Adopted and ratified by the FBN General Assembly of 28 May 2020

The Farmabrend Nova Code of Practice constitutes the collection of ethical rules agreed by Farmabrend Nova (FBN) members for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility.

This Code applies to all types of communication and interaction (traditional and digital).

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DEFINITIONS	
Definitions of capitalised terms are included to ensure their consistent understanding.	
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.	
Europe: includes those countries in which the EFPIA Member Associations' National Codes apply[1]	
Farmabrend Nova (FBN): is the representative body of the pharmaceutical industry in N. Macedonia	
Member Company: as defined in the FBN Statutes, means legal entities: research-based companies, developing and manufacturing Medicinal Products in Europe for human use, operating through representative or agent in N. Macedonia or MAH which cumulatively met the conditions in the FBN Statute	
Member Company Staff: personnel employed by a Member Company or retained by way of contract with Third Parties, who are concerned with any matter covered by this Code	
FBN code: The FBN Code of Practice, including those Annexes which are expressly mentioned as binding and which form part of this Code	
National Code: The code of practice of a FBN.	
Applicable Codes: (a) (i) in the case of Promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a Member Company located within Europe, the Member Association National Code of the country in which such Member Company is located; or (ii) in the case of Promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a Member Company located outside of Europe, the EFPIA Code; and (b) the Member Association's National Code of the country in which the Promotion or the interaction takes place. In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions must apply, except for the application of Section 10.05 of this Code, where the monetary threshold set in the country where the event takes place (i.e. the "host country") must prevail.	

1 - As of June 2019, these countries include: Austria, Belgium, Bosnia and Hezegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom

In case of international Event for which a Member Company sponsors the attendance of a HCP, if any funding is provided to such HCP in accordance with the provisions of Article 13, such funding is subject to the rules of the National Code where such HCP carries out his/her profession, as opposed to those in which the international Event takes place.	
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 Member Company	
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 HCP or PO Representative to an Event organised or created by a Member Company and/or a Third Party	
Donations and Grants: collectively, mean 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	
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 POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services	
Healthcare 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 Europe. For the purpose of this Code, the definition of HCPs 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 Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products	
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	
Informational or Educational Material: constitutes inexpensive material directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients	
Item of Medical Utility: constitutes inexpensive item aimed directly at the education of HCPs enhancing the provision of medical services and patient care and that do not offset routine business practices of the HCPs.	
Location: refers to the geographic place where the Event is organized (e.g. the city, town).	
Medical Education: includes education related to human health and diseases and specific non-promotional training related to Medicinal Products	
Medical Sales Representative: personnel employed by a Member Company or retained by way of contract with Third Parties, who interact with HCPs and HCOs, in connection with the Promotion of Medicinal Products	
Medical Sample: has the meaning set forth in the Directive 2001/83/EC, namely sample of Medicinal Product free of charge to persons qualified to prescribe or supply them so that they can familiarize themselves with new products and acquire experience in dealing with them.	

Medicinal Product: has the meaning set forth in Article 1 of the Directive 2001/83/EC, namely: (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	
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 authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the Medicinal Product is clearly 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[2]	
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 which business address, place of incorporation or primary place of operation is in Europe	
Patient Organisation Representative: is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area[3].	
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[4].	
Prescription-Only Medicines (POM): is a Medicinal Product that requires a medical prescription issued by a professional person qualified to prescribe	

2 - Article 2 of the Directive 2001/20/EC
3 - EUPATI definition
4 - Definition based on the definitions of “personal data”, “genetic data” and “data concerning health” in Article 4 of GDPR

Promotion: includes any activity undertaken, organised or sponsored by a Member Company, or with its authority, which promotes the prescription, supply, sale, administration, recommendation or consumption of its Medicinal Product(s).	
Recipient: any HCP or HCO or PO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.	
Reporting Period: refers to the annual disclosure cycle and covers a full calendar year	
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 536/2014); or (iii) NIS 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	
Sponsorship: is a support provided by or on behalf of a Member Company, when permitted by law, as a contribution to support an activity (including an Event) performed, organised or created by a HCO, a PO or a Third Party	
Third Party: is a legal person/entity or individual that represents a Member Company or interacts with other Third Parties on behalf of a Member Company or relating to the Member 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	
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 POM exclusively for human use. Direct ToVs are those made directly by a Member Company for the benefit of a Recipient. Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or those made through a	

Third Party and where the Member Company knows or can identify the Recipient that will benefit from the Transfer of Value	
Venue: refers to the logistic place where the Event is organized (i.e. the hotel, the congress center)	
PREAMBLE	
This document replaces previous codes issued by FBN, namely:	
a. Code of Farmabrend Nova's Conduct during promotion of drugs issued issued under a prescription and communication towards the Healthcare Professionals (Ver.1 March/2017, Ver. 2 June/2018)	
b. Farmabrend Nova's Code of Practice on relationship between Pharmaceutical Industry and Patients Organizations (Ver.1 March/2017, Ver. 2 June/2018); and	
c. Farmabrend Nova's Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (approved by the General Assembly on July 2018)	
ETHICAL PRINCIPLES	
As pharmaceutical companies, we work in collaboration with various stakeholders including HCPs, HCOs, POs 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 there is somewhere a patient whose health and wellbeing is, directly or indirectly, dependent on our work. We aim at creating an 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 FBN and its members, self-regulation means being fully committed to define, implement, comply with and enforce the highest ethical standards through EFPIA and FBN Codes, where breaches are not tolerated. Self-regulation includes the concept of continuous challenge for us to exceed society's expectations and openness regarding suggestions from others on how we might further strengthen confidence in our industry and our behavior. Stakeholders who share the values and principles enshrined in this self-regulation are invited to adhere to these rules and guidance[5]	
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 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 respect to 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	

5 - EFPIA Leadership statement on ethical practices – June 2010

INTRODUCTION	
The FBN's membership[6] is composed of:	
Members:(i) research-based pharmaceutical companies, developing and manufacturing Medicinal Products in Europe for human use; (ii) organisations representing research-based pharmaceutical companies at national level in N.Macedonia	
FBN and its members[7] 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 share 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. Chapters 1, 2 and 3 reflect the requirements of Council Directive 2001/83/EC, 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. FBN encourages competition among pharmaceutical companies. The FBN 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, it 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 FBN Code thereby aims to foster an 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 society at large. HCPs	

6 - Article 11 of FBN Statute
7 - The updated list of FBN membership can be found on www.fbn.mk

and HCOs should be fairly remunerated for the legitimate expertise and services they provide to the industry. FBN believes that interactions between Member Companies and HCPs have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. FBN recognises that interactions between the industry and HCPs/HCOs can create the potential for conflicts of interest. Consequently, professional and industry associations, including FBN and its Members, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect. In order, to continue to be successful, self-regulation needs to respond to the evolving demands of society. In particular, FBN recognises 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 patient's 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 careers 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. Member Companies disclose the amounts provided to POs in the framework of these interactions. FBN strongly supports public scrutiny and the understanding of these relationships and disclosure contributes to the confidence of stakeholders in the pharmaceutical industry. In relation to working with HCPs and HCOs, since the introduction of the FBN Disclosure Code, FBN has worked to encourage Member Companies to always look to disclose and to encourage HCPs (and HCOs where relevant) to agree to individual disclosure. Member Companies will not be criticized for over-disclosure.	
SCOPE OF THE CODE	
This Code covers:	

• promotion of POMs to HCPs, • interactions between Member Companies and HCPs, HCOs and POs; • disclosure of ToVs from Member Companies to HCPs, HCOs and POs; and • Procedural provisions of the Code.	
Member 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, Member 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 Member Company (e.g. joint ventures, licensees) comply with Applicable Codes. This Code covers all methods of Promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail advertising, the activities of Medical Sales Representatives, the use of 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. This Code also covers interactions between Member 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 Member Companies and POs. This is not intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription Medicinal Products.	
This Code does not cover the following: a) the labelling, summary of product characteristics, package leaflet and other documents, approved by the	

competent authority at granting of marketing authorisation or at any later time, as well as other general precautionary measures aimed at safer and more efficient consumption of the medicinal product; b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular Medicinal Product; c) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims; d) activities which relate solely to non-prescription Medicinal Products; or e) Non-promotional, general information about Member Companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and regulatory developments affecting a Member Company and its Medicinal Products.	
The following documents are attached to the FBN Code and are binding for FBN members: -ANNEX A: Standardised Disclosure template; -ANNEX B: EFPIA guidance; -ANNEX C: Guidance obligations for Member Companies under the FBN Code; and -ANNEX D: FBN Standard Operating Procedure related to processing of complaints and questions submitted to FBN Ethic Council.	
APPLICABILITY OF THE CODE	
This Code sets out the minimum standards which FBN considers must apply, In a manner compatible with the respective national laws and regulations. Member Companies are encouraged to tailor their Company Codes to adapt to national conditions and to adopt additional provisions which might extend further than the minimum standards included in the FBN Code. Promotion and interactions which take place within N.Macedonia must comply with applicable laws and regulations. In addition, Promotion and interactions	

which take place within N.Macedonia must also comply with this Code. All EFPIA Member Companies with operations in N.Macedonia shall either (i) be a member of FBN where it conducts activities covered by the FBN Code (either directly or through the relevant subsidiary) or (ii) agree in writing with FBN that it (or its relevant subsidiary) is bound by FBN Code (including any applicable sanctions that may be imposed there under). FBN has established a Council for supervision of the provisions of this Code, which is composed of independent experts with appropriate expert knowledge and representatives of FBN (ANNEX D) The Council oversees the implementation of this Code and proposes amendments to codes or procedures adopted for their implementation. The Council has been established to assess information on medicinal products, assess the appropriateness of member cooperation with healthcare professionals, healthcare organizations and patient organisations and compliance of publishing transfers of funds from member companies to healthcare professionals and healthcare organisations and patients' organizations. The Council operates as a voluntary and self-regulating body for all FBN members.	
CHAPTER 1. - PROMOTION OF POM TO HCPs	
ARTICLE 1 MARKETING AUTHORIZATION	
Section 1.01. A Medicinal Product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply or outside of its approved indications. **Section 1.02.** Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant Medicinal Product.	
ARTICLE 2 INFORMATION TO BE MADE AVAILABLE	
Section 2.01. Subject to applicable national laws and regulations, all promotional material must include the following information clearly and legibly:	

- essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised; - the supply classification of the Medicinal Product; and - when appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies **Section 2.02**. Subject to applicable national laws and regulations, where an advertisement is intended only as a reminder, the requirements of Section 2.01 above need not be complied with, provided that the advertisement includes no more than the name of the Medicinal Product or its international non-proprietary name, where this exists, or the trademark.	
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 need not be provided, however, in relation to the validity of elements approved in the marketing authorization. **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, illustrations, photographs and tables taken from published studies included in promotional material must: (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 Code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified	

ARTICLE 5 - ACCEPTABILITY OF PROMOTION	
Member 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; and (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 to be removed from mailing lists must be complied with. **Section 6.03.** Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other digital 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-authorization studies (including those that are retrospective in nature) must not be disguised Promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose. **Section 7.03.** Where a Member 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 Member Company must clearly indicate that it has been sponsored by that Member 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 locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the Medicinal Product is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally	
ARTICLE 9 PERSONAL MEDICAL MATTERS	
In the case of requests from individual members of the public for advice on personal medical matters, the enquirer must be advised to consult a HCP.	
CHAPTER 2-INTERACTIONS WITH HCPs, HCOs AND POs	
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, avoiding those that are "renowned" for their entertainment facilities or are "extravagant" For the events organized in inappropriate venues by 3rd parties only registration fee for individuals will be allowed.	

Section 10.02. No Member Company may organise or sponsor an Event that takes place outside its home country unless: • most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country; or • 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. Member Companies may only offer hospitality when such hospitality is "appropriate" and otherwise complies with the provisions of this Code	
Section 10.04. Hospitality extended in connection with Events must be limited to travel, meals, accommodation and genuine registration fees and shall be reasonable and appropriately documented	
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 50 EUR (in local currency). If the event is set abroad the monetary threshold set in the country, where the event takes place (i.e. "host country" principle) shall prevail. HCPs must not be provided or have paid any individual leisure activities or other extra-curricular or social activities. Moderate (simple) entertainmen[8] at events is allowed but must be of secondary importance in comparison to refreshing beverages and/or food.	
Section 10.06. Hospitality may only be extended to persons who qualify as participants in their own right. 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	

[8] When a company is organizing an event and provides refreshments and / or meals, such as lunch or dinner, it is allowed to play music in the background (i.e. ambient music)

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	
Section 11.02. A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Chapter 1). Providing or offering them to HCPs, HCOs' members or POs' Representatives in relation to the promotion of POM is prohibited.	
ARTICLE 12 - DONATIONS AND GRANTS TO HCOs AND POs	
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 of this Code	

ARTICLE 13 - CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP	
Section 13.01. Member 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, FBN Code. 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 Member 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. Member 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 broad funding and sponsorship of POs and HCOs from multiple sources	
ARTICLE 15 - CONTRACTED SERVICES	
Section 15.01. Contracts between Member Companies and HCPs, HCOs, POs or POs' Representatives under which those provide any type of services to Member 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 and documented 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 consultant meets those criteria; d. the number of consultants retained and the extent of the service are not greater than reasonably necessary to achieve the identified need; e. the contracting Member 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 HCPs or PO Representatives	
Section 15.03. In their written contracts with consultants, Member Companies are strongly encouraged to include provisions regarding the obligation of the consultants to declare that they are consultants to the Member 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 Member Company. Similarly, Member Companies that employ, on a part-time basis, HCPs that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare their employment arrangements with the Member 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 Member Company. The provisions of this Section 15.03 apply even though the FBN Code does not otherwise cover non-promotional, general information about Member Companies (as discussed in the "Scope of the FBN Code" section).[9]	
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	
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 of this Code must apply	
CHAPTER 3 - SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HCPs AND HCOs	
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. Member Companies can be engaged in different types of Medical Education but such activities must not constitute Promotion. When funding independent Medical Education or organizing Medical Education activities directly or in collaboration with Third Parties, Member Companies must ensure that their participation and role is 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 recognized opinions	
ARTICLE 17 - INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY	

9 -- Member Companies are encouraged to publicly disclose the summary details and results of NIS in a manner that is

Section 17.01. The provision of Informational or Educational Materials is permitted provided it is: (i) "inexpensive" (up to 10 euro); (ii) directly relevant to the practice of medicine or pharmacy; and (iii) 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 Member Company name, 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	
ARTICLE 18 - NON-INTERVENTIONAL STUDIES	
Section 18.01. Non-Interventional Studies must be conducted with a primarily scientific purpose and must not be disguised 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 plan must be submitted to the National Ethics Committee for review; c. The study plan must be approved by the Member Company's scientific service and the conduct of the study must be supervised by the Member 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 Member Company and summaries thereof must be made available within a reasonable period of time to the Member 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 Member 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 or enforcing Applicable Codes 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;[10] and e. Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Member 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. To the extent applicable, Member Companies are encouraged to comply with Section 18.02 for all other types of NIS, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Article 15.01	
ARTICLE 19 - MEDICAL SAMPLES	
Section 19.01. In principle, no Medical Samples should be given, except on an exceptional basis. Medical Samples must not be given as an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products, and must not be given for the sole purpose of treating patients. Medical Samples are provided to HCPs so that they may familiarise themselves with the Medicinal Product and acquire experience in dealing with them. In accordance with national and/or EU laws and regulations, a limited number of Medical Samples may be supplied on an exceptional basis and for a limited period. A reasonable interpretation of this provision is that each HCP should receive, per year, not more than 4	

10 - Member Companies are encouraged to publicly disclose the summary details and results of NIS in a manner that is consistent with the parallel obligations with respect to clinical trials

Medical Samples of a particular Medicinal Product he/she is qualified to prescribe for 2 years after the HCP first requested samples of each particular Medicinal Product (i.e. the "4x2" standard or according to the local legislation requirements), or in accordance with local regulations if stricter" [11] In this context, a new Medicinal Product is a product for which a new marketing authorisation has been granted, either following an initial marketing authorisation application or following an extension application for new strengths/dosage forms that include a new indication Extensions of the marketing authorisation to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new Medicinal Product. Without prejudice to the ban on medical sampling of Medicinal Product containing psychotropic and narcotic substances, Medical Samples can only be given in response to a written request from HCPs qualified to prescribe that particular Medicinal Product. Written requests must be signed and dated by those who ask for the Medical Samples. On an exceptional basis, FBN may allow, through additional guidance, a longer period than 2 years if required by local healthcare conditions	
Section 19.02. Member Companies must have adequate systems of control and accountability for Medical Samples which they distribute and for all Medicinal Products handled by theirs Medical Sales Representatives. This system must also clearly establish, for each HCP, the number of Medical Samples supplied in application of the provisions in Section 19.01.	
Section 19.03. Each Medical Sample must be no larger than the smallest presentation of that particular Medicinal Product in the relevant country. Each Medical Sample must be marked "free medical sample – not for sale" or words to that effect and must be accompanied by a copy of the summary of product characteristics.	
ARTICLE 20 - MEMBER COMPANY STAFF	

11 – Zakon za lekovi (link)

Section 20.01. All Member Company staff must be fully conversant with the relevant requirements of the FBN Code and laws and regulations. a) Each Member Company must ensure a scientific service (medical department) either locally or through HQ resources in charge of information about its Medicinal Products and the approval and supervision of NIS. Member Companies are free to decide how best to establish such service(s) in accordance with this Section 20.01 (i.e. whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organisation. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the FBN Code and any relevant 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, where appropriate, a pharmacist, who will be responsible for the oversight of any NIS (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives). Such person must certify that he or she has examined the protocol relating to the NIS and that in his or her belief it is in accordance with the requirements of this Code and any relevant laws and regulations. b) Each Member Company must appoint at least one senior employee who must be responsible for supervising the Member Company and its subsidiaries to ensure that the standards of the FBN Code are met	
Section 20.02. Each Member Company must ensure that its Medical Sales Representatives are familiar with the relevant requirements of the FBN 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 this Code, and all applicable laws and regulations, and Member Companies are responsible for ensuring their compliance. b. Medical Sales Representatives must approach their duties responsibly and ethically. c. During each visit, and subject to applicable laws and regulations, Medical Sales Representatives must give the persons visited, or have available for them, a summary of the product characteristics for each Medicinal Product they present. d. Medical Sales Representatives must transmit to the scientific service of 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, do not cause inconvenience. 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 Member Company they represent.	
CHAPTER 4 - SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs	
ARTICLE 21 - INTERACTIONS WITH POs	
Section 21.01. For cooperation with POs Member Companies must comply with the following principles: 1. The independence of POs, in terms of their political judgement, policies and activities, must be assured. 2. All interactions between POs and Member Companies must be based on mutual respect, with the views and decisions of each partner having equal value. 3. Member Companies must not request, nor shall POs undertake, the Promotion of a particular POM. 4. The objectives and scope of any collaboration must be transparent. Financial and non-financial support	

provided by Member Companies must always be clearly acknowledged and disclosed.	
Section 21.02. EU and national laws and regulations prohibit the advertising of POM to the general public	
Section 21.03. When Member Companies provide financial support, significant indirect support and/or significant non-financial support to POs, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency´s time and the nature of its involvement) and significant non-financial support.	
Section 21.04. Member Companies must not influence the text of PO's material they sponsor in a manner favorable to their own commercial interests. This does not preclude Member Companies from correcting factual inaccuracies. In addition, at the request of POs, Member Companies may contribute to the drafting of the text from a fair and balanced scientific perspective	
CHAPTER 5 - DISCLOSURE OF ToVs FROM MEMBER COMPANIES	
ARTICLE 22 - DISCLOSURE OF ToVs TO HCPs, HCOs, AND POs	
Section 22.01 - Time of Disclosure Disclosures must be made by each Member Company within 6 months after the end of the relevant Reporting Period and 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 applicable national laws or regulations, or (ii) the relevant data protection legal basis (e.g. the legitimate interest grounds, a legal duty or the Recipient's consent relating to a specific disclosure) is no longer applicable. The common reporting period for publication of ToVs to Recipients is set during the time interval from 20th to 30th June each year at the latest.	
ARTICLE 23 - DISCLOSURE OF ToVs TO HCPs AND HCOs	

Section 23.01 - Rationale The following article provides for disclosures of ToVs to HCPs and HCOs, whether directly or indirectly. When deciding how a ToV must be disclosed, Member Companies should, wherever possible, identify and publish at the individual HCP (rather than HCO) level, as long as this can be achieved with accuracy, consistency and in compliance with applicable laws and regulations	
Section 23.02 - Implementation and deviations This Article sets out the minimum standards which FBN considers must apply to all Member Companies	
Section 23.03. Disclosure Obligation <u>General Obligation</u>. Subject to the terms of this article, each Member Company must document and disclose ToVs it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 23.05. <u>Excluded Disclosures</u>. Without limitation, ToVs that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 23.05 of this article, such as Items of Medical Utility (governed by Article 17), meals (governed by Article 10, especially Section 10.05), Medical Samples (governed by Article 19); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation described above in "General Obligation"	
Section 23.04 - Form of Disclosure <u>Annual Disclosure Cycle</u>. Disclosures must be made on an annual basis and each Reporting Period must cover a full calendar year. <u>Template.</u> For the sake of greater consistency, disclosures under this Article shall be made on a standardised template set out in Annex A. <u>Platform of Disclosure.</u> Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available on the relevant	

Member Company's website or their affiliates provided that they are unrestricted and publicly available Applicable National Code. Disclosures must be made pursuant to the National Code of the country where the Recipient has its professional address. If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its physical address, the Member Company must disclose such ToV in a manner consistent with the relevant National Code in its home country. Language of Disclosure. Disclosures must be made in Macedonian language. Member Companies are encouraged to make disclosures in English in addition to the mandatory disclosures in Macedonian language. Documentation and Retention of Records. Each Member Company must document all ToVs required to be disclosed pursuant to Section 23.03 and maintain the relevant records of the disclosures made under this article for a minimum of 5 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national laws or regulations.	
Section 23.05. Individual and Aggregate Disclosure Individual Disclosure. Except as expressly provided by this article, ToVs must be disclosed on an individual basis. Each Member Company must disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to ToVs to such Recipient in each Reporting Period, which can be reasonably allocated to one of the categories set out below. Such ToVs may be aggregated on a category-by-category basis, provided that itemised disclosure must be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities. 1.For **ToVs to a HCO**, an amount related to any of the categories set forth below: **Donations and Grants.** Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 12).	

Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or Third Parties10, including support to HCPs to attend Events, such as: • Registration fees; • Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event; and • Travel and accommodation (to the extent governed by Article 10). **Fees for Service and Consultancy.** ToVs resulting from or related to contracts between Member Companies and HCOs under which such HCOs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts. 2.For **ToVs to a HCP**: **Contribution to costs related to Events.** Contribution to costs related to Events, such as: • Registration fees; • Travel and accommodation (to the extent governed by Article 10). **Fees for Service and Consultancy.** ToVs resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand, ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts. Aggregate Disclosure. For ToVs where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 23.05, cannot be disclosed on an individual basis for legal reasons, a Member Company must disclose the amounts attributable to such ToVs in each Reporting Period on an aggregate basis. Such aggregate disclosure must identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the	

aggregate amount attributable to ToVs to such Recipients. Non duplication. Where a ToV required to be disclosed pursuant to Section 23.05 is made to an individual HCP indirectly via a HCO, such ToV must only be required to be disclosed once. To the extent possible, such disclosure must be made on an individual HCP named basis pursuant to Section 23.05. Research and Development ToV. Research and Development ToVs in each Reporting Period must be disclosed by each Member 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 Member Company must publish a note summarising the methodologies used by it in preparing the disclosures and identifying ToVs for each category described in Section 23.05. The note, including a general summary and/or country specific considerations, must describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amounts of ToVs for purposes of this article, as applicable.	
ARTICLE 24 - DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO POs	
Each Member Company must disclose a list of POs to which it provides financial support and/or significant indirect/non-financial support or with whom it has engaged to provide contracted services for that Member Company. This disclosure 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 must be included: a) For support:	

i. the monetary value of financial support and of invoiced costs. ii. the non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value. b) For contracted services: the total amount paid per PO over the Reporting Period. This information must be disclosed on the Member Company website either on a national or European level on an annual basis and each Reporting Period shall cover a full calendar year. Methodology. Each Member 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 through Member Companies Member Companies must, within current applicable laws and regulations enforce the provisions of this Code. In the event that a breach is established pursuant to the procedures of this Code, FBN shall require from the offending company an immediate cessation of the offending activity and a signed undertaking by the company to prevent recurrence. FBN has set forth the framework for the implementation of this Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other laws and regulations.	
ARTICLE 26 - AMENDMENTS TO, AND GUIDANCE REGARDING COMPLIANCE WITH, THE FBN CODE	
Section 26.01. Code Compliance Responsibility for assuring compliance with the present Code is borne by all FBN members. FBN Ethical Council shall assist FBN members to comply with their obligations under this Code. The key tasks of the Council are set forth in ANNEX D**.**	

Section 26.02. Amendments to the FBN Code The FBN Ethical Council shall regularly review this Code and any guidance issued regarding compliance with this Code. Amendments or adjustments of the Code may be adopted on the basis of a majority vote of Member Companies at the General Assembly. The Code may also be amended: a) upon amendment of the EFPIA Code of conduct. b) upon a request submitted to the FBN Board by a one or more Member Companies, which shall, after review, be submitted for approval to the General Assembly. Adoption shall require the majority of present votes at a General Assembly.	
ARTICLE 27 - ENFORCEMENT OF THE CODE	
Section 27.01 – This Code comes into force on the date of its adoption	
Section 27.02 - This Code obliges all members of the FBN Association to fully comply with its provisions and to respect them	

ANNEX A (binding)

FBN disclosure template

Прилог 2: МОДЕЛ НА ТАБЕЛА

Датум на објавување: .....

	Име и презиме на здравственият работник/Име на здравствената организација	**Здравствени работници:** Град на примарното работно место **Здравствени организации:** Град каде се регистрирани	Држава	Службена адреса	Единствен број на државата ОПЦИОНАЛНО	Донации и неповратни средства за здравствени установи *(Чл.3.01.1.а)*	Трошоци за собири *(Чл. 3.01.1.б и 3.01.2.а)*			Хонорари за услуги и консултации *(Чл. 3.01.1.ц и 3.01.2.ц)*			ВКУПНА СУМА ОПЦИОНАЛНО
	(ЧЛ. 1.01)	*(Чл. 3)*	*(Прилог 1)*	*(Чл. 3)*	*(Чл. 3)*		Договори за спонзорство со здравствени организации/трети лица именувани од здравствената организација за организирање на собирот	Трошоци за регистрација	Трошоци за пат и сместување	Хонорари	Трошоци поврзани со хонорари за услуги и консултации, вклучително и трошоци за пат и сместување		
ЗДРАВСТВЕНИ ПРОФЕСИОНАЛЦИ	***ОБЈАВУВАЊЕ НА ИНДИВИДУАЛНА ОСНОВА - еден ред по здравствен работник*** *(собрани сите преноси на вредност во тек на годината по еден здравствен работник; поделба по ставки би требало да се овозможи на барање на самиот здравствен работник или државни органи)*												
	Др. А					N/A	N/A	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*		
	ДР.Б					N/A	N/A	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*		
	итн					N/A	N/A	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*		
	ОСТАНАТО, ШТО НЕ Е ВКЛУЧЕНО ГОРЕ - таму каде што поради законски ограничувања не е можно објавување на индивидуална основа												
	Обединето објавување на податоци за пренос на вредност - *Чл. 3.02*					N/A	N/A	*Вкупно на здравствени работници*	*Вкупно на здравствени работници*	*Вкупно на здравствени работници*	*Вкупно на здравствени работници*		*Опционално*
	Број на здравствени работници во обединетото објавување на податоци - *Чл. 3.02*					N/A	N/A	*број*	*број*	*број*	*број*		*Опционално*
	% на здравствени работници вклучени во обединетото објавување во однос на вкупниот број на здравствени работници за кои се објавуваат податоци - *Чл. 3.02*					N/A	N/A	%	%	%	%		N/A
ЗДРАВСТВЕНИ ОРГАНИЗАЦИИ	***ОБЈАВУВАЊЕ НА ИНДИВИДУАЛНА ОСНОВА - по еден ред за здравствена организација*** *(собрани сите преноси на вредност во тек на годината по една здравствена организација; поделба по ставки би требало да биде овозможена на барање на здравствената организација или државен орган)*												
	ЗДРАВСТВЕНА ОРГНИЗАЦИЈА 1					*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*		*Опционално*
	ЗДРАВСТВЕНА ОРГНИЗАЦИЈА 2					*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*		*Опционално*
	итн					*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*	*Годишна сума*		*Опционално*
	ОСТАНАТО, ШТО НЕ Е ВКЛУЧЕНО ГОРЕ - таму каде што поради законски ограничувања не е можно објавување на индивидуална основа												
	Обединето објавување на податоци за пренос на вредност - *Чл. 3.02*					*Вкупно на здравствени организации*	*Вкупно на здравствени организации*	*Вкупно на здравствени организации*	*Вкупно на здравствени организации*	*Вкупно на здравствени организации*	*Вкупно на здравствени организации*		*Опционално*
	Број на ЗО во обединетото објавување на податоци - *Чл. 3.02*					*број*	*број*	*број*	*број*	*број*	*број*		*Опционално*
	% на ЗО вклучени во обединетото објавување во однос на вкупниот број на ЗО за кои се објавуваат податоци - *Чл. 3.02*					%	%	%	%	%	%		N/A
ИСТРАЖУВАЊЕ И РАЗВОЈ	***ОБЕДИНЕТО ОБЈАВУВЊЕ НА ПОДАТОЦИ***												
	Преноси на вредности во врска со истражување и развој, како што е дефинирано во Чл. *3.04 и Прилог 1*											*ВКУПНА СУМА*	*ОПЦИОНАЛНО*

ANNEX B (binding)
GUIDANCE ON DISCLOSURE OF NON-INTERVENTIONAL STUDIES

Transfers of Value relating to non-interventional studies (NIS) that are not within the definition of R&D ToVs under the FBN Disclosure Code must be reported on an individually named basis. In this regard, prospective versus retrospective NIS will be considered following classification in the table below:

PROSPECTIVE NIS	RETROSPECTIVE NIS
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 sake of clarity, activities not falling within the definition of R&D ToVs, including NIS that are not conducted to maintain a marketing authorisation (in application and following definitions of the "Clinical Trials" Regulation 536/2014), will be disclosed under "consultancy/fee-for-services".

Member Companies are encouraged to include a comment in the Methodological Note, where appropriate

DISCLOSURE OF INDIRECT TRANSFERS OF VALUES (ToVs) THROUGH THIRD PARTIES
Support to / Sponsorship to Events through Professional Conference Organisers (PCOs

Guidance

Contributions provided to Events through PCOs – that would therefore be the Recipient of the ToVs – must be considered as indirect ToVs.

When a Member Company contributes to the costs related to Events through PCOs, the following reporting approaches are considered compliant with EFPIA reporting requirements:

- All ToVs to an HCO (either as Recipient or as Beneficiary) are reported in the relevant category under the name of the HCO
- ToVs through PCOs are reported:

- either in the name of benefitting HCO (through *include the name of Recipient PCO*), if not included in direct ToVs to the HCO;
- or in the name of Recipient PCO (to the benefit of *include the name of benefitting HCO*)

This Guidance applies whether PCOs organise Events on their own initiative, or at the request of an HCO.

For further clarification, the attached table reviews scenarios of support / sponsorship to Events through PCOs that may help in preparation of reporting according to this Guidance.

For good order, it is reminded that contribution to costs related to Events paid through third parties to the benefit of individual HCPs that the Member Company knows, must be reported on an individually named basis, as Indirect ToVs to HCPs.

Further recommendation

EFPIA recommend that Member Companies confirm support / sponsorship to Events through PCOs in written agreements, and encourage them to include provisions relating to information that the PCOs must communicate to the Member Company to allow appropriate reporting of ToVs following the EFPIA Disclosure Code.

The Member Companies are encouraged to describe the process followed to collect the information in their Methodological Note, where it must also be stated that the full value ToVs to the PCO will not constitute a benefit (in cash or in kind) to the HCO as the PCO may retain a "service fee".

Additional Guidance adopted at national level or requested by national legal requirements may complement this EFPIA Guidance (for such cases, Article 4.03 of EFPIA Disclosure Code applies).

Additional Guidance on ToVs through PCOs
SUPPORT TO / SPONSORSHIP TO EVENTS
THROUGH PROFESSIONAL CONFERENCE ORGANISERS (PCOs)

For further clarification, the table below reviews scenarios of support / sponsorship to Events through PCOs, which may help in preparation of reporting according to this EFPIA Guidance.

Examples of possible scenarios in support of Events
These examples are offered to help Member Companies when preparing their disclosure reports in the perspective of optimal reporting of Events which they sponsor / support

Recipient PCO receiving the ToVs	Beneficiary HCP/HCO benefitting	Disclosure
PCO on behalf of / in collaboration with a HCO	**where the Member Company knows the HCP/HCO benefitting**	**Individual disclosure following guidance**
PCO on behalf of / in collaboration with HCO	where the Member Company does not known the HCP/HCO benefitting	Whilst disclosure on an individual HCP/HCO named basis, the Member Company may consider disclosing under the PCOs name with indication of the specialty area
PCO with HCO Scientific Committee	**HCO(s) is (are) known to the Member Company**	**Individual disclosure following guidance**
PCO with HCP Scientific Committee	**HCP(s) is (are) known to the Member Company**	**Individual disclosure following relevant EFPIA HCP/HCO Disclosure Code provisions**
PCO developing / organising an Event at its own initiative (independent event)	**where the Member Company knows the HCP/HCO participating in the Event**	**Individual disclosure following guidance**
PCO developing / organising an Event at its own initiative (independent event)	where the Member Company does not know the HCP/HCO participating in the Event	Whilst disclosure on an individual HCP/HCO named basis, the Member Company may consider disclosing under the PCOs name with indication of the specialty area

Disclosures on an individual names basis are subject to appropriate consent; where such consent cannot be secured, related ToVs will be disclosure in aggregate

ANNEX C (binding)
Guidance obligations for Member Associations under the EFPIA Code

Member Companies must comply with any relevant guidance provided under this Annex or in connection with any Applicable Code(s).

Article 10 Events and hospitality

Member Association must set a monetary threshold in its National Code, failing which EFPIA will set such threshold in lieu of such Member Association.

Member Associations must provide guidance on the meaning of the term "reasonable", as used in the Article 10. Member Associations must also provide guidance on "appropriate", "renowned" and "extravagant" Venues, as used in the Article 10.

FBN guidance on the meaning of the following terms:

For the purpose of this Article 10, an **"appropriate**" Location with the most convenient access for majority of participants and available capacities for organisation of the Event.
By "**appropriate**" is considered venue with no more than 4*, out of season (summer resorts July-August, winter resorts Jan-Feb)
"**Renowned**" – places that are known for their entertainment, recreational or luxury content.
"**Extravagant**" - 'Extravagant and luxurious hotels for the purposes of this Code are all 5 star hotels, located in year-round resort destinations, as well as all hotels, regardless of the class, located in seasonal resort destinations during the summer or winter tourist season respectively; wine tourism complexes, regardless of their class and location
"Reasonable" hospitality in the sense of this Article shall mean hospitality within the limitations healthcare organisations would normally observe in the organisation of events for their own needs, whereby events aimed predominantly at leisure should be avoided.

Article 15 Contracted services

Member Associations must provide guidance on the meaning of "**minimal**" under the Section 15.03 or in connection with any Applicable Code(s).

FBN guidance on "**minimal" -** does not exceed 30 EUR per survey or questionnaire

Article 21.03

Member Associations must provide guidance on the meaning of the term "significant".

FBN guidance on the term "**significant**" support shall mean any support or service, with an attributable monetary value exceeding 5% of the total project value or exceeding:
25% of POs' annual budget
50% of POs' annual budget in the 1st year
50% of POs' annual budget if no other sponsors from pharma industry (eg. Rare disease)

ANNEX D (binding)
FBN standard operating procedure in case of violation of the Farmabrend Nova's (FBN) Codes

Section 01.01- Member Companies Implementation The Implementation and Procedure Rules set forth herein establish the framework for the implementation of this Code, the processing of complaints and the initiation or administration of sanctions by FBN Ethical Council It is recommended that members of the FBN Association endeavor to resolve all cases of alleged violation of this Code, which only applies to these two companies, amicably and in direct conversation. The principle of amicable settlement is also recommended in case of disputes between members of FBN and pharmaceutical companies that are not members. If a reasonable solution cannot be reached, an application for a violation of the Code may be filed.	
Section 01.02. Two-stage procedure Members of the FBN Association are aware that adherence to the rules of the FBN Code is crucial to building and maintaining public confidence in the integrity of members. The further provisions stipulate a two-stage procedure that it implements: - The Ethical Council, in the first instance, and - Assembly of FBN, in the second instance	
Section 01.03 - Appointment of the Ethical Council (EC)	
Section 01.03.01 The Ethical Council consists of 5 members, 3 association's members, by one representative from the three working groups of the Association and besides any industry members, membership from other stakeholders, including legal adviser. The members of the EC should not be from the same FBN member companies. If any member of the EC has a conflict of interest, it is replaced with another	

representative from the same working group for the first instance procedure. The legal adviser has the right to advice, but has no right to vote.	
Section 01.03.02. The members elect an EC president and his/her deputy that is designated to handle complaints and consists of a non-industry chairperson, for a term of 1 year, and they report to the president of FBN about it.	
Section 01.03.03. All members participating in the procedure have an obligation to keep the confidentiality of the data during the first and second instance proceedings, but also afterwards.	
Section 01.04 - Application for violation of this Code	
Section 01.04.01- All members of FBN and non-members have the right to file an application for breach of the provisions of the Code.	
Section 01.04.02. The application for violation of the Code against a member and nonmember of the FBN Association shall be addressed in writing to the President of the FBN at the address of the Association or at the email: prijaviprekrsok@gmail.com	
Section 01.04.03 - An application against a FBN member may be filed only for alleged violations occurred from the moment of the entry into force of this Code.	
Section 01.04.04 - The application must contain the following information: (a) name and address of the applicant; (b) information on the activities considered to be in violation of the provisions of the Code and appropriate evidence thereof (the application must contain an accurate and detailed description of the activities, documentation and argumentation of the party submitting the application, as well as other available data and facts);	

(c) indicating the provisions of the Code in accordance with which the application is filed	
Section 01.04.05 - If the application does not contain all the requested information, the president of FBN shall notify the applicant thereof. The applicant has a deadline of 15 days from the receipt of the notification to complete the application. If this is not done by the expiry of the deadline, the application shall be rejected	
Section 01.04.06 - If the application is filed in accordance with the requirements of paragraph 28.04.04, the President of FBN shall forward the application to the President of the EC. The President of the EC shall forward the said application to the member to whom the application relates within 8 days, with a request to declare the allegations in the application	
Section 01.04.07 - The registered member has a deadline of 15 days from the receipt of the request to submit a written explanation regarding the application. The written explanation may contain: (a) a statement to acknowledge the violation of the Code by taking the obligation to immediately discontinue the activities that constitute a violation of the Code and refrain from future activities that could lead to violation of the Code by signing the statement of termination of the Code violation (Statement of Termination); (b) a statement for challenging the violation of the Code by stating arguments for such an attitude	
Section 01.04.08 - If the President of the EC assesses that the statement for challenging the violation of the Code is valid and substantiated, it shall notify the applicant thereof within 8 days. If the applicant does not agree with such an opinion of the President of the EC, he/she must notify the President of the EC within 8 days	
Section 01.04.09 - The EC President shall schedule an EC meeting if:	

(a) the reported member did not submit a written statement within the requested deadline; (b) he/she assessed that the statement of the reported member with which the violation of the Code is disputed is not supported and substantiated; (c) the applicant does not agree with the decision of the President of the European Union that, based on the statement of the reported member, the application is unfounded. The EC meeting must be scheduled within 15 days from fulfilling the conditions for scheduling. The President of the EC, when scheduling the meeting, submits all the documents received about the case to the members of the EC	
Section 01.04.07 - The registered member has a deadline of 15 days from the receipt of the request to submit a written explanation regarding the application. The written explanation may contain: (a) a statement to acknowledge the violation of the Code by taking the obligation to immediately discontinue the activities that constitute a violation of the Code and refrain from future activities that could lead to violation of the Code by signing the statement of termination of the Code violation (Statement of Termination); (b) a statement for challenging the violation of the Code by stating arguments for such an attitude	
Section 01.05 - Ethical Council, the first instance procedure	
Section 01.05.01 - The EC takes decisions by a simple majority of votes, in the presence of at least 75% of its members. The EC can make the following decisions: - refusal of the application in case it is found to be unfounded because the action which is the subject of the application does not constitute a violation of the Code or there is insufficient evidence that can be reliably confirmed that there has been a violation of the Code; - declaring the reported member guilty of violating the Code.	

Section 01.05.02 - If the EC decides that the reported member is guilty, at this stage it may invite the member to act in accordance with the requirements of paragraph 28.04.07 (a).	
Section 01.05.03 - The decision must also contain a legal advice for lodging an appeal against the decision. The applicant and the reported member have the right to appeal within 15 days of receiving the decision of the EC. The appeal shall be submitted to the President of the FBN, who must initiate a second-instance procedure within 15 days of receiving the appeal.	
Section 01.06. Assembly of the FBN, the second instance procedure In the second-instance procedure, the Assembly of FBN decides, which consists of legal representatives of all FBN member companies, except the companies that are directly involved in the dispute. The representatives of companies involved in the dispute can participate in the work of the Assembly, but do not have the right to vote. The Assembly in the second instance procedure shall make a decision with a simple majority of votes, with more than 50% of the voting members being present.	
Section 01.06.01 - The Assembly may make the following decisions: (a) rejection of the appeal and confirmation of the decision of the EC; (b) abolishing or amending the decision of the EC, wholly or in part.	
Section01.06.02. Based on the Assembly decision: (a) The EC shall ensure that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, in a level of detail that is linked to the seriousness and/or persistence of the breach as follows: (i) in cases of a serious/repeated breach, the company name(s) should be published together with details of the case; (ii) in cases of a minor breach, or where there is no breach,	

publication of the details of the case may exclude the company name(s). (b) The EC is encouraged to publish summaries in English of cases that have precedential value and are of international interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest). The decision of the Assembly is final, without the right of appeal and it is submitted to both parties within 15 days of the adoption.	
Section 01.07. Sanctions available to the EC and Assembly: (a) a warning requesting immediate termination of the Code violation; (b) publishing the decision on the FBN website if the warning is not respected; (c) a notification to the head office of the parent company about the final decision by which the member is found guilty of violating the provisions of the Code; (d) a notification to the competent authorities if local laws are violated; (e) a suspension of the member at 3, 6 or 12 months. During the duration of the suspension, the member must fulfil all obligations to the Association, but its representatives may not participate in the work of the Association; (f) exclusion of a member from the Association. The sanctions may be cumulative.	
Section 01.07.01. When imposing sanctions, it is necessary to take into account the following aspects: (a) the severity of offense; (b) the impact of the offense on the integrity of the pharmaceutical companies; (c) whether it is a matter of first or repeated an offense; (d) internal penalties and corrective measures taken by the sanctioned member of the Association; (e) the constructiveness of the sanctioned member during the whole procedure.	