HCP/HCO DISCLOSURE CODE

PHARMACEUTICAL COMPANIES MUST DISCLOSE INFORMATION ABOUT TRANSFERS OF VALUE TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

Annex D of the Code of Ethics for Pharmaceutical Marketing **Lithuania**

Adopted on the 26 November 2013 by IFPA General Assembly
Adopted on the 16 January 2014 by VGA General Assembly

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PREAMBLE

Healthcare professionals (HCP) and healthcare organisations (HCO) provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. This knowledge helps the industry improve the quality of patient care, with benefits to individuals and society at large. Healthcare professionals and healthcare organisations should be fairly compensated for the legitimate expertise and services they provide to the industry.

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

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

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

In line with these “Guiding Principles“, members of IFPA and VGA believe that future success of the pharmaceutical industry to respond to society‘s heightened expectations. Following the requirements of EFPIA and HCP/HCO Disclosure Code declared on the 24th of June 2013 (the “**Disclosure Code**“), the members of IFPA and VGA and associated parties have therefore decided to supplement the Code of Ethics for Pharmaceutical Marketing (the “**CEPM**“) by requirements for disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organisations. Members of IFPA and VGA hope that, by taking this step, it can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stakeholders in the pharmaceutical industry.

Members of IFPA and VGA believe that the interest of patients and other stakeholders in the transparency of these interactions is compelling. Members of IFPA and VGA recognise that disclosure can raise data privacy concerns and seek to work with healthcare professionals to ensure that these concerns are addressed. Members of IFPA and VGA and other associated parties believe that transparency can be achieved without sacrificing the legitimate privacy interests of healthcare professionals and legislation should not therefore impose excessive restrictions on disclosure by the industry.

Disclosure Code provides for disclosures of transfers of value to healthcare professionals, whether directly or indirectly. When deciding how a transfer of value should be disclosed, companies should, wherever possible, identify and publish at the individual healthcare professional (rather than healthcare organisation) level, as long as this can be achieved with accuracy, consistency and compliance with applicable law.

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

APPLICABILITY OF DISCLOSURE CODE

Disclosure Code governs disclosures regarding interactions with HCPs and HCOs. It is intended that this Code shall apply to interactions with HCPs and HCOs to the same extent as the existing Code of Ethics

for Pharmaceutical Marketing and Code of Relationships with Patient Organisations[1].

Disclosure Code applies to companies engaged in pharmaceutical marketing in Lithuania ("Companies"), their representatives and CEPM affiliated organisations, associations and (or) other legal entities and (or) their subsidiaries.

ARTICLE 1. DISCLOSURE OBLIGATION

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

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

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

ARTICLE 2. FORM OF DISCLOSURE

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

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

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

Section 2.04. *Platform of Disclosure.* Disclosures must be published on the Company's or Parent Company's website in accordance with Section 2.05, and there should be links to the data published on Companies' websites on the website of the Code of Ethics for Pharmaceutical Marketing www.vaistukodeksas.lt.

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

Section 2.06. *Language of Disclosure.* Disclosures shall be made in two languages – Lithuanian and English.

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

ARTICLE 3. INDIVIDUAL AND AGGREGATE DISCLOSURE

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

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

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

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

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

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

Section 3.05. *Methodology.* Each Company shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 3.01. The note, including a general summary and Lithuania specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other

tax aspects, currency aspects and issues related to the timing and amount of Transfers of Value for purposes of Disclosure Code, as applicable.

Article 4. ENFORCEMENT

Section 4.01. Members of IFPA and VGA are responsible for the enforcement of the regulations of this Code in a manner consistent with applicable laws and regulations. When a violation of the Disclosure Code is determined, each Company CEPM and its Annex Disclosure Code affiliated Company must demand the correction of the violation from the relevant Company without delay.

Section 4.02. Disclosure Code violation assessment procedure and sanctions are the same as CEPM violation assessment procedure and sanctions, see Annex A of CEPM, Pharmaceutical Marketing Ethics Committee.

Section 4.03. Reports regarding violations of the Disclosure Code should be sent directly to the Pharmaceutical Marketing Ethics Committee as indicated in the Section 4 of Annex A of CEPM. Reports on Lithuania related violations received by EFPIA shall be forwarded to the office of IFPA without analysing, the latter passing it on to the CEPM Committee, respectively. Process of examining the report is set forth in Sections 4, 5 and 6 of Annex A of CEPM.

SCHEDULE 1. TERMS USED IN HCP/HCO DISCLOSURE CODE

Donations and Grants

Donations and Grants (either in cash or benefits in kind) within the scope of Articles 11 and 13 of the CEPM, and grants for activities of scientific research and other cases as indicated in the Schedule 2, Template of Report.

Events

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a company. (*Article 10 of the CEPM Code*).

Healthcare Organisation (HCO)

Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of Annex C of the CEPM Code, "Code of Ethics in the Relations between the Pharmaceutical Industry and Patient Organisations") whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Healthcare Professionals (HCP)

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

CEPM Code

Code of Ethics for Pharmaceutical Marketing.

Medicinal Products

Medicinal Products as used in the Disclosure Code has the meaning set forth in Article 1 of the Directive 2001/83/EC:

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 2001/83/EC.

Company

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).

PO Code

Annex C of CEPM – "Code of Ethics in the Relations between the Pharmaceutical Industry and Patient Organisations".

Recipient

Any HCP or HCO whose primary practice, principal professional address or place of incorporation is in Lithuania.

Research and Development Transfers of Value

Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (*Section 15.01* of the CEPM).

Transfers of Value

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

SCHEDULE 2 - TEMPLATE / ATASKAITOS ŠABLONAS

Article 2 - Section 2.03 / 2 straipsnio 2.03 dalis *Date of publication/ Paskelbimo data.....*

	Full Name *(Art. 1.01)*/ Vardas, pavardė arba pavadinimas *(1.01 dalis)*	HCPs: City of Principal Practice HCOs: city where registered *(Art. 3)*/ SPS: miestas, kuriame vykdoma pagrindinė praktika SPO: registracijos miestas *(3 str.)*	Country of Principal Practice *(Schedule 1)* / Valstybė, kuriame vykdoma pagrindinė praktika *(1 priedas)*	Principal Practice Address *(Art. 3)* / Pagrindinės praktikos vietos adresas *(3 str.)*	Unique country local identifier OPTIONAL *(Art. 3)* / Unikalus valstybės identifikatorius PASIRINK-TINA *(3 str.)*	Donations and Grants to HCOs *(Art. 3.01.1.a)* / Parama SPO *(3.01.1.str)*	Contribution to costs of Events *(Art. 3.01.1.b & 3.01.2.a)* / Prisidėjimas prie Renginio išlaidų *(3.01.1.b ir 3.01.2.a)*			Fee for service and consultancy *(Art.3.01.1.c & 3.01.2.c)* / Atlygis už paslaugas ir konsultacijas *(3.01.1.c ir 3.01.2.c)*			**TOTAL** *OPTIONAL* / **IŠ VISO** *PASIRINKTINA*
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event / Rėmimo sutartys su SPO/ trečiosiomis šalimis, kurias SPO paskyrė Renginiui valdyti	Registration Fees/ Registracijos mokesčiai	Travel & Accommodation/ Kelionės ir apgyvendinimas	Fees / Atlygis	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract Susijusios išlaidos, dėl kurių susitarta atlygio už paslaugas arba konsultacijas sutartyje, įskaitant kelionės ir apgyvendinimo išlaidas pagal sutartį		
HCPs / SPS	*INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)* *INDIVIDUALI INFORMACIJA SU PAVARDĖMIS – viena eilutė skirta vienam SPS (t. y. visų verčių, perleistų vienam SPS per metus, suma: detalizuojama tik pareikalavus Gavėjui ar valstybinei institucijai,)*												
	Dr A / Dr. A					N/A N. D.	N/A N. D.	*Yearly amount / Suma per metus*	*Yearly amount / Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount / Suma per metus*		
	Dr B / Dr. B					N/A N. D.	N/A N. D.	*Yearly amount / Suma per metus*	*Yearly amount / Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount / Suma per metus*		
	etc. / ir t. t.					N/A N. D.	N/A N. D.	*Yearly amount / Suma per metus*	*Yearly amount / Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount / Suma per metus*		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons *KITA, KAS NEBUVO PIRMIAU NURODYTA – kai dėl teisinių priežasčių informacija negali būti atskleista individualiai*												
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02* / **Bendra tokiems Gavėjams perleistų verčių suma,** *3.02 dalis*					N/A N. D.	N/A N. D.	*Aggregate HCPs / Bendrai SPS*	*Aggregate HCPs / Bendrai SPS*	*Aggregate HCPs / Bendrai SPS*	*Aggregate HCPs / Bendrai SPS*		*Optional / Pasirinktina*
	Number of Recipients in aggregate disclosure *Art. 3.02* / **Gavėjų skaičius** *aotskleidžiamas apibendrintoj sumoje 3.02 dalis*					N/A N. D.	N/A N. D.	*number / skaičius*	*number / skaičius*	*number / skaičius*	*number / skaičius*		*Optional / Pasirinktina*
	% of the number of Recipients included in the aggreate disclosure in the total number of Recipients disclosed- Art. 3.02 Gavėjų atskleidžiamų apibendrintai skaičius, bendrame gavėjų skaičiuje , išreikštas % , *3.02 dalis*					N/A N. D.	*N/A N. D.*	*%*	*%*	*%*	*%*		N/A N. D.
HCOs / SPO	*INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)* *INDIVIDUALI INFORMACIJA SU PAVADINIMAIS – viena eilutė skirta vienai SPO (t. y. visų vienai SPO per metus perleistų verčių suma: detalizuojama tik pareikalavus Gavėjui ar valstybinei institucijai)*												
	HCO 1 / SPO1					*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*		*Optional / Pasirinktina*
	HCO2 / SPO2					*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*		*Optional / Pasirinktina*
	etc. / ir t. t.					*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*	*Yearly amount/ Suma per metus*		*Optional / Pasirinktina*
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02* / **Bendra tokiems Gavėjams perleistų verčių suma** *3.02 dalis*					*Aggregate HCOs / Bendrai SPO*	*Aggregate HCOs / Bendrai SPO*	*Aggregate HCOs / Bendrai SPO*	*Aggregate HCOs / Bendrai SPO*	*Aggregate HCOs / Bendrai SPO*	*Aggregate HCOs / Bendrai SPO*		*Optional / Pasirinktina*
	Number of Recipients in aggregate disclosure - *Art. 3.02* / **Gavėjų skaičius** *aotskleidžiamas apibendrintoj sumoje 3.02 dalis*					*number / skaičius*	*number / skaičius*	*number / skaičius*	*number / skaičius*	*number / skaičius*	*number / skaičius*		*Optional / Pasirinktina*
	% of the number of Recipients included in the aggreate disclosure in the total number of Recipients disclosed- Art. 3.02 Gavėjų atskleidžiamų apibendrintai skaičius, bendrame gavėjų skaičiuje , išreikštas % , *3.02 dalis*					*%*	*%*	*%*	*%*	*%*	*%*		N/A N. D.
R &D	**AGGREGATE DISCLOSURE APIBENDRINTAS ATSKLEIDIMAS**												
	Transfers of Value re Research & Development as defined - Article 3.04 and Schedule 1 Perleistos vertės, susijusios su moksliniais tyrimais ir plėtra, kaip apibrėžta 3.04 str ir 1 Priede											*TOTAL AMOUNT / SUMA IŠ VISO*	*OPTIONAL/ PASIRINKTINA*