Ravimitootjate Liit

Association of Pharmaceutical Manufacturers in Estonia

CODE OF THE ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS IN ESTONIA ON THE PROMOTION OF PRESCRIPTION MEDICINES AND COOPERATION WITH HEALTHCARE PROFESSIONALS

Adapted and adopted by the Association of Pharmaceutical Manufacturers in Estonia on the basis of the EFPIA code*

* In the form adopted by the APME General Assembly of 29.05.2008, with supplements adopted at the APME General Assembly of 28.05.2009, 11.06.2010, 09.12.2010, 03.06.2011, 07.06.2012, 06.12.2013 and 19.06.2014.

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INTRODUCTION

The code of the Association of Pharmaceutical Manufacturers in Estonia on the Promotion of Prescription Medicines and Cooperation with Healthcare Professionals is based on the EFPIA code on the Promotion of Prescription-Only Medicines to, and Interaction with, Healthcare Professionals, adopted by the EFPIA Board on 05.10.2007.

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 thirty European countries and over forty leading pharmaceutical companies. EFPIA's primary mission is to promote the technological and economic development of the pharmaceutical industry in Europe and to assist in introducing to the market medicinal products that improve human health worldwide.

The Association of Pharmaceutical Manufacturers in Estonia (APME) is a non-profit organisation, which represents research-based and generic pharmaceutical manufacturers operating in Estonia, whose production is meant for sale on the basis of prescriptions or under the control of healthcare professionals and who follow ethical principles in their operation

EFPIA and its members 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 Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the **EFPIA Code**).[1] The EFPIA Code reflects the requirements of Council Directive 2001/83/EC, as amended, relating to medicinal products for human use (the "**Directive**"). The EFPIA Code fits into the general framework established by

[1] 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 upon companies certain obligations 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) Section 14.02; and (b) 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 Code beginning on the Implementation Date; however, companies are encouraged to take such actions in advance of the Implementation Date.

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.

APME supports competition among pharmaceutical companies. The APME 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, the code 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 APME Code thereby aims to foster an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients.

SCOPE OF THE APME CODE

The APME Code regulates the promotion of medicinal products to healthcare professionals, and cooperation between healthcare professionals and manufacturers of medicinal products. The APME Code applies to APME member companies, their subsidiaries, and any companies affiliated with APME member companies or their subsidiaries if such affiliated companies have agreed to be bound by the APME Code (**Member Companies**).

Member Companies shall also be responsible for the obligations imposed under any relevant Applicable Code (defined below) even if they authorise other parties (e.g. contracted sales force, consultants, market research companies, advertising agencies) to design, implement or perform activities covered by the Applicable Code (defined below) on their behalf. In addition, Member Companies shall take reasonable steps to ensure that any other parties that they authorise to design, implement or perform 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/advertising", as used in the APME Code, includes any activity undertaken, organised or sponsored by a Member Company, or with its authority, promoting the prescription, supply, sale, administration, recommendation or consumption of its medicinal product(s). "**Medicinal products"**, as used in the APME Code, has the meaning set forth in Article 1 of the Directive: (a) any substance[2] or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting

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

or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. The APME Code covers promotional activities and communication directed towards, and cooperation with, any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his/her professional activities may prescribe, purchase, supply or administer a medicinal product (each, a **healthcare professional**).

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

The APME Code also regulates cooperation 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 regulated by the APME Code of Practice on Relationships between Pharmaceutical Companies and Patient Organisations, and the APME Code on the Promotion of Prescription Medicines and Cooperation with Healthcare Professionals requires compliance with such rules.

The APME 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 APME 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 data and reference material relating, for example, to package changes, adverse-reaction warnings as a 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 discussions on regulatory developments affecting a company and its products.

Attached to the APME Code are: Annex A, the "**Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU**", which provides guidance to Member Associations and Companies with respect to the content of websites containing information on medicinal products subject to prescription and Annex B **Common application forms for sponsorship**, Annex C **Methodology of disclosure of payments made either directly or indirectly to health care professionals and pharmacists or health care providers** and Annex C1 **Data disclosure form**.

APPLICABILITY OF CODES

The APME Code sets out the minimum standards considered to be applicable by APME. In a manner compatible with their respective national laws and regulations, Member Associations must, at a minimum, adopt in their national codes provisions that are no less rigorous than the provisions contained in the EFPIA Code.

*Promotion and interaction which take place within Europe must comply with applicable laws and regulations. "**Europe**" as used in the EFPIA 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, an enterprise located within Europe, the national code of the Member Association of such an enterprise's country of location; or (ii) in the case of promotion or cooperation that is undertaken, sponsored or organised by or on behalf of, or with, an enterprise located outside of Europe, the EFPIA Code; and

(b) the national code of the Member Association located in the country where 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 otherwise provided by Section 13.01). For the avoidance of doubt, the term "**company/enterprise**", as used in this EFPIA 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 an entity is 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 all Applicable Codes and any laws and regulations to which they are subject. All enterprises that are members of EFPIA must either (i) be a member of the Member Association in each country where it conducts activities regulated by the EFPIA Code (either directly or through a relevant subsidiary) or (ii) agree in writing with each such Member Association that it (or its relevant

subsidiary) is bound by the code of such a Member Association (including any applicable sanctions that may be imposed there under).

To facilitate compliance with Applicable Codes, APME shall establish adequate procedures to ensure that each of its Member Companies complies with the requirements of the national code of such a Member Association and the national code of any other Member Association which may be applicable to its activities, even if the company does not belong to the other Member Association. In order to establish adequate procedures to ensure compliance with Applicable Codes, APME will be required, among other things, to introduce appropriate complaint procedures and sanctions for breaches of its respective codes. Additionally, any relevant local subsidiary shall be notified of all international events (as defined in Section 9.02 of the EFPIA Code) or, alternatively, local advice must be taken.

Both the spirit and the form of the provisions of the EFPIA Code have been adhered to.

PROVISIONS OF THE APME CODE

ARTICLE 1
MARKETING AUTHORISATION

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. Pursuant 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.

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. Advertisements intended as reminders are prohibited in Estonia

pursuant to the requirements for the advertising of medicinal products determined by the Medicinal Products Act.

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/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 authorisation.

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 and included in promotional material, shall:

(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 promotional material is not misleading regarding the nature of a medicine (for example whether it is appropriate for children) or a claim or comparison thereof (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 justification.

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-authorisation 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 an enterprise purchases, orders or otherwise arranges the publication of promotional material in newspapers and journals, such promotional material must not resemble independent editorial matter.

Section 7.04. Material, which is sponsored by an enterprise and relates to medicines and their uses, whether promotional in nature or not, must clearly indicate the name of the sponsoring enterprise

Section 7.05. The publications that are prepared and/or whose preparation has been supported by manufacturers shall indicate the date of its completion as well as the name of the sponsoring enterprise clearly and in a distinguishable manner.

ARTICLE 8
NO ADVICE ON PERSONAL MEDICAL MATTERS

Section 8.01. In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

ARTICLE 9
EVENTS AND HOSPITALITY

Section 9.01. All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigatory meetings for clinical trials and non-interventional studies) (each, an **event**) organised or sponsored by or on behalf of an enterprise must be held in an "appropriate" venue that is conducive to the main purpose of the event. In this context, APME considers venues equipped with conference halls to be "appropriate" places for meetings.

Section 9.02. No enterprise may organise or sponsor an event that takes place outside its home country, unless:

(a) most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or

(b) given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "**international event**").

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

Section 9.04. Hospitality extended in connection with events shall be limited to travel, meals, accommodation and registration fees. The provision, sponsoring or organisation of entertainment (e.g. sports, cultural and leisure events) as separate events or as a part of another event is not allowed.

Section 9.05. Hospitality may only be extended to persons who participate in the events as professionals.

Section 9.06. All forms of hospitality offered to healthcare professionals shall be "reasonable" in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves. Any meals (food and beverages) shall not be

Section 9.07. provided or offered to healthcare professionals, unless, in each case, the value of such meals (food and beverages) does not exceed the monetary threshold of 80 euros per person including VAT. The monetary threshold for meals (food and beverages) outside of Estonia is the threshold set by the country.. Enterprises should avoid using venues that are "renowned" for their entertainment facilities or that are "extravagant".

Section 9.08. Below, APME shall provide guidance on the meaning of the term "**reasonable**", as used in this article. APME shall also provide guidance on "**appropriate**", "**renowned**" and "**extravagant**" venues, as used in Section 9.01 and Section 9.06. The provided hospitality is "**reasonable**" if its costs remain within the average limits that the invitees would be prepared to pay for themselves. The

prerequisite for an "**appropriate**" venue is the availability of conference halls; it is also important that the invitees not participate because of the venue and that they not use the entertainment options (even if the venue does include such additional value). Since in Estonia, most venues for holding conferences are "**renowned**" as places of entertainment in one way or another, then it must be considered that the place itself cannot be the motivation for attending the event. Pursuant to this Code, a venue is "**extravagant**" if its uniqueness can be considered as motivation for attending the event. Enterprises must comply with any relevant guidance provided under Section 9.07 in connection with the APME Code.

ARTICLE 10
GIFTS, INFORMATIONAL AND EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

Section 10.01. No gift or pecuniary advantage in cash or benefit in kind (such as tickets to entertainment events, trips, gift cards, stationery, notepaper, etc) may be supplied, offered or promised to a healthcare professional.

Section 10.02. The transmission of informational or educational materials is permitted provided it is:

(i) "inexpensive";
(ii) directly relevant to the practice of medicine or pharmacy;
(iii) directly beneficial to the care of patients.

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

Section 10.03. The meaning of the term "inexpensive" for informational or educational materials and Items of medical utility in APME code is based on the value set in Medicinal Products Act that states the object must remain within the limits of 6.40 euros and to be work-related, objects manufactured in 2013 can be utilized until the end of the transitional period that is 1-st of July 2014.

Section 10.04. Companies must comply with any relevant guidance provided under the article 10 in connection with, any Applicable Code(s).

ARTICLE 11
DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE OR RESEARCH

Section 11.01. Donations, grants and benefits in kind to institutions, organisations or associations to which healthcare professionals belong and/or which provide healthcare services or conduct research (that are not otherwise covered by the Code or the 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. Enterprise sponsorship of healthcare professionals to attend international events is covered by Article 13. Pursuant to the provisions of the Medicinal Products Act, by 1 February each year, a holder of a marketing authorisation in respect of a medicinal product shall submit to the State Agency of Medicines a report concerning support awarded to dispensing chemists, pharmacists, doctors and their associations for participation in medical or pharmaceutical events or for organisation of such events, and concerning the meetings and patient information events organised, samples distributed and discounts given during the previous year. A report on advertising of medicinal products submitted by a marketing authorisation holder is public information.

ARTICLE 12
FEES FOR SERVICE AND DISCLOSURE OF TRANSFERS OF VALUE

Section 12.01. Contracts between companies and institutions, organizations or associations of healthcare professionals under which such institutions, organizations 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 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.

Section 12.02. Donations and grants, contribution to event related costs such as registration fees, travel and accommodation costs, fees for service and consultancy paid either directly or indirectly to health care professionals and pharmacists or health care providers in the previous year shall be disclosed six months after the end of financial year at APME member companies website according to the APME ethical code Appendix C methodology and Table C1 Data disclosure form.

Section 12.03. The disclosure of the data shall be made at APME member companies website in Estonian and if needed in English no later than 1-st of June after the end of the relevant reporting year. The first disclosure of the data shall be made on 1-st of June 2016 based on the year of 2015 data.

Section 12.04. Donations and grants, contribution to event related costs such as registration fees, travel and accommodation costs, fees for service and consultancy paid either directly or indirectly to health care professionals and pharmacists or health care providers shall be disclosed on an individual basis and research and development transfers of value shall be disclosed on an aggregate basis.

Section 12.05. Disclosed fees shall be kept available at the APME member companies' website a minimum of 3 years after the time such information is first disclosed. APME member companies shall maintain the relevant records of the disclosures made for a minimum of 5 years after the end of the relevant reporting year according to the archiving rules established within the member companies.

Section 12.06. Violations of the obligation to disclose payments made either directly or indirectly to health care professionals and pharmacists or health care providers shall be handled by the APME Ethics Committee according to the Article 18 procedures and sanctions of this code.

ARTICLE 13
SPONSORSHIP OF HEALTHCARE PROFESSIONALS

Section 13.01. Enterprises must comply with criteria governing the selection and sponsorship of healthcare professionals to attend training or events as provided in, or in connection with, 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 where an enterprise 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 the Article hereof. In case of requesting or assigning sponsor support, it is recommended to be guided by common application forms (ANNEX C, *09.12.2010*).

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 actual consultancy or other services must, to the extent relevant to the particular arrangement, meet all the following criteria:

(a) a written contract or agreement is entered into in advance of the commencement of the services to specify 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 of consultants reasonably necessary to achieve the identified need;

(e) the contracting enterprise 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 compensations to healthcare professionals.

Section 14.02. (a) Good practice foresees that written agreements with consultants shall include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the enterprise 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 enterprise.

(b) Enterprises that employ, on a part-time basis, healthcare professionals that are still practising their profession, are obligated to ensure that such persons have an obligation to declare their employment arrangement with the enterprise whenever they write or speak in public about a matter relating to that enterprise. The provisions of clause (a) of this Section apply even when the Code does not otherwise cover non-promotional, general information about enterprises (as discussed in the "Scope of the Code" section).[3] Pharmaceutical companies are fully responsible for avoiding a conflict of interests between the work of a Medical Sales Representative and the prescription of medicines. A pharmaceutical company employee who engages in the sales of medicines shall not simultaneously work in a position granting the right to prescribe or dispense

[3] Enterprises are strongly encouraged to include such provisions in any contracts, which are entered into or renewed on or after the Implementation Date, and covered by Section 14.02. In addition, enterprises are encouraged to renegotiate existing contracts at their earliest convenience to include such provisions.

medicine. A Medical Sales Representative shall not have economic interests in the sales of medicines (wage schemes, bonuses etc.) whose prescription he/she can influence in his/her professional activities.

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 Section, provided that the healthcare professional is not consulted with 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. APME shall provide guidance on the meaning of "**minimal**" in connection with the Code. "**Minimal**" and "**reasonable**" remuneration is one that corresponds to the time spent and the average wages of the doctor.

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

ARTICLE 15
NON-INTERVENTIONAL STUDIES OF MARKETED MEDICINES

Section 15.01. A non-interventional study of a marketed medicine is defined as a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.

Section 15.02. Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study must comply with all of the following criteria:

(a) The study is conducted with a scientific purpose;

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

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

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

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

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

(g) The study protocol must be approved by the company's scientific service and the conduct of the study must be supervised by the company's scientific service as described in Section 17.02(a);

(h) The study results must be analyzed 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 17.02(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;[4] and

(i) Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

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

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

ARTICLE 16
SAMPLES

Section 16.01. As samples of medicinal products, one healthcare professional can be issued with up to four smallest packets marketable under a sales permit, and not in excess of the total of 300 packets a year for up to two years from the issue of the first samples of medicinal product and over up to five years from the registration of a new medicinal product or indication. Samples of a particular medicinal product may be provided on the basis of a written and signed application only to healthcare professionals who are qualified to prescribe that medicinal product. The time and place of providing a sample of a medicinal product, as well as the persons of the provider and the recipient shall be documented in an instrument of two copies, one of which shall be kept by the provider and the other by the recipient, and the recipient of the sample shall confirm the receipt of the sample with his/her signature. Samples must not be provided as an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Section 16.02. Enterprises must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by its representatives.

Section 16.03. Each sample of a medicinal product shall be marked with the words "*Mitte müügiks*" (not for sale), the package shall conform to the marketing authorisation and each sample shall be accompanied by a copy of the summary of product characteristics. Samples of medicinal products shall not be sold or transferred for non-medical purposes.

Section 16.04. Pursuant to the Medicinal Products Act, no samples of medicinal products containing narcotic drugs and psychotropic substances, and antibiotics may be supplied to any person.

ARTICLE 17
PHARMACEUTICAL COMPANY STAFF

Section 17.01. Each enterprise shall ensure that its Medical Sales Representatives, including personnel retained by way of contracts with third parties, and any other representatives of the enterprise calling 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 all Applicable Code(s), and all applicable laws and regulations, and enterprises are responsible for ensuring their compliance.

(b) Medical Sales Representatives must perform 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 enterprises forthwith any information they receive in relation to the use of the enterprise's medicinal products, particularly reports on 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, and the manner, in which they are made, do not cause inconveniences.

(f) Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. During an interview, or when seeking an appointment for an interview, Medical Sales Representatives must, from the outset, take reasonable steps to ensure that they are not misleading as to their identity or that of the enterprise they represent.

(g) The provisions of 15.02(i) are also applicable to the activities of Medical Sales Representatives.

(h) A representative of a pharmaceutical company must declare to the audience of the presentation which enterprise and which position he/she represents, while Medical Sales Representatives with a medical degree (doctors, pharmacists, nurses etc.) shall be obligated to declare a simultaneous connection/non-connection with any medical activity as e.g. a doctor, pharmacist, nurse etc. (*11.06.2010*).

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

(a) Every enterprise must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non-interventional studies. Enterprises are free to decide how best to establish such service(s) in accordance with Section 17.02 (i.e. whether one service in charge of both duties or separate services with clearly determined duties), taking into account the enterprise's 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 a person must certify that he/she has examined the final form of the promotional material and that in his/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 a person must certify that he/she has examined the protocol relating to the non-interventional study and that in his/her belief it is in accordance with the requirements of the Applicable Code(s).

(b) Each enterprise must appoint at least one senior employee who shall be responsible for supervising the enterprise and its subsidiaries to ensure that the standards of the Applicable Code(s) are met.

ARTICLE 18
IMPLEMENTATION OF THE CODE AND RULES OF PROCEDURE

Section 18.01 Breach of the Code can be filed by by the APME member pharmaceutical companies or by the representatives of the public

Section 18.02 Code breaches shall be handled by the Pharmaceutical Manufacturers' Ethics Committee (Ethics Committee) established under APME.

Section 18.03 In its work, the Ethics Committee shall pay equal attention to breaches of the APME Code that are committed both by companies belonging and companies not belonging in APME. If the case concerns a company not belonging in APME neither via its local office nor its parent company, the Committee shall handle the case analogously to cases concerning Member Companies

Section 18.04 Complaints must be filed in the written form and include the following information:

1) Name of the person filing the complaint
Personal data of the submitter of the complaint, his/her exact postal address, e-mail address, and if necessary, fax number.

2) Name of the enterprise in alleged violation of the Code
In every case referred to in the complaint, the name of the company in alleged violation of the Code and the name of the relevant product or products.

3) Reference material
In every case, evidence on the promotion or another activity that the complaint is based on shall be presented in print or in another form.

4) Date
The date of the alleged breach of the Code.

5) Content of the complaint
For every case, a short description of the breach with a reference to the Section or Clause of the Code, whose violation the complaint addresses, must be given.

Section 18.05 All mail shall be addressed to:
APME
J. Poska 51a
Tallinn 10150
E-mail: info(at)rtl.ee

Section 18.06 One complaint may include several cases, i.e. a complaint may refer to promotion by various companies and/or concerning various products. The Ethics Committee shall handle each case separately.

Section 18.07 If a complaint, which is in compliance with the requirements described in Article 18 of the APME Code, and refers to an alleged breach of the Code, reaches the coordinator of the Ethics Committee, he/she will register the complaint and send it to all members of the Ethics Committee as soon as possible (in a computer-readable form).

Section 18.08 In each case, first the company referred to in the complaint is determined, then its location in Estonia (if the company has an office in Estonia), and its headquarters or parent company and address.

Section 18.09 A summary of the case presented in the complaint and possible evidence is sent to the Estonian address of the company that has breached the APME Code (if the company has no Estonian address, to the address of its headquarters or the parent company).

Section 18.10 When a complaint reaches the Ethics Committee on the matter of an alleged breach of the Code of pharmaceutical manufacturers, it should first be determined whether:

(a) the complaint is true and made in good faith;
(b) the information presented is adequate enough to handle the complaint.

Section 18.11 If the initial information provided in the complaint is insufficient to handle the case, the coordinator of the Ethics Committee will contact the person who filed the complaint as soon as possible to obtain additional information.

Section 18.12 If a complaint does not constitute grounds to initiate proceedings or is clearly guided by the submitter's commercial interests, the Ethics Committee shall have the right to deny the complaint.

Section 18.13 Should the submitter of the complaint wish, he/she can withdraw the complaint before the first meeting of the Ethics Committee regarding the specific complaint. The withdrawal must be justified to the Ethics Committee (28.05.2009). The Ethics Committee will decide whether or not to satisfy the withdrawal application on the meeting following the receipt of the application.

Section 18.14 Within 5 working days since registering the initial complaint (during the holiday period, as soon as possible), the coordinator of the Ethics Committee shall send the complaint to the head of the pharmaceutical company referred to as the alleged Code violator in the complaint. The head shall be given the chance to submit his/her explanations to the Ethics Committee within 10 working days.

Section 18.15 A case shall be included in the agenda of the next planned Ethics Committee meeting, if 15 working days remain between forwarding the complaint to the alleged Code violator and the date of the planned meeting. Otherwise, discussions on the case shall be postponed.

Section 18.16 Information concerning complaints and relevant materials shall only remain known to the Ethics Committee, the coordinator of the Ethics Committee and the effective manager of APME. The information shall not be disclosed to third parties without the corresponding decision of the Ethics Committee.

Section 18.17 If the Ethics Committee is unable to make a relevant decision on the basis of the information provided in the complaint and by the alleged violator, the Ethics Committee may request additional information from the parties and postpone the making of the decision until the next Ethics Committee meeting..

Section 18.18 If necessary, the Ethics Committee may involve experts in handling the case or ask the opinion of an expert.

Section 18.19 If a complaint is filed against an enterprise belonging in the Ethics Committee, then the representative of the enterprise shall remove himself/herself from making decisions on the case.

Section 18.20 The representatives of both the submitter of the complaint as well as the company that the complaint is filed against may participate in the meeting and give explanations about the case concerning them, should they so wish.

Section 18.21 In case of a repeat breach of the Code damaging the reputation and credibility of the Ethics Committee, the Ethics Committee may request that the APME Board remove the representative of the company belonging in the Committee from the work of the Committee, if the representative has not resigned himself/herself.

Section 18.22 Upon a first-time breach, the Ethics Committee shall have the right to issue a warning to the enterprise that violated the provisions of the Code, along with the order to terminate the breach immediately. In case of a serious first-time breach, the Ethics Committee shall have the right to make a financial claim of up to 1300 euros,

which shall be transferred to the bank account of APME within 10 working days since receiving the claim.

Section 18.23 Serious first-time breaches are considered to be cases of obvious malicious activity, which ignore ethical standards on purpose.

Section 18.24 In case of a repetitive and malicious breach of the APME Code, the Ethics Committee shall have the right to present the violator of the Code's provisions with a financial claim of up to 6391 euros, and demand that the violator terminate the breach immediately and compensate for any damage.

Section 18.25 The Ethics Committee's decision shall be disclosed on APME website. The decisions shall be published in summary and do not contain data on individuals. If necessary, the parent company of the enterprise in violation of the provisions of the Code, the State Agency of Medicines, and EFPIA can be notified of the breach, and the case can also be publicised in the media.

Section 18.26 The Ethics Committee shall include 5 members of which 3 members are not associated with the pharmaceutical companies. The Ethics Committee shall be elected for three years on the proposal of the APME members and on the approval of APME Supervisory Board.

Section 18.27 The external members receive a fee for the work in Ethics Committee in the amount which is agreed with the APME Board. The Chairman of the Ethics Committee shall be elected from the members associated with the pharmaceutical companies; the members not associated with the pharmaceutical companies take part of the election.

Section 18.28 The work formats of the Ethics Committee are meetings, phone meetings and virtual communication. The meetings of the Ethics Committee take place according to the number of the complaints filed and the questions arisen, but no less frequently than 3 times a year.

Section 18.29 The coordinator of the work of the Ethics Committee will also take part in the Ethics Committee's meetings as an employee of the Association of Pharmaceutical Manufacturers in Estonia (he/she will take minutes of the meeting, concord the minutes/decision after the meeting with the members of the Ethics Committee, inform the members of APME about the decisions of the Ethics Committee, and perform other relevant information exchange, meeting planning and document management of the Ethics Committee).

Section 18.30 The Ethics Committee has a quorum, if all 3 external members take part of the meeting. The Ethics Committee decisions shall be taken open vote by a simple majority. The Ethics Committee's decisions are final and shall not be reconsidered.

Section 18.31 The Ethics Committee is authorised to give advice and recommendations on implementing and interpreting the requirements of the APME code.

ANNEX A (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*.

(a) 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.

(b) 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; and (iv) non-promotional information intended for patients and the general public about specific medicinal products marketed by the company.

(iv) 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.

(v) 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.

(vi) 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. According to the Medicinal Products Act, advertising of medicinal products subject to medical prescription over the Internet is permitted only if access to the information is limited to persons qualified to prescribe medicinal products, dispensing chemists and pharmacists. For such a purpose, the person publishing the advertising is required to register the users, verify their inclusion in the group of persons specified above, and issue a personal code to each user. Such acts shall be recorded. Advertising of medicinal products subject to medical prescription over the Internet shall include the summary of product characteristics. Summary of the product characteristics and the package leaflet displayed on the Internet without any additions is not regarded to be advertising of medicinal products.

(vii) Non-promotional information for patients and the general public. Subject to any applicable national laws and regulations, websites may include non-promotional information for patients and the general public on products distributed by the company (including information on their indications, side-effects, interactions with other medicines, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each product that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the full, unedited copy of any public assessment report issued by the Committee for Medicinal Products for Human Use or a relevant national

competent authority. Brand names should be accompanied by international non-proprietary names. The website may include links to other websites containing reliable information on medicinal products, including websites maintained by government authorities, medical research bodies, patient organisations, etc. The website must always advise persons to consult a healthcare professional for further information.

SECTION 3. *E-mail Enquiries*. A website may invite electronic mail communications from healthcare professionals and patients or the general public seeking further information regarding the company's products or other matters (e.g., feedback regarding the website). The company may reply to such communications in the same manner as it would reply to enquiries received by post, telephone or other media. In communications with patients or members of the general public, discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a healthcare professional be consulted for further information.

SECTION 4. *Links From Other Websites*. Links may be established to a company-sponsored website from websites sponsored by other persons, but companies should not establish links from websites designed for the general public to company-sponsored websites that are designed for healthcare professionals. In the same manner, links may be established to separate websites, including websites sponsored by the company or by other persons. Links should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

SECTION 5. *Website Addresses In Packaging*. Subject to any applicable national laws and regulations, uniform resource locators (URLs) of company-sponsored websites that comply with these guidelines may be included in packaging of medicinal products.

SECTION 6. *Scientific Review*. Companies should ensure that scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the Applicable Code(s). The scientific service established within the company pursuant to those provisions of the Applicable Code that adopt Section 17.02 of the EFPIA 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.

APPENDIX B (Application forms 1 and 2)

SPONSORSHIP APPLICATION FOR PHARMACEUTICAL COMPANIES
NAME OF COMPANY
NAME OF CONTACT PERSON OF COMPANY

1. APPLICATION FOR PARTICIPATION IN PROFESSIONAL CONFERENCE

Details of applicant

First name and surname/profession/position of applicant		
Institution and department/clinic of applicant		
Contact details (e-mail; phone)		
Travel data and travel agency details	Name and details of travel agency, incl. bank account No:	
	Services provided: Transport: type/cost document Accommodation: place, number of days/cost document Participation fees: Original copy of registration document	

PLEASE ATTACH INVITATION FROM THE EVENT ORGANISER TO THE APPLICATION

Purpose of sponsorship:

Title of the event and purpose of participation in the event:	
Event organiser (research institution/professional organisation)	
Date and place (city, country) of the event	
Period of assignment	

Please note: the processing of the application may take up to one month from the registration of the application by the company receiving the application.

Applicant's signature: *Date of submission of application:*

SPONSORSHIP APPLICATION FOR PHARMACEUTICAL COMPANIES FOR ORGANISING CONFERENCES

NAME OF COMPANY
NAME OF CONTACT PERSON OF COMPANY

General details of applicant

First name and surname/profession/position of applicant	
Institution and department/clinic of applicant	
Contact details (e-mail; phone)	
Settlement details: Name of legal person/settlement account number/name of contact person	

Purpose of use of sponsorship

Title of the conference	
Institution/organisation organising the conference	
Date and place of the conference	
Conference organisation expenses: • Rental of premises (attach invoice) • Fees to lecturers (names of lecturers/individual fees) • Catering expenses (invoice from catering service provider, indicating the number of persons catered for, and the cost rate) • Cost of preparation of materials for the conference (invoices for ordered materials) • Transport expenses (invoice from transport service provider) • Other expenses (specify and attach invoices)	

The processing of the application may take up to one month.

Applicant's signature: Date

Appendix C. Methodology of disclosure of payments made either directly or indirectly to health care professionals and pharmacists or health care providers

1. Disclosure of payments made either directly or indirectly to health care professionals and pharmacists or health care providers shall be made according to the Table C1 Data disclosure form.
2. Contribution to event related costs such as registration fees, travel and accommodation costs, fees for service and consultancy paid to health care professionals and pharmacists shall be disclosed in a personalized way aggregating all payments made to the person in one year.
3. Donations and grants, contribution to event related costs such as registration fees, travel and accommodation costs, fees for service and consultancy paid to health care providers shall be disclosed in the provider-based way aggregating all payments made to the provider in one year.
4. For transfers of value where certain information, which can be otherwise reasonably allocated to one of the categories mentioned above cannot be disclosed on an individual basis for legal reasons, shall be disclosed on an aggregate basis. Such aggregate disclosure shall identify the number of recipients covered by such disclosure, absolute basis and a percentage of all recipients and the aggregate amount attributable to transfers of value to such recipients.
5. In order to avoid duplication of disclosing the data in cases where payments to health care professionals and pharmacists are made through the health care provider the data shall be published once, to the extent possible in personalized way.
6. Research and development transfers of value, including clearly event related costs shall be disclosed on an aggregate basis.
7. All payments made either directly or indirectly to health care professionals and pharmacists or health care providers shall be disclosed in net amount of euros. Payments agreed in multiannual contracts shall be disclosed in the actual payment amount of the reporting year.
8. Each APME member company shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category. The note 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.