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

as amended by
the Statutory General Assembly on 14 June 2011 – amending Article 17 on Medical Samples (previously Article 16), and requiring implementation in national codes by 31 December 2011

as amended by
the Statutory General Assembly on 24 June 2013 – amending Article 10 (previously Article 9) on Events & Hospitality, Article 17 (previously Article 10) on Gifts, and introducing a new Article 9 on Informational & Educational Materials, and Items of Medical Utility, and requiring implementation in national codes by 31 December 2013

FINAL CONSOLIDATED VERSION
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SUBSEQUENT VERSIONS OF THE EFPIA HCP CODE


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 with a requirement on Member Associations to implement the amendment by 31 December 2011.

The European pharmaceutical industry understands the need to provide a well-managed framework for collaboration that should introduce greater transparency around industry’s interactions with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs). The General Assembly of 24 June 2013 adopted a new Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA HCP/HCO DISCLOSURE CODE). Concomitantly, amendments to the EFPIA HCP Code have been approved, which tighten up the rules applicable to gifts and hospitality. Member Associations are required to transpose the revised EFPIA HCP Code into their national codes by no later than 31 December 2013, and in compliance with national laws and regulations.
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 (EBE); and (ii) Vaccines Europe (VE).

Separate entities belonging to the same multinational company – which could be the 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 – shall be deemed to constitute a single company, and are as such committed to compliance with the EFPIA Codes.

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.

¹ The updated list of the EFPIA membership can be found on www.efpia.eu.
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 companies or their subsidiaries ("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 2001/83/EC, including: medicinal products, immunological medicinal products, radiopharmaceuticals, medicinal products derived from human blood or human plasma, for which a marketing authorisation has been delivered in application of Directive 2001/83/EC.

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 18.01), 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 informational or educational materials, items of medical utility, hospitality in relation to events and medical samples.

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 Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (the EFPIA PO Code) and the EFPIA HCP Code 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-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 Europe” 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 10.02 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 whose 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
INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

Section 9.01. The transmission of informational or educational materials is permitted provided it is: (i) "inexpensive"; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients. The transmission of such materials or items shall
not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

Section 9.02 Items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they are “inexpensive” and do not offset routine business practices of the recipient.

Section 9.03 EFPIA and Member Associations shall provide guidance on the meaning of the term “inexpensive”, as used in this Article 9. Companies must comply with any relevant guidance provided under this Section 9.03 or in connection with any Applicable Code(s).

ARTICLE 10
EVENTS AND HOSPITALITY

Section 10.01. 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 10.02. 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 10.03. 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 10.04. Hospitality extended in connection with events shall be limited to travel, meals, accommodation and genuine registration fees.

Section 10.05. Member Companies shall not provide or offer any meal (food and beverages) to healthcare professionals, unless, in each case, the value of such meal (food and beverages) does not exceed the monetary threshold set by the relevant Member Association in its national code. Each Member Association shall set such monetary threshold in its national code.
code by 31 December 2013, failing which EFPIA will set such threshold in lieu of such Member Association.

Section 10.06. Hospitality may only be extended to persons who qualify as participants in their own right.

Section 10.07. 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 10.08. 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 10.09. Member associations shall provide guidance on the meaning of the term "reasonable", as used in this Article 10. Member associations shall also provide guidance on "appropriate", "renowned" and "extravagant" venues, as used in Section 10.01 and Section 10.08. Companies must comply with any relevant guidance provided under this Section 10.09 in connection with any Applicable Code(s).

ARTICLE 11
DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE OR RESEARCH

Section 11.01. Donations and grants (in cash or in kind or otherwise) 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 PO Code 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 and grants (in cash or in kind or otherwise) 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 10 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, fulfill 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).

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 10 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;

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.
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 18.02.a;

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 18.02.a, 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;3 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.

3 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.
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.

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
PROHIBITION OF GIFTS

Section 17.01. No gift or pecuniary advantage (in cash or benefit in kind) may be supplied, offered or promised to a healthcare professional.

ARTICLE 18
PHARMACEUTICAL COMPANY STAFF

Section 18.01. 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 Section 15.02.i are also applicable to the activities of Medical Sales Representatives.

Section 18.02. 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 18.02 (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 19
ENFORCEMENT

Section 19.01. 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 19.02. 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 20
AWARENESS AND EDUCATION

Section 20.01. 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 regular meetings organised by EFPIA (see Annex A, Section 2 to this Code) and through the IFPMA Code Compliance Network (CCN).
ANNEX A (binding)

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 Codes 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, who will elect a chair among their peers, 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 Codes 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. Member Associations or 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).
ANNEX B (guidelines)

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

The Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in Europe 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 updated.

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; (v) disclosure of transfers of value to healthcare professionals (HCP) and healthcare organisations (HCO):

(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 18.02 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.
EFPIA CODE OF PRACTICE ON RELATIONSHIPS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS

Initially approved in 2007
Amended by decision of the General Assembly in June 2011

This updated EFPIA Patient Organisation Code of Practice was adopted by the Statutory General Assembly on 14 June 2011. Member Associations are asked to implement the revised code provisions by 31 December 2011.
INTRODUCTION

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the representative body of the pharmaceutical industry in Europe. Its members are the national industry associations of countries in Europe (i.e. member associations) and leading pharmaceutical companies (i.e. corporate members). EFPIA membership also includes two specialised groups: the “European Biopharmaceutical Enterprises” (EBE) and the “European Vaccines Manufacturers” (EVM).

EFPIA’s primary mission is to promote the technological and economic development of the pharmaceutical industry in Europe and to assist in bringing to market medicinal products which improve human health.

The pharmaceutical industry recognises that it has many common interests with patient organisations, which represent and/or support the needs of patients and/or caregivers.

In order to ensure that relationships between the pharmaceutical industry and patient organisations take place in an ethical and transparent manner, EFPIA has adopted the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (The EFPIA Patient Organisation (PO) Code).

This Code builds upon the following principles that EFPIA, together with pan-European patient organisations, subscribed to:

1. The independence of patient organisations, in terms of their political judgement, policies and activities, shall be assured.
2. All partnerships between patient organisations and the pharmaceutical industry shall be based on mutual respect, with the views and decisions of each partner having equal value.
3. The pharmaceutical industry shall not request, nor shall patient organisations undertake, the promotion of a particular prescription-only medicine.
4. The objectives and scope of any partnership shall be transparent. Financial and non-financial support provided by the pharmaceutical industry shall always be clearly acknowledged.
5. The pharmaceutical industry welcomes broad funding of patient organisations from multiple sources.

SCOPE

This EFPIA Patient Organisation Code covers relationships between EFPIA corporate members including their subsidiaries and contracted third parties (e.g. agencies) and patient organisations which operate in Europe.

Patient organisations are defined as not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers.

APPLICABILITY

The EFPIA Patient Organisation Code sets out the standards which EFPIA considers must apply. In a manner compatible with their respective national laws and regulations, member associations must adopt provisions in their national codes which are no less rigorous than the provisions contained in the EFPIA Patient Organisation Code.

1 The complete list of EFPIA membership is available on www.efpia.eu
Pharmaceutical companies must comply with the following applicable codes (‘Applicable Codes’) and any laws and regulations to which they are subject:

1. If the company is located within Europe, the industry code of the country in which the company is located or, if the company is located outside Europe, the EFPIA Patient Organisation Code; AND

2. a) in the case of partnerships and activities taking place in a particular country within Europe, the industry code of the country in which the activity takes place; or

   b) in the case of cross-border partnerships and activities, the industry code of the country in which the patient organisation has its main European location.

The requirements apply to activities or funding within Europe. ‘Europe’ as used in this EFPIA Patient Organisation Code, includes those countries in which the EFPIA member associations’ codes of practice apply.

The Applicable Codes that will apply must be specified in a written agreement between the company and the patient organisation. 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.

For the avoidance of doubt, the term “company” as used in this EFPIA Patient Organisation Code, shall mean any legal entity that provides funds or engages in activities with patient organisations 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.

“Activity” as used above, shall mean any interaction covered by an Applicable Code, including the provision of funding.

**PROVISIONS**

**Article 1  
Non-promotion of prescription-only medicines**

EU and national legislation and codes of practice, prohibiting the advertising of prescription-only medicines to the general public, apply.

**Article 2  
Written agreements**

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support. Each pharmaceutical company should have an approval process in place for these agreements.

A template for a written agreement is available in Annex I.

**Article 3  
Use of logos and proprietary materials**

The public use of a patient organisation’s logo and/or proprietary material by a pharmaceutical company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.
Article 4
Editorial control

Pharmaceutical companies must not seek to influence the text of patient organisation material they sponsor in a manner favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies. In addition, at the request of Patient Organisations, companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

Article 5
Transparency

a) Each company must make publicly available a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description must include the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit that the patient organisation receives. This information may be provided on a national or European level and should be updated at least once a year.²

b) Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.

c) Each company must make publicly available a list of patient organisations that it has engaged to provide significant contracted services. This should include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Companies must also make public the total amount paid per patient organisation over the reporting period.³

ARTICLE 6
Contracted Services

Contracts between companies and patient organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research.

It is permitted to engage Patient Organisations as experts and advisors for services such as participation at advisory board meetings and speaker services. The arrangements that cover 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 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 and documented in advance of requesting the services and entering into the arrangements;

² The requirement to include the monetary value of support must be made by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of, or ongoing on, 1 January 2012).

³ The requirement to include details of contracted services must be made by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of or ongoing on 1 January 2012).
c) The criteria for selecting services are directly related to the identified need and the persons responsible for selecting the service have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria;
d) The extent of the service is not greater than is reasonably necessary to achieve the identified need;
e) The contracting company maintains records concerning, and makes appropriate use of, the services;
f) The engaging of Patient Organisations is not an inducement to recommend a particular medicinal product;
g) The compensation for the services is reasonable and does not exceed the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating patient organisations;
h) In their written contracts with Patient Organisations, companies are strongly encouraged to include provisions regarding an obligation of the Patient Organisation to declare that they have provided paid services to the company whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company;
i) Each company must make publicly available a list of patient organisations that it has engaged to provide paid-for services – see Article 5.e above.

Article 7
Single company funding

No company may require that it be the sole funder of a patient organisation or any of its major programmes.

Article 8
Events and hospitality

All events sponsored or organised by or on behalf of a company including scientific, business or professional meetings, must be held in appropriate locations and venues that are conducive to the main purpose of the event, avoiding those that are ‘renowned’ for their entertainment facilities or are ‘extravagant’.

All forms of hospitality provided by the pharmaceutical industry to patient organisations and their members shall be reasonable in level and secondary to the main purpose of the event, whether the event is organised by the patient organisation or the pharmaceutical industry.

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

Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases, in case of clear health needs (e.g. disability), the travel meals, accommodation and registration fees cost of an accompanying person considered to be a carer can be taken.

All forms of hospitality offered to patient organisations and their representatives shall be “reasonable” in level and strictly limited to the purpose of the event.

Hospitality shall not include sponsoring or organising entertainment (e.g. sporting or leisure events).

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.
Article 9
Enforcement

Attached to this EFPIA Patient Organisation Code as Annex II, are “Implementation and Procedure Rules” which are binding upon member associations and corporate members and set forth the framework for the implementation of this EFPIA Patient Organisation Code, the processing of complaints and the initiation or administration of sanctions by member associations.

Member associations shall provide guidance on the meaning of the terms ‘appropriate, ‘significant’, ‘major’, ‘reasonable’, ‘renowned’ and ‘extravagant’ as used in this code.

Annex I – Model template for written agreements between the pharmaceutical industry and patient organisations

Annex II – Implementation and Procedure Rules
ANNEX I

Model template for written agreements between the pharmaceutical industry and patient organisations

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement.

Below is a model template, which may be used in its entirety or adapted as appropriate, setting out key points of a written agreement. It is intended as a straightforward record of what has been agreed, taking into account the requirements of EFPIA’s Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations:

- Name of the activity
- Names of partnering organisations (pharmaceutical company, patient organisation, and where applicable, third parties that will be brought in to help, as agreed by both the pharmaceutical company and the patient organisation)
- Type of activity (e.g. whether the agreement relates to unrestricted grant, specific meeting, publication, etc.)
- Objectives
- Agreed role of the pharmaceutical company and patient organisation
- Time-frame
- Amount of funding
- Description of significant indirect/non-financial support (e.g. the donation of public relations agency’s time, free training courses)

All parties are fully aware that sponsorship must be clearly acknowledged and apparent from the outset.

Arrangements for making transparent the details of the activities subject to the agreement

Code/s of practice that apply: to be completed

Signatories to the agreement:

Date of agreement:
ANNEX II

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 Relationships between the Pharmaceutical Industry and Patient Organisations (the "EFPIA PO Code"), the processing of complaints and the initiation or administration of sanctions by member associations.

SECTION 1. Member Associations' 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 Codes 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

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

b) 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.

c) 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.

d) EFPIA Codes Committee will, at least annually, invite member associations and representatives to participate in a meeting at which the participants will be encouraged to share their respective relevant experiences relating to the EFPIA PO Code. Any conclusions from the meeting shall be summarised in the annual codes report (referred to under (e) of this Section 2 below) and be presented to the EFPIA Executive Committee, and to the EFPIA Board, if appropriate.

e) EFPIA shall publish an annual codes 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.

f) On an annual basis, the EFPIA Codes Committee shall (i) advise the EFPIA Executive Committee, and the EFPIA Board, if appropriate, 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 Executive Committee, and the EFPIA Board, if appropriate, any additional recommendations to improve the EFPIA PO 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. Complaints will be processed at the national level through the procedures and structures established by the member associations pursuant to Section 1(a) above.

b) 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. 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.

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).
EFPIA HCP/HCO DISCLOSURE CODE

EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

Adopted by the EFPIA Statutory General Assembly of 24 June 2013, and requiring implementation in national codes by 31 December 2013

FINAL EDITED VERSION
Following General Assembly Approval
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PREAMBLE

Healthcare professionals and healthcare organisations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. This expertise makes an important contribution to the industry’s efforts to improve the quality of patient care, with benefits for individuals and society at large. Healthcare professionals and healthcare organisations should be fairly compensated for the legitimate expertise and services they provide to the industry.

Prescription medicines developed by the industry are complex products designed to address the needs of patients and educating healthcare professionals about medicines and the diseases they treat benefits patients. The pharmaceutical industry can provide a legitimate forum for the education of healthcare professionals and the exchange of knowledge among healthcare professionals and industry.

EFPIA believes that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe a medicine is one of the pillars of the healthcare system. EFPIA recognises that interactions between the industry and healthcare professionals can create the potential for conflicts of interest. Consequently, professional and industry associations, including EFPIA and its member associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In order to continue to be successful, self-regulation needs to respond to the evolving demands of the society. In particular, there is a growing expectation that interactions between corporations and society are not only conducted with integrity but are also transparent. Following the EU Commission initiative on Ethics & Transparency in the pharmaceutical sector, a multi-stakeholders’ platform – including, among others, EFPIA – has adopted a “List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector” (the “Guiding Principles”).

In line with these “Guiding Principles”, EFPIA believes that it is critical to the future success of the pharmaceutical industry to respond to society’s heightened expectations. EFPIA has therefore decided that its existing Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the “HCP Code”) and Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (the “PO Code”) should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organisations. EFPIA hopes that, by taking this step, it can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stakeholders in the pharmaceutical industry.

EFPIA believes that the interest of patients and other stakeholders in the transparency of these interactions is compelling. EFPIA recognises that disclosure can raise data privacy concerns and seeks to work with healthcare professionals to ensure that these concerns are addressed. EFPIA nonetheless believes that transparency can be achieved without sacrificing the legitimate privacy interests of healthcare professionals and legislation should not therefore impose excessive restrictions on disclosure by the industry.
The following Code provides for disclosures of transfers of value to healthcare professionals, whether directly or indirectly. When deciding how a transfer of value should be disclosed, companies should, wherever possible, identify and publish at the individual healthcare professional (rather than healthcare organisation) level, as long as this can be achieved with accuracy, consistency and compliance with applicable law.

The following code imposes obligations to disclose transfers of value to healthcare professionals and healthcare organisations commencing with reporting in 2016 in respect of transfers of value for the calendar year 2015. The provisions of this Code shall be implemented by EFPIA’s member associations in a manner consistent with applicable competition and data protection laws and regulations and all other applicable legal requirements.

**APPLICABILITY OF THIS CODE**

This Code governs disclosures regarding certain interactions with HCPs and HCOs. It is intended that this Code shall apply to interactions with HCPs and HCOs to the same extent as the existing HCP Code and PO Code\(^1\). Therefore, this Code applies to Member Companies, including:

- Full members: research-based pharmaceutical companies, developing and manufacturing medicinal products in Europe for human use – called corporate members;
- Affiliate members: companies specialising in particular fields of pharmaceutical research and/or development or in new technologies of particular interest to the pharmaceutical industry – called “affiliate corporate members”;
- Research-based pharmaceutical companies operating in a particular segment of the pharmaceutical market that join a specialised group within EFPIA: (i) European Bio-pharmaceutical Enterprises (EBE); and (ii) Vaccines Europe (VE).

Separate entities belonging to the same multinational company – which could be the 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 – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.

“Europe”, as used in this Code, refers to, collectively, those countries for which there is an EFPIA Member Association.\(^2\)

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\(^1\) This Code is not intended to apply to Transfers of Value the disclosure of which is already provided for under, or that are otherwise regulated by, the PO Code.

\(^2\) Those countries currently include the following 33 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.
This Code sets out the minimum standards which EFPIA considers must apply to all EFPIA Member Associations in all member states. All EFPIA Member Associations will be required to transpose this Code into their national codes in full, except where its provisions are in conflict with applicable national laws or regulations, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation.

Where an EFPIA Member Association has determined that this Code cannot be implemented in full due to national law or regulation, such EFPIA Member Association will not be in breach of its obligations under this Code if the deviation from this Code is no broader than necessary to comply with such national law or regulation and if it clearly documents the legal issues limiting full implementation. It is understood that if there is an inconsistency between this Code and the applicable law or regulation to which a Member Company is subject which would make adherence to this Code not reasonably possible, the Member Company must comply with such law or regulation and such lack of adherence shall not constitute a breach of this Code.

Member Companies shall be bound by the relevant EFPIA Member Association’s code in each country in Europe in which they operate (whether directly or through its relevant subsidiary). If an EFPIA Member Association where a Member Company operates fails to transpose this Code into its national code by the relevant deadline, such Member Company will be required to comply with this Code. If a Member Company is not a member of the EFPIA Member Association in any given country in Europe, it agrees, as a consequence of its membership in EFPIA (either directly or through its relevant subsidiary), to be bound by that EFPIA Member Association’s code (including any applicable sanctions that may be imposed under such code).

Non-member associations and companies that decide to voluntarily implement this Code shall require that each of their respective members, affiliates and subsidiaries, as applicable, comply with all of the provisions of this Code.

ARTICLE 1
DISCLOSURE OBLIGATION

Section 1.01. General Obligation. Subject to the terms of this Code, each Member Company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 3.

Section 1.02. Excluded Disclosures. Without limitation, Transfers of Value that (i) are solely related to over-the-counter medicines; (ii) are not listed in Article 3 of this Code, such as items of medical utility (governed by Article 9 of the EFPIA HCP Code), meals and drinks (governed by Article 10, especially Section 10.05 of the EFPIA HCP Code), medical samples (governed by Article 16 of the HCP Code); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and an HCP (such as a pharmacist) or an HCO do not fall within the scope of the disclosure obligation described in Section 1.01.

Section 1.03. Schedules. Each of the attached Schedules forms part of this Code. Definitions of capitalised terms are included in Schedule 1 to ensure consistent understanding of such terms.

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Section 1.03. Schedules. Each of the attached Schedules forms part of this Code. Definitions of capitalised terms are included in Schedule 1 to ensure consistent understanding of such terms.
ARTICLE 2
FORM OF DISCLOSURE

Section 2.01. Annual Disclosure Cycle. Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the “Reporting Period”). The first Reporting Period shall be the calendar year 2015.

Section 2.02. Time of Disclosure. Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period and the information disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed in accordance with Section 2.04, unless, in each case, (i) a shorter period is required under applicable national data privacy or other laws or regulations, or (ii) the Recipient’s consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked.

Section 2.03. Template. Subject to Section 2.04(ii), for consistency purposes, disclosures pursuant to this Code will be made using a structure set forth in Schedule 2 for reference, reflecting the requirements of this Code.

Section 2.04. Platform of Disclosure. Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:

(i) on the relevant Member Company’s website in accordance with Section 2.05; or

(ii) on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or a Member Association, provided that disclosures made on a central platform developed at the initiative of Member Associations shall be made, so far as possible, using a structure set forth in Schedule 2 for reference.

Section 2.05. Applicable National Code. Disclosures shall be made pursuant to the national code of the country where the Recipient has its physical address. If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its physical address, the Member Company shall disclose such Transfer of Value in a manner consistent with the national code to which it is subject.

Section 2.06. Language of Disclosure. Disclosures shall be made in the language(s) prescribed in the national code by the relevant Member Association. Member Companies are encouraged to make disclosures in English in addition to the mandatory disclosures in the local language (if other than English).

Section 2.07. Documentation and Retention of Records. Each Member Company shall document all Transfers of Value required to be disclosed pursuant to Section 1.01 and maintain the relevant records of the disclosures made under this Code for a minimum of 5 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national data privacy or other laws or regulations.
ARTICLE 3
INDIVIDUAL AND AGGREGATE DISCLOSURE

Section 3.01. Individual Disclosure. Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis. Each Member Company shall disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to Transfers of Value to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

1. For Transfers of Value to an HCO, an amount related to any of the categories set forth below:
   a. Donations and Grants. Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 11 of the HCP Code).
   b. Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:
      i. Registration fees;
      ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and
      iii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code).
   c. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

2. For Transfers of Value to an HCP:
   a. Contribution to costs related to Events. Contribution to costs related to Events, such as:
      i. Registration fees; and
      ii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code).
   b. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on
the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

Section 3.02. **Aggregate Disclosure.** For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 3.01, cannot be disclosed on an individual basis for legal reasons, a Member Company shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

Section 3.03. **Non Duplication.** Where a Transfer of Value required to be disclosed pursuant to Section 3.01 or 3.02 is made to an individual HCP indirectly via an HCO, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual HCP named basis pursuant to Section 3.01(2).

Section 3.04. **Research and Development Transfers of Value.** Research and Development Transfers of Value in each Reporting Period shall be disclosed by each Member Company on an aggregate basis. Costs related to events that are clearly related to activities covered in this section can be included in the aggregate amount under the “Research and Development Transfers of Value” category.

Section 3.05. **Methodology.** Each Member Company shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 3.01. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

ARTICLE 4
ENFORCEMENT

Section 4.01. **Enforcement through Member Associations.** Each Member Association shall adopt Implementation and Procedure Rules (as set forth in more detail in Schedule 3), which will be binding upon its members, and set forth the framework for the implementation of this Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other applicable laws and regulations.³

³ When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, companies are encouraged to include provisions relating to the Recipients’ consent to disclose Transfers of Value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.
Section 4.02. *Transposition in Member Associations’ Codes.* Each Member Association shall transpose the provisions of this Code into its national code by 31 December 2013. This Code sets out the minimum standards applicable to Member Associations, except where it is in conflict with applicable national law or regulation, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation. Any provisions contained in national codes that embody higher standards than those of this Code shall not be deemed to constitute deviations from this Code.

Section 4.03. *Disclosure Requirements Different from this Code.* Any proposal to transpose this Code into a national code, or to amend any provision transposing this Code, that requires disclosures different from those required under this Code, shall be clearly and conspicuously so identified in the relevant Member Association’s consultative process and any materials relating to such proposal. In such case, the EFPIA General Assembly shall be asked to confirm consistency with this Code, following an EFPIA Board decision after consultation with the EFPIA Codes Committee. Member Companies abiding by such Member Associations’ codes as confirmed by the EFPIA General Assembly shall not be considered to have failed to meet their obligations under this Code.

If the applicable national law or regulation, the relevant national code or other industry self-regulation prescribes equivalent or more stringent disclosure requirements, the relevant Member Company shall comply with such equivalent or more stringent requirements in a manner as consistent as possible with the substantive disclosure requirements of this Code.

Section 4.04. *Sanctions.* Each Member Association should include in its code provisions governing the imposition of sanctions for violations of its 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 will generally be considered to be the most effective sanction; however, each Member Association may use any other appropriate sanction to enforce its code. Each Member Association should consider any applicable legal, regulatory or fiscal requirements which would affect the nature or extent 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.

Section 4.05. *Reporting.* The EFPIA Codes Committee shall produce at least annually reports summarising:

(i) the transposition by Member Associations of this Code into their national codes (such report to be produced by 31 March 2014, which date is three months after the deadline for the transposition of this Code by Member Associations and prior to the 2014 General Assembly so as to allow sufficient time to remedy inadequate or incomplete transposition by any Member Association); and

(ii) once this Code has been transposed into national codes and disclosures are made for the first time in 2016 (no later than 30 June 2016), activities related to this Code (first such report to be produced in September 2016).
ARTICLE 5
AMENDMENTS TO, AND GUIDANCE REGARDING COMPLIANCE WITH, THE CODE

Section 5.01. Code Compliance. The EFPIA Codes Committee shall assist Member Associations to comply with their obligations under this Code. The key tasks of the Committee are set forth in Schedule 3 attached to this Code.

Section 5.02. Amendments to the Code. The EFPIA Codes Committee shall regularly review this Code and any guidance issued regarding compliance with this Code.

Any proposed amendments to the Code will be submitted for the EFPIA Board decision and the EFPIA General Assembly ratification. Proposed amendments to this Code shall be reviewed by the Codes Committee following consultation with the EFPIA membership and the relevant EFPIA committees.
Schedule 1

Definition of terms used in the EFPIA HCP/HCO Disclosure Code

Donations and Grants
Donations and Grants, collectively, means those donations and grants (either cash or benefits in kind) within the scope of Article 11 of the HCP Code.

Events
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. (Article 10 of the HCP Code).

HCO
Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

HCP
Any natural person that is a 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, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

HCP Code
EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopted by the EFPIA Board on 5 July 2007 and ratified by the EFPIA Statutory General Assembly on 19 June 2008, amended on 14 June 2011, and as further amended on 24 June 2013, and as may be amended, supplemented or modified from time to time.

Medicinal Products
Medicinal Products as used in the EFPIA HCP/HCO Disclosure Code has the meaning set forth in Article 1 of the Directive 2001/83/EC, including: medicinal products, immunological medicinal products, radiopharmaceuticals, medicinal products derived from human blood or human plasma, for which a marketing authorisation has been delivered in application of Directive 2001/83/EC.
**Member Associations**
Collectively, the national Member Associations or their constituent members, as the context may require, and bound by the EFPIA codes of practice, including the EFPIA HCP Code, the EFPIA PO Code and the EFPIA HCP/HCO Disclosure Code.

**Member Companies**
Collectively, "corporate members" (as defined in the HCP Code) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organisation) and any companies affiliated with corporate members or their subsidiaries
Separate entities belonging to the same multinational company – which could be the 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 – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.

**PO Code**
EFPIA Code of Practice on Relationships between Pharmaceutical Industry and Patient Organisations, adopted in 2007 and as amended by the General Assembly on 14 June 2011, and as may be amended, supplemented or modified from time to time.

**Recipient**
Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

**Research and Development Transfers of Value**
Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) 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, HCPs specifically for the study (Section 15.01 of the HCP Code).

**Transfers of Value**
Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.
Schedule 2

Model of a Standardised Template

For reference

Insert template
Schedule 3

IMPLEMENTATION AND PROCEDURE RULES

The Implementation and Procedure Rules set out below establish the framework for the implementation of the European Federation of Pharmaceutical Industries and Associations (“EFPIA”) Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (the “Code”), the processing of complaints and the enforcement of sanctions ordered by Member Associations.

SECTION 1. Member Association Implementation

Each Member Association is required to:

a. establish national procedures to receive and process complaints, to determine sanctions to be ordered 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 Codes Committee an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the applicable 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, who will elect a chair among their peers, 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 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 Code and to encourage best practice among Member Associations, 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 Code. Any conclusions from the meeting shall be summarised in the Annual Codes 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 will summarise 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 summarised in the Member Association’s annual reports; and (ii)
review with the EFPIA Board any additional recommendations to improve the Code with a view towards increasing transparency and openness within the pharmaceutical industry and among Member Associations and companies.

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Complaints may be lodged either with a Member Association or with EFPIA. Adjudication of complaints shall be a matter solely for the Member Associations.

Complaints received by EFPIA shall be processed as follows:
   a. EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant Member Association(s).
   b. EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant Member Association(s) to which the complaint has been sent for processing and adjudication.
   c. In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar matter(s) lodged from outside the industry against several subsidiaries of any company), EFPIA will communicate these complaints to the Member Association either of the parent company or of the European 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 made the complaint.
   b. Complaints will be processed at the national level using the procedures established by the relevant Member Association(s) pursuant to Section 1(a) above. Each Member Association's national body shall take decisions and order 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 the applicable national 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 at the national level.
   e. Member Associations shall ensure, to the extent permissible, that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, including a level of detail that takes into account 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. Member Associations or national disciplinary bodies 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).