

# **CODE OF ETHICS FOR PHARMACEUTICAL MARKETING**

Regulating pharmaceutical marketing and relations with healthcare professionals as well as relations between the pharmaceutical industry and patient organisations and disclosure of information about transfers of value to healthcare professionals and healthcare organisations, applicable to companies engaged in pharmaceutical marketing in Lithuania

Approved by IFPA (Edition of 2013)

Adopted on the 26<sup>th</sup> of November 2013 by IFPA General Assembly

## INTRODUCTION

The Code of Ethics for Pharmaceutical Marketing (“**the Code**” or “**CEPM**”) has been adopted at the will and upon common agreement of IFPA and VGA – associations of companies engaged in pharmaceutical marketing in Lithuania. It seeks to ensure that pharmaceutical companies engage in an ethical promotion, restrain from deceitful practices and potential conflicts of interest with healthcare professionals, and comply with applicable laws and regulations. Thus the Code seeks to enable an environment where the general public may be sure that the choices regarding their medicinal products are made based on the merit of each product and the patients’ clinical needs. This Code does not aim at restraining the promotion of medicines in such a way as to hinder fair competition or limit interaction with healthcare professionals.

The Innovative Pharmaceutical Industry Association (“**IFPA**”) is the association of companies engaged in the development and/or marketing of medicines in Lithuania. IFPA is a member of the institution representing the pharmaceutical industry in Europe, the European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”).

The Pharmaceutical Manufacturers’ Association (“**VGA**”) is the association of companies which develop, produce and/or are engaged in the marketing of medicines and their representatives in Lithuania.

Both associations (IFPA and VGA) contribute to EFPIA mission – to promote development of technologies and economics of pharmaceutical industry, helping to put on the market medicines that improve human health around the world.

Members of IFPA and VGA 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, IFPA and VGA approved the Code of Ethics for Pharmaceutical Marketing, which regulates pharmaceutical marketing and relations with healthcare professionals as well as relations between the pharmaceutical industry and patient organisations, as well as disclosure of information about transfers of value to healthcare professionals and healthcare organisations. The Code has been developed according to the Code of Ethics adopted in Lithuania in 2004 in compliance with the regulations of the EFPIA code of the 19<sup>th</sup> of November 2004, recommendation of EFPIA of 2007 and general ethical principles, as amended on the 24<sup>th</sup> of June 2010, on the 14<sup>th</sup> of June 2011 and on the 24<sup>th</sup> of June 2013. It also reflects the requirements of the EU Council Directive 2001/83/EC, as amended (the “**Directive**”) concerning the use of medicinal products for human use. The Code is consistent with the general provisions of the Directive, which acknowledge voluntary control over promotion of medicinal products implemented through organisations (institutions) which represent the pharmaceutical industry sector by providing the opportunity to apply to such organisations when complaints occur. In addition, the Code incorporates the principles set out in the Law on Pharmaceutics of the Republic of Lithuania (*Official Gazette*, 2006 No. 78-3056), the Law on Advertising of the Republic of Lithuania (*Official Gazette*, 2000, No. 64-1937, 2002, No. 123-5508) and the Law on Provision of Information to the Public of the Republic of Lithuania (*Official Gazette* 1996, No. 71-1706, 2000, No. 75-2272, 2006, No. 82-3254). Members of IFPA and VGA understand the need of platform for well governed cooperation. This platform shall ensure more transparent interaction of the industry with healthcare professionals (HCP) and healthcare organisations (HCO). EFPIA General Assembly approved the new version of the Disclosure Code regarding disclosure of information about transfers of value to healthcare professionals and healthcare organisations (the “**HCP/HCO Disclosure Code**”, or “**Disclosure Code**”). The changes of EFPIA HCP code, tightening regulations regarding receiving gifts and the use of hospitality, were approved as well. These changes were implemented in the renewed version of the Code.

Guided by the mission of EFPIA and common goals with IFPA and VGA, other parties, not belonging to IFPA and VGA, can also join the Code.

## **SCOPE OF THE CODE OF ETHICS FOR PHARMACEUTICAL MARKETING**

This Code covers pharmaceutical marketing (of prescription medicines and over-the-counter drugs) and interactions between healthcare professionals and pharmaceutical companies, as well as relations between pharmaceutical companies and patient organisations. The Code is applicable to companies engaged in pharmaceutical marketing in Lithuania (“**Companies**”), their representatives and organisations, associations and/or other legal entities and/or their subsidiaries which join the Code later.

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

The Code covers all methods of promotion including, but not limited to, oral and written promotional activities, cooperation, advertising in specialized journals aimed for healthcare professionals and direct mail advertising, the activities of medical sales representatives (defined in Section 18.01), the use of internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage services and the like, and the provision of items of free medical samples, gift distribution, representative events.

The Code also covers interactions between Companies and healthcare professionals including, but not limited to, those in the context of research or contractual agreements (including studies of clinical research, non-interventional studies and consultancy and advisory board arrangements). This Code also covers interactions between Companies and patient organisations which – regulations of Annex C of this Code are applicable, “Code of Ethics on the Relationships between the Pharmaceutical Industry and Patient Organisations” (Annex C) and disclosure of information about transfers of value to healthcare professionals and healthcare organisations, “HCP/HCO Disclosure Code” (Annex D).

The Code is not intended to restrain or regulate the provision of non-promotional medical, scientific and factual information.

The Code does not cover the following:

- a) the labelling of medicinal products and accompanying package leaflets, which are subject to the provisions of Title V of the Directive;
- b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- c) 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;
- d) non-promotional information relating to human health or diseases;
- e) non-promotional, general information about companies (such as information directed to investors and/or to current (prospective) employees), including financial data, descriptions of research and development programmes, and discussion of regulatory developments affecting a company and its products.

Attached to the Code are: Annex A, the “Implementation and Procedure Rules”, which are binding upon member associations and other joining parties and set forth the framework for the implementation of the Code, the processing complaints and the initiation or administration of sanctions by member associations; Annex B, the “Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in European Union” which provide guidance to Companies with respect in the content of websites containing information on medicines; Annex C, “Code of Ethics on the Relationships between the Pharmaceutical Industry and Patient Organisations”, and Annex D, “HCP/HCO Disclosure Code”.

## **APPLICABILITY OF THE CODE**

The Code sets out the key ethical standards which are considered binding upon the Companies and other members. IFPA and VGA must comply and ensure their members’ compliance with the Code and legislative provisions. IFPA and VGA must legitimize certain procedures in order to ensure compliance with all the codes referred to above by their member companies and other joining parties.

The spirit, as well as the letter of the provisions of the Code must be complied with. For example, Companies should follow consistent standards while interacting with healthcare professionals, especially as far as gifts and representation are concerned. IFPA and VGA also encourage 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.

The Code, its content, structure and order may be amended only upon common agreement between IFPA and VGA associations. Pharmaceutical Marketing Ethics Committee may recommend amendments of the Code, its content, structure and order based on the experience. The Code shall be revised and supplemented at the initiative of Ethics Committee, IFPA or VGA or other joining parties, as well as following amendments of the effectual laws and regulations of the Republic of Lithuania (when in conflict with the provisions of the Code) or of the EFPIA Code.

For the avoidance of doubt, the term “Company” as used in this Code, shall mean any legal entity that organises or sponsors (commissions) promotional activities, or, within the frames of the Code, having relations with healthcare professionals, healthcare organisations or patient organisations in Lithuania, irrespective of whether the subject is the parent company (the headquarters, principal office or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation. In case the legal entity operating in Lithuania is a subsidiary company, the parent company is also recognised as part of the Company and can perform certain actions on behalf of the legal person operating in Lithuania (e.g., publish declarations on its website).

In order to ensure compliance with the provisions of the Code, IFPA and VGA, among other things, must establish appropriate complaint reporting and assessment procedures, as well as sanctions for breaches of the Code. Additionally, all international events (as defined in Section 10.02 of the Code) must be notified to any relevant local subsidiary or, alternatively, local advice must be taken.

## **TERMS USED**

*Participation in an international conference* - considered as arrival of the healthcare professional to the venue of the conference no earlier than 1 day before the start of the conference and departure no later than 1 day after the event, registration and payment of the fee, participation in scientific sessions, and acquisition of participant’s certificate.

*Extravagant venues* - venues distinguished by luxury and splendour or visiting them could affect the image of healthcare professionals or the pharmaceutical industry.

*Medical (pharmaceutical) sales representative* - a person appointed by a pharmaceutical or any other company engaged in the marketing of medicines in Lithuania for the promotion of medicines, presentation of relevant, precise and evidence-based information about medicines and medical aids, and about innovations of the medical and the pharmaceutical industries, including personnel employed by way of contract with the third parties, any other company employees who visit healthcare professionals, pharmacies, hospitals or other healthcare institutions aiming to provide relevant, precise and evidence-based information about medicines and medical aids and innovations of the medical and the pharmaceutical industries, and to promote medicines. The qualification and competence of the Medical Representative to carry out the above-listed functions falls within the responsibility of the Company they represent.

*Company* - pharmaceutical or any other company engaged in pharmaceutical marketing in Lithuania. For the avoidance of doubt, the term “Company” as it is applied in this code, means any legal person organising or sponsoring (commissioning) promotional activities or, within the frames of the Code, having relations with healthcare professionals, healthcare organisations or patient organisations in Lithuania, irrespective of whether the subject is the parent company (the headquarters, principal office or controlling company of the commercial enterprise), subsidiary company or any other form of enterprise or organisation. In case the legal person operating in Lithuania is a subsidiary company, the parent company is also recognised as part of the Company and can perform certain actions on behalf of the legal person operating in Lithuania (e.g., publish declarations on its website).

*Entertainment (amusement) venues* – venues for leisure and entertainment which advertise their entertainment facilities in promotional leaflets, also publicly in the press or internet, and which are primarily intended for recreation and (or) entertainment – leisure activities, and not for professional (business) meetings.

*Promotion* – as applicable in this Code, is consistent with the definition provided in the Pharmaceutical legislation.

*Healthcare professionals* – as applicable in this Code, a doctor, a member of medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply or administer any medicinal product.

*Medicinal product* – as used in the Code has the meaning set forth in Article 1 of the Directive:

- a) any substance 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 whether with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

This term includes medicinal products, immunological medicinal products, radiopharmaceuticals, medicinal products derived from human blood or human plasma, for which a marketing authorisation has been delivered in application of Directive.

# **PROVISIONS OF THE CODE OF ETHICS FOR PHARMACEUTICAL MARKETING**

## **ARTICLE 1. MARKETING AUTHORISATION**

1.01. It is forbidden to promote (sponsor) sales of medicinal products prior to the grant of marketing authorization allowing its sale or supply or outside of its approved indications.

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. Subject to effectual laws and other regulations of the Republic of Lithuania, all promotional material must include the following basic information clearly and legibly:

- a) essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated (if the text has not been revised) or last revised;
- b) the supply classification of the product (prescription or over-the-counter medicine);
- c) when appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

2.02. Requirements for the information provided in promotion of medicines are set out in laws and regulations of the Republic of Lithuania regulating promotion of medicines.

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

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

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. Promotion must not mislead by distortion, omission or exaggeration of certain facts, undue emphasis or in any other way.

3.02. Promotion must be capable of substantiation which must be promptly provided in response to reasonable requests from health care professionals. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorization.

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, based on published scientific proofs. Comparative advertising must not be misleading or disparaging.

3.06. All artwork, including graphs (diagrams), 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 Codes, in which case it must be clearly stated that the artwork has been adapted and/or modified.

Particular care must be taken to ensure that artwork included in promotion does not mislead about the nature of a medicine (for example whether it is appropriate for use in children) or mislead about a claim or comparison (for example by using incomplete or statistically irrelevant information or unusual scales).

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

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

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

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

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 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**

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);
- c) never be likely to cause offense.

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

6.03. Subject to applicable laws and other regulations of the Republic of Lithuania, 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 request, of the recipient.

#### **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 Company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial manner.

7.04. Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a Company must clearly indicate that it has been sponsored by that Company.

## **ARTICLE 8. NO ADVICE ON PERSONAL MEDICAL MATTERS**

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

## **ARTICLE 9. INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY**

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

- a) “inexpensive”;
- b) directly relevant to the practice of medicine or pharmacy; and
- c) directly beneficial to the care of patients.

The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.

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

9.03. The term “inexpensive” means that it cost for the Company no more than 10 EUR (35 LTL), including the logo and other additional expenses but excluding VAT. Companies must comply with any relevant guidance provided under this Section 9.03 or in connection with any Applicable Code(s).

## **ARTICLE 10. EVENTS AND HOSPITALITY**

10.01. All promotional, scientific or professional meetings, congresses, conferences, symposia, congress exhibitions and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an “**event**”) organised or sponsored by or on behalf of a Company must be held in an “appropriate” venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any Applicable Code(s). The term “appropriate” is considered as compliant with the provisions of Article 10 of this Code and not in conflict with the applicable laws and regulations of the Republic of Lithuania. Any activities forming presumption of confusing scientific and training aims with entertainment or other aims must be avoided in such events.

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

- a) most of the invitees are from outside of Lithuania 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).

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 genuine registration fees.

10.05. 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 Code of Ethics of the country where the meal is offered. In Lithuania, the cost of one meal cannot exceed 50 EUR (172.64 LTL) including VAT. If the Code of Ethics for Pharmaceutical Marketing of a foreign country does not set the monetary threshold for a meal, applicable Lithuanian standards must be complied with.

10.06. Hospitality may only be extended to persons who qualify as (registered) participants in their own right (if registration is obligatory).

10.07. All forms of hospitality offered to healthcare professionals shall be reasonable in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

10.08. Hospitality shall not include sponsoring or organising entertainment (e.g., sporting or leisure) events. Companies should avoid using venues that are renowned for their “entertainment (amusement)” facilities or are “extravagant”. Entertainment (amusement) venues are considered as venues for leisure and entertainment which advertise their entertainment facilities in promotional leaflets, also publicly in the press or internet, and which are primarily intended for recreation and (or) entertainment – leisure activities, and not for professional (business) meetings. Extravagant venues are considered as venues distinguished by luxury and splendour or visiting them could affect the image of healthcare professionals or the pharmaceutical industry.

10.09. Companies should comply with the regulations related to the term “reasonable” in a sense in which it is used in the Article 10 of this document, and with regulations of other Applicable Codes.

## **ARTICLE 11. DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE OR RESEARCH**

11.01. Donations and grants to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the Code regulating Relations Between the Pharmaceutical Industry and Patient Organisations) 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;
- c) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

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

## **ARTICLE 12. FEES FOR SERVICE**

12.01. Contracts between companies and institutions, organisations or associations of healthcare professionals under which such institutions, organisations or associations provide any type of services to companies (or any other type of funding not covered under Article 11 or not otherwise covered by the Code) are only allowed if such services (or other funding):

- a) are provided for the purpose of supporting healthcare or research;
- b) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

## **ARTICLE 13. SPONSORSHIP OF HEALTHCARE PROFESSIONALS**

13.01. Companies must comply with criteria governing the selection and sponsorship of healthcare professionals to attend training or events as provided in, or in connection with, provisions of any Applicable Codes. Funding must not be offered to compensate merely for the time spent by healthcare professionals in attending events. In the case of international events for which a company sponsors the attendance of a healthcare professional, if any funding is provided to such healthcare professional in accordance with the provisions of this Section (13.01), such funding is subject to the rules of the jurisdiction where such healthcare professional carries out his profession, as opposed to those in which the international event takes place. For the avoidance of doubt, this Section 13.01 is not intended to prohibit the extension of hospitality to healthcare professionals in accordance with Article 10 hereof.

13.02. Companies may sponsor participation of healthcare professionals in international scientific events organised by Global, European, North American, Scandinavian and Baltic professional organisations of healthcare professionals and scientific institutions.

13.03. Company(-ies) must report such sponsorship of healthcare professionals to the Pharmaceutical Marketing Ethics Committee no later than 30 calendar days after the end of events (all international scientific events indicated in Section 13.02), indicating:

- a) name, venue and time of the event;
- b) speciality and number of the sponsored healthcare professionals;
- c) full names of sponsored healthcare professionals.

Information about the sponsorship provided by the Companies shall be announced publicly on the website of the Pharmaceutical Marketing Ethics Committee. The term “sponsorship” includes sponsorship through healthcare institutions, trade unions of healthcare professionals, speciality societies, subsidiaries of the Companies operating in foreign countries, etc.

## **ARTICLE 14. THE USE OF CONSULTANTS**

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 or scientific studies, clinical trials or training services, participation at advisory board meetings, and

participation in market research where such participation involves remuneration and/or travel. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria.

a) A written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services.

b) A legitimate need for the services has been clearly identified in advance of requesting the services and making an agreement or contract 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 this criteria.

d) The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need.

e) The contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants.

f) The hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.

g) The compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating healthcare professionals.

14.02. In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to confirm (declare) that he is a consultant to the company whenever he or she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that Company. Similarly, Companies that employ, on a part-time basis, healthcare professionals that are still practising their profession are strongly encouraged to ensure that such persons have an obligation to reveal (declare) his or her employment arrangement with the Company whenever he or she writes or speaks in public about a matter that is the subject of the employment or any other issue relating that Company. The provisions of this Section 14.02 apply even though the Code does not otherwise cover non-promotional, general information about Companies<sup>1</sup>.

14.03. Limited market research, such as one-off phone interviews or mail/e-mail or internet questionnaires are excluded from the scope of this Article 14, provided that the healthcare professional is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal (does not exceed the salary for the direct employment of the doctor during the time spent on market research).

14.04. If a healthcare professional attends an international event in a consultant or advisory capacity the relevant provisions of Article 10 and methods of reporting of Section 13.03 shall apply.

## **ARTICLE 15. NON-INTERVENTIONAL STUDIES OF MARKETED MEDICINES**

15.01. A non-interventional study of a marketed medicine is defined as a study where the medicinal products 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

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<sup>1</sup>Companies are strongly encouraged to include such provisions in any contracts entered into or renewed on or after the implementation date that are covered by this Section 14.02. In addition, Companies are encouraged to renegotiate existing agreements and contracts at their earliest convenience to include such provisions.

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.

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

a) The study is conducted with a scientific purpose.

b) There is a written study plan (protocol) and there are written contracts between healthcare professionals and/or institutes at which the study will take place, on 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 these services.

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

d) The study protocol should be submitted to the ethics committee for review according to the law and other regulations of the Republic of Lithuania.

e) Applicable laws and requirements of other regulations of the Republic of Lithuania on personal data privacy (including the collection and use of personal data) must be complied with.

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 18.02 (a).

h) The study results must be analysed by or on behalf of the contracting Company and summaries thereof must be made available within a reasonable period of time to the Company's scientific service (as described in Section 18.02 (a)), which service shall maintain records of such reports for a reasonable period of time. The Company should send the summary report to the ethics committee reviewing the protocol (upon the request of the committee or if it is required according to the law) and to 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 State Medicines Control Agency.

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 or device.

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

## **ARTICLE 16. SAMPLES**

16.01. When promoting medicinal products to healthcare professionals qualified to prescribe medicinal products, promoters of medicines may use samples of medicinal products which are not intended for sale. A sample of the medicinal product not intended for sale must be no larger than the smallest presentation of the medicinal product of the same title, form and strength and the package must be marked "Free sample". Leaving the samples of medicinal products not intended for sale for healthcare professionals, distributing them to the public and using them for healthcare purposes are prohibited.

16.02. For samples of medicines not intended for sale, as well as all medicines, Companies must apply corresponding control and accountability systems, administered by their representatives.

#### **ARTICLE 17. PROHIBITION OF GIFTS\***

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

\* Distribution of “inexpensive” objects intended for reminder advertising, as they were allowed in Section 10.2 of 2012 version of the Code, must be finished no later than the 30<sup>th</sup> of June, 2014.

#### **ARTICLE 18. PHARMACEUTICAL COMPANY STAFF**

18.01. Medical Sales Representatives must ensure that the frequency, timing and duration of visits aiming to meet just one or two healthcare professionals and to pharmacies, hospitals or other healthcare facilities, as well as the method of presentation used by Medical Sales Representatives, do not cause inconvenience to healthcare professionals or patients.

Each Company shall ensure that its sales representatives, including personnel retained by way of contract with third parties, and any other Company representatives, who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicinal products (each, a “**Medical Sales Representative**”) are familiar with the relevant requirements of the corresponding requirements of the Code, and all applicable laws and other regulations, and are adequately trained and have sufficient knowledge to be able to provide precise and complete information about the medicinal products they promote.

a) Medical Sales Representatives must comply with all relevant requirements of the Applicable Codes, and all applicable laws and other regulations. Companies are responsible for ensuring their compliance with all mentioned requirements and regulations.

b) Medical Sales Representatives must approach their duties responsibly and ethically.

c) During each visit, and subject to applicable laws and regulations, Medical Sales Representatives must give the persons visited, or have available for them, a summary of the product characteristics for each medicinal product they present.

d) Medical Sales Representatives must transmit to the scientific service of their Companies forthwith any information they receive in relation to the use of their Company’s medicinal products, particularly report 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, correspond to the statutory procedures.

f) Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. Medical Sales Representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the Company they represent.

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

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

a) Every company must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non-interventional studies. Companies are free to decide

how best to establish such services in accordance with this Section 18.02 (i.e., whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organisation. This service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he/she has examined the final form of the promotional material and that in his/her belief it is in accordance with the requirements with the Applicable Codes and any applicable advertising laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the medicine. In addition, the scientific service must include a medical doctor or, where appropriate, a pharmacist, who will be responsible for the oversight of any non-interventional study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives). Such person must certify that he/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 Codes.

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

18.03. The following do not have a right to promote medicines: (a) institutions of national and local government and their employees; (b) healthcare professionals providing healthcare and pharmaceutical services.

## **ARTICLE 19. ENFORCEMENT**

19.01. IFPA and VGA are responsible for the enforcement of the provisions of this Code within current applicable rules and legislation. In the event that a breach is established pursuant to the procedures of national code, IFPA, VGA or any other Company joining the Code, shall require from the offending Company an immediate cessation of the offending activity and a signed undertaking by the company to prevent recurrence.

19.02. Assessment procedure of the breaches Code and sanctions for breaches of the Code are set forth in Annex A hereto.

## **ARTICLE 20. AWARENESS AND EDUCATION**

20.01. IFPA and VGA must, within current applicable rules and legislation facilitate Companies' awareness of and education about the Code and, in order to prevent breaches of the Code, share the respective interpretations of the provisions of the Code with the Companies and other parties joining the Code.

## **Annex A**

### **PHARMACEUTICAL MARKETING ETHICS COMMITTEE**

#### **INTRODUCTION**

Supervision of the Code of Ethics for Pharmaceutical Marketing, which governs pharmaceutical marketing and relations with healthcare professionals as well as relations between the pharmaceutical industry and patient organisations (the “Code”), is performed by the Pharmaceutical Marketing Ethics Committee (the “Committee”). The names of reporting individuals outside the pharmaceutical industry are kept confidential. In special cases the Company specified in the report to the Committee needs to know the identity of the reporting person in order to analyse the case properly. Even in such cases the identity of the reporting person shall be disclosed only with his permission. The Committee shall submit the analysed reports on breaches to IFPA, VGA, organisations joining the Code later, associations and (or) other legal entities and (or) their subsidiaries on a quarterly basis.

The Committee shall ensure that pharmaceutical industry subjects and non-industry complaints are processed in the same manner, without regard to who has made the complaint.

#### **ORGANISATION AND RESPONSIBILITY**

##### **1. The Pharmaceutical Marketing Ethics Committee is responsible for:**

- 1.1 Organising the Committee’s activities, selection of the required technical staff, tools and consultants.
- 1.2. Supervision of the Code, including advice, comments and guidelines related to the applicability and improvement of the Code.
- 1.3. Analysing the reports submitted regarding the breaches of the Code.
- 1.4. Imposition and enforcement of sanctions for the violations of the Code.
- 1.5. Maintenance of the Committee’s website.

##### **2. Organisation of the Pharmaceutical Marketing Ethics Committee**

2.1. The Committee is accountable to IFPA, VGA and Other members. On an annual basis the Committee shall generate its report of the work undertaken by it, which shall be presented by the chairperson of the Committee separately at the general assemblies of IFPA and VGA members, and to the Other members upon request. The Committee’s annual report shall be posted on the Committee’s website.

2.2. The Committee is composed of 7 members – the independent chairperson, 3 members delegated by IFPA, and 3 members delegated by VGA.

2.3. The Committee shall be elected for the period of one year. IFPA and VGA shall approve members of the Committee for the next term of office no later than one month before the expiration of the preceding term. If a member of the Committee in person or the company he represents violates the CEPM more than once a year, the Chairperson of the Committee may, at the Committee’s decision, propose to the association to replace the Committee member.

2.4. The Committee shall be chaired by an individual outside the pharmaceutical sector. The Chairperson of the Committee shall be approved by IFPA and VGA upon common agreement.

2.5. Decisions shall be adopted by majority voting. The Committee's quorum shall comprise of the Chairperson (in his absence – his deputy) and three members. At least one member must represent VGA or IFPA. In the event of equal distribution of votes, the vote of the Chairperson (or in his absence - his deputy) shall be decisive.

2.6. The deputy Chairperson of the Committee shall be elected by rotation from Committee members representing IFPA or VGA for the entire term of office of the Committee.

2.7. The Committee shall have the right to receive the material required for the examination of the reported violation of the Code from pharmaceutical companies suspected of violating the Code. The company may refuse to provide the information which is considered as its commercial secret.

### **3. Work and Funding Procedure of the Pharmaceutical Marketing Ethics Committee**

3.1. The Committee shall sit for the session upon receiving information about or whenever intending to address any other matters in connection with the Code or the Committee's area of responsibility. Each Committee member shall have the right of initiative to convene a Committee session. Committee sessions shall be convened at the decision of the Chairperson of the Committee (or in his absence, his deputy).

3.2. At the sessions of the Committee minutes shall be taken. The draft minutes shall be emailed to members of the Committee for information and comments. The minutes shall be signed by the Chairperson and the Secretary of the session. The Chairperson of the Committee shall be responsible for storage of minutes and other materials of the Committee.

3.3. The Committee may seek assistance from experts. Consulting experts may be invited to attend Committee sessions without the right to vote.

3.4. For the prevention of conflicts of interest it is required that members of the Committee name all interests related to the violation prior to the examination of the violation. The Chairperson (deputy) shall determine whether such a member can participate in the examination of the reported violation. If a member of the Committee is related to the complainant or to the respondent, he shall suspend himself (the Committee shall decide which parties may attend the session) from the adoption of the relevant decision as long as the Committee examines that particular violation report.

3.5. While the Committee examines the violation report, both the complainant and the respondent may be invited to attend or be represented at its session. At a Committee session, the Company may not be represented by the same individual who is a member of the Committee, even if he has suspended himself from the case.

3.6. If it is impossible to properly determine the circumstances of the violation report between the complainant and the respective Company according to the report only, the Committee shall have the right to invite directly related persons to attend the session as well as to provide and receive information in oral form.

3.7. The costs of the Committee shall be covered from the IFPA and VGA budget in equal contributions which shall ensure the activities of the Committee. When making the budget, IFPA and VGA must include funds on a separate line according to the planned estimated costs provided in advance by the Committee.

3.8. The Committee may incur costs in connection with the remuneration of the Committee member outside the pharmaceutical industry and with hiring experts whose opinions are reasonably required to examine specific reports, but without exceeding the estimated budget funds. The Committee shall report its expenditure to IFPA and VGA Boards in the form of a financial statement.

## PROCEDURE FOR SUBMITTING AND PROCESSING VIOLATION REPORTS

### 4. Submission of Violation Reports

4.1. Reports of potential violations of the Code may be submitted by representatives of pharmaceutical Companies, healthcare professionals, representatives of patient organisations, representatives of legal entities, natural persons. After receiving information about a potential violation(s) of the Code, the Committee may start investigating the violation on its own initiative.

4.2. Violations of this Code, unless the Committee initiates investigation of the violation itself, shall be reported in writing to the Chairperson of the Committee. The Committee Secretary shall register the received report and notify members of the Committee about it.

4.3. A report of a potentially committed violation of the Code must include:

4.3.1. The full name, address, email address (if any) and phone number of the reporting person;

4.3.2. The institution, company or organisation represented by the reporting person;

4.3.3. Information about the violation and available evidence (place, time, circumstances and persons involved);

4.3.4. The articles and sections of the Code which include provisions that were violated under the circumstances specified in the Report. A violation report submitted by a pharmaceutical company must be signed by the Company's manager or his authorised person indicating the clauses of the Code which in the company's belief have been breached;

4.3.5. The documents and other evidence substantiating the circumstances indicated in the Report must be submitted along with the Report.

4.4. Reports of potential violations of the Code may be submitted by mail, by email or through the section "Contact us" on the Committee's website.

4.5. Anonymous reports shall not be processed.

### 5. Action upon Receiving a Violation Report

5.1. Suspected violations of the Code must be reported in writing along with all the information about the violation and with the available evidence. Upon receipt of a report of a potential violation, the Chairperson of the Committee shall within 10 business days following the receipt convene a Committee session to review the received material and to assess whether the report of a violation of the Code falls within the scope of the Code. The matter may be solved by an email voting of the Committee members. If no responses "AGAINST" are received within 5 business days, it will be considered that the Committee have agreed that the report falls within the scope of the Code. After deciding that the violation report falls within the scope of the Code, the Committee shall notify the complainant and respondent about it.

5.2. If the Committee decides that the report of a violation of the Code does not fall within the scope of the Code, the reporting person shall be notified about it.

5.3. The Committee shall address to the manager of the relevant Company suspected of breaching the respective provisions of the Code in writing (the letter must be faxed, emailed or posted by registered mail to the Company's headquarters) asking to comment on the material stated in the report and shall determine the term for providing responses and comments.

5.4. Upon receipt of the Committee's appeal regarding a potential violation, the relevant Company shall give a written response to the Committee within 5 business days following the dispatch of the Committee's letter by fax or email. When the response is posted by registered mail, it must also be

faxed or emailed to the Committee on the sending day. Failing to receive the company's response within 5 business days following the dispatch of the appeal, the Committee shall examine the violation without waiting for the response.

5.5. While examining the report, the Commission may apply to the Public institutions requesting information available to them, necessary for investigation of the circumstances stated in the report, or ask those institutions to carry out an investigation within their purview and to provide the obtained information to the Committee.

5.6. After the Committee has collected sufficient information about the potential violation, but no later than within 6 (six) weeks following the receipt of the violation report, a Committee session shall be convened to adopt the decision regarding the violation of the Code. If the session fails to adopt a decision, another session must be arranged within 2 (two) weeks, where the final decision shall be made.

5.7. The violation report must be examined substantially and the final decision must be adopted within no more than 8 (eight) weeks following the receipt of the report.

5.8. The Committee's decision may be appealed against to a competent court of the Republic of Lithuania in accordance with the law within 15 (fifteen) calendar days. The Committee's decision shall come into effect only following expiry of the defined appeal term. During this appeal term implementation of the Committee's decision and enforcement of imposed sanctions shall be suspended.

5.9. The Committee and its members undertake to keep confidential any information received from the Companies during the examination of the violation and to refrain from using it for any purposes other than its primary purpose.

## **6. Decisions of the Pharmaceutical Marketing Ethics Committee**

6.1. If the Committee decides that the Code was breached, the complainant and the respondent shall be informed about it indicating reasons for adopting such a decision.

6.2. When the Committee decides that the Code was breached, it may impose on the relevant company one or more (depending on the severity of the violation) of these sanctions:

- a) warn the Company in written;
- b) inform the Company's headquarters;
- c) inform IFPA, VGA and Other members;
- d) report the violation to the EU member associations;
- e) propose to the general assembly of IFPA or VGA members to exclude the breaching Company from the association;
- f) forward the material to public institutions for further investigation.

6.3. The Committee shall publish effective decisions on its website:

- 1) in the case of severe or repeated violation, the Company's name and details of the violation must be announced;
- 2) in the case of minor violation, it is not necessary to indicate the Company's name when announcing the details of the violation.

6.4. In case the Committee states that there was no breach, such a decision of the Committee shall not be announced; only the complainant and the respondent Companies shall be informed about it.

## **Annex B**

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

The Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in Europe set forth herein are intended as a supplement for the Code for Pharmaceutical Marketing (“the Code”).

#### **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);
- e) the purpose or objective of the website.

#### **Section 2. Content of Website**

a) Information included in the website shall be regularly updated. The website 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: (1) general information on the Company; (2) health education information; (3) information intended for healthcare professionals (as defined in the Code), including promotion of over-the-counter medicines; (4) non-promotional information intended for patients and the general public about specific medicinal products marketed by the Company.

##### **1) 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 on 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.

##### **2) 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.

##### **3) Information for healthcare professionals**

Any information on websites directed to healthcare professionals that constitutes promotion (as defined in the Code) must comply with the Code and legislative provisions of the Republic of Lithuania. Such information must be clearly identified as information for healthcare professionals. In addition, access to such information must be technically restricted for patients and for the general public and shall be made available only if requested by a healthcare professional.

#### 4) Non-promotional information for patients and the general public

Subject to 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 State Medicines Control Agency. Brand name 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 and must not be publicized. 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, the Company-sponsored website address that complies 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 Codes. The scientific service established within the Company pursuant to those provisions of the Applicable Code that adopt Section 18.02 of this 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 provisions of other applicable codes of conduct governing the privacy, security and confidentiality of personal information

## **Annex C**

### **CODE OF ETHICS ON RELATIONSHIPS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS**

#### **INTRODUCTION**

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

In order to ensure that relationships between the pharmaceutical industry and patient organisations take place in an ethical and transparent manner, IFPA and VGA have adopted the Code of Ethics on Relationships between the Pharmaceutical Industry and Patient Organisations, which is considered as an integral part of the Code of Ethics for Pharmaceutical Marketing governing pharmaceutical marketing and relationships with healthcare professionals, as well as relationships between the pharmaceutical industry and patient organisations (the “**HCO Code**”).

#### **The HCO Code builds upon the following principles:**

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

#### **Scope**

These provisions of the HCO Code shall apply to relationships between IFPA and VGA member companies operating in Lithuania and their subsidiaries (the “**Companies**”) or contracted third parties as well as other parties joining this Code and patient organisations.

Patient organisations are defined as non-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers.

#### **Applicability**

The Companies must comply with this HCO Code and any laws and other regulations to which they are subject; and:

- a) in the case of partnership or other mode of joint activity with a patient organisation taking place in Lithuania, the provisions of this Code and laws and regulations of the Republic of Lithuania shall apply;

b) in the case of cross-border partnerships and activities, the industry code of the country where the patient organisation has its principal headquarters shall apply. In the event of discrepancies between the codes, more stringent provisions of a code shall apply.

“Activity” as used in this Code shall mean any interaction covered between the Company and patient organisation, including the provision of funding.

## **Provisions**

### ***Article 1 Promotion of Prescription-only Medicines***

Promotion of prescription-only medicinal products to the general public is prohibited, unless permitted by the law of the Republic of Lithuania.

### ***Article 2 Written Agreements***

When the 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. When support is provided to a patient organisation in another country, the agreement must specify the codes of ethics that apply to cooperation relations in the home countries of the Company and of the patient organisation. Each Company should have an approval process in place for these agreements.

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

### ***Article 3 Use of Logos and proprietary Materials of Patient Organisations***

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

### ***Article 4 Editorial Control***

The Companies must not seek to influence the text of patient organisations material they sponsor in a manner favourable to their own commercial interests. This must not preclude Companies from correcting factual inaccuracies.

### ***Article 5 Transparency***

Each Company must make publicly available a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a short description of the nature of the support that is complete and clear enough for the average reader to perceive the meaning of the support. The description must include the monetary value of financial support and of costs involved. For significant non-financial support that cannot be assigned a reasonable

monetary value the description must clearly describe the non-monetary benefit that the patient organisation receives. This information may be provided on a national and European level. In Lithuania, information about financial support and/or significant indirect/non-financial support shall be provided to the Pharmaceutical Marketing Ethics Committee once per calendar year before the 1<sup>st</sup> of February of the following year.

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

Each Company must make publicly available a list of patient organisations providing significant contracted services for the Company. This list should include a description of services provided that does not disclose confidential information but is complete enough to enable the average reader to perceive the nature of the agreement. Each Company shall also announce the total amount paid to every patient organisation over the reporting period in accordance with the procedure and terms described above.

#### ***Article 6 Contracted Services***

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

Members of patient organisations may be invited to deliver presentations or to provide expert or advisory services for a fee at the events organised by the Companies or advisory boards. Arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, meet each of 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 making an agreement or contract 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 this criteria;
- d. The extent of the service is not greater than it is reasonably necessary to achieve the identified need;
- e. The contracting Company maintains records concerning, and makes appropriate use of, the services provided;
- f. The involvement of patient organisations in the paid activities is not an inducement to recommend a particular medicinal product;
- g. The compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard the payment of remuneration to patient organisations may not be justified with symbolic or formal agreements for consulting and other services;
- h. In their written contracts with patient organisations Companies are strongly encouraged to include provisions regarding an obligation of the patient organisation to declare that they have

- provided paid services to the Company whenever they write or speak in public about a matter than is the subject of the agreement or any other issue related to that Company;
- i. Each Company must publicly announce the list of patient organisations trusted to provide paid services – see Section 5c.

### ***Article 7 Single Company Funding***

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

### ***Article 8 Events and Hospitality***

All events sponsored or organised by or on behalf of a Company must be held in an appropriate venue that is conducive to the main purpose of the event, avoiding those that are “renowned” for their “entertainment (amusement) facilities” or are “extravagant”. Entertainment (amusement) venues are considered as venues for leisure and entertainment which advertise their entertainment facilities in promotional leaflets, also publicly in the press or internet, and which are primarily intended for recreation and/or entertainment – leisure activities, and not for professional (business) meetings. “Extravagant” venues are considered as venues distinguished by luxury and splendour or visiting them could affect the image of patient organisations or the pharmaceutical industry.

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

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

Hospitality may only be extended to persons who are invited and participate in the event in their own right. In exceptional cases, in case of apparent health needs (e.g. disability), expenses related to travel, meals, accommodation and registration fee of the accompanying person considered a caregiver can be covered.

Forms of hospitality offered to patient organisations and their representatives shall be adequate and related to the main purpose of the event.

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

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

- a) most of the invitees are from outside of its home country (not from the country where the Company organising an event is registered) 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 professional expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

### ***Article 9 Enforcement and Implementation***

Supervision of the Code of Ethics on Relationships between the Pharmaceutical Industry and patient organisations and accordingly compliance with the provisions of this HCO Code is performed

by the Pharmaceutical Marketing Ethics Committee, as it is determined in Annex A of this Code. The procedure of submission and assessment of violation reports shall be the same as that of the Code of Ethics for Pharmaceutical Marketing (Annex A).

## Annex I

201.... Declaration of Interests  
of the member of the Pharmaceutical Marketing Ethics Committee  
.....(full name)

1. Did you have any financial relations with pharmaceutical manufacturers other than your represented company (employment relations, the pharmaceutical manufacturer paid for your participation in a conference, congress, advisory board meeting, symposium, etc., paid you a honorarium for a presentation, copyright work, letter, advice or studies, you were involved in clinical trials conducted by the pharmaceutical manufacturer or received gifts of the value exceeding 1 MSL, etc.) in the past 5 years?

YES

NO

2. If “YES”, please provide more detailed information specifying the nature of interest, name of the pharmaceutical manufacturer etc.

.....  
.....

3. Are there any other circumstances that could affect your objectivity and impartiality in making decisions as a member of Pharmaceutical Marketing Ethics Committee?

YES

NO

4. If “YES”, please provide more detailed information specifying the nature of interest, name of the pharmaceutical manufacturer, etc.

.....  
.....

If your answer to at least one of the questions was “YES”, the Committee may propose that you do not participate in the consideration of related matters or voting, due to the potential conflict of interest.

I confirm that the above information is true and complete. In case any of the details provided in this declaration change, I commit to provide the changes within 20 days. I agree that my declaration is communicated to the members of IFPA or VGA.

-----  
(signature, full name of the person completing the declaration; declaration completion date)

The declaration is completed once a year before March 1 of the current year and is handed to the Chairperson of the Committee.

-----  
(signature, full name of the person accepting the declaration; date)

## Annex II

### Model Template for Written Agreements between the Pharmaceutical Industry and Patient Organisations

When pharmaceutical companies (the “**Companies**”) provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement.

The key elements of the written agreement are given below. The agreement must directly indicate its subject, i.e. what is the subject of agreement, consistent with the requirements of the Code of Ethics on the Relationships between the Pharmaceutical Industry and Patient Organisations.

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

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

Code(s) of Ethics that apply:

Signatories to the agreement:

Date of agreement: