THE CODE OF ETHICS FOR PHARMACEUTICAL MARKETING

FINAL CONSOLIDATED VERSION 2020

APPROVED BY IFPA AND VGA

ADOPTED BY THE IFPA GENERAL ASSEMBLY OF 18 JUNE 2020

ADOPTED BY THE VGA

GENERAL ASSEMBLY OF 25 JUNE 2020

The Code of Ethics for Pharmaceutical Marketing is a set of ethics rules adopted by the members of the Innovative Pharmaceutical Industry Association (IFPA) and the Medicinal Product Manufacturers' Association (Vaistų gamintojų asociacija, VGA), which regulates the promotion of medicinal products to healthcare professionals and interactions with healthcare specialists, healthcare organisations and patient organisations in order to ensure that these activities are carried out in compliance with the strictest ethical principles of professionalism and responsibility. This Code applies to communication and interactions of all types (in both traditional and digital manner). The Code applies to Companies engaged in the promotion of medical products in Lithuania.

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DEFINITIONS

Member Association: as defined in the EFPIA Statutes, means an organisation representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies. The Member Associations or their constituent members, as the context may require, may be bound by the EFPIA Code. In Lithuania, the Member Association of EFPIA is the Innovative Pharmaceutical Industry Association (IFPA).

Reporting Period: refers to the annual disclosure cycle and covers a full calendar year.

Company: means Companies, who are IFPA and VGA Members, as well as other Companies developing and manufacturing medicinal products for human use and engaged in the promotion of medicinal products in Lithuania.

Company Staff: personnel employed by a Company or retained by way of contract with third parties, who are concerned with any and all matters covered by this Code of Ethics for Pharmaceutical Marketing.

Contribution to Costs related to Events: is a support providing or covering the costs of meals, travel, accommodation and/or registration fees to support the attendance of an individual healthcare professional or patient organisation representative to an event organised or created by a Company and/or a third party.

European Federation of Pharmaceutical Industries and Associations (EFPIA): is the representative body of the pharmaceutical industry in Europe.

EFPIA Code: The EFPIA Code of Practice, including those Annexes which are expressly mentioned as binding and which form part of this Code.

Recipient: any healthcare professional or healthcare organisation or patient organisation as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Lithuania.

Informational or Educational Material: constitutes inexpensive material directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

Innovative Pharmaceutical Industry Association (hereinafter the "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 (hereinafter the "EFPIA").

Code: is the Code of Ethics for Pharmaceutical Marketing approved by IFPA and VGA and effective in the Republic of Lithuania.

***Medicines for Europe*:** means the European association uniting generic, biosimilar and value added pharmaceutical industries, representing, supporting, and developing common scientific and technical interests in the European Union and across Europe as well as between the European Union and third countries. VGA is a member of *Medicines for Europe*.

Medical Education: includes education related to human health and diseases and specific non-promotional training related to medicinal products.

Item of Medical Utility: constitutes an inexpensive item aimed directly at the education of healthcare professionals enhancing the provision of medical services and patient care and that not offsetting routine business practices of the healthcare professionals.

National Code: The code of practice of a Member Association adopted and applicable in a particular country.

Non-Interventional Study (NIS): is a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided upon in advance by a trial protocol but falls within current practice, while the prescription of the medicinal product is strictly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures must be applied to the patients and epidemiological methods must be used for the analysis of collected data.

Patient Organisation (PO): non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and the business address, place of incorporation or primary place of operation of which is in Lithuania.

Patient Organisation Representative: is a person who is authorised to represent and express the collective views of a PO on a specific issue or disease area.

Donations and Grants: providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research, or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

Transfers of Value (ToV): direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicines and non-prescription medicinal products for human use. Direct ToVs are those made directly by a Company for the benefit of a Recipient. Indirect ToVs are those made on behalf of a Company for the benefit of a Recipient, or those made through a Third Party and where the Company knows or can identify the Recipient that will benefit from the Transfer of Value.

Research and Development Transfers of Value: Transfers of Value to Health Professionals or Healthcare Organisations 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 trials that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare specialists specifically for the study.

Host Country Principle: refers to the primacy of the monetary threshold for a meal (food and beverages) set by the relevant Member Association in its National Code. The monetary threshold set in the country where the Event takes place must prevail.

Professional Events: are defined in accordance with the criteria of the Rules for the Advertising of Medicinal Products.

Prescription-Only Medicines (POM): is a Medicinal Product that requires a medical prescription issued by a professional person qualified to prescribe.

Promotion: includes any activity undertaken, organised or sponsored by a Company, or with its authority, which promotes the prescription, supply, sale, administration, recommendation, or consumption of its Medicinal Product(s).

Promotional Events: are defined in accordance with the criteria of the Rules for the Advertising of Medicinal Products.

Events: All professional, promotional, scientific, educational 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.

Sponsorship: is a support provided by or on behalf of a Company, when permitted by law, as a contribution to support an activity (including an Event) performed, organised, or created by HCO, a PO, or a Third Party.

Venue: refers to the logistic place where the Event is organised (i.e. the hotel, the congress centre).

Healthcare Organisation (HCO): any legal person/entity (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 Article 21) whose business address, place of incorporation or primary place of operation is in Lithuania or (ii) through which one or more healthcare professionals provide services.

Healthcare Professional (HCP): any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/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 purpose of this Code, the definition of Healthcare Professionals 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, recommend or administer Medicinal Products and (ii) any employee of a Company whose primary occupation is that of a practising Healthcare Professional, but excludes (x) all other employees of a Company and (y) a wholesaler or distributor of Medicinal Products.

Personal Health Data: is any information related to the physical, mental health or to the inherited or acquired genetic characteristics of an identified or identifiable natural person, including the provision of health care services, which reveal information about his or her physiology or health status.

Applicable Codes:

- The Code. In the case of promotion of medicinal products that is undertaken, sponsored, or organised by or on behalf of, or with, a Company in the Republic of Lithuania, the Code shall apply.
- The National Code. In the case of promotion of medicinal products that is undertaken, sponsored, or organised by or on behalf of, or with, a Company in another European country, the National Code of that country shall apply.
- The EFPIA Code. In the case of promotion of medicinal products that is undertaken, sponsored, or organised by or on behalf of, or with, a Company that is a member of EFPIA and is established outside Europe, in Lithuania, the EFPIA Code and the Code shall apply.

If the Company sponsors a Healthcare Professional's attendance of an international Event, such funding is subject to the rules of the National Code where such Healthcare Professional carries out his/her profession, as opposed to those in which the international Event takes place.

In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions must apply, except for the application of Section 10.05 of the Code, where the monetary threshold set in the country where the event takes place (i.e. the "host country") must prevail.

Third Party: is a legal person/entity or individual that represents a Company or interacts with other Third Parties on behalf of a Company or relating to the Company's Medicinal Product, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, providers of services related to Events, public relations services, non-clinical, non-interventional studies management services.

Medicinal Product: has the meaning set forth in Article 1 of Directive 2001/83/EC of the European Parliament and the Council, namely:

(a) (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 either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Medicinal Product Manufacturers' Association (Vaistų gamintojų asociacija, hereinafter the "VGA"): unites pharmaceutical companies operating in Lithuania and represents manufacturers of generic, biosimilar, value added, and innovative medical products, marketing authorisation holders and registrars of medical products. VGA is a member of the European Association *Medicines for Europe*.

Medical Sales Representative: personnel employed by a Company or retained by way of contract with Third Parties, who interact with HCPs and HCOs, in connection with the Promotion of Medicinal Products.

Code of Ethics for Pharmaceutical Marketing (the Code): as adopted and applied by IFPA and VGA as well as by the Companies who have acceded to the Code and operate in Lithuania.

Medical Sample: has the meaning set forth in Directive 2001/83/EC of the European Parliament and the Council, namely sample of Medicinal Product free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them.

Location: refers to the geographic place where the Event is organised (e.g. the city, town).

PREAMBLE

This document replaces the previous version of the Code of Ethics for Pharmaceutical Marketing approved by the General Assemblies of IFPA and VGA (2013 version, including all annexes and amendments).

ETHICAL PRINCIPLES

As pharmaceutical companies, we work in collaboration with various stakeholders including healthcare professionals, healthcare organisations, patient organisations and their representatives, regulatory authorities, governments and the public to improve health and quality of life.

We continuously invest in research and development to deliver new treatments for medical needs and improving the quality of treatment.

As commercial organisations, we encourage competition and economic development to sustain investment and foster innovation.

We believe in what we do and know that somewhere there is a patient whose health and well-being is, directly or indirectly, dependent on our work.

We aim at creating the environment where our stakeholders and the general public, consider pharmaceutical companies as trusted partners.

In addition to complying with extensive legal requirements (i.e. laws and regulations applicable to our industry such as pharmaceutical, competition, intellectual property, and data protection laws as well as anti-bribery and anti-corruption legislation), the pharmaceutical industry has agreed to comply with additional standards in its self-regulatory codes and joint positions.

For IFPA, VGA and their members as well as other Companies who have acceded to the Code, self-regulation means being fully committed to define, implement, comply with, and enforce the highest ethical standards through the application of the Code, where breaches are not tolerated.

Self-regulation includes the concept of continuous challenge for us to exceed the society's expectations and openness regarding suggestions from others on how we might further strengthen confidence in our industry and our behaviour.

Stakeholders who share the values and principles enshrined in this self-regulation are invited to adhere to these rules and guidance.

This demonstrates our commitment to the following ethical principles:

First and foremost, the PATIENTS ARE AT THE HEART OF WHAT WE DO. We aspire to ensure that everything we do will ultimately benefit patients. Our primary contribution to the society is to make high quality Medicinal Products and to encourage their appropriate and rational use in the care pathway.

We act with INTEGRITY, interact in a responsible manner, and aim to ensure that our communications with stakeholders are accurate, legitimate, and balanced. We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.

We interact with all our stakeholders with RESPECT. We commit to approach our stakeholders in an open manner, with a responsive, constructive, and learning attitude and mutual respect. We value the importance of independent decision-making by stakeholders, based on evidence and including patient interest. With due respect to the society, we listen to what is expected from us and adapt our way of working accordingly. We follow applicable laws and make ethical judgements when processing Personal Health Data.

We are committed to ensure that TRANSPARENCY is respected. We are open about our activities and interactions and encourage stakeholders to act with the same openness.

INTRODUCTION

The Code has been adopted at the will and upon common agreement of IFPA and VGA – associations of companies engaged in pharmaceutical marketing in Lithuania.

IFPA and VGA and their members are conscious of the importance of (i) providing accurate, fair and objective information about Medicinal Products so that rational decisions can be made as to their use, (ii) ensuring that interactions with HCPs, HCOs and POs, which are key to sharing knowledge aiming to improve the quality of patient care, take place in an ethical manner and (iii) introducing greater transparency around the pharmaceutical industry's interactions with HCPs, HCOs and POs.

The associations that have adopted the Code as well as the Companies who have acceded to the Code aspire to promote the 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.

The Code has been acceded by IFPA, VGA and other independent Companies engaged in the promotion of medicinal products in Lithuania.

Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of an enterprise or organisation – are deemed to constitute a single Company, and are as such committed to comply with the Code.

Chapters 1, 2 and 3 reflect the requirements of Directive 2001/83/EC of the European Parliament and the Council, as amended, relating to Medicinal Products, and fit into the general framework established by the Directive, which recognises the role of voluntary control of advertising of Medicinal Products by self-regulatory bodies and recourse to such bodies when complaints arise.

IFPA and VGA encourage competition among pharmaceutical companies. The Code is not intended to restrain the Promotion of Medicinal Products to HCPs, or limit interactions with HCPs, HCOs, and POs in a manner that is detrimental to fair competition. Instead, the Code seeks to ensure that pharmaceutical companies conduct such Promotion and interactions in a truthful manner, avoiding deceptive practices and potential conflicts of interest with stakeholders, and in compliance with applicable laws and regulations.

The Code thereby aims to foster the environment where the general public can be confident that the choices regarding their Medicinal Products are being made on the basis of the merits of each product and the healthcare needs of patients.

HCPs and HCOs provide the pharmaceutical industry with valuable, independent, and expert knowledge derived from their clinical and scientific experience. This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and the society at large. HCPs and HCOs should be fairly remunerated for the legitimate expertise and services they provide to the pharmaceutical industry.

IFPA and VGA believe that interactions between Companies and HCPs have a profound and positive influence on the quality of patient treatment and the value of future research. The integrity of the decision of HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. IFPA and VGA recognise that interactions between the pharmaceutical industry and HCPs/HCOs can create the potential for conflicts of interest. Consequently, IFPA and VGA and their Member Companies have adopted the Code and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments, and other stakeholders expect.

In order to continue to be successful, self-regulation needs to respond to the evolving demands of the society. In particular, IFPA and VGA recognise the growing expectation that interactions with society are not only conducted with integrity but are also transparent.

In the same way, the pharmaceutical industry works with POs to learn from their knowledge and experience of patients' condition that is able to provide a true picture of what it is like to live with a specific condition, how care is delivered, how that impacts on them, their carers, and families and how medicines and other treatments can change their quality of life and meet their needs.

POs have a key role in helping to shape, develop and define the outcomes that make the most difference to patients. Companies disclose the amounts provided to POs in the framework of these interactions.

IFPA and VGA strongly support public scrutiny and the understanding of these relationships and disclosure contributes to the confidence of stakeholders in the pharmaceutical industry.

Since the introduction of the Disclosure Code, IFPA and VGA have worked to encourage Companies cooperating with HCPs and HCOs to always look to disclose and to encourage HCPs (and HCOs where relevant) to agree to individual disclosures of Transfers of Value. Companies will not be criticised for over-disclosure.

SCOPE OF THE CODE

The Code covers:

- Promotion of Prescription-Only Medicines and non-prescription Medicinal Products;
- Interactions between Companies and HCPs, HCOs, and POs;
- Disclosure of Transfers of Value from Companies to HCPs, HCOs, and POs;
- Procedural requirements of the Code.

Companies are responsible for the obligations imposed under any relevant Applicable Code even if they commission a Third Party to design, implement or engage in activities covered by the Applicable Code on their behalf. In addition, Companies must take reasonable steps to ensure that any other parties that they commission to design, implement, or engage in activities covered by the Applicable Code but that do not act on behalf of the Company (e.g. joint ventures, licensees) comply with Applicable Codes.

The Code covers all methods of Promotion including, but not limited to, oral and written promotional activities and communications, magazine and direct mail advertising, the activities of Medical Sales Representatives, the use of digital communications and channels, such as websites and social media, the use of audio-visual systems such as films, video recordings, data storage services and the like. It also covers the provision of Informational or Educational Materials, Items of Medical Utility, hospitality in relation to Events and Medical Samples.

The Code also covers interactions between Companies and HCPs and HCOs including, but not limited to, those in the context of research or contractual arrangements (including certain aspects of clinical trials, non-interventional studies as well as consultancy and advisory board). It also covers the interactions between Companies and POs.

The Code does not cover the following:

- The labelling of packages of Medicinal Products and accompanying package leaflets, which are subject to the provisions of Title V of Directive 2001/83/EC of the European Parliament and the Council;
- Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular Medicinal Product;
- Factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- Non-promotional, 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 regulatory developments affecting the Company and its Medicinal Products.

The following documents are attached to the Code:

- Annex A – Standardised Disclosure template.
- Annex B – Guidance on the disclosure of non-interventional studies.
- Annex C – Standard Operating Procedure related to processing of complaints and questions submitted to the Pharmaceutical Marketing Ethics Committee.
- Annex D – Examples of ethical principles.
- Annex E – Principles of the use of digital channels.

APPLICABILITY OF THE CODE

Promotion and interactions which take place within Lithuania must comply with applicable laws and regulations as well as all Applicable Codes.

Companies engaged in the promotion of medicinal products in Lithuania must comply with any Applicable Codes and any applicable laws and regulations. The Code is binding to Companies which are (i) a member of IFPA or VGA or (ii) have submitted to the IFPA and VGA a written consent to accede to the Code (including any applicable sanctions that may be imposed thereunder).

In order to ensure compliance with the Code, IFPA and VGA shall develop and implement adequate complaint examination procedures and procedures for the imposition of sanctions for breaches of the Code. Additionally, all international Events and/or activities as relevant must be notified to any relevant local enterprise in advance or, alternatively, advice in the country of the Event must be taken.

The spirit as well as the provisions of the Code must be complied with. IFPA also encourages compliance with the letter and spirit of the provisions of the International Federation of Pharmaceutical Manufacturers and Associations ('IFPMA") Code of Practice, where applicable.

CHAPTER 1 PROMOTION OF MEDICINAL PRODUCTS TO HEALTHCARE PROFESSIONALS

ARTICLE 1. MARKETING AUTHORISATION

Section 1.01 Only registered Medicinal Products may be promoted in the Republic of Lithuania. A Medicinal Product must not be promoted prior to the grant of the marketing authorisation allowing its sale or supply or outside of its approved indications.

Section 1.02 Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant Medicinal Product.

ARTICLE 2. INFORMATION TO BE MADE AVAILABLE

Section 2.01 Subject to applicable laws and regulations of the Republic of Lithuania, all promotional material must include the following information clearly and legibly:

a) Essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
b) The supply classification of the Medicinal Product; and
c) When appropriate, the selling price or recommended indicative price of the various presentations of the Medicinal Product and the conditions for reimbursement by social security bodies.

Section 2.02 Subject to applicable laws and 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

Section 3.01 Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the HCP to form his/her own opinion of the therapeutic value of the Medicinal Product concerned. It must be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

Section 3.02 Promotion must be capable of substantiation which must be promptly provided in response to reasonable requests from HCPs. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. Substantiation needs not be provided, however, in relation to the validity of elements approved in the Summary of Product Characteristics.

Section 3.03 Promotion must encourage the rational use of Medicinal Products by presenting them objectively and without exaggerating their properties. Claims must not imply that a Medicinal Product, or an active ingredient, has some special merit, quality, or property unless this can be substantiated.

Section 3.04 When Promotion refers to published studies, clear references must be given.

Section 3.05 Any comparison made between different Medicinal Products must be based on relevant and comparable aspects of the Medicinal Products. Comparative advertising must not be misleading or disparaging.

Section 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 Code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.

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

Section 3.07 The word “safe” must never be used to describe a Medicinal Product without proper qualification.

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

Section 3.09 It must not be stated that a Medicinal Product has no side-effects, toxic hazards or risks of addiction or dependency.

ARTICLE 4. USE OF QUOTATIONS IN PROMOTION

Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with any Applicable Codes, 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

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 Medicinal Products and the professional standing of the intended audience;
c) not be likely to cause offence.

ARTICLE 6. DISTRIBUTION OF PROMOTION

Section 6.01 Promotion must only be directed at those HCPs whose need for, or interest in, the particular information can reasonably be assumed.

Section 6.02 Mailing lists must be kept up-to-date. Requests by promotion addressees to be removed from mailing lists must be complied with.

Section 6.03 Subject to applicable laws and 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 the request, of those who receive it.

ARTICLE 7. TRANSPARENCY OF PROMOTION

Section 7.01 Promotion must not be disguised.

Section 7.02 Clinical assessments, post-marketing surveillance and experience programmes and post-authorisation studies (including those that are retrospective in nature) must not be disguised as Promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

Section 7.03 Where a Company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

Section 7.04 Material relating to Medicinal Products 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. PROMOTIONAL INFORMATION PROVIDED DURING INTERNATIONAL EVENTS

Promotional information which appears on exhibition stands or is communicated 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, as long as: (i) any such promotional material is accompanied by a suitable statement indicating the countries in which the Medicinal Product is registered and makes clear that the Medicinal Product or indication is not registered in the country where the Event takes place, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) authorised in a country or countries where the Medicinal Product is registered must be accompanied by an explanatory statement indicating that registration conditions may differ from country to country.

ARTICLE 9. ADVICE ON PERSONAL MEDICAL MATTERS

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer must be advised to consult HCP.

CHAPTER 2 INTERACTIONS WITH HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

ARTICLE 10. EVENTS AND HOSPITALITY

Section 10.01 All Events must be held in appropriate Locations and Venues that are conducive to the main purpose of the Event. Companies may not organise or sponsor Events in the venues that are renowned for their “entertainment (amusement) facilities” or are “extravagant”. “Entertainment (amusement) facilities” are understood as venues for leisure and entertainment which advertise their entertainment infrastructure 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. Companies should comply with the regulations related to the term “adequate” in a sense in which it is used in the Article 10 of this document, and with regulations of other Applicable Codes.

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

a) Most of the invitees are from outside of Lithuania and, given the place of residence 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.

Section 10.03 Companies may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any Applicable Code.

Section 10.04 Hospitality extended in connection with scientific Events must be limited to travel, meals, accommodation, and genuine registration fees. Hospitality extended in connection with promotional Events shall be limited to meals.

Section 10.05[*] Member Companies must not provide or offer any meal (food and beverages) to HCPs, HCOs' members or POs' Representatives, unless, in each case, the value of such meal does not exceed the monetary threshold for meals set in the Code of Ethics of the country where the meal is offered. If the monetary threshold for meals is not set in the Code of Ethics of the host country, the principle of moderate hospitality must be followed. In Lithuania, one meal allowance is no more than 80 EUR including VAT. The daily meals should not exceed 120 EUR including VAT. The pharmaceutical industry does not support consumption of strong alcoholic beverages.

Section 10.06 Hospitality may only be extended to persons who are fully-fledged participants in the Event. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation, and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.

Section 10.07 All forms of hospitality offered to HCPs, HCOs' members or POs' Representatives must 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 those individuals would normally be prepared to pay for themselves.

Section 10.08 Hospitality must not include sponsoring or organising entertainment events (e.g., sporting or leisure).

ARTICLE 11. PROHIBITION OF GIFTS

Section 11.01 Gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts) of HCPs, HCOs' members, or POs' Representatives (either directly or indirectly) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the Recipient.

[*] Adopted by the IFPA General Assembly of 24 November 2022 Adopted by the VGA General Assembly of 19 December 2022

Section 11.02 Providing or offering promotional aid to HCPs, HCOs' members, or POs' Representatives in relation to the promotion of a Medicinal Product is prohibited. A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Chapter 1) (e.g. cups, sticky notes, pens, etc.).

ARTICLE 12. DONATIONS AND GRANTS TO HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

Section 12.01 Donations and Grants (in cash or in kind or otherwise) to HCOs and/or POs are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

Section 12.02 Donations and Grants to individuals are not permitted. The Contribution to Costs related to Events for HCPs to attend international Events is covered by Article 13.

ARTICLE 13. CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP

Section 13.01 Companies must comply with criteria governing the selection and support of HCPs or POs' Representatives to attend Events as provided in, or in connection with, any Applicable Codes. No payment must be offered to compensate merely for the time spent by the HCP or PO's Representative in attending Events.

Section 13.02 The public use of an HCO or PO's logo and/or proprietary material by a Company requires written permission from that organisation. In seeking such permission, the specific purpose, and the way the logo and/or proprietary material will be used must be clearly stated.

Section 13.03 Companies must ensure that their Sponsorship to HCOs and POs is always clearly acknowledged and apparent from the outset.

ARTICLE 14. MEMBER COMPANY FUNDING

No Member Company may require that it be the sole funder or sponsor of a PO or HCO or any of its programmes. Member Companies welcome funding and sponsorship of POs and HCOs from multiple sources.

ARTICLE 15. CONTRACTED SERVICES

Section 15.01 Contracts between Companies and HCPs, HCOs, POs or POs' Representatives under which those provide any type of services to Companies (not otherwise covered by the Code) are only allowed if such services: (i) are provided for the purpose of supporting healthcare, research or education; and (ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

Section 15.02 It is permitted to contract HCPs or POs' Representatives as consultants, whether in groups or individually, for services such as speaking at and/or chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or hospitality. 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 is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
b. A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements;
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 professionals meet those criteria;
d. The number of consultants selected and the extent of the service are not greater than 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 engagement of the consultant to provide the relevant service is not an inducement to recommend and/or prescribe, purchase, supply, sell or administer a particular Medicinal Product;
g. The remuneration for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating the Healthcare Professionals or Patient Organisation's Representatives.

Section 15.03 In their written contracts with consultants, Companies are strongly encouraged to include provisions regarding the obligation of the consultants to disclose that they are consultants to the Company whenever they write or speak in public about a matter that is the subject of the agreement or any other matter relating to that Company.

Similarly, Companies that employ, on a part-time basis, HCPs that are still practising their profession are strongly encouraged to ensure that such persons have an obligation to disclose their employment arrangements with the Company whenever they write or speak in public about a matter that is the subject of the employment or any other matter relating to that Company. The provisions of this Section 15.03 apply even though the Code does not otherwise cover non-promotional, general information about Companies.

Section 15.04 Limited market research, such as one-off phone interviews or mail / e-mail / internet questionnaires are excluded from the scope of this Article 15, provided that the HCP, HCO's member or PO's Representative 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 amount which the medical doctor would earn by performing his or her direct job functions over the time spent during the market research).

Section 15.05 If an HCP or a PO's Representative attends an Event (an international Event or otherwise) in a consultant capacity, the relevant provisions of Article 10 must apply.

CHAPTER 3 SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

ARTICLE 16. MEDICAL EDUCATION

Medical Education is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcome.

Companies can be engaged in different types of activities relating to Medical Education but such activities must not constitute Promotion.

When funding independent Medical Education or organising Medical Education activities directly or in collaboration with Third Parties, Companies must ensure that their participation and role are clearly acknowledged and apparent from the outset.

When organising Medical Education activities in which Member Companies have input in the content, they are responsible for what is communicated during the activities. Such content must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognised opinions.

ARTICLE 17. INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

Section 17.01 The provision 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.

Section 17.02 Items of Medical Utility aimed directly at the education of HCPs and patient care can be provided if they are "inexpensive" and do not offset routine business practices of those who receive them.

Section 17.03 The nature of Informational or Educational Materials and Items of Medical Utility considered may not constitute a circumvention of the prohibition on gifts defined under Article 11 of this Code. The transmission of such materials or items must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer a Medicinal Product.

Section 17.04 Informational or Educational Materials and Items of Medical Utility can include the Company logo, but must not be product branded, unless the Medicinal Product's name is essential for the correct use of the material or item by the patient.

17.05. The term "inexpensive" means that its cost for the Company does not exceed EUR 12, including the logo and other overheads but excluding VAT.

ARTICLE 18. NON-INTERVENTIONAL STUDIES

Section 18.01 Non-Interventional Studies must be conducted with a primarily scientific purpose and must not be disguised as Promotion.

Section 18.02 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, HCPs specifically for the study must comply with all of the following criteria:

a) There is a written study plan (observational plan/protocol).
b) The study protocol must be submitted for review to the Ethics Committee as provided for by the laws and regulations of the Republic of Lithuania.
c) The study protocol must be approved by the Company's scientific service. The conduct of the study must be supervised by the Company's scientific service as described in Section 20.01.a.
d) The study results must be analysed by or on behalf of the contracting Company. Summaries thereof must be made available within a reasonable period of time to the Company's scientific service (as described in Section 20.01.a), which service must maintain records of such reports for a reasonable period of time. The Company must send the summary report to all HCPs that participated in the study and must make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising the Code upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority.
e) 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 Medical Sales Representatives are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Product.

Section 18.03 Following the same principle, Companies are encouraged to comply with the requirements of Section 18.02 for all other types of Non-Interventional Studies, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Section 15.01.

ARTICLE 19. MEDICAL SAMPLES

Section 19.01 When promoting medicinal products to HCPs qualified to prescribe Medicinal Products, Medical Sales Representatives may use Medical Samples which are not intended for sale. A Medical Sample not intended for sale must correspond to the smallest presentation of the medicinal product of the same name, shape, and strength available in the Lithuanian market and the package must be marked "Sample not for sale". Leaving Medical Sample not intended for sale with HCPs, distributing them to the public and using them for healthcare purposes is prohibited.

Section 19.02 Companies must have adequate systems of control and accountability for Medical Samples.

ARTICLE 20. COMPANY STAFF

Section 20.01 All Company Staff must be fully conversant with the requirements of the Code and relevant laws and regulations.

a) Every Company must establish a scientific service in charge of information about its Medicinal Products and the approval and supervision of Non-Interventional Studies. Companies, taking into account their own resources and organisation, are free to decide how best to establish such service(s) in accordance with Section 20.01 (i.e. whether there is one service in charge of both duties or two separate services with clearly delineated duties). The scientific service must include at least one medical doctor or pharmacist who will be responsible for approving any promotional material before release. Such a person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the Code and any relevant advertising laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the Medicinal Product. In addition, the scientific service must include a medical doctor or pharmacist, who will be responsible for the oversight of any Non-Interventional Study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives). Such a person must certify that he or she has examined the protocol relating to the Non-Interventional Study and that in his or her belief it is in accordance with the requirements of the Code and any relevant laws and regulations.
b) Each Company must appoint at least one senior employee who must be responsible for supervising the Company and its subsidiaries to ensure that the standards of the Code are met.

Section 20.02 Each Company must ensure that its Medical Sales Representatives are familiar with the relevant requirements of the Code and all applicable laws and regulations and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the Medicinal Products they promote.

a) Medical Sales Representatives must comply with all relevant requirements of the Code and all applicable laws and regulations. Companies are responsible for ensuring their compliance with all the said requirements and regulations.
b) Medical Sales Representatives must approach their duties responsibly and ethically.
c) During each meeting with HCP, Medical Sales Representatives must give or have available a summary of the product characteristics for each Medicinal Product they present.

d) Medical Sales Representatives must transmit to the scientific service of their Companies forthwith any information they receive in relation to the use of their Company's Medicinal Products, particularly reports of side effects.
e) Medical Sales Representatives must ensure that the frequency, timing, and duration of visits to HCPs, pharmacies, hospitals, or other healthcare facilities, together with the manner in which they are made, are in compliance with the procedure prescribed by law.
f) Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. In an interview, or when seeking an appointment for an interview, Medical Sales Representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the Company they represent.

CHAPTER 4 SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH PATIENT ORGANISATIONS

ARTICLE 21. INTERACTIONS WITH PATIENT ORGANISATION

Section 21.01 In interactions with POs, Companies must comply with the following principles:

a) The independence of POs, in terms of their political judgement, policies and activities, must be assured.
b) All interactions between POs and Companies must be based on mutual respect, with the views and decisions of each partner having equal value.
c) Companies must not request, nor shall POs undertake, the Promotion of a particular Medicinal Product.
d) The objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Companies must always be clearly acknowledged.
e) Companies welcome funding of POs from multiple sources.

Section 21.02 Laws and regulations of the Republic of Lithuania prohibit the advertising of Prescription-Only Medicines to the general public.

Section 21.03 When Companies provide financial support, significant indirect support, and/or significant non-financial support to POs, they must conclude a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting, or publication, etc.). The agreement must also include a description of significant indirect support and significant non-financial support (e.g. the donation of public relations agency's time and the nature of its involvement).

Section 21.04 Companies must not influence the text of PO's material they sponsor in a manner favourable to their own commercial interests. This must not preclude Companies from correcting factual inaccuracies. In addition, at the request of POs, Companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

CHAPTER 5 DISCLOSURE OF TRANSFERS OF VALUE FROM COMPANIES

ARTICLE 22. DISCLOSURE OF TRANSFERS OF VALUE TO HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

Section 22.01 Time of Disclosure.

Disclosures must be made by each Company within 6 months after the end of the relevant Reporting Period. The information disclosed must be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed unless, in each case, (i) a shorter period is required under the applicable laws or regulations of the Republic of Lithuania, or (ii) the relevant data protection legal basis (e.g. the legitimate interest grounds, a legal duty or the Recipient's withdrawal of his or her consent relating to a specific disclosure) is no longer applicable.

Reports on Transfers of Value to HCPs and HCOs during the last year shall be provided by Companies to the State Medicines Control Agency in accordance with Article 2 Part 51^1 of the Law on Pharmacy, No X-709.

Reports on Research and Development Transfers of Value during the last year and Transfers of Value to POs shall be published by Companies during the time interval from 20th to 30th June each year and inform the Third Party specified by IFPA and VGA to that effect. References to each Company's report on support and services provided to POs shall be published at www.vaistukodeksas.lt by 30th June, inclusively.

ARTICLE 23. INFORMATION ON RESEARCH AND DEVELOPMENT TRANSFERS OF VALUE

Section 23.01 Disclosure of Research and Development Transfers of Value

Such information 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.

Methodology. Each Company must publish a note summarising the methodologies used by it in preparing the disclosures. The note, including a general summary and Lithuania-specific considerations, must describe the methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amounts of the Transfers of Value.

ARTICLE 24. DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO PATIENT ORGANISATIONS

Each Company must disclose a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support or with whom it has signed an agreement to provide contracted services for that Company.

This list must include a description of the nature of the support or services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the support or the arrangement without the necessity to divulge confidential information. In addition to the name of the PO, the following elements shall be included:

- For support:
  - The monetary value of financial support and of costs incurred;
  - The non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value.
- For contracted services: the total amount paid per PO over the Reporting Period.

This information shall be disclosed on the Company's website on an annual basis. Each Reporting Period shall cover a full calendar year. References to each Company's report on support and services provided to POs shall be published at www.vaistukodeksas.lt by 30th June, inclusively.

Methodology. Each Company must publish the methodologies used by it in preparing the disclosures and identifying supports and services provided.

CHAPTER 6. PROCEDURAL REQUIREMENTS

ARTICLE 25. ENFORCEMENT

Section 25.01 Enforcement

IFPA, VGA and their members as well as other Companies who have acceded to the Code, within current applicable laws and regulations, enforce the provisions of the Code. In the event that a breach is established pursuant to the procedures of the Code, the Pharmaceutical Marketing Ethics Committee shall require from the offending Company an immediate cessation of the offending activity and a signed undertaking by the Company to prevent recurrence.

The procedure of assessment of the breaches of the Code and sanctions for breaches of the Code are set forth in Article 28.

ARTICLE 26. AMENDMENTS TO, AND GUIDANCE REGARDING COMPLIANCE WITH, THE CODE

Section 26.01 Code compliance

IFPA and VGA shall assist Companies to comply with their obligations under this Code. They shall do so by consulting Companies, providing respective explanations and answers to most frequently asked questions as well as by ensuring the proper compliance with the Code.

Section 26.02 Amendments to the Code

IFPA and VGA must regularly review this Code and any guidance issued regarding compliance with this Code, i.e. frequently asked questions.

Any proposed amendments to the Code shall be submitted to the IFPA and VGA Boards for consideration and to the IFPA and VGA General Assemblies for adoption.

ARTICLE 27. AWARENESS AND EDUCATION

IFPA and VGA shall, within current applicable laws and regulations, facilitate Companies' awareness of and education about the Code, including by providing guidance to Companies in order to prevent breaches of the Code.

ARTICLE 28. PROCEDURE RULES

The supervision of the Code shall be exercised by the Pharmaceutical Marketing Ethics Committee (hereinafter the "VREK").

Section 28.01 IFPA and VGA are required to:

a) Establish national procedures and structures to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same including, inter alia, Pharmaceutical Marketing Ethics Committee that is designated to handle complaints and consists of a non-pharmaceutical industry chairperson and, besides any pharmaceutical industry members, membership from other stakeholders.
b) Ensure that the Code, together with its administrative procedures and other relevant information, are easily accessible. For this purpose, IFPA must publish the Code on the Pharmaceutical Marketing Ethics Committee's website at www.vaistukodeksas.lt.
c) IFPA must prepare, and provide to the EFPIA Codes Committee, an annual report summarising the measures undertaken by it in connection with the implementation and development of the Code during the year. It must provide the report before the EFPIA General Assembly to be held on 31st March.

Section 28.02 Reception and processing of complaints and imposition of sanctions

Complaints shall be submitted to IFPA and VGA Pharmaceutical Marketing Ethics Committee (VREK). The procedure for the reception and processing of complaints and imposition of sanctions is described in Section 1 of Annex C “Pharmaceutical Marketing Ethics Committee” to the Code. The consideration of appeals is described in Section 2 of Annex C.

ANNEX A. STANDARDISED DISCLOSURE TEMPLATE

STANDARDISED DISCLOSURE TEMPLATE FOR TRANSFERS OF VALUE TO PATIENT ORGANISATIONS

Optional PO disclosure template DRAFT						
PO name	**Country**	**Types of the support or services provided**	**Description of the support or services 1**	**Monetary value of financial support and of invoiced costs**	**Non-monetary benefit for PO 2**	**Fees for services paid**
		Financial support		In euros		
		Significant indirect support		In euros		
		Non-financial support			In euros	
		Contracted services				In euros
1 Add a clear description of the purpose of the support or services						
2 For example, employee hours or companies facilities offered to support a Patient Organisation activity						

[Final version to be inserted after EFPIA approval]

STANDARDISED DISCLOSURE TEMPLATE FOR RESEARCH AND DEVELOPMENT TRANSFERS OF VALUE

Informacijos apie perleistas vertes, susijusias su tyrimais ir plėtra, agreguotas atskleidimas **Aggregated disclosure of transferred values re Research & Development**		
Perleistos vertos, susijusias su tyrimais ir plėtra, kaip tai apibrėžia Kodeksas **Transfers of value re Research & Development as defined by Kodekas**	**Suma, EUR** **Amount, EUR**	**Atskleidimo data (neprivaloma)** **Date of disclosure (optional)**

ANNEX B. GUIDANCE ON THE DISCLOSURE OF NON-INTERVENTIONAL STUDIES

This Guidance provides a basis for distinguishing between prospective versus retrospective Non-Interventional Studies. This Guidance aims at ensuring consistency in reporting of Transfers of Value relating to Non-Interventional Studies. This Guidance is relevant to the clarification of Article 18 of the Code.

Definitions

Information on 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 Regulation No 536/20412); 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, Healthcare Specialist(s) specifically for the study (Section 15.01 of the HCP Code).

Guidance

Information on Transfers of Value relating to non-interventional studies that are not within the definition of Research and Development Transfers of Value shall be reported on an individually named basis in accordance with the provisions of the Law of the Republic of Lithuania on Pharmacy. In this regard, prospective versus retrospective non-interventional studies shall be considered following classification in the table below:

PROSPECTIVE NON-INTERVENTIONAL STUDIES	RETROSPECTIVE NON-INTERVENTIONAL STUDIES
Prospective cohort studies in which the prescription of the medicine is independent from the inclusion of the patient in the study A retrospective study to which a prospective element is subsequently introduced Long-term extension studies with patient follow up beyond trial protocol specified time for observation and active collection of additional data	Purely observational database review and/or research Retrospective review of records where all the events of interest have already happened, - e.g. case-control, cross-sectional, and purely retrospective cohort studies Studies in which the prescriber later becomes an investigator, but prescribing has already occurred - e.g. retrospective data collection from individual medical records at the site of the investigator

For the sake of clarity, activities not falling under the definition of Research and Development Transfers of Value, including non-interventional studies that are not conducted to maintain a marketing authorisation (in application and following definitions of the "Clinical Trials" Regulation 536/2014), shall be disclosed under "consultancy/fee-for-services".

ANNEX C. STANDARD OPERATING PROCEDURE RELATED TO PROCESSING OF COMPLAINTS AND QUESTIONS SUBMITTED TO THE PHARMACEUTICAL MARKETING ETHICS COMMITTEE

I. PHARMACEUTICAL MARKETING ETHICS COMMITTEE

INTRODUCTION

Supervision of the Code of Ethics for Pharmaceutical Marketing, which governs pharmaceutical marketing and interactions with healthcare professionals as well as interactions between the pharmaceutical industry and patient organisations (hereinafter "the Code"), shall be exercised by the Pharmaceutical Marketing Ethics Committee (hereinafter "VREK").

The Pharmaceutical Marketing Ethics Committee shall ensure that pharmaceutical industry subjects and non-industry notifications are processed in the same manner, without regard to who has presented the notification.

ORGANISATION AND RESPONSIBILITY

1. The Pharmaceutical Marketing Ethics Committee is responsible for:

1.1. Organising the activities of the Pharmaceutical Marketing Ethics Committee, 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 breaches of the Code.

1.5. Supervision of the website of the Pharmaceutical Marketing Ethics Committee.

2. Organisation of the Pharmaceutical Marketing Ethics Committee

2.1. VREK shall be accountable to IFPA and VGA. On an annual basis, VREK shall generate its activity report, which shall be presented by the chairperson of VREK to IFPA and VGA, as well as individually upon request. VREK's annual report shall be posted on VREK's website.

2.2. The Pharmaceutical Marketing Ethics Committee shall consist of 8 members, including the independent chairperson, 3 members delegated by IFPA, 3 members delegated by VGA, and 1 member from other stakeholders.

2.3. VREK shall be elected for a period of two calendar years. IFPA and VGA, by decisions of their Boards, shall approve members of VREK for the next term of office no later than one month before the end of the current term. A written extract from the minutes of the Board meetings shall be submitted to the Chairperson of VREK. If a Company represented by a VREK member commits a breach of the Code of Ethics for Pharmaceutical Marketing more than once a year, the Chairperson of VREK may, by a decision of the Committee, propose the association to replace the VREK member.

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

2.5. Decisions shall be adopted by a majority of votes. The quorum of VREK shall be deemed to be present when its Chairperson (or, in his or her absence, Deputy Chairperson) and three members are present. At least one member must represent VGA or IFPA each. In the event of a tie, the vote of the Chairperson (or, in his or her absence, Deputy Chairperson) shall have the casting vote..

2.6. The Deputy Chairperson of VREK shall be elected by rotation out from VREK members for the entire term of office of VREK.

2.7. VREK shall have the right to receive materials required for the examination of a reported breach of the Code from Companies suspected of breaches of the Code. A Company may refuse to provide information which is considered as its commercial secret.

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

3.1. VREK shall hold a session upon receiving information about or whenever intending to address any other matters in connection with the Code or VREK's area of responsibility. Each VREK member shall have the right of initiative to convene a session of VREK. VREK sessions shall be convened by a decision of the Chairperson of VREK (or, in his or her absence, Deputy Chairperson).

3.2. Minutes shall be taken during sessions of VREK. The draft minutes shall be e-mailed to VREK members for information and comments. The minutes shall be signed by the Chairperson and the Secretary of the session. The Chairperson of VREK shall be responsible for the storage of minutes and other materials of VREK. Documents shall be stored and archived in accordance with the procedure established by VREK.

3.3. VREK may seek assistance from consultants. Consulting experts may be invited to attend VREK sessions without the right to vote and under a written commitment to preserve confidentiality.

3.4. For the prevention of conflicts of interest members of VREK are required to name all interests related to a breach prior to the examination of the breach. The Chairperson (Deputy Chairperson) shall determine whether such a member can participate in the examination of the reported breach. If a member of VREK is related to the informer or to the possible breacher, he or she shall suspend himself or herself (VREK shall decide on the parties' participation in the session) from the adoption of the relevant decision as long as VREK examines that particular breach report.

3.5. While VREK examines the breach report, both the informer and the possible breacher may be invited to attend or be represented at its session. At a VREK session, the Company may be represented by a VREK member; however, in such a case, that person must withdraw from and not attend the discussion and voting.

3.6. If it is impossible to properly determine the circumstances of the breach report between the informer and the respective Company according to the report only, VREK 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 VREK shall be covered by contributions from the IFPA and VGA budget which ensure the activities of VREK. The costs of VREK shall be covered upon common agreement of IFPA and VGA Boards.

PROCEDURE FOR SUBMITTING AND PROCESSING VIOLATION REPORTS

4. Submission of Breach Reports

4.1. Reports of potential breaches of the Code may be submitted by representatives of pharmaceutical Companies, healthcare professionals, representatives of patient organisations, representatives of legal entities, and individuals. After receiving information about a potential breach(es) of the Code, VREK must start investigating the breach.

4.2. Reports of breaches of this Code shall be submitted to the Chairperson of VREK in writing. The Chairperson of VREK shall register the received report and include it in the agenda of the VREK session.

4.3. A report of a possibly committed breach 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 breach and available evidence (place, time, circumstances, and persons involved);

4.3.4. The articles and sections of the Code which include provisions that were possibly breached under the circumstances specified in the Report. A Breach Report submitted by a Company must be signed by the Company's manager or his or her authorised person.

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

4.4. The information referred to in Points 4.3.1 and 4.3.2 is confidential and shall be known only to the Chairperson of VREK.

In special cases, the Company specified in the report to VREK necessarily needs to know the identity of the reporting person in order to examine the report properly. Even in such cases, the identity of the reporting person shall be disclosed only with his or her consent.

4.5. Reports of potential breaches of the Code may be submitted by regular mail to the address of the Chairperson of the Pharmaceutical Marketing Ethics Committee indicated on VREK's website at www.vaistukodeksas.lt, by e-mail (pirmininkas@vaistukodeksas.lt) or at VREK's website under the heading "Write to us".

4.6. Anonymous reports shall not be processed.

5. Action upon Receiving a Breach Report

5.1. Suspected breaches of the Code must be reported in writing along with presentation of all information about the breach and with the available evidence. Upon receipt of a report of a potential breach of the Code, the Chairperson of VREK shall, within one month following receipt, convene a session of VREK to review the received material and to assess whether the report of a breach of the Code falls within the scope of the Code. The matter may be solved by an e-mail voting of the members of VREK within 5 business days. If VREK decides that the breach report falls within the scope of the Code, VREK shall notify the informer and possible breacher to that effect within 5 business days.

5.2. If VREK decides that the report of a breach of the Code does not fall within the scope of the Code, the reporting person shall be notified to that effect within 5 business days following the decision.

5.3. VREK shall address the manager of the relevant Company suspected of breaching the respective provisions of the Code in writing (the letter shall be faxed, e-mailed or posted by registered mail to the Company's registered office address) asking to comment on the material stated in the report and shall set the time limit for providing responses and comments.

5.4. Upon receipt of VREK's notification regarding a potential breach, the relevant Company shall give a written response to the Pharmaceutical Marketing Ethics Committee within 20 business days following the dispatch of VREK's letter by fax or e-mail. When the response is sent by registered mail, it must also be faxed or e-mailed to the Pharmaceutical Marketing Ethics Committee on the day of dispatch. If VREK does not receive the Company's response within 20 business days following the day of dispatch of the notification, VREK shall examine the breach without waiting for a response.

5.5. While examining the report, VREK may apply to state institutions requesting information available to them that is necessary for investigation into the circumstances stated in the report or requesting those institutions to carry out an investigation within their scope of powers and to provide VREK with the information obtained.

5.6. After VREK has collected sufficient information about a potential breach, a session of VREK shall be convened to begin the consideration of the potential breach of the Code. Sessions of VREK may be

organised remotely, with the use of electronic means. VREK members who take part in a session remotely are required to ensure confidentiality.

5.7. A breach report must be examined and a decision must be adopted within three months following the receipt of the report. The Chairperson of VREK has the right to extend the time limit for adopting a decision for another three months, taking into account the nature of the breach and/or progress of its examination. The Chairperson of VREK shall communicate such a decision to the Companies of the informer and the possible breacher.

5.8. The members of VREK shall undertake to keep confidential any information received by them 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 VREK decides that the Code has been breached, VREK shall notify the informer and the possible breacher to that effect.

6.2. If the report is exclusively or mostly aimed at commercial interest, VREK may reject such a report.

6.3. If VREK decides that the Code has been breached, it may impose on the Company that has committed the breach one or more (depending on the severity and frequency of the breach) of the following sanctions :

a) provide the Company with a written recommendation;
b) warn the Company in writing;
c) inform the Company's headquarters;
d) inform IFPA, VGA, other members, and other entities of the pharmaceutical market;
e) report the breach to the associations of the EU countries;
f) propose to the General Assembly of IFPA or VGA members to exclude the Company that has committed the breach from the association;
g) forward the material to public institutions for further investigation.

6.4. The decision of VREK may be appealed against to the Appeal Commission within 30 business days following the day of VREK's decision.

6.5. VREK's decision that has not been appealed against shall become final after the end of the time limit for appeal specified in Point 6.4. A decision that has been appealed against in accordance with the appeal procedure shall become final upon the decision of the Appeal Commission.

6.6. VREK shall publish final decisions on its website at https://www.vaistukodeksas.lt. A final decision adopted in each individual case shall be published either as a whole or as its separate parts and the degree of detail of data to be published shall reflect the severity and/or recurrence of the breach.

1) in the case of a severe/recurring breach, the Company's name and details of the breach shall be published;

2) in the case of a minor breach, it is not necessary to indicate the Company's name when publishing the details of the breach, except for those cases when the Company fails to admit a breach based on evidence;

3) VREK's decisions on offences shall be published for one year following the decision.

6.7. In case VREK finds that there was no breach, such a decision of VREK shall not be published and only the informer shall be informed to that effect.

II. APPEAL COMMITTEE

INTRODUCTION

Appeals regarding decisions made by the Pharmaceutical Marketing Ethics Committee shall be examined by the Appeal Committee. The Appeal Committee shall be established upon receipt of an appeal.

1. FUNCTIONS AND RIGHTS OF THE APPEAL COMMITTEE

1.1. The Appeal Committee shall examine registered appeals.

1.2. The Appeal Committee shall adopt findings on the claims stated in the appeal and provide information on decisions adopted.

2. ORGANISATION OF THE APPEAL COMMITTEE

2.1. In the case of an appeal, the Appeal Committee shall be established by a decision of the Boards of IFPA and VGA.

2.2. The Appeal Committee shall consist of 6 members, i.e. 3 members delegated by each IFPA and VGA.

2.3. The members of the Appeal Committee delegated by IFPA and VGA must avoid a conflict of interests related to the appeal being examined. Persons who have taken part in adopting the decision of the Pharmaceutical Marketing Ethics Committee that has been appealed against in accordance with the appeal procedure or when there are other circumstances which may cause a conflict of interests may not be members of the Appeal Committee. If a representative of the Company that has filed an appeal or a breach report on the breach which served as the basis for the decision of the Pharmaceutical Marketing Ethics Committee that has been appealed against in accordance with the appeal procedure is elected as a member of the Appeal Committee, such a member must withdraw from participation in examining the appeal and adopting the decision. If a member of the elected Appeal Committee has withdrawn, the IFPA or VGA Board, respectively, shall delegate a new member.

2.4. The Chairperson of the Appeal Committee shall be approved by the members of the Appeal Committee upon common agreement.

2.5. Decisions of the Appeal Committee shall be adopted by a majority of votes. In the event of a tie, the Chairperson of the Appeal Committee shall have a casting vote.

3. OPERATING PROCEDURE OF THE APPEAL COMMITTEE

3.1. The main form of activities of the Appeal Committee is sessions which are arranged according to need, taking into account submitted appeals and time limits for their examination.

3.2. Sessions of the Appeal Committee shall be convened by a decision of IFPA and VGA.

3.3. Sessions of the Appeal Committee may be organised remotely, with the use of electronic means. The members of the Appeal Committee who take part in a session remotely are required to ensure confidentiality.

3.4. Minutes shall be taken during sessions of the Appeal Committee. The draft minutes shall be emailed to members of the Appeal Committee for information and comments. The minutes shall be signed by the Chairperson of the Appeal Committee. The signed minutes shall be sent to the Chairperson of the Pharmaceutical Marketing Ethics Committee.

3.5. The Chairperson of the Pharmaceutical Marketing Ethics Committee shall be responsible for storage of minutes and other materials of the Appeal Committee. Documents shall be stored and archived in accordance with the procedure established by the Pharmaceutical Marketing Ethics Committee.

3.6. The Appeal Committee may address consultants and competent authorities if it is required for adopting a decision. Consulting experts may be invited to attend sessions of the Appeal Committee without the right to vote.

3.7. When examining an appeal, representatives of the Companies directly related to the appeal may be invited to attend the session of the Appeal Committee.

3.8. The costs of the Appeal Committee shall be covered upon common agreement of IFPA and VGA Boards.

4. PROCEDURE FOR THE EXAMINATION OF APPEALS

4.1. An appeal shall be submitted in writing to the Chairperson of the Pharmaceutical Marketing Ethics Committee (VREK). An appeal submitted by a Company must be signed by the Company's manager or his or her authorised person. Anonymous reports shall not be registered.

4.2. An appeal must contain details of the reason for appealing against the decision of the Pharmaceutical Marketing Ethics Committee.

4.3. An appeal shall be submitted within 30 business days following the decision adopted by the Pharmaceutical Marketing Ethics Committee (VREK).

4.4. The Chairperson of the Pharmaceutical Marketing Ethics Committee shall register the received appeal and inform the Chairpersons of IFPA and VGA Boards and Directors of IFPA and VGA within 5 business days. During vacation, the Chairperson of the Pharmaceutical Marketing Ethics Committee shall indicate the name of another member of VREK in an autoreply message.

4.5. Upon receipt of a notice of an appeal, the IFPA and VGA Boards shall make a decision on establishing the Appeal Committee and announcement of a session, taking into account the appeal submitted, by common agreement within 10 business days following receipt of the appeal.

4.6. The Appeal Committee may require that the applicant should provide additional information.

4.7. The Appeal Committee's conclusion shall be documented in the form of the minutes of the session to be signed by the Chairperson of the Appeal Committee.

4.8. A decision on the appeal shall be adopted within 30 business days following the day of the first session of the Appeal Committee. In exceptional cases, the time limit may be extended up to 60 business days.

4.9. Having examined an appeal, the Appeal Committee shall adopt one of the following decision: to satisfy the appeal, to satisfy the appeal partially, or to reject the appeal. The decision shall become final on the day of the decision.

ANNEX D. EXAMPLES OF ETHICAL PRINCIPLES

1. We keep PATIENTS AT THE HEART OF WHAT WE DO, therefore we:

   - Continue to improve existing treatments and deliver innovative new medicines
   - Support the common objective of timely access to medicines
   - Maintain a dialogue to better understand the needs of patients
   - Work with stakeholders including research communities to tackle healthcare challenges
   - Continue appropriate collaboration with Healthcare Professionals and others to support their role in treating patients

2. We act with INTEGRITY, therefore we:

   - Engage with Healthcare Professionals / Healthcare Organisations / Patient Organisations only when there is a legitimate need
   - Take into consideration the role and responsibility of stakeholders with whom we interact to avoid conflicts of interest or improper influence
   - Consider the values, standards, procedures, and decision-making processes of other stakeholders
   - Support evidence-based decision making
   - Facilitate access to medical education and help rapid dissemination of scientific information

3. We act with RESPECT, therefore we:

   - Are conscious of the importance of providing accurate, fair, and objective information about medicinal products so that rational decisions can be made about their appropriate use
   - Support the independence of the prescribing decisions of Healthcare Professionals
   - Assure mutual respect and independence, in terms of political judgment, policies and activities, in all partnerships with Patient Organisations
   - Promote an attitude and environment of mutual regard for other stakeholders, taking into account differences such as cultures, views, and ways of working

4. We are TRANSPARENT about our actions, therefore we:

   - Share clinical trial data in a responsible way
   - Publish details of the Transfers of Value made to Healthcare Professionals and Healthcare Organisations
   - Publish details of financial support and significant non-financial support to Patient Organisations
   - Clearly indicate pharmaceutical company sponsorship of any material relating to medicinal products and their uses
   - Disclose activities through other relevant registers (such as the European Institutions' Transparency Register)

ANNEX E. PRINCIPLES OF THE USE OF DIGITAL CHANNELS

This document is not of binding nature. This document describes most frequently used digital channels as well as aspects which must be known in maintaining interactions with the general public and/or healthcare service providers.

1. PRINCIPLES APPLICABLE TO COMMUNICATION OF ALL TYPES

Compliance with laws and regulations and codes of practice

A digital channel is a communication platform. Laws and regulations applicable to other platforms and media are also applicable to digital media. Important factors include the content, target group, and use of the platform rather than the media themselves.

Therefore, digital communication shall be subject to the provisions of Directive 2001/83/EC and the Code related to the promotion of medicinal products.

Personal data must be processed in accordance with the procedure established by effective data protection regulations.

Responsibility

Companies shall be responsible for all materials distributed via any digital channel that is initiated, branded, and/or sponsored by the Company or the third party acting on its behalf, including the promotion of medicinal products.

The Company which owns a page in a social network or a website shall be responsible for its content. For example, mentioning of any prescription-only-medicine may be considered as the promotion of the medicinal product intended for the general public and may be prohibited. Another example can be the use of a public-oriented social network in order to inform healthcare service providers about a publication on the trial of a medicinal product, which can also be considered the promotion of that medicinal product and, therefore, must be prohibited.

Companies may also have obligations related to communication via digital channels owned by other companies or organisations.

Companies shall also be responsible for information which is disseminated by the Company's employees via their private social network channels, inter alia (a) when they can be reasonably considered the Company's representatives or (b) when the Company instructs, allows, or enables them to do so. The Company shall apply internal guidelines regarding the conduct of the Company's employees in using digital channels, including activities on their personal accounts.

In those cases when a Company owns digital channels, it is necessary to establish processes intended to control, limit and/or timely erase inappropriate comments to the extent allowed by data protection rules,

effective laws, and codes. Companies may also need to implement similar processes in using digital channels owned by other companies or organisations.

Pharmacovigilance

Companies should consider the possibility of developing specific guidelines for digital channels, while involving pharmacovigilance experts in specific projects to fulfil their pharmacovigilance responsibilities, including the obligation to register and report any adverse reactions to their medicinal products.

Transparency

Article 7.04 of the Code requires that the Companies shall clearly indicate the cases of the communication of their promotion. When providing information in a digital channel, the Company or individual acting on its behalf shall clearly indicate his or her role in the Company, while defining inter alia the content and whether the provision of information is financed either partially or fully.

Also, in performing the obligation to disclose information established in the Code (Chapter 5), it is necessary to notify of the Transfers of Value to HCPs, HCOs, and POs.

When possible, it is also necessary to indicate the target audience of the channel (e.g. healthcare specialists, the general public, or both).

2. HOW TO DETERMINE INFORMATION TO BE RELEASED IN DIFFERENT DIGITAL CHANNELS

It is important for the Company to understand what content is appropriate for various digital channels and respective audience. All requirements of laws and regulations shall be executed in this respect in the same manner as in cases of other types of media.

Information published on a digital channel shall be regularly updated, indicating respectively the date of the last update of each page and/or point.

The questions provided below can be useful for evaluating the risks related to digital communication and appropriateness of the content of, access to, structure and maintenance of the digital channel.

- What is the purpose of the communication (to promote, inform, exchange information)?
- What content will be published on the digital channel?
    - Is the content related to medicinal products?
    - Is the content of promotional or non-promotional nature?
    - Is the content related to informing about a disease?
    - Is the content related to information about healthcare, e.g. diagnosis, education on treatment issues, assistance on nutrition issues?
    - Is the role of the member company providing and/or creating the content clear?

- Who is the target audience (e.g. the general public, healthcare service providers, or both)?
    - Is it necessary to check the audience?
    - If so, how?
- What is the standard structure of the channel?
    - Is the digital channel open to the general public, i.e. can members of the general public share the content, provide contents, and exchange information?
    - How is information distributed over various digital channels?
    - Is the digital channel an open platform and is it intended for a closed audience?
    - Is the volume of the content limited? For example, Twitter
    - Are there any applicable community guidelines? For example, Facebook, YouTube
    - How is information about the audience of the channel processed?
- How is the content inter alia supervised, approved and managed by the member company?

3. RECOMMENDATIONS ON VARIOUS DIGITAL CHANNELS

The following is a brief description of the general procedure for the use of different types of digital channels. When making a decision on which digital channel to use and how to develop it, the principles set out above should be taken into account.

The content published by the Company on each channel shall be appropriate and compliant with relevant rules, laws, and the Code.

Websites

Websites are defined as a channel open to the general public where the verification of identity is not required for the purposes of accessing the website, e.g. websites intended for healthcare professionals (e.g. when there is a pop-up window for identification or a password). Some websites may use forums, where the general public can exchange information or discuss various topics.

Since most websites are visited through a search system, the optimisation of keywords has become an important tool. Companies must ensure that the applicable optimisation of keywords is appropriate for the target audience. For example, websites publishing treatment-oriented information and information about medicinal products that is intended for the general public, or websites intended for healthcare professionals which may be visited only by authorised persons.

Companies may apply an appropriate search optimisation tool in order to ensure that their websites are found on the top of the search result list by respective keywords.

Companies may support the preparation of the materials published on the website when such materials are prepared by a third party, in which case the role of the Company should be clearly defined. If a Company (i) initiates the preparation of a material or creation of its concept; (ii) influences the content of the material in a certain way; (iii) selects authors or directly pays them, it may be considered responsible for the content of the website. Otherwise, the Company that has concluded a support agreement shall not be considered responsible if it does not influence the content of the website and the parties act independently.

Companies shall ensure that selected websites links to which they post are reliable and that they do not advertise any prescription-only medicines to the general public. If a Company indicates website addresses in advertising of prescription-only medicines intended for healthcare professionals, the essential principles of the appropriateness of the content published on those websites shall apply.

Social networks

In general, social networks are digital channels intended for the general public.

Social networks are websites or apps by using which people can communicate in social networks (e.g. Facebook, Twitter, Snapchat, LinkedIn, Youtube, Instagram, WhatsApp). There are some exceptions but in most cases, social networks are used to establish and maintain relations with the public. The platform of a social network may be a channel open to the general public or a closed channel intended for the target audience; in the latter case, access shall be granted only after verifying the person's identity.

Bearing it in mind that Companies may not limit access on some digital channels, they should be careful in using short-term and encrypted apps, e.g. WhatsApp, Snapchat.

Blogs

The difference between posts of a website and a blog is that a blog is usually owned and updated by a person or a group of persons who regularly posts on the blog.

A blog may be owned by a Company, or a Company may (by providing support or paying consulting fees) agree with the owner of the blog (e.g. an opinion maker) on writing posts on the blog. The role of the Company must be clearly indicated in either case.

Given the nature of a blog and the fact that it allows bloggers to freely and spontaneously express their personal views on specific matters, Companies should not support blogs if they are intended or can reasonably be believed to be intended for the promotion of prescription-only medicines and dissemination of information about their uses.

Podcasts

A Company may have its own podcast which shall be subject to the rules applicable to websites.

A podcast can be downloaded from any podcast distributor. The essential principles of recipient definition, purposefulness of the podcast and appropriateness of the content shall apply. For example, a podcast promoting prescription-only medicines should only be available to healthcare professionals.

Apps

An app is an application that is downloaded to an electronic device (e.g. a smartphone, computer, or tablet).

A Company may develop apps for external stakeholders (e.g., healthcare professionals, healthcare organisations, patients, or payers) provided that they comply with the rules applicable to websites. If the app meets the requirements for the medical device, the relevant regulatory requirements should be taken into account. Essential principles, including requirements for target audience definition and purposefulness of information, shall apply.

An app can also be developed to better match the treatment method. If an app is intended for a specific group (e.g., healthcare professionals, patients, nurses), it is important that access to the content of the app is provided only to that group.

Webinars

A webinar is an event organised on-line that can be arranged via live or non-live broadcast.

A Company may be the direct organiser of a webinar and/or may engage a third party to help to organise the event. The Company shall be responsible for those webinars and also for their content and must, inter alia, ensure the target audience definition and purposefulness of information. Similar requirements apply to third-party webinars sponsored by Companies.

Such webinars may be intended for communication with external stakeholders (e.g., healthcare professionals, healthcare organisations, patients, or payers) provided that they comply with the rules applicable to websites.

Direct channels

These are channels for individual communication, which can be private or non-private; these may be responses to a specific person on social networks.

Companies must obtain the consent of the information recipients for communication to be maintained with them and the information recipients must have the possibility to easily opt out of notifications. The appropriateness of the frequency of communication should be taken into account.

Discussion forums

If a Company facilitates a discussion forum on a third party platform or organises a forum on its own platform, it must ensure that the content of the moderated website complies with applicable rules, laws, and the Code. The target audience must be identified in order to meet the relevant requirements. If

discussion forums are used for the purposes of market research, Companies must ensure that they comply with applicable legal and ethical requirements.