professionals

Content of scientific information

Scientific information on medicinal products which is addressed to authorized prescribers or suppliers of medicinal products must include:

• Essential information corresponding to the summary of product characteristics (SmPC).
• The requirements for prescribing a medicinal product (e.g. a doctor's prescription only or without a doctor's prescription).

The information must:

- Be **accurate, balanced, fair, objective** and **complete**
- Be based on the evaluation of all the relevant findings available up to the present and to clearly reflect it.
- Be substantiated through the **relevant literature**
- **Encourage the rational use of medicinal products** by presenting them in an objective way and without overstating their benefits

The Information must NOT:

- Be **misleading, distorting** the truth, using **exaggerations**, unjustified emphasis, omission or by any other means

- Include claims that a medicinal product or an active ingredient has some particular value, quality or property, other than the one that may be substantiated by evidence.

Disguised promotion

The promotional material and activities should not be disguised. Clinical assessment, post – marketing surveillance, experience programs and post authorization studies must always be performed for a scientific or educational purpose.

Scientific or Medical Department

Pharmaceutical companies are obliged to have a scientific department responsible for providing information on the medicinal products they market, and responding to any question coming from sales representatives, patients or any other sources.

The Scientific Department should include a doctor, a pharmacist or any other healthcare professional

The scientific department approves any promotional material and ensures its compliance with the Code of Practice and applying legislation.

Sales representatives

Healthcare Professionals are informed by sales representatives who:

- **are adequately trained**
- **provide complete and clear information**
- **comply with the regulations of the area they visit.**
- **maintain high standards of ethical conduct.**

Donations and sponsorships Promotional Gifts

Personal gifts to healthcare professionals are not allowed, with the exception of :

- scientific publications and subscription to scientific reviews up to the amount of 500 Euros per physician.
- promotional gifts of negligible value of up to 20 Euros per item.

Donations to Hospital Institutions (Legal Entities of Public Law) are allowed in the form of:

- Sponsorships for independent Scientific and Research programs.
- Donations of scientific books, diagnostics and medical equipment contributing to the improvement of the patient's care.

All sponsorships or donations must be approved by the Hospital Managing Board.

Sponsorship of scientific congresses / events

- Pharmaceutical companies may sponsor the organization of scientific meetings and medical information events, planned and organized under the auspices of a scientific body and having obtained the EOF approval.

- Pharmaceutical companies may organize events aiming at promoting their medicinal products (under conditions concerning the venue, the duration of hospitality and the duration of the training program).

Participation of doctors to congresses

Aiming at upgrading the services that healthcare professionals provide to patients, pharmaceutical companies sponsor only the participation of healthcare professionals to scientific events organized in Greece or abroad.

Expenses covered are only limited to the registration, accommodation, and transportation to and from the meeting venue. No other expense is covered either in the framework of the meeting or otherwise.

The participation of all healthcare professionals is allowed to all events and meetings with the exception of University professors and National Health System (ESY) physicians to events organized aiming at promoting medicinal products.

Provision of expert advice or other similar services by Healthcare professionals to the Pharmaceutical Industry

Pharmaceutical companies may request physicians to provide expert advice or other similar services related directly to their specialty, without prejudice to the provisions applying for the NHS (ESY) physicians and University professors and without prejudice to article 6 & 4 of law 3418 / 2005 regarding the Code of Medical Ethics.

The services provided shall be performed on grounds of a special Agreement signed between the company and the assigned Healthcare Professional. The remuneration shall be set in accordance with the related legislation and in any case in compliance with compulsory tax provisions.

Market Research

Market research conducted by pharmaceutical companies should be unbiased and undertaken in such a way that it does not harm the credibility of the pharmaceutical industry.

Clinical Trials

The following principles must be applied to all clinical trials:

- The relative legislation regarding clinical trials.
- The ICH Good Clinical Practice principles.
- The legislation governing the financial relationship between companies/ sponsors and the research community.
- The medical ethics code.
- The Declaration of Helsinki regarding human rights.

05. Procedure for the control of the Code of Practice Implementation

The significant importance attributed by SFEE to the implementation of the Code of Practice is shown by the fact that all SFEE member companies have adopted and accepted it.
A prerequisite for a pharmaceutical company to become a member of SFEE is to commit to the compliance and harmonization with the Code of Practice provisions.

As such, a framework of self-regulation is established for the relationship between healthcare professionals and companies, limiting unfair competition.

The Committees controlling the implementation of the Code of Practice are:

- **The First Degree Committee of the Code,** which processes reports / complaints submitted regarding Code violations by SFEE member – companies.
- **The Second Degree Committee** for the implementation of the Code which meets following the request of one or both disputing parties and provided that the decision of the First Degree Committee was previously issued.
- **The Disciplinary Council of SFEE**, the members of which are determined by the SFEE Statutes, deals with cases of companies brought before the Council following the relevant request of the Second Degree Committee and their SFEE membership is questioned.

For further information regarding the Code, please visit the SFEE website

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