



European Federation of Pharmaceutical
Industries and Associations

EFPIA HCP CODE

EFPIA CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS

Adopted by EFPIA Board on 5 July 2007, and ratified by the EFPIA
Statutory General Assembly of 19 June 2008

Amended following Statutory General Assembly approval of 14 June 2011

**Member Associations are required to implement the revisions of Article 16
of the EFPIA HCP Code, and no later than 31 December 2011.**

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SUBSEQUENT VERSIONS OF THE EFPIA HCP CODE

Adopted in 1991 at the initiative of the European pharmaceutical industry, the EFPIA HCP Code took effect on 1 January 1992. On 31 March 1992, the Council of the European Communities adopted Council Directive 92/28/EEC to govern the advertising of medicinal products for human use in European Community Member States. The EFPIA HCP Code was therefore adapted in 1992 to make it fully consistent with Directive 92/28/EEC. The revised version of the EFPIA HCP Code took effect on 1 January 1993.

In November 2001, Council Directive 2001/83/EC superseded Council Directive 92/28/EEC. Council Directive 2001/83/EC was amended in 2004 by Council Directive 2004/27/EC. The EFPIA HCP Code was further revised in 2004 to adopt various improvements and to make it fully consistent with Directive 2001/83/EC, as amended. This revised version of the EFPIA HCP Code was adopted by EFPIA on 19 November 2004 and took effect in January 2006.

In late 2006 and early 2007, the EFPIA HCP Code was further revised to adopt various improvements and address additional topics suggested by the EFPIA General Assembly. This revised version of the EFPIA HCP Code was adopted by EFPIA Board on 28 September 2007, with effect from no later than 1 July 2008 (depending on national transposition dates) (the "Implementation Date"). General Assembly ratified this revised version at its 19 June 2008 meeting.

Recognising that the 2007 revision imposed certain obligations upon companies that may take time in order to be implemented fully, the EFPIA HCP Code included footnotes in the following sections to provide guidance to companies as to their obligations under the EFPIA HCP Code during the transition period: (a) Section 14.02; and (b) Section 15.02. In general, companies should include any applicable provisions in their contracts with healthcare professionals or make any additional disclosures required by the EFPIA HCP Code beginning on the "Implementation Date"; however, companies were encouraged to take such actions in advance of the "Implementation Date".

Following the Leadership Statement issued by leaders of industry on 24 June 2010, the General Assembly of 14 June 2011 amended Article 16 of the EFPIA HCP Code, formalising the "4x2 standard" applicable to medical samples.

INTRODUCTION

The European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”) is the representative body of the pharmaceutical industry in Europe. Its membership is composed of:

- Full members, including: (i) research-based pharmaceutical companies, developing and manufacturing medicinal products in Europe for human use – *called corporate members*; and (ii) those organisations representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies – *called member associations*.
- Affiliate members, including: (i) companies specialising in particular fields of pharmaceutical research and/or development or in new technologies of particular interest to the pharmaceutical industry – *called "affiliate member company"*; and (ii) organisations representing research-based pharmaceutical companies at national level in Europe that have been granted the title of “*affiliate member associations*”.
- Research-based pharmaceutical companies operating in a particular segment of the pharmaceutical market that joint a *specialised group within EFPIA*: (i) European Bio-pharmaceutical Enterprises; and (ii) European Vaccine Manufacturers.

EFPIA and its members¹ are conscious of the importance of providing accurate, fair and objective information about medicinal products so that rational decisions can be made as to their use. With this in mind, EFPIA has adopted the EFPIA HCP Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the “**EFPIA HCP Code**”). The EFPIA HCP Code reflects the requirements of Council Directive 2001/83/EC, as amended, relating to medicinal products for human use (the “**Directive**”). The EFPIA HCP Code fits into the general framework established by the Directive, which recognises the role of voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise.

EFPIA encourages competition among pharmaceutical companies. The EFPIA HCP Code is not intended to restrain the promotion of medicinal products to, or limit interactions with, healthcare professionals in a manner that is detrimental to fair competition. Instead, it seeks to ensure that pharmaceutical companies conduct such promotion and interaction in a truthful manner, avoiding deceptive practices and potential conflicts of interest with healthcare professionals, and in compliance with applicable laws and regulations.

The EFPIA HCP Code thereby 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 patients.

SCOPE OF THE EFPIA HCP CODE

The EFPIA HCP Code covers the promotion to healthcare professionals of prescription-only medicinal products and interactions between healthcare professionals and pharmaceutical companies. The EFPIA HCP Code is applicable to EFPIA member companies, their subsidiaries, and any companies affiliated with EFPIA member

¹ The updated list of the EFPIA membership can be found on www.efpia.eu.

companies or their subsidiaries if such affiliated companies have agreed to be bound by the EFPIA HCP Code ("**Member Companies**").

Member Companies shall also be responsible for the obligations imposed under any relevant Applicable Code (defined below) even if they commission other parties (e.g., contract sales forces, consultants, market research companies, advertising agencies) to design, implement or engage in activities covered by the Applicable Code (defined below) on their behalves. In addition, Member Companies shall take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Applicable Code (defined below) but that do not act on behalf of the Member Company (e.g., joint ventures, licensees) comply with Applicable Codes (defined below).

"**Promotion**", as used in the EFPIA HCP Code, includes any activity undertaken, organised or sponsored by a Member Company, or with its authority, which promotes the prescription, supply, sale, administration, recommendation or consumption of its medicinal product(s). "**Medicinal products**", as used in the EFPIA HCP Code has the meaning set forth in Article 1 of the Directive: (a) any substance² 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 either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. The EFPIA HCP Code covers promotional activity and communication directed towards, and interactions with, any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, purchase, supply or administer a medicinal product (each, a "**healthcare professional**").

The EFPIA HCP Code covers all methods of promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail advertising, the activities of Medical Sales Representatives (defined in Section 17.01), the use of internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage services and the like, and the provision of samples, gifts and hospitality.

The EFPIA HCP Code also covers interactions between Member Companies and healthcare professionals including, but not limited to, those in the context of research or contractual arrangements (including certain aspects of clinical trials, non-interventional studies and consultancy and advisory board arrangements). Interactions between Member Companies and patient organisations are covered by the EFPIA HCP Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations and the EFPIA HCP Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals requires compliance with such rules.

The EFPIA 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-

² "Substance" is defined in Article 1 of the Directive as: Any matter irrespective of origin which may be (a) human (e.g., human blood and human blood products), (b) animal (e.g., micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products), (c) vegetable (e.g., micro-organisms, plants, parts of plants, vegetable secretions, extracts, or (d) chemical (e.g., elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis).

prescription medicinal products. EFPIA, however, acknowledges that some member associations address these activities in their respective national codes, and encourages other member associations to do so, where appropriate.

The EFPIA HCP Code does not cover the following:

- the labelling of medicinal products and accompanying package leaflets, which are subject to the provisions of Title V of the Directive;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- non-promotional information relating to human health or diseases;
- activities which relate solely to non-prescription medicinal products; or
- 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.

Attached to the EFPIA HCP Code are: Annex A, the “**Implementation and Procedure Rules**” which are binding upon member associations and companies and set forth the framework for the implementation of the EFPIA HCP Code, the processing of complaints and the initiation or administration of sanctions by member associations; and Annex B, the “**Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU**” which provide guidance to member associations and companies with respect to the content of websites containing information on medicinal products subject to prescription.

APPLICABILITY OF CODES

The EFPIA HCP Code sets out the minimum standards which EFPIA considers must apply. In a manner compatible with their respective national laws and regulations, member associations must, at a minimum, adopt in their national codes provisions no less rigorous than the provisions contained in the EFPIA HCP Code. Member associations are encouraged to tailor their national codes to adapt to national conditions and to adopt additional provisions which extend further than the minimum standards included in the EFPIA HCP Code.

Promotion and interaction which take place within Europe must comply with applicable laws and regulations. “**Europe**” as used in the EFPIA HCP Code includes those countries in which the EFPIA member associations’ codes of practice apply. In addition, promotion and interaction which take place within Europe must also comply with each of the following “**Applicable Codes**”:

- (a) (i) in the case of promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a company located within Europe, the member association national code of the country in which such company is located; or (ii) in the case of promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a company located outside of Europe, the EFPIA HCP Code; and
- (b) the member association’s national code of the country in which the promotion or interaction takes place.

In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions shall apply (unless as otherwise covered by Section 13.01).

For the avoidance of doubt, the term “**company**” as used in this EFPIA HCP Code, shall mean any legal entity that organises or sponsors promotion, or engages in interactions with healthcare professionals covered by an Applicable Code, which takes place within Europe, whether such entity be a parent company (e.g., the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation.

Member Companies must comply with any Applicable Codes and any laws and regulations to which they are subject. All companies that are members of EFPIA must either (i) be a member of the member association in each country where it conducts activities covered by the EFPIA HCP Code (either directly or through the relevant subsidiary) or (ii) agree in writing with each such member association that it (or its relevant subsidiary) is bound by such member association’s code (including any applicable sanctions that may be imposed there under).

To facilitate compliance with Applicable Codes, each member association must establish adequate procedures for ensuring that each of its member companies complies with the requirements of such member association’s national code and any other member association’s national code which may be applicable to its conduct, even if the company does not belong to the other member association. In order to establish adequate procedures for ensuring compliance with Applicable Codes, member associations will be required to, among other things, establish appropriate complaint procedures and sanctions for breaches of their respective codes. Additionally, all international events (as defined in Section 9.02 of the EFPIA HCP Code) must be notified to any relevant local subsidiary or, alternatively, local advice must be taken.

The spirit, as well as the letter of the provisions of the EFPIA HCP Code must be complied with. EFPIA also encourages compliance with the letter and spirit of the provisions of the International Federation of Pharmaceutical Manufacturers and Associations (“**IFPMA**”) Code of Pharmaceutical Marketing Practices, where applicable.

PROVISIONS OF THE EFPIA HCP CODE

ARTICLE 1 MARKETING AUTHORIZATION

Section 1.01. A medicinal product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply or outside of its approved indications.

Section 1.02. Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant medicinal product.

ARTICLE 2 INFORMATION TO BE MADE AVAILABLE

Section 2.01. Subject to applicable national laws and regulations, all promotional material must include the following information clearly and legibly:

- a. essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
- b. the supply classification of the product; and
- c. when appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

Section 2.02. Subject to applicable national laws and regulations, where an advertisement is intended only as a reminder, the requirements of Section 2.01 above need not be complied with, provided that the advertisement includes no more than the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark.

ARTICLE 3 PROMOTION AND ITS SUBSTANTIATION

Section 3.01. Promotion must 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 evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

Section 3.02. Promotion 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 elements approved in the marketing authorization.

Section 3.03. 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 3.04. When promotion refers to published studies, clear references should be given.

Section 3.05. 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.

Section 3.06. All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material should:

- a. clearly indicate the precise source(s) of the artwork;
- b. 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.

Particular care must be taken to ensure that artwork included in promotion does not mislead 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 scales).

Section 3.07. The word “**safe**” must never be used to describe a medicinal product without proper qualification.

Section 3.08. The word “**new**” must not be used to describe any product or presentation which has been generally available or any therapeutic indication which has been generally promoted, for more than one year.

Section 3.09. It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency.

ARTICLE 4 USE OF QUOTATIONS IN PROMOTION

Section 4.01. 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 any Applicable Code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

ARTICLE 5 ACCEPTABILITY OF PROMOTION

Section 5.01. Companies must maintain high ethical standards at all times. Promotion must: (a) never be such as to 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); and (c) not be likely to cause offence.

ARTICLE 6
DISTRIBUTION OF PROMOTION

Section 6.01. Promotion should only be directed at those who's need for, or interest in, the particular information can reasonably be assumed.

Section 6.02. Mailing lists must be kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with.

Section 6.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient.

ARTICLE 7
TRANSPARENCY OF PROMOTION

Section 7.01. Promotion must not be disguised.

Section 7.02. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies (including those that are retrospective in nature) must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

Section 7.03. Where a company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

Section 7.04. 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.

ARTICLE 8
NO ADVICE ON PERSONAL MEDICAL MATTERS

Section 8.01. 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.

ARTICLE 9
EVENTS AND HOSPITALITY

Section 9.01. All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings ,visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an **“event”**) organised or sponsored by or on behalf of a company must be held in an “appropriate” venue that is conducive to the main purpose of the event and may only offer hospitality

when such hospitality is appropriate and otherwise complies with the provisions of any Applicable Code(s).

Section 9.02. No company may organise or sponsor an 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 the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an “**international event**”).

Section 9.03. Promotional information which appears on exhibition stands or is distributed to participants at international events may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicinal products (or uses) which are not registered in the country where the event takes place, or which are registered under different conditions, so long as (i) any such promotional material (excluding promotional aids) is accompanied by a suitable statement indicating countries in which the product is registered and makes clear that the product or use is not registered locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the medicinal product is registered should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

Section 9.04. Hospitality extended in connection with events shall be limited to travel, meals, accommodation and genuine registration fees.

Section 9.05. Hospitality may only be extended to persons who qualify as participants in their own right.

Section 9.06. All forms of hospitality offered to healthcare professionals 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.

Section 9.07. Hospitality shall not include sponsoring or organising entertainment (e.g., sporting or leisure) events. Companies should avoid using venues that are “renowned” for their entertainment facilities or are “extravagant”.

Section 9.08. Member associations shall provide guidance on the meaning of the term “**reasonable**”, as used in this Article 9. Member associations shall also provide guidance on “**appropriate**”, “**renowned**” and “**extravagant**” venues, as used in Section 9.01 and Section 9.07. Companies must comply with any relevant guidance provided under this Section 9.08 in connection with any Applicable Code(s).

ARTICLE 10 GIFTS

Section 10.01. No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a healthcare professional as an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.

Section 10.02. Subject to Section 10.01 above, where medicinal products are being promoted to healthcare professionals, gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons only if they are “inexpensive” and relevant to the practice of medicine or pharmacy.

Section 10.03. Except where they carry all the information stipulated in Section 2.01 above, gifts may bear no more than the name and logo of the company and the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark.

Section 10.04. Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) should not be offered or provided.

Section 10.05. Member associations shall provide guidance on the meaning of the term “**inexpensive**”, as used in this Article 10. Companies must comply with any relevant guidance provided under this Section 10.05 in connection with, any Applicable Code(s).

ARTICLE 11 DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE OR RESEARCH

Section 11.01. Donations, grants and benefits in kind 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 HCP Code 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 or research; (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. Donations and grants to individual healthcare professionals are not permitted under this section. Company sponsorship of healthcare professionals to attend international events is covered by Article 13. Companies are encouraged to make available publicly information about donations, grants or benefits in kind made by them covered in this Section 11.01.

ARTICLE 12 FEES FOR SERVICE

Section 12.01. 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 11 or not otherwise covered by the EFPIA HCP 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.

ARTICLE 13 SPONSORSHIP OF HEALTHCARE PROFESSIONALS

Section 13.01. Companies must comply with criteria governing the selection and sponsorship of healthcare professionals to attend training or events as provided in, or in connection with, any Applicable Code(s). 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 this Section 13.01, such funding is subject to the rules of the jurisdiction 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, this Section 13.01 is not intended to prohibit the extension of hospitality to healthcare professionals in accordance with Article 9 hereof.

ARTICLE 14 THE USE OF CONSULTANTS

Section 14.01. 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:

- a. a written contract or agreement 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 in advance of requesting the services and entering into arrangements with the prospective consultants;
- 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 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 the healthcare professional 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.

Section 14.02. 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 employ, on a part-time basis, 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 Section 14.02 apply even though the EFPIA HCP Code does not otherwise cover non-promotional, general

information about companies (as discussed in the “Scope of the EFPIA HCP Code” section).³

Section 14.03. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Article 14, 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 is minimal. Member associations shall provide guidance on the meaning of “**minimal**” in connection with any Applicable Code(s).

Section 14.04. If a healthcare professional attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of Article 9 shall apply.

ARTICLE 15 NON-INTERVENTIONAL STUDIES OF MARKETED MEDICINES

Section 15.01. A non-interventional 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.

Section 15.02. Non-interventional 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 (protocol) 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. In countries where ethics committees are prepared to review such studies, the study protocol should be submitted to the ethics committee for review;
- 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 protocol must be approved by the company’s scientific service and the conduct of the study must be supervised by the company’s scientific service as described in Section 1.01b;

³ Companies are strongly encouraged to include such provisions in any contracts entered into or renewed on or after the Implementation Date that are covered by this Section 14.02. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such provisions.

- 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 scientific service (as described in Section 1.01a), which service shall maintain records of such reports for a reasonable period of time. The company should send the summary report to all healthcare professionals that participated in the study and should make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing Applicable Codes upon their 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;⁴ and
- i. Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

Section 15.03. To the extent applicable, companies are encouraged to comply with Section 15.02 for all other types of studies covered by Section 15.01, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Section 12.01.

ARTICLE 16 MEDICAL SAMPLES

Section 16.01. In accordance with the EU Directive 2001/83/CE, in principle, no medical samples should be given, except on an exceptional basis.

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 so that they may familiarise themselves with the medicines and acquire experience in dealing with them.

In accordance with national and/or EU laws and regulations, a limited number of medical samples may be supplied on an exceptional basis and for a limited period. A reasonable interpretation of this provision is that each health professional should receive, per year, not more than 4 medical samples of a particular medicine he/she is qualified to prescribe for 2 years after he/she first requested samples of each particular medicine.

In this context, a new medicine is a product for which a new marketing authorisation (MA) has been granted, either following an initial MA application or following an extension application for new strengths/dosage forms that include a new indication. Extensions of the MA to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new medicines.

⁴ Companies must begin to comply with these obligations in connection with any non-interventional studies that are completed after 1 July 2008, though companies are encouraged to do so prior to 1 July 2008. In addition, companies are encouraged to publicly disclose the summary details and results of non-interventional studies in a manner that is consistent with the parallel obligations with respect to clinical trials.

Without prejudice to the ban on medical sampling of medicines containing psychotropic and narcotic substances, medical samples can only be given in response to a written request from health professionals qualified to prescribe that particular medicine. Written requests must be signed and dated by the recipient.

On an exceptional basis, member associations may allow, through additional guidance, a longer period than 2 years if required by local healthcare conditions.

Section 16.02. Companies must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by its representatives. This system shall also clearly establish, for each health professional, the number of samples supplied in application of the provisions in Section 16.01 (i.e. the “4x2” standard).

Section 16.03. Each sample shall be no larger than the smallest presentation of that particular medicine in the relevant country.

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.

ARTICLE 17 PHARMACEUTICAL COMPANY STAFF

Section 17.01. Each company shall ensure that its sales representatives, including personnel retained by way of contract with third parties, 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, a “**Medical Sales Representative**”) 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.

- a. Medical Sales Representatives must comply with all relevant requirements of the Applicable Code(s), and all applicable laws and regulations, and companies are responsible for ensuring their compliance.
- b. Medical Sales Representatives must approach their duties responsibly and ethically.
- c. During each visit, and subject to applicable laws and regulations, Medical Sales Representatives must give the persons visited, or have available for them, a summary of the product characteristics for each medicinal product they present.
- d. Medical Sales Representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their company’s medicinal products, particularly reports of side effects.
- e. Medical Sales Representatives must ensure that the frequency, timing and duration of visits to healthcare professionals, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.
- f. Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. In an interview, or when seeking an appointment for an interview, Medical Sales Representatives 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.
- g. The provisions of i are also applicable to the activities of Medical Sales Representatives.

Section 17.02. All company staff, and any personnel retained by way of contract with third parties, who are concerned with the preparation or approval of promotional material or activities must be fully conversant with the requirements of the Applicable Code(s) and relevant laws and regulations.

- a. Every company must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non- interventional studies. Companies are free to decide how best to establish such service(s) in accordance with this Section 17.02 (i.e., whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organisation. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. 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 scientific service must include a medical doctor or, where appropriate, 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 Medical Sales Representatives). 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).
- b. Each company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met.

ARTICLE 18 ENFORCEMENT

Section 18.01. Member associations must, within current applicable rules and legislation enforce the provisions of the EFPIA HCP Code. In the event that a breach is established pursuant to the procedures of its national code, each member association shall require from the offending company an immediate cessation of the offending activity and a signed undertaking by the company to prevent recurrence.

Section 18.02. Each member association shall also include in its national code provisions governing the imposition of sanctions for breaches of its national code. Sanctions should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. A combination of publication and fines is generally considered to be the most effective sanction; however, each member association may use any other effective sanction to enforce its national code. Each member association should consider any applicable legal, regulatory or fiscal requirements which would affect the nature of sanctions which may be imposed. Where publication or fines are not permitted due to applicable legal, regulatory or fiscal requirements, member associations should impose the best alternative effective sanction.

ARTICLE 19
AWARENESS AND EDUCATION

Section 19.01. Member associations must, within current applicable rules and legislation facilitate companies' awareness of and education about the EFPIA HCP Code, including by providing guidance to companies in order to prevent breaches of the EFPIA HCP Code. EFPIA member associations are encouraged to share their respective interpretations of the EFPIA HCP Code through the IFPMA Code Compliance Network and the regular meetings organised by EFPIA (see Annex A, Section 2).

IMPLEMENTATION AND PROCEDURE RULES

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the “**EFPIA HCP Code**”), the processing of complaints and the initiation or administration of sanctions by member associations.

SECTION 1. Member Association Implementation

Each member association is required to:

- a. establish national procedures and structures to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same including, at a minimum, a national body of the member association that is designated to handle complaints and consists of a non-industry chairman and, besides any industry members, membership from other stakeholders;
- b. ensure that its national code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its national code on its website; and
- c. prepare, and provide to the EFPIA HCP Code Committee (defined below), an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the year.

SECTION 2. EFPIA Codes Committee Implementation and Key Tasks

The EFPIA Codes Committee shall assist member associations to comply with their obligations under Section 1 above.

- a. The EFPIA Codes Committee will be composed of all the national code secretaries, and chaired by the EFPIA Director General, assisted by one person from the EFPIA staff.
- b. As a key part of its role of assisting member associations in their national code compliance activities, the EFPIA Codes Committee shall monitor the adoption of compliant national codes. The EFPIA Codes Committee will not participate in the adjudication of any individual complaint under any national code.
- c. In order to promote the EFPIA HCP Code and to share best practice, the EFPIA Codes Committee will, at least annually, invite member associations and company representatives to participate in a meeting at which the participants will be encouraged to share their respective relevant experiences relating to the EFPIA HCP Code. Any conclusions from the meeting shall be summarised in the annual code report (referred to under (e) of this Section 2 below) and, if appropriate, be presented to the EFPIA Board.
- d. The EFPIA Codes Committee shall publish an annual code report which summarizes the work and operations which have taken place in connection with the implementation, development and enforcement of the various national codes during the applicable year, based on the country reports provided by the member associations pursuant to Section 1(c) above.
- e. On an annual basis, the EFPIA Codes Committee shall: (i) advise the EFPIA Board of its work and operations and the work and operations of the member associations, as summarized in the member association annual reports; and (ii) review with the EFPIA Board any additional recommendations to improve the

EFPIA HCP Code with a view towards increasing transparency and openness within the pharmaceutical industry and among member associations and companies.

SECTION 3. Reception of Complaints

Complaints may be lodged either with a member association or with EFPIA. Adjudication of complaints shall be a matter solely for the national associations.

Complaints received by EFPIA shall be processed as follows:

- i. EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant member association(s).
- ii. EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant national association(s) to which the complaint has been sent for processing and decision.
- iii. In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA will communicate these complaints to the national association either of the parent company or of the EU subsidiary designated by the parent company.

SECTION 4. Processing of Complaints and Sanctions by Member Associations

- a. Member associations shall ensure that industry and non-industry complaints are processed in the same manner, without regard to who has made the complaint.
- b. Complaints will be processed at the national level through the procedures and structures established by the member associations pursuant to Section 1(a) above. Each member association's national body shall take decisions and pronounce any sanctions on the basis of the national code in force in its country.
- c. Where a complaint fails to establish a prima facie case for a violation of an Applicable Code, such complaint shall be dismissed with respect to that national code. Member associations may also provide that any complaint which pursues an entirely or predominantly commercial interest shall be dismissed.
- d. Each member association should establish effective procedures for appeals against the initial decisions made by its national body. Such procedures and appeals should also take place at the national level.
- e. National committees shall ensure that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, in a level of detail that is linked to the seriousness and/or persistence of the breach as follows:
 - (i) in cases of a serious/repeated breach, the company name(s) should be published together with details of the case;
 - (ii) in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the company name(s).
- f. National committees are encouraged to publish summaries in English of cases that have precedential value and are of international interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest).

GUIDELINES FOR INTERNET WEBSITES AVAILABLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND THE PUBLIC IN THE EU

The Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU set forth herein are intended as a supplement to the provisions of the European Federation of Pharmaceutical Industries and Associations Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the “**EFPIA HCP Code**”). Member associations and companies may find it necessary to adapt these guidelines to meet their particular requirements or needs and are encouraged to adopt additional measures which extend further than the provisions included in these guidelines.

SECTION 1. Transparency Of Website Origin, Content And Purpose

Each website shall clearly identify:

- a. the identity and physical and electronic addresses of the sponsor(s) of the website;
- b. the source(s) of all information included on the website, the date of publication of the source(s) and the identity and credentials (including the date credentials were received) of all individual/institutional providers of information included on the website;
- c. the procedure followed in selecting the content included on the website;
- d. the target audience of the website (e.g., healthcare professionals, patients and the general public, or a combination thereof); and
- e. the purpose or objective of the website.

SECTION 2. Content Of Websites

Information included in the website shall be regularly updated and shall clearly display, for each page and/or item, as applicable, the most recent date as of which such information was up-dated.

Examples of the information that may be included in a single website or in multiple websites are: (i) general information on the company; (ii) health education information; (iii) information intended for healthcare professionals (as defined in the EFPIA HCP Code), including any promotion; and (iv) non-promotional information intended for patients and the general public about specific medicinal products marketed by the company:

- (i) General information on the company. Websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programmes, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising law.
- (ii) Health education information. Websites may contain non-promotional health education information about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to medicinal products, provided that the discussion is balanced and accurate. Relevant information may be given about

alternative treatments, including, where appropriate, surgery, diet, behavioural change and other interventions that do not require use of medicinal products. Websites containing health education information must always advise persons to consult a healthcare professional for further information.

- (iii) Information for healthcare professionals. Any information on websites directed to healthcare professionals that constitutes promotion (as defined in the EFPIA HCP Code) must comply with Applicable Code(s) (as defined in the EFPIA HCP Code) and any other industry codes of practice governing the content and format of advertisement and promotion of medicinal products. Such information must be clearly identified as information for healthcare professionals, but need not be encrypted or otherwise restricted.
- (iv) Non-promotional information for patients and the general public. Subject to any applicable national laws and regulations, websites may include non-promotional information for patients and the general public on products distributed by the company (including information on their indications, side-effects, interactions with other medicines, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each product that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the full, unedited copy of any public assessment report issued by the Committee for Medicinal Products for Human Use or a relevant national competent authority. Brand names should be accompanied by international non-proprietary names. The website may include links to other websites containing reliable information on medicinal products, including websites maintained by government authorities, medical research bodies, patient organisations, etc. The website must always advise persons to consult a healthcare professional for further information.

SECTION 3. e-mail Enquiries

A website may invite electronic mail communications from healthcare professionals and patients or the general public seeking further information regarding the company's products or other matters (e.g., feedback regarding the website). The company may reply to such communications in the same manner as it would reply to enquiries received by post, telephone or other media. In communications with patients or members of the general public, discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a healthcare professional be consulted for further information.

SECTION 4. Links From Other Websites

Links may be established to a company-sponsored website from websites sponsored by other persons, but companies should not establish links from websites designed for the general public to company-sponsored websites that are designed for healthcare professionals. In the same manner, links may be established to separate websites, including websites sponsored by the company or by other persons. Links should

ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

SECTION 5. Website Addresses in Packaging

Subject to any applicable national laws and regulations, uniform resource locators (URLs) of company-sponsored websites that comply with these guidelines may be included in packaging of medicinal products.

SECTION 6. Scientific Review

Companies should ensure that scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the Applicable Code(s). The scientific service established within the company pursuant to those provisions of the Applicable Code that adopt Section 17.02 of the EFPIA HCP Code may perform this function, or it may be entrusted to other appropriately qualified persons.

SECTION 7. Privacy

The website must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information.
