



**Starptautisko inovatīvo farmaceitisko  
firmu asociācija**

Skolas iela 3, Rīga, LV-1010  
Tālrunis: + 37129253093  
Fakss: + 371 67332148  
e-pasts: [siffa@siffa.lv](mailto:siffa@siffa.lv)  
web: [www.siffa.lv](http://www.siffa.lv)



**Latvijas Patentbrīvo Medikamentu  
Asociācija**

Krišjāņa Valdemāra iela 33-48, Rīga, LV-1010  
Tālrunis: + 371 67844977  
Fakss: + 371 67844976  
e-pasts: [lpma@lpma.lv](mailto:lpma@lpma.lv)  
web: [www.lpma.lv](http://www.lpma.lv)

**CODE OF PRACTICE ON THE PROMOTION  
OF MEDICINAL PRODUCTS**

*Approved by the Decision of the Meeting of Members of the Association of International  
Research-based Pharmaceutical Manufacturers  
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## INTRODUCTION

The Association of International Research-based Pharmaceutical Manufacturers (hereinafter: SIFFA), the Latvian Generic Medicines Association (hereinafter: LPMA), and their members (hereinafter SIFFA, LPMA and their members jointly referred to as Manufacturers) 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, the Manufacturers have adopted the Code of Practice on the Promotion of Medicinal Products (hereinafter referred to as the Code). The Code reflects the requirements of Council Directive 2001/83/EC, as amended, relating to medicinal products for human use (hereinafter: the "Directive"). The 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.

Manufacturers encourage competition among pharmaceutical companies. The Code is not intended to restrain the promotion of medicinal products 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 wholesale companies, owners of pharmacies, pharmacists, healthcare professionals, patients and non-governmental organizations uniting them, and in compliance with applicable laws and regulations. The 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.

The SIFFA and LPMA members recognise that they have many common interests with patient organisations, which represent and/or support the needs of patients and/or caregivers.

## SCOPE OF THE CODE

- (1) This Code covers the promotion to the public, healthcare professionals and pharmacists of prescription-only and over-the-counter medicinal products and interactions between pharmaceutical companies and wholesale companies, owners of pharmacies, pharmacists, owners and the staff of healthcare institutions, healthcare professionals, professional organizations of healthcare professionals and patient organisations with the aim to promote sales of medicinal products.
- (2) The Code is applicable to:
  1. Manufacturers;
  2. Any company affiliated to the Manufacturers, including wholesale companies, pharmacies, providers of advertisements and others (hereinafter referred to as Member Companies);
  3. Any company that is not a Manufacturer, but manufactures medicinal products sold and/or distributed in Latvia (hereinafter referred to as Affiliated Manufacturers);
  4. Any company related to Affiliated Manufacturers referred to in the Article (2), Sub-paragraph 3, including wholesale companies, pharmacies, providers of advertisements and others (hereinafter referred to as Affiliated Companies).

Subjects referred to in the Sub-paragraphs 1 to 4 of this Article hereinafter are referred to as Pharmaceutical Companies.

- (3) Pharmaceutical Companies shall be responsible for the obligations imposed under any applicable Code 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 Code on their behalves. In addition, Pharmaceutical Companies shall take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Code, but that do not act on behalf of the Pharmaceutical Companies (e.g., joint ventures, licensees) comply with the Code.
- (4) "Promotion", as used in the Code, includes any activity undertaken, organised or sponsored by a Pharmaceutical Company, or with its authority, which promotes and/or facilitates the prescription, supply, sale, administration, recommendation or consumption of its medicinal product(s).
- (5) „Patient organisations" are defined as organisations (including the umbrella organisations to which they belong), that represent and/or support the needs of patients and/or caregivers.
- (6) „Medicinal products", as used in the Code have the meaning set forth in Paragraph 1 of the Directive:
  - (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

*Explanation:*

*"Substance" is defined in Paragraph 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) *herbage (e.g., micro-organisms, plants, parts of plants, vegetable secretions, extracts), or*
- (d) *chemical (e.g., microelements, naturally occurring in chemical materials and chemical products obtained by chemical reactions or synthesis);*

or

- (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

or

- (c) any medical device containing a medicinal product.

- (7) The Code covers medicinal products promotional activity and communication:
  - 1. directed towards the patient;
  - 2. directed towards cooperation with any member of the medical, dental 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");
  - 3. directed towards cooperation with patient organizations;
  - 4. directed towards activities of wholesale companies, owners of pharmacies and pharmacists regarding advising, dispensation and selling of medicinal products to patients.
- (8) The 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, the use of internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage services and the like, and the provision of samples, gifts and hospitality, as well as cooperation with patient organizations.
- (9) The Code also covers interactions between Pharmaceutical 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, consultancy and advisory board arrangements).
- (10) 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.
- (11) The Code does not cover the following:
  - 1. the packaging of medicinal products and accompanying package leaflets, which are subject to the provisions of Title V of the Directive;
  - 2. correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
  - 3. 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;
  - 4. non-promotional information relating to human health or diseases;
  - 5. 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.
- (12) Pursuant to the Code:
  - 1. The independence of patient organisations, in terms of their political judgement, policies and activities, shall be assured by the Pharmaceutical Companies;
  - 2. All partnerships between patient organisations and the Pharmaceutical Companies shall be based on mutual respect, with the views and decisions of each partner having equal value.
  - 3. Pharmaceutical Companies shall not request, nor shall patient organisations undertake, the promotion of a particular prescription-only medicine.
  - 4. The objectives and scope of any partnership between Pharmaceutical Companies and patient organisations shall be transparent. Financial and non-financial support provided by Pharmaceutical Companies shall always be clearly stated and acknowledged.
  - 5. SIFFA, LPMA and their members welcome broad funding of patient organisations from multiple and various sources.
- (13) Attached to this Code are:
  - 1. Annex A - "Implementation and Procedure Rules" which set forth the framework for the implementation of the Code, the processing of complaints and the initiation or administration of sanctions on the SIFFA and LPMA part;
  - 2. Annex B - "Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public", which provide guidance to member companies with respect to the content of the website

containing information on medicinal products.

3. Annex C - Guidelines for a Written Agreement between Pharmaceutical Company and Patient Organisation.

### **APPLICABILITY OF CODES**

- (14) This Code sets out the minimum standards which Manufacturers consider must apply.
- (15) Pharmaceutical Companies must observe and assure their activities in compliance with this Code, other codes binding to the specific Manufacturer, as well as all laws, regulations and directives, which they are subject to.
- (16) Pharmaceutical Companies must comply both with the spirit and the letter of the provisions of the Code. For example, the companies must observe the consequent standards in relationships with healthcare professionals and patient organisations, especially as regards gifts and hospitality.
- (17) Promotion and cooperation which take place outside the Republic of Latvia must comply with applicable laws and regulations of the relevant country. In addition, promotion and interaction which take place outside Latvia must also comply with codes applicable in the relevant country. In the event of a conflict between the provisions of applicable codes, the more restrictive of the conflicting provisions shall apply (unless Article 14.01 provides otherwise) with the exception of the applicability of Section 10.05, when the governing is the financial threshold in the country where the event is held (e.g. in the “host country”).
- (18) For the avoidance of doubt, the term "company" as used in this Code, shall mean any legal entity that organises or sponsors promotion directly or indirectly, or engages in cooperation with healthcare professionals and/or patient organisations covered by an Applicable Code, which takes place within Europe, whether such entity be a parent company (e.g., the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation.
- (19) Pharmaceutical Companies must comply with any Applicable Codes and any laws and regulations to which they are subject.
- (20) The relevant local affiliate must be informed of any international events; or else local recommendations must be received.
- (21) If a Pharmaceutical Company is located in any country of Europe, the national industry code of that country will apply; whereas the Code of the country will be applicable in case the company is located outside Europe. In case of a partnership, whose activities take place in a particular European country, the Pharmaceutical Industry Code of the country, where those activities take place, must be complied with.
- (22) In case of cross-boundary partnerships and activities, one must comply with the Pharmaceutical Industry Code of the country where the pharmaceutical company or patient organization's headquarters is located in Europe.
- (23) SIFFA and LPMA 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 CODE**

### **ARTICLE 1 - MARKETING AUTHORIZATION**

- 1.01. A medicinal product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply. Likewise, unapproved indications must not be promoted.
- 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**

- 2.01. All promotional materials must comply with the Code and laws and regulations of the Republic of Latvia, as well as 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.
- 2.02. Subject to applicable national laws and regulations, where an advertisement is intended only as a reminder, the requirements of Article 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, or the trademark.

### **ARTICLE 3 - PROMOTION AND ITS SUBSTANTIATION**

- 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.
- 3.02. Promotion must be capable of substantiation which must be promptly provided by the Pharmaceutical Company in response to reasonable requests. 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.
- 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.
- 3.04. When promotion refers to published studies, clear references should be given.
- 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.
- 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;
  - (c) 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).
- 3.06. The word "safe" must never be used without proper qualification.
- 3.07. 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.
- 3.08. It must not be stated that a product has no risks of addiction or dependency, as well as side-effects and toxic hazards.

### **ARTICLE 4 - USE OF QUOTATIONS IN PROMOTION**

- 4.01. Quotations from medical and scientific literature or from personal communication must be faithfully reproduced (except where adaptation or modification is required in order to comply with any Applicable Code, 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**

5.01. Pharmaceutical Companies always must maintain high ethical standards.

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**

- 6.01. Promotion should only be directed at those whose need for, or interest in, the particular information can reasonably be assumed.
- 6.02. Promotional mailing lists must be regularly updated.
- 6.03. Requests by Pharmaceutical Companies and/or healthcare professionals to be removed from promotional mailing lists and/or not be visited by sales and/or medical representatives promoting medicinal products must be complied with.
- 6.04. 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.
- 6.05. Healthcare professionals or third parties representing them shall not be provided, offered or promised any gifts, financial compensation, pecuniary advantages or benefits as an inducement and/or guarantee for accepting sales and/or medical representatives' visits where medicinal products are being promoted. Conclusion of contracts that is substantiated, directly or indirectly, by the fact that physicians will prescribe medicinal products of the Pharmaceutical company, is prohibited.
- 6.06. When a medicinal product is being promoted, no competitions, games or similar undertakings or activities where participants and/or winners would receive some benefit - a gift for the participation or prizes for the victory, are allowed.

## **ARTICLE 7 - TRANSPARENCY OF PROMOTION**

- 7.01. Promotion must not be disguised.
- 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.
- 7.03. Where a Pharmaceutical Company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.
- 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 - INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY**

- 8.01. The transmission of informational or educational materials to healthcare professionals 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.  
Exceptions from provisions of (i) are permitted when informative materials shall be transmitted to healthcare professionals according to requirements defined in the international and/or Latvian legislation.
- 8.02. Items of medical utility can be provided to healthcare professional if they correspond to all of the following criteria: (i) are directly relevant to the education of healthcare professionals and patient care; (ii) are inexpensive; (iii) do not replace such items that should be at the disposal of healthcare professionals according to provisions of the legislation for the routine business practices of the healthcare professional.
- 8.03. Restrictions provided in Sub-paragraphs 8.01. and 8.02. shall be applicable to the promotion of prescription-only medicinal products.
- 8.04. The range of informative and educational materials and items of medical utility governed by this Code shall not be regarded as an exception to the prohibition of gifts defined in the Article 11 of the Code.

## **ARTICLE 9 - ADVICE ON MEDICAL MATTERS**

9.01. In the case of requests from individual members of the general public for advice on medical matters, the Pharmaceutical Company should advise the enquirer to consult a healthcare professional.

## **ARTICLE 10 - EVENTS AND HOSPITALITY**

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 Pharmaceutical Companies 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 the Code.

10.02. No Pharmaceutical 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.

10.03. Promotional information which appears on exhibition stands or is distributed to participants at international events may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicinal products (or uses) which are not registered in the country where the event takes place, or which are registered under different conditions, so long as

- a) 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
- b) 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.

10.04. Hospitality extended in connection with events shall be limited to travel, meals, accommodation and registration fees. Snacks and/or meals in relation to the main purpose of the event may be provided:

- only and exceptionally to the participants of the event;
- if they are moderate and justified from the aspect of local standards.

10.05. Pharmaceutical Companies shall not provide or offer any meal (food and beverages) to healthcare professionals, unless, in each case, the value of such meal (food and beverages) does not exceed the monetary threshold set by the relevant Implementation Rules of the Code of Practice on the Promotion. The governing monetary threshold is the one set in the country where the event is held (e.g. in the "host country").

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

10.07. 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.

10.08. Hospitality shall not include sponsoring or organising entertainment (sporting or leisure) events. Companies should avoid using venues that are "newly opened" (never used before) or are "extravagant".

## **ARTICLE 11 - PROHIBITION OF GIFTS**

11.01. Unless the Code provides otherwise, no gift or funds may be supplied, offered or promised to a healthcare professional.

11.02. Despite the Sub-paragraph 11.01. above, Pharmaceutical Companies may provide pens or notepads only during events organized by the company, unless these products do not include a brand of a definite product, and are inexpensive. A company may not provide pens or notepads in exhibition stands. Pens or notepads included in the conference member kits shall not contain a specific brand (neither a product nor a company logo).

11.03. Despite the Sub-paragraphs 11.01. and 11.02. above, where over-the-counter medicinal products are being promoted, gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised



only if they are inexpensive and relevant to the practice of medicine or pharmacy. Except where they carry all the information stipulated in Sub-paragraph 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, if applicable, or the trademark.

- 11.04. Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events and others) must not be offered or provided.
- 11.05. Pharmaceutical Companies shall observe guidance on the meaning of the term "cheap/inexpensive", in accordance with the applicable Code, other ethical provisions and/or legislation in force in the country.

#### **ARTICLE 12 - DONATIONS AND GIFTS THAT SUPPORT HEALTHCARE OR RESEARCH**

- 12.01. Donations, grants and material benefits in kind to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare (including supply of medicinal products in the wholesale and/or pharmacies) or conduct research are only allowed if:
  - (a) they are made for the purpose of supporting healthcare or research;
  - (b) they are documented and kept on record by the donor/grantor; and
  - (c) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.
- 12.02. Donations and grants to individuals are not permitted. Pharmaceutical Company sponsorship of healthcare professionals to attend international events is covered by Article 14 of the Code. Pharmaceutical Companies are encouraged to make available publicly information about donations, grants or material benefits made by them covered in Article 12.

#### **ARTICLE 13 - FEES FOR SERVICES**

- 13.01. Relationships and communication with institutions, organisations or associations of healthcare professionals under which such institutions and establishments, organisations or associations provide any type of services to Pharmaceutical Companies (or any other type of funding not covered under Article 12 or not otherwise covered by the EFPIA Code) are only allowed if such services (or other funding):
  - (a) are provided for the purpose of supporting healthcare or research; and
  - (b) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

#### **ARTICLE 14 - SPONSORSHIP OF HEALTHCARE PROFESSIONALS**

- (1) 14.01. Pharmaceutical Companies must comply with criteria governing the selection and sponsorship of healthcare professionals and pharmacists to attend training or events as provided in, or in connection with, any Applicable Code(s). Funding must not be offered to compensate for the time spent by healthcare professionals and pharmacists in attending events. In the case of international events for which a company sponsors the attendance of healthcare professionals and pharmacists, if any funding is provided to such healthcare professional in accordance with the provisions of Article 13.01 of this code, 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 Article 13.01 is not intended to prohibit the extension of hospitality to healthcare professionals in accordance with Article 10 of the Code.
- (2) 14.02. Pharmaceutical Companies are not allowed to organize, fund or take part in such activities of a healthcare professional as related to examination or treatment of patients, except for activities related to:
  - clinical trials of medicinal products and observations of administration of medicines, which have been sanctioned by the State Agency of Medicines,
  - supervision of side effects caused by the use of medicinal products.

#### **ARTICLE 15 - USE OF CONSULTANT SERVICES**

- 15.01. It is permitted to use healthcare professionals and pharmacists 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 travel. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:
  - (a) a written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the

basis for payment of those services;

- (b) a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- (c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- (d) the number of healthcare professionals retained does not exceed the number reasonably necessary to achieve the identified need;
- (e) the contracting Pharmaceutical 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, consultancy arrangements should not be used to justify financial compensations for healthcare professionals.

- 15.02. In their written contracts with consultants, Pharmaceutical Companies are encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the Pharmaceutical 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 the Pharmaceutical Company. Similarly, Pharmaceutical 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 Pharmaceutical 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 the Pharmaceutical Company. Provisions of Article 15.02 apply even though the Code does not otherwise cover non-promotional and/or general information about Pharmaceutical Companies.

*Note. Pharmaceutical Companies are encouraged to include such provisions in any contracts entered into or renewed on or after the implementation date of this Code, according to the Article 15.02. In addition, Pharmaceutical Companies are encouraged to renegotiate existing contracts at their earliest convenience to include such provisions.*

- 15.03. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of Article 15, 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. Guidance on the meaning of "minimal" in connection with any Applicable Code(s) shall be developed in the case of need.
- 15.04. If a healthcare professional or a pharmacist attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of Article 10 of the Code shall apply.

## **ARTICLE 16 - NON-INTERVENTIONAL STUDIES OF MARKETED MEDICINES**

- 16.01. A non-interventional study of a marketed medicine is defined as a study where the medicinal product is 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 the 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.
- 16.02. Non-interventional studies that are prospective and involve the collection of patient data from individuals or groups of individuals, or healthcare professionals specifically for the study must comply with all of the following criteria:
- (a) The study is conducted with a scientific purpose;
  - (b) (1) There is a written study plan (protocol) and (2) there are written contracts between healthcare professionals and/or the institutes at which the study will take place, on the one hand, and the Pharmaceutical Company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to clause (c) 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 and regulations 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 medicinal products;
- (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 Article 16.02(b);
- (h) The study results must be analysed by the Pharmaceutical Company, which has hired the persons, and summaries thereof must be made available within a reasonable period of time to the Pharmaceutical company's scientific management (as described in Section 16.02(a)), and the scientific service shall maintain records of such reports for a reasonable period of time.

Pharmaceutical Company should send the summary report to all healthcare professionals that participated in the study and should make the summary report available to the industry self-regulatory bodies and/or committees that are in charge of supervising and enforcing Applicable Codes upon their request. If the study shows results that are important for the assessment of benefit or risk, the summary report should be immediately forwarded to the relevant competent authority; and

*Note. Pharmaceutical 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.*

- (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.

16.03. Pharmaceutical Companies are encouraged to comply with Article 16.02 for all other types of studies covered by Article 16.01, including epidemiological studies and other studies that are retrospective in nature. In any case, such studies are subject to Article 13.01.

#### **ARTICLE 17 - SAMPLES**

17.01. Medicinal product samples are provided to healthcare professionals so that they may familiarise themselves with the medicines and acquire experience in dealing with them.

17.02. Medicinal product samples should be given on an exceptional basis only.

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

17.04. Each sample must be marked "free sample - not for sale" or words to that effect and must be accompanied by a copy of the summary of product characteristics.

17.05. Each healthcare professional should receive, per year, not more than four medicinal product samples of a particular medicine within two years of the first request of the specific medicinal product samples (i.e. standard of "4 x 2"). The healthcare professional may request only those medicinal product samples he/she is qualified to prescribe. Altogether, no more than 1000 samples per year of a particular medicine shall be provided to all healthcare professionals.

17.06. Without prejudice to the ban on medical sampling of medicines containing psychotropic and narcotic substances, medicinal product 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.

17.07. Medicinal product 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.

17.08. Pharmaceutical companies must have adequate systems of control and accountability for samples of medicines distributed by its representatives. This system shall also clearly establish, for each healthcare professional, the number of samples supplied in application of the provision in Sub-paragraph 17.05.

17.09. For the purposes of this Code, a "new" medicinal product is a medicinal product just authorised: either a new authorisation or a line extension with new strengths/pharmaceutical forms having also new indications. Line extension with new strengths/pharmaceutical forms with existing indications or package sizes (number of units per package) can not be regarded as a new medicinal product.

#### **ARTICLE 18 - PHARMACEUTICAL COMPANY STAFF**

18.01. Each Pharmaceutical 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 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 Code, 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 the Pharmaceutical company 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 to the person visited.
- (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 Article 18.02 are also applicable to the activities of Medical Sales Representatives.

18.02. All Pharmaceutical 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 Code and relevant laws and regulations. Each Pharmaceutical Company must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non-interventional studies. Pharmaceutical Companies are free to decide how best to establish such service(s) in accordance with Article 18.02 (i.e., whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organisation. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release.

- (a) 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 laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the particular 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.
- (b) Each Pharmaceutical 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 are met.

18.03. It is not forbidden to combine the job of a healthcare practitioner with a job in a Pharmaceutical Company or a company that renders pharmaceutical services to the Pharmaceutical Company. To ensure transparency of the work of healthcare professionals, Pharmaceutical Companies that have concluded:

- a permanent labour contract with a healthcare practitioner;
- a permanent contract with a legal entity for provision of services to the company by the staff member(s) of the said legal entity - healthcare practitioners;
- are obliged to submit to the Association the member of which is the particular Pharmaceutical Company, i. e. SIFFA or LPMA, the following information:
- about any healthcare practitioner working for the Pharmaceutical Company,
- about any contracts concluded with legal entities for provision of services to the Pharmaceutical Company by the staff member(s) of the said legal entity - healthcare practitioners,

so that SIFFA or LPMA, depending on the association the information has been provided to, could process, update and publish the above information on the Intranet website (internal website).

## **ARTICLE 19 - COOPERATION OF PHARMACEUTICAL COMPANIES WITH PATIENT ORGANISATIONS**

### 19.01. Promotion of prescription-only medicinal products to the public

Promotion of prescription-only medicinal products to the public including patient organisations is prohibited.

### 19.02. Written agreements

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

### 19.03. Use of logos and proprietary materials

The public use of a patient organisation's logo and proprietary material by a Pharmaceutical Company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

### 19.04. Editorial control

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

### 19.05. Transparency

- (a) Each Pharmaceutical Company must make publicly available a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description must include the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit that the patient organisation receives. This information must be available on the Latvian or European level and should be updated at least once a year<sup>1</sup>.
- (b) Pharmaceutical Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.
- (c) Each pharmaceutical company must make publicly available a list of patient organisations that it has engaged to provide significant contracted services. This should include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Pharmaceutical companies must also make public the total amount paid per patient organisation over the reporting period<sup>2</sup>.

### 19.06. Contract services

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

It is permitted to engage patient organisations as experts and advisors for services such as participation at advisory board meetings and speaker services. The arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- (a) A written contract or agreement is agreed in advance which specifies the nature of the services to

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

<sup>2</sup>The requirement to include details of contracted services must be made by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of or ongoing on 1 January 2012).

- be provided and, subject to clause (g) below, the basis for payment of those services;
- (b) A legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into the arrangements;
  - (c) The criteria for selecting services are directly related to the identified need and the persons responsible for selecting the service have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria;
  - (d) The extent of the service is not greater than is reasonably necessary to achieve the identified need;
  - (e) The contracting company maintains records concerning, and makes appropriate use of, the services;
  - (f) The engaging of patient organisations is not an inducement to recommend a particular medicinal product;
  - (g) The compensation for the services is reasonable and does not exceed the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating patient organisations;
  - (h) In their written contracts with patient organisations, companies are strongly encouraged to include provisions regarding an obligation of the patient organisation to declare that they have provided paid services to the Pharmaceutical company whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company;
  - (i) Each Pharmaceutical company must make publicly available a list of patient organisations that it has engaged to provide paid-for services - *see Article 18.5.c.*

#### 19.07. Single company funding

No Pharmaceutical Company may require that it be the sole funder of a patient organisation or any of its major programmes. The total amount of financial support from a single Pharmaceutical Company to one patient organization per year must not exceed 50% of the organization's total annual budget. The advisable amount of financial support from a single Pharmaceutical Company is up to 25% per year. Funding from outside the pharmaceutical industry is welcomed.

#### 19.08. Events and hospitality

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

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

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

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

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

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

No Pharmaceutical Company may organise or sponsor an event that takes place outside its home country unless:

- most of the invitees are foreigners and, given the countries of origin of most of the invitees, it makes greater logistical sense to organise the event in another country; or
- given the location of the relevant resource or expertise, it makes greater logistical sense to hold the event in another country.

#### 19.09. Enforcement

Enforcement of the Code, the processing of complaints and the initiation or administration of sanctions is performed in accordance with provisions of this Code and other documents.

When needed, guidance on the meaning of the terms 'appropriate', 'significant', 'major', 'reasonable', 'renowned' and 'extravagant' as used in this code shall be provided.

### **ARTICLE 20 - SANCTIONS**

20.01. In the event that a breach is established pursuant to the procedures of the Code, Manufacturers shall require from the offending Pharmaceutical Company an immediate cessation of the offending activity, and the offending Pharmaceutical Company shall immediately discontinue the offending activity. Should an immediate discontinuation of the offending activity by the offending Pharmaceutical Company is not implemented within the procedure of this Article, the Manufacturer

is empowered to refer to the Ethics Committee for Promotion of Medicinal Products in accordance with the procedure provided by Annexes to this Code.

- 20.02. Sanctions should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. A combination of publication and fines is generally considered to be the most effective sanction.

#### **ARTICLE 21 - FINAL PROVISION**

- 21.01. This Code of Practice for Promotion of Medicinal Products and its Annexes shall come into force on 1st of January, 2015;
- 21.02. Article 8 and Sub-paragraphs 11.01. and 11.02. of the Article 11 of this Code of Practice on the Promotion of Medicinal Products shall be implemented by the Pharmaceutical Companies on July 1, 2014 at the latest.
- 21.03. Sub-paragraph 11.03. of the Article 11 of this Code of Practice on the Promotion of Medicinal products shall be applicable to the promotion of both prescription-only and over-the-counter medicines till June 30, 2014.
- 21.04. On the day the Code comes into force, the Code of Practice on the Promotion of Medicinal Products and all of its annexes adopted prior to the enforcement of the Code shall become invalid.

## **Annex A**

### **IMPLEMENTATION OF THE CODE AND PROCEDURE RULES**

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the Code, the processing of complaints and the initiation or administration of sanctions on the part of Manufacturers.

#### **1. Implementation of the Code:**

- (a) Manufacturers will ensure easy availability of this Code, administrative procedure and other relevant information on the Manufacturers website;
- (b) Manufacturers will establish national procedures and structures - a body that is designated to monitor complaints and consists of a non-industry chairman and members authorized by the relevant association, i. e. LPMA and SIFFA, to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same.

#### **2. Reception of complaints.**

Complaints may be lodged either with the institution responsible for the monitoring of complaints, or with the European Union institutions. Adjudication of complaints shall be a matter solely for Manufacturers.

#### **3. Processing of complaints and sanctions.**

- (a) Manufacturers 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 through the procedures and structures pursuant to Article 1(b) above. Manufacturers' body shall take decisions and pronounce any sanctions on the basis of this Code and the legal acts in force in Latvia.
- (c) Where a complaint fails to establish a prima facie case for a violation of the current Code, such complaint shall be dismissed with respect to this Code. Manufacturers may also provide that any complaint which pursues predominantly commercial interest shall be dismissed.
- (d) Manufacturers should establish effective procedures for appeals against the initial decisions made by the body. Such procedures and appeals should also take place at the national level.
- (e) Manufacturers 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:
  - (1) in cases of a serious/repeated breach, the Pharmaceutical Company name should be published together with details of the case;
  - (2) in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the Pharmaceutical Company name.



## **Annex B**

### **GUIDELINES FOR INTERNET WEBSITES AVAILABLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND THE PUBLIC IN LATVIA**

This is to establish common guidelines for internet websites, hereinafter: Internet Websites Available to any Internet Websites User, and set forth herein are intended as a supplement to this Code.

1. Transparency of the website origin, content and purpose.  
Each website shall clearly identify:
  - (a) the identity and physical and electronic addresses of the sponsor of the website;
  - (b) the source of all information included on the website, the date of publication of the source and the identity and credentials (including the data 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.
2. Content of the website:
  - (a) Information included on the website shall be regularly updated and shall clearly display, for each page and/or item, as applicable, the most recent date as of which such information was updated.
  - (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 this Code), including any promotion; and (iv) non-promotional information intended for patients and the general public about specific medicinal products marketed by the company.
  - (I) General information on the Pharmaceutical Company. Website 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. Website 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 this Code), must comply with this Code and/or 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 the applicable laws and regulations of Latvia, websites may include non-promotional information for patients and the general public on products distributed by the Pharmaceutical 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.

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 Pharmaceutical Company's products or other matters (e.g., feedback regarding the website). The Pharmaceutical 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.

4. Links from other websites.

Links may be established to a Pharmaceutical Company-sponsored website from websites sponsored by other persons, but the Pharmaceutical Company should not establish links from websites designed for the general public to Pharmaceutical company-sponsored websites that are designed for healthcare professionals only. 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.

5. Website addresses in packaging.

Subject to the applicable laws and regulations of Latvia, company-sponsored websites that comply with these guidelines may be included in the patient information leaflet of medicinal products.

6. Scientific reviews.

Pharmaceutical 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. The scientific service established within the Pharmaceutical Company, which is mentioned in the provisions of the Applicable Code and conform to Section 17 hereof, may perform this function, or it may be entrusted to other appropriately qualified persons.

7. Confidentiality.

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

## **GUIDELINES FOR WRITTEN AGREEMENT BETWEEN PHARMACEUTICAL COMPANY AND PATIENT ORGANISATION**

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

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

- Name of the project or activity;
- Names of partnering organisations (Pharmaceutical Company, patient organisation, and where applicable, third parties that will be brought in to help, as agreed by both the Pharmaceutical Company and the patient organisation);
- Type of activity (i.e. whether the agreement relates to unrestricted grant, specific meeting, sponsorship, publications, information campaign, training programs, etc.);
- Project objectives;
- Agreed role of the Pharmaceutical Company and patient organisation;
- Time-frame of the project;
- Amount of funding for the project;
- Description of significant indirect/non-financial support (i.e. the donation of public relations agency's time, free training courses).

All parties are fully aware that sponsorship must be clearly acknowledged and apparent from the outset. The contract shall include provision of the information transparency regarding contractual activities.

Code(s) of practice that apply:

Signatories to the agreement:

Date of agreement: