FORUM OF INTERNATIONAL RESEARCH & DEVELOPMENT PHARMACEUTICAL COMPANIES, EIG

efpia
European Federation of Pharmaceutical Industries and Associations

CODE ON THE INFORMING AND COMMUNICATION OF PRESCRIPTION-ONLY MEDICINES TO, AND COOPERATION WITH, HEALTHCARE PROFESSIONALS

(HCP Code)

Prepared by EFPIA and FORUM of International Research and Development Pharmaceutical Companies, EIG*

* As approved by General Assembly of EFPIA on June 6th 2014.

* As approved by General Assembly of Forum International Research and Development Pharmaceutical Companies, EIG on July 4th 2014.

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IMPLEMENTATION OF CODE PROVISIONS

The Forum of International Research and Development Pharmaceutical Companies, EIG (hereinafter: Forum) is introducing appropriate procedures to assure that companies, members of the Forum, operate in accordance with the European (as adopted by the European Federation of Pharmaceutical Industries and Associations (hereinafter: EFPIA)) and appropriate national codes (Code on the informing and communication of prescription-only medicines to, and cooperation with, healthcare professionals (hereinafter: HCP Code)) and resolve eventual complaints due to failure to meet obligations pursuant to the above procedures.

The Forum has established a Committee for supervision of the provisions of ethical codes (hereinafter: Committee), which is composed of independent experts in various fields with appropriate expert knowledge and representatives of the Forum.

The Committee oversees the implementation of this Code and other Forum Codes and proposes amendments to codes or procedures adopted for their implementation.

The Committee has been established to assess information on medicinal products, assess the appropriateness of member cooperation with healthcare professionals and patient organisations and compliance of publishing transfers of funds from member companies to healthcare professionals and healthcare organisations. The Committee operates as a voluntary and self-regulating body for all Forum members.

INTRODUCTION

The main task of the pharmaceutical industry is the development of new and effective medicinal products and improvement of existing ones to aid patients and the provision of reliable information regarding such products.

To that end, the pharmaceutical industry pursues activities of marketing such medicinal products and also organises expert meetings, thereby contributing to a constant elevation of knowledge and expertise in public healthcare. The level of scientific expertise at such events must be high, while other elements should remain reasonable.

<u>Marketing of medicinal products is carried out pursuant to the following national and international rules:</u>

1. All Forum member companies are obliged to operate in line with the applicable Medicinal Products Act and other applicable legislation. All pharmaceutical companies must provide healthcare professionals with relevant, reliable and appropriate information regarding the medicinal products they market.

2. Provisions of the HCP code are based on the rules adopted by EFPIA, the representing body of the European pharmaceutical industry, of which the Forum is an associate member. The EFPIA Code on the promotion of prescription-only

medicines to, and interactions with, healthcare professionals has been adopted with the purpose of harmonisation with Council Directive 2001/83/EC of November 2001 and its amendments. Forum member companies are also obliged to observe the provisions of applicable Slovenian legislation in the field of marketing, advertising and informing of medicinal products.

3. The Forum promotes competition among pharmaceutical companies. The HCP Code is not intended to restrain fair competition. Rather, it seeks to ensure honest and truthful promotion activities, avoid deceptive practices and potential conflicts of interest with healthcare professionals, and operation in compliance with applicable laws and regulations. The HCP code aims to foster an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of each individual patient.

SCOPE OF IMPLEMENTATION OF CODE PROVISIONS

Provisions apply for all forms of marketing. This includes all information and activities pertaining to promotion of sales, performed either by the manufacturer of medicinal products or another party on its behalf, of such a nature that they may influence the prescription, marketing, sales and consumption of medicinal products of such a manufacturer.

The HCP code regulates the promotion of prescription-only medicinal products to healthcare professionals. The term “promotion”, as used in the HCP code, includes any activity undertaken, organised or sponsored by a pharmaceutical company, or with its authority, which promotes the prescription, supply, sale, administration, recommendation or consumption of its medicinal product(s).The HCP code covers promotional activity and communication directed towards physicians or other members of medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe or administer medicinal products (hereinafter: “healthcare professional”).

The HCP code is not intended to restrain or regulate the provision of non-promotional medical, scientific and factual information; nor is it intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription medicinal products.

<u>The HCP code does not cover the following:</u>

- packaging, SmPC, package leaflets and other documents approved by a competent body at issuing of marketing authorization or later;

- correspondence and other materials of a informative nature, needed to answer a specific question about a particular pharmaceutical product;

- specific or informative publications, e.g. regarding new packaging or adverse-reaction warnings, trade catalogues and price lists, provided they include no product information;

- information related to human health or illnesses, provided there is no reference, even implied, to a medicinal product and that information is quality, unambiguous, integral, balanced, comprehensible to users and do not contain elements of direct or hidden advertising;

- activities pertaining exclusively to non-prescription medicinal products;

- non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and discussion of regulatory developments affecting a company and its products.

PROVISIONS OF THE CODE

1. MARKETING

1.1. A medicinal product must not be promoted prior to the grant of the marketing authorization.

1.2. All the elements of promotion must be consistent with the particulars listed in the summary of product characteristics (SmPC), and must be limited to approved indications.

1.3. All promotional materials shall in accordance with applicable national legislation and regulations contain the following information, provided in a clear and legible manner:

a) essential information consistent with the summary of product characteristics (composition of medicinal product, therapeutic indications, dosage and manner of application, summary of adverse reactions, precautionary measures and warnings, contraindications and interactions, name, sign and address of the marketing authorisation holder), specifying the date on which such essential information was generated or last revised;

b) product classification with regard to the manner and regime of dispensing.

2. PROMOTION

2.1. PROMOTION

a) Information on medicinal products shall be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the

therapeutic value of the medicinal product concerned. It should be based on an up-to-date evaluation of all relevant materials and shall reflect that evidence clearly. Information must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Information on medicinal products must normally be marked as “only for the expert public”.

b) The word “safe” shall never be used without appropriate explanation.

c) The word »new« must not be used to describe any medicinal product or marketing form that is generally accessible, or any therapeutic indications that are being promoted for more than one year from the date of first availability in the Slovenian market.

d) No claims may be made that the medicinal product has no side-effects and no risks of causing poisoning or addiction.

e) When promotional materials refer to published studies, data must be stated correctly and clear references should be given.

f) Promotion activities must be capable of substantiation which must be promptly provided in response to reasonable requests from healthcare professionals. 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 indications approved in the marketing authorization.

g) 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.

h) Any comparison made between different medicinal products must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.

i) All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material should:

   – clearly indicate the precise source(s) of the artwork;

   – be faithfully reproduced, except where adaptation or modification is required in order to comply with any applicable code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.

Artwork included in promotion must in no way mislead the prescriber or user about the nature of a medicine (for example whether it is appropriate for use in children) or mislead about a claim or comparison (for example by using incomplete or statistically irrelevant information or unusual criteria).

2.2. DOCUMENTATION

Any information included in promotion must be supported by documentation that can be provided on request.

Such documentation need not be provided for information that has been approved in the marketing authorization.

Clinical data that refers to unpublished company sources must be marked with the following notation: “Data is accessible at local company headquarters upon request.” Recipients of promotion materials must have sufficient information available to verify such materials, whereby such information must be an integral part of promotional materials, reference a published report or available upon request. The company must submit the sources of its claims within 15 days of the date of relevant request.

2.3. UNAPPROVED INDICATIONS

Promotions of medicinal products must be done in accordance with the marketing authorisation for the relevant medicinal product and using data listed in the summary of the main characteristics.

Promotion of indications not included in the marketing authorisation is prohibited. The medical department of a Forum member company may provide information on the indications of a medicinal product that are not included in the marketing authorisation (“unapproved indications”) at the request of a healthcare professional, but must not use such indications for promotion.

2.4. GIFTS

Expert associates may not offer any gifts or use pretences to assure a visit with a healthcare professional. Visits or talks with healthcare professionals must not be subject to any payment.

The term “gift” is understood in a wider sense of the word and is not limited only to direct financial or material incentives for healthcare professionals (e.g. expert associates are not allowed to make charity donations in exchange for visits with healthcare professionals).

2.5. USE OF QUOTATIONS IN PROMOTION

Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in

order to comply with the HCP Code, in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

2.6. ACCEPTABILITY OF PROMOTION

Companies must maintain high ethical standards at all times. Promotions must:

a) never bring discredit upon, or reduce confidence in the pharmaceutical industry;
b) be of a nature which recognises the special nature of medicines and the professional standing of the recipient(s);
c) not be likely to cause offence.

2.7. DISTRIBUTION OF PROMOTION MATERIALS

a) Promotion should only be directed at those healthcare professionals whose need for, or interest in, the particular information can reasonably be assumed.

b) Mailing lists of healthcare professionals must be kept up-to-date. Requests by healthcare professionals to be removed from such lists must be complied with.

c) Subject to applicable national laws and regulations, the use of faxes, e- mails, automated calling systems, text messages (SMS) and other electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient.

2.8. TRANSPARENCY OF PROMOTION

a) Promotion and promotional materials must not be disguised or disguise their actual intent.

b) Clinical assessments, post-marketing programmes and post-authorization studies must not be disguised promotion. Such programmes and studies must be conducted with a primarily scientific or educational purpose.

c) Where a company pays for or otherwise secures or arranges the publication of promotional material in newspapers and magazines, such promotional material must not resemble independent editorial matter.

d) Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a company must clearly indicate that it has been sponsored by that company.

2.9 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

a) The transmission of informational or educational materials is permitted provided if is: (i) “of reasonable value”; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients. The distribution of such materials or items shall not constitute an incentive to prescribe, purchase, supply, sell or administer a Medicinal Product.

b) Items of medical utility, aimed directly at the education of healthcare professionals and patient care can be provided if they are “of reasonable value” and do not offset routine business practices of the recipient.

c) The scope of Informational or educational materials and Items of medical utility considered may not constitute of the prohibition on gifts defined under Article 4 of this Code.

The meaning of the term “reasonable value” as used herein, shall be defined by an exception set out by the Income Tax Act which states that individual gifts are not included in the tax base if their value does not exceed 42 EUR (including VAT), or if the total annual value of all gifts received in a fiscal year from the same legal person does not exceed 84 EUR (including VAT).

2.10. PROMOTION TO THE GENERAL PUBLIC SHALL NOT BE CARRIED OUT

a) Promotion of the following medicinal products to the general public shall be prohibited:

- prescription-only medicinal products;

- medicinal products containing active substances classified as psychotropic or narcotic by an international convention, e.g. the UN Conventions of 1961 and 1971;

- any other medicinal products the promotion of which to the general public is prohibited by law. This prohibition shall not apply to notifications of vaccinations carried out by the pharmaceutical industry and approved by competent bodies.

b) In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

2.11. EVENTS AND HOSPITALITY

1) All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (hereinafter: “event”) organised or sponsored by a company must be held in an “appropriate” venue that is appropriate to the main purpose of the event, costs may only be covered

when this is appropriate and otherwise complies with legally prescribed amounts and the provisions of the HCP Code.

An “appropriate” location or venue in the sense of the present item shall mean any location or venue normally used for organising such events, with the exception of “leisure” or “luxury” locations as set out below. The list of inappropriate locations is enclosed as Appendix 1.

2) No company may organise or sponsor an event that takes place outside its home country (international event) 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;

b) given the location of a relevant resource or expert that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (“international event”).

3) Coverage of costs related to promotion, expert or scientific events shall be limited to travel, meals, accommodation and participation fees and shall not exceed the amounts set out by the Medicinal Products Act or another act referred to in the Medicinal Products Act.

Costs of travel, accommodation, food and participation fees shall not be deemed as gifts pursuant to the Public Employees Act. Reasonable costs of travel, accommodation and food shall be presented in a transparent manner.

4) Costs shall be covered only to event participants and not also to accompanying persons.

5) Companies shall not provide any meal (food and beverages) to healthcare professionals, unless the value of such individual meals (food and beverages) does not exceed 60 EUR (including VAT) if the event is set in Slovenia. If the event is set abroad the monetary threshold set in the country where the event takes place (i.e. “host country”) shall prevail. All forms of hospitality offered shall be “reasonable” in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

“Reasonable” hospitality in the sense of the present Item shall mean hospitality within the limitations healthcare organisations would normally observe in the organisation of events for their own needs, whereby events aimed predominantly at leisure should be avoided.

Healthcare professionals must not be provided or have paid any individual leisure activities or other extra-curricular or social activities. Moderate (simple)

entertainment[1] at events is allowed, but must be of secondary importance in comparison to refreshing beverages and/or food. Members shall avoid organising events at “leisure” locations or venues “renowned” for their entertainment offer or for being “extravagant”.

A “leisure” location or venue in the sense hereof means a location known predominantly for providing special types of entertainment (outside the scope of congress activity), such as a casino and golf course. The list of hotels corresponding to this definition is enclosed in Appendix 1.

An “extravagant” location in the sense hereof shall means a hotel or similar venue of a higher luxury category, used predominantly for leisure and entertainment activities and rarely for scientific, business or expert meetings.

6) Costs of sponsoring or organisation of entertainment (e.g. sports or leisure) events may not be covered. Companies should avoid venues that are renowned for their entertainment offers.

3. QUALITY OF INFORMATION

Promotion materials must be of satisfactory quality and must not cause offence.

4. PROHIBITION OF GIFTS

Healthcare professionals may not be given, offered or promised any gifts, financial benefits or benefits in kind.

5. SPONSORSHIP OF HEALTHCARE PROFESSIONALS

Companies must comply with criteria governing the selection and sponsorship of healthcare professionals to attend training or events as provided in the applicable Medicinal Products Act or the HCP Code or pertaining thereto. Funding must not be offered to compensate merely for the time spent by healthcare professionals in attending events. In the case of international events for which a company sponsors the attendance of a healthcare professional, if any funding is provided to such healthcare professional in accordance with the provisions of Article 5, such funding is subject to the rules of the country where such healthcare professional carries out his/her profession, as opposed to those in which the international event takes place. (For the avoidance of doubt, Article 5 is not a prohibition of the extension of hospitality to healthcare professionals in accordance with Article 2.11.)

[1] When a company is organizing an event and provide refreshments and / or meals, such as lunch or dinner, it is allowed to play music in the background (i.e. ambient music).

6. DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE, RESEARCH OR EDUCATION[2]

Giving donations, grants and material or other benefits to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals or the EFPIA Code of Practice on relationships between the pharmaceutical industry and patient organisations) are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products; and (iv) if the donor has no influence on the selection of participants of an event and the selection is carried out independently by the institution receiving a donation. Donations and grants to individual healthcare professionals and/or independent entrepreneurs are not permitted under this section. Company sponsorship of healthcare professionals to attend international events is covered by Article 5. Companies are encouraged to make available publicly information about donations and grants (in cash or in kind or otherwise) made by them covered in this Article 6.

7. FEES FOR SERVICE

Contracts between companies and institutions, organisations or associations of healthcare professionals under which such institutions, organisations or associations provide any type of services to companies (or any other type of funding not covered under Article 8 or not otherwise covered by the Code) are only allowed if such services (or other funding): (i) are provided for the purpose of supporting healthcare or research; and (ii) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

8. THE HIRING OF CONSULTANTS

8.1. It is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

[2] The provisions of Article 6 shall not apply to discounts, rebates and free medicines provided by member companies to organizations or associations where healthcare professionals conduct research or provide health care.

a) a written contract or agreement is concluded 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 is clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;

c) the criteria for selecting consultants is directly related to the identified need and the persons responsible for selecting the consultants shall have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;

d) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;

e) the contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;

f) the hiring of healthcare professionals to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and

g) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating healthcare professionals.

8.2. In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that on a part-time basis employ healthcare professionals that are still practising their profession are strongly encouraged to ensure that such persons have an obligation to declare his/her employment arrangement with the company whenever he/she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company. The provisions of this Article 8.2 apply even though the Code does not otherwise cover non-promotional, general information about companies.

8.3. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Article 8, provided that the healthcare professional is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration does not exceed 20 EUR (including VAT) per questionnaire or interview.

8.4. If a healthcare professional attends an event (an international event or otherwise) in a consultant, the relevant provisions of Article 2.11 shall apply.

9. NON-INTERVENTIONAL CLINICAL STUDIES OF MEDICINAL PRODUCTS

9.1. A non-interventional clinical study of a marketed medicine is defined as a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data. Patients must be informed that data is collected on them that shall be used for studies and must be assured that the confidentiality will be strictly enforced.

9.2. Non-interventional clinical studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study must comply with all of the following criteria:

a) the study is conducted with a scientific purpose;

b) (i) there is a written study plan and (ii) there are written contracts between healthcare professionals and/or the institutes at which the study will take place, on the one hand, and the company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to clause (c) immediately below, the basis for payment of those services;

c) any remuneration provided is reasonable and reflects the fair market value of the work performed;

d) prior to commencement of study the consent of the competent medical ethics committee must be acquired;

e) local laws, rules and regulation on personal data privacy (including the collection and use of personal data) must be respected;

f) the study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;

g) the study plan must be approved by the company's medical department and the conduct of the study must be supervised by the company's medical department as described in Section 10.2.c);

h) the study results must be analysed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company's service responsible for conducting clinical studies (as described in Article 10.2.b), which shall maintain records of such reports for a reasonable period of time. The company should submit the summary report to all healthcare professionals that participated in the study and should make the

summary report available to the competent medical ethics committee upon its request. If the study shows results that are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the relevant competent authority;

i) expert associates may only be involved in an administrative capacity and such involvement must be under the supervision of the company's medical department that shall also ensure that the expert associates are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

9.3. Members are obliged to observe additional stricter conditions, as stipulated by applicable legislation.

9.4. To the extent applicable, companies are encouraged to comply with Article 9.2 for all other types of studies covered by Section 9.1, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Article 8.1.

10. PERSONS EMPLOYED IN PHARMACEUTICAL PROMOTIONAL ACTIVITIES

10.1. EXPERT ASSOCIATES OF PHARMACEUTICAL COMPANY

a) Each company shall ensure that its expert associates, including personnel operating on behalf of the company and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicinal products (each, an "expert associate") are familiar with the relevant requirements of the applicable code(s), and all applicable laws and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the medicinal products they promote.

b) Expert associates must approach their duties responsibly and ethically.

c) Expert associates shall perform their activities in accordance with the Forum Code and all applicable laws and regulations, while companies shall be obliged to assure compliance.

d) During each visit, and subject to applicable laws and regulations, expert associates must give the visited healthcare professionals, or have available for them, a summary of the product characteristics for each medicinal product they present.

e) Expert associates must transmit to the company forthwith any information they receive in relation to the use of their company's medicinal products, particularly reports of side-effects.

f) Expert associates must ensure that the frequency, timing and duration of visits to healthcare professionals, pharmacies, hospitals or other healthcare facilities, remain within appropriate boundaries.

g) Expert associates must not use any inducement or subterfuge to gain an interview. In an interview, or when seeking an appointment for an interview, expert associates must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

10.2. OTHER STAFF

a) All company staff that is in any way concerned with the preparation or approval of promotional material or information must be fully conversant with the requirements of the Rules on advertising of medicines.

b) Every company must have a department or a responsible person in charge of information about its products and supervision of non-interventional studies. Such a medical department shall employ a physician or pharmacist responsible for the approval of promotion materials prior to publishing. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the applicable code(s) and any applicable advertising laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the medicine. In addition, the company must ensure a medical doctor or a pharmacist, who will be responsible for the oversight of any non-interventional study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by expert associates). Such person must certify that he or she has examined the protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the applicable code(s).

c) Each company must appoint a responsible person for supervising the company to ensure that the standards of the applicable code(s) are met.

11. MEDICINAL PRODUCT SAMPLES

11.1. In accordance with the EU Directive 2001/83/EC and current Rules on advertising of medicinal products, in principle, no medical samples should be given to persons authorized to prescribe medicinal products, except exceptionally under the following conditions:

– the medicinal product has due marketing authorisation;
– the medicinal product does not require any special storage conditions, such as a cold chain;
– no more than two years have elapsed from acquisition of the marketing authorisation or approval of a change of marketing authorisation that requires a new application;
– samples may only be delivered upon a written request signed and dated by the prescriber;
– the recipient must keep a record of received samples and must not resell them;
– samples must be in the smallest packaging on the market;
– samples must be accompanied by SmPC;
– each sample has to be in packaging with leaflet enclosed as approved by marketing authorisation, and marked “free medical sample - not for sale”;
– samples must not contain narcotic and psychotropic substances.

Members are obliged to observe additional stricter conditions, as stipulated by applicable legislation.

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

Medical samples are provided to health professionals when the patient needs to be instructed on the method of use of the new medicinal product, if not intended for oral use.

11.2. Companies must have adequate systems of recording, control and accountability for samples which they distribute and for all medicines handled by its representatives. These systems shall also clearly establish that each health professional authorised to prescribe medicinal products may receive only one sample of each medicinal product in its smallest packaging registered in the market and for which the Marketing Authorization Holder has informed in writing the regulatory authority of actual launch in the market.

Each 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.

12. SANCTIONS

If the Forum finds out or is informed about a violation of the HCP code, it shall request the violating company to immediately cease the violation and sign a statement that it shall not repeat it. Sanctions must be proportionate to the nature of the violation, have a deterrent effect and take into account repeated violations of the same type or patterns of various violations. Generally the most effective sanction is

the combination of notifying all the Forum members and financial fine for the violating company, however, the Forum may impose any other effective sanction to enforce the implementation of the HCP code. The Forum must also study all the applicable legal or financial requirements that could influence the nature of sanctions.

13. RESPONSIBILITY

13.1. SCOPE OF RESPONSIBILITY

Responsibility for pharmaceutical information shall apply to information as a whole: for form and content.

13.2. RESPONSIBLE PERSONS

Responsibility for assuring compliance with the present HCP code is borne by all Forum members. Authorised representatives of Forum members are responsible also for compliance with this code.

14. SUPERVISION

The Committee as a Forum body assesses information on medicinal products and the appropriateness of member cooperation with healthcare professionals and patient organisations and provides guidelines.

15. COMPLAINTS

Complaints regarding violations of these rules shall be submitted to the Committee within 30 days from the occurrence of violation.

16. AMENDMENTS

Amendments or adjustments of the HCP code may be instituted on the basis of an opinion of the majority of Forum members. The HCP code may be amended several times per year:
a) Upon amendment of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals.
b) Upon a request submitted to the Forum Board by a member company (or several thereof), which shall be submitted for approval to the Forum General Assembly.
Adoption shall require the majority of present votes at a General Assembly.

17. ENFORCEMENT

This amended code shall enter into force with July 4th 2014, once approved by the majority of members of Forum`s General Assembly.

MEMBERS OF THE FORUM OF INTERNATIONAL RESEARCH AND DEVELOPMENT PHARMACEUTICAL COMPANIES:

Abbott

Abbvie

Alcon

Amgen

Astellas

AstraZeneca

Bayer

Biogen Idec

Boehringer Ingelheim

Celgene

Eli Lilly

GlaxoSmithKline

Janssen

Lundbeck

Merck Sharp & Dohme

Novartis

Novo Nordisk

Pfizer

Roche

sanofi-aventis

Servier