PHARMACEUTICAL RESEARCH-BASED INDUSTRY MALTA ASSOCIATION

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

Adopted by PRIMA*

* As adopted by PRIMA Board on August 25th 2014

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SUBSEQUENT VERSIONS OF THE EFPIA HCP CODE

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

In November 2001, Council Directive 2001/83/EC superseded Council Directive 92/28/EEC.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

In late 2006 and early 2007, the EFPIA Code was further revised to adopt various improvements and address additional topics suggested by the General Assembly. This revised version of the EFPIA Code was adopted by EFPIA Board on 28/09/2007 [date of written approval] with effect from no later than 1 July 2008 (depending on national transposition dates) (the "Implementation Date"). Recognising that the 2007 revision imposes certain obligations upon companies that may take time in order to be implemented fully, the EFPIA Code includes footnotes in the following sections to provide guidance to companies as to their obligations under the EFPIA Code during the transition period: (a) 0; and (b) 0. In general, companies should include any applicable provisions in their contracts with healthcare professionals or make any additional disclosures required by the EFPIA Code beginning on the Implementation Date, however, companies are 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 Pharmaceutical Research Based Industry Malta Association, PRIMA, is affiliated with EFPIA and its code (approved 13th November 2008) outlined below is based on the EFPIA code approved on 05/10/2007.

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 is as such committed to compliance with the EFPIA Codes.

EFPIA and its members[1] 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 PRIMA CODE

The PRIMA Code covers the promotion to healthcare professionals of prescription-only medicinal products and interactions between healthcare professionals and pharmaceutical companies. The PRIMA Code is applicable to PRIMA 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 PRIMA 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 PRIMA 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 authorization has been delivered in application of directive 2001/83/EC.

The PRIMA 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 PRIMA 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 0), 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 PRIMA 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 PRIMA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations and the PRIMA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals requires compliance with such rules.

The 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.

The PRIMA Code does not cover the following:

- the labeling 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 PRIMA Code are: Annex A, the "**Implementation and Procedure Rules**" which are binding upon member companies and companies who have signed to abide by the PRIMA Code and set forth the framework for the implementation of the PRIMA Code, the processing of complaints and the initiation or administration of sanctions by member associations; Annex B, the "**Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU**" which provide guidance to member associations and companies with respect to the content of websites containing information on medicinal products subject to prescription; and Annex C, also binding upon member companies and companies who have signed to abide by the PRIMA Code **Disclosure Requirements**

APPLICABILITY OF CODES

The PRIMA Code sets out the minimum standards which PRIMA considers must apply and is based on the EFPIA Codes. In a manner compatible with the Maltese law specified in the Medicinal Products (Advertising) Regulation Legal Notice 380 of 2005 as part of Medicines Act of 2003 (attached annex).

Member Companies must comply with any Applicable Codes and any laws and regulations to which they are subject

The spirit, as well as the letter of the provisions of the PRIMA Code must be complied with. PRIMA 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 PRIMA 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 0 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 The scope of Informational or educational materials and items of medical utility considered may not constitute a circumvention of the prohibition on gifts defined under Article 17 of this Code.

Section 9.04 Interpretation of terms used in section 9

Examples of items of medical utility :

- Monitoring or training devices including lung capacity disc, lung age monitor, COPD predictor, peak flow meters and disposable mouth pieces, trainers and demonstrators

- Anatomical charts / models / posters and other miscellaneous charts / posters (e.g. pictures of pills, inhalers, vaccine schedules)

- Calculators, software or mobile Apps including BSA calculator, VTE risk calculator, BMI, lung function, antiepileptic drug interactions, osteoporosis, dosage calculators, as long as the calculator is specific and can only be used for that purpose (i.e. it is not a general calculator)

- Pen drive (thumb drive, memory stick) or CD containing relevant medically approved educational materials (as long as the storage capacity is commensurate with the amount of data to be stored)

- Medical/scientific publications including:

    - Conference abstracts as a book or CD of conference proceedings

    - Single recent issue of a journal relevant to a relevant therapy area

    - Compilation of up to 6 articles (papers or abstracts) from various journals on a specific disease area or topic

The term "inexpensive", as used in this Article 9: Educational materials and items of medical utility should not exceed €15 per item.

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**").

Section10.03. 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 meals (food and beverages) to healthcare professionals, unless, in each case, the value of such meals (food and beverages) does not exceed the monetary threshold of €60 per HCP set by the PRIMA code. The monetary threshold set in the country where the event takes place (i.e. the "host country") shall prevail.

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. Interpretation of terms used in section 10.

Reasonable hospitality should be limited to the main scientific objective of an event and restricted to the healthcare professional for the duration of the event, and not extended beyond 24 hours from commencement or adjournment of event subject to flight availability. It must not be extended to persons other than health care professionals. Hospitality during local events should not exceed €60 per HCP.

Venues should be chosen on the basis of their suitability for conducting a scientific meeting. They should not be chosen for their entertainment and sporting facilities (eg Golfing/ sailing/ go-carting etc. offered as an extension to the meeting)

ARTICLE 11
DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE OR RESEARCH

Section 11.01. Donations, grants and benefits in kind to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the PRIMA Code or the PRIMA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations) are only allowed if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Donations and grants to individual healthcare professionals are not permitted under this section. Company sponsorship of healthcare professionals to attend international events is covered by 0. Companies are encouraged to keep all records and information about donations, grants or benefits in kind made by them covered in this 0. and to make them available to PRIMA for transparency should clarification be requested.

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 0 or not otherwise covered by the PRIMA 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 0, 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 0 is not intended to prohibit the extension of hospitality to healthcare professionals in accordance with 0 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 0 apply even though the PRIMA Code does not otherwise cover non-promotional, general information about companies (as discussed in the "Scope of the PRIMA Code" section).[2]

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 0, 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.

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) 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;

[2] 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 0. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such provisions.

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

d) In countries where ethics committees are prepared to review such studies, the study protocol should be submitted to the ethics committee for review;

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

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

g) The study protocol must be approved by the company's scientific service and the conduct of the study must be supervised by the company's scientific service as described in b);

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 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 0 for all other types of studies covered by 0, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to 0.

[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.

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.

For POM products launched on the local private market after 1st April 2012, 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 healthcare 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 the date that the first pack is placed on the local private market.

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.

For medicines launched before 1st April 2012, a transition period until December 2013 should apply. During this transition period, the local regulation of a maximum of 12 samples of a particular medicine per year per prescriber will still hold.

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 healthcare professional, the number of samples supplied in application of the provision in Section 16.01 (i.e. the “4x2” standard).

Section16.03. Each sample shall be no larger than the smallest presentation on the market.

Each sample must be marked 'free medical sample– not for resale' 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 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 g) (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
AWARENESS AND EDUCATION

Section 19.01. PRIMA will circulate amongst all its members a copy of the code whenever it is reviewed and updated. An informative meeting for discussion and clarification will be held for all members and their representatives once the PRIMA Code is approved by PRIMA board. PRIMA will share its interpretations

of the EFPIA Code through the IFPMA Code Compliance Network and the regular meetings organised by EFPIA (see Annex A, Section 2).

ANNEX A (binding)

IMPLEMENTATION AND PROCEDURE RULES

SECTION 1. *PRIMA will*

(a) Establish, as outlined in this Annex (Annex A), 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) make accessible to all members as outlined in Article 19, publication of its national code,

(c) prepare, and provide to the EFPIA Code Committee (defined below), an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the year.

SECTION 2. *Reception of Complaints*.

(a) Complaints may be lodged either with PRIMA or with EFPIA. Adjudication of complaints shall be a matter solely for PRIMA.

(d) 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 PRIMA*

(a) PRIMA 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 by PRIMA through the procedures and structures established by it 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 as detailed above.

(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 the PRIMA code. Any complaint which pursues an entirely or predominantly commercial interest shall be dismissed.

(d) A company found to be in breach of the code has a right to appeal to decisions taken by the board within a month of receiving notice of such decision. An independent appeals board will be set up to review the case, a meeting with the company set up within 1 month and a decision communicated with the company within another month.

(e) PRIMA 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:

PRIMA Member associations must, within current applicable rules and legislation enforce the provisions of the PRIMA 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.

The offending company should comply with the above within 1 month from date of first communication of compliance officer with the offending company. After the stipulated 1 month, non-compliance will oblige the company to pay PRIMA a penalty of €300 for the first offence and €500 for each repeated offence. Following three proven offences by the same company, the board of PRIMA will apply its jurisdiction in determining the future of the said company within the Association for a period of time as determined by the same Board. The offence will be made public during the annual general meeting.

(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).

PRIMA will 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).

Section 5. Template for Processing of Complaints

Date of Complaint: _____

Details of Complaint: _____

Workings of Sub-Committee: _____

Decision Taken: _____

Date of Closure of Case: _____

Appeal Lodged: Yes ☐ No ☐

Date of Appeal: _____

Workings of Sub-Committee: _____

Decision Taken: _____

Date of Closure of Case: _____

ANNEX B (guidelines)

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

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

SECTION 1. *Transparency Of Website Origin, Content And Purpose*. Each website shall clearly identify:

(a) the identity and physical and electronic addresses of the sponsor(s) of the website;

(b) the source(s) of all information included on the website, the date of publication of the source(s) and the identity and credentials (including the date credentials were received) of all individual/institutional providers of information included on the website;

(c) the procedure followed in selecting the content included on the website;

(d) the target audience of the website (e.g., healthcare professionals, patients and the general public, or a combination thereof); and

(e) the purpose or objective of the website.

SECTION 2. *Content of Websites*.

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

Examples of the information that may be included in a single website or in multiple websites are: (i) general information on the company; (ii) health education information; (iii) information intended for healthcare professionals (as defined in the EFPIA Code), including any promotion; (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 organizations (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 Code) must comply with Applicable Code(s) (as defined in the EFPIA 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 an 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 PRIMA 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.

ANNEX C binding (PRIMA HCP/HCO Disclosure Requirements)

PRIMA REQUIREMENTS ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

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.

PRIMA 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. PRIMA 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", PRIMA believes that it is critical to the future success of the pharmaceutical industry to respond to society's heightened

expectations. PRIMA has therefore decided that its existing Code covering the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals and Relationships between the Pharmaceutical Industry and Patient Organisations should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organisations. PRIMA 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.

PRIMA believes that the interest of patients and other stakeholders in the transparency of these interactions is compelling. PRIMA recognises that disclosure can raise data privacy concerns and seeks to work with healthcare professionals to ensure that these concerns are addressed. PRIMA 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 Disclosure requirements provide 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 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. These provisions of this Code shall be implemented by PRIMA in a manner consistent with applicable competition and data protection laws and regulations and all other applicable legal requirements.

APPLICABILITY

The Disclosure requirements govern disclosures regarding certain interactions with HCPs and HCOs. It is intended that these shall apply to interactions with HCPs and HCOs to the same extent as the existing provisions of this Code.. These provisions are 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 requirements.

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, Annex C.

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, Annex C , such as items of medical utility *(governed by Article 9),* meals and drinks *(governed by Article 10, especially Section 10.05)*, medical samples *(governed by Article 16)*; 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 Annex C.

Section 1.03. *Schedules*. Each of the Schedules to Annex C forms part of these requirements. 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 Annex C will be made using a structure set forth in Schedule 2 Annex C, for reference, reflecting the requirements of this Code.

Section 2.04. *Platform of Disclosure.* Disclosures are to be made on the relevant Member Company's website in accordance with Section 2.05.

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 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, Annex C, 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 these requirements, 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*).

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)*

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)*

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, Annex C, 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, Annex C, 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), Annex C.

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, Annex C. 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 and Sanctions: Annex A (binding) sets out the Implementation and Procedural riles which apply equally to Annex C (binding)*

Schedule 1

Definition of terms used in the PRIMA HCP/HCO Disclosure Requirements

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)*

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 PRIMA 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.

Medicinal Products

Medicinal Products as used in the Annex C Disclosure Requirements 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 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 PRIMA 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.