THE INOVIA CODE

BASED ON THE EFPIA CODE

INOVIA

Udruženje proizvođača inovativnih lekova

The INOVIA Code is a collection of ethical rules agreed upon by the INOVIA members in order to promote Medicines to Healthcare Professionals and to interact with Healthcare Professionals, Healthcare Organisations and Patient Organisations, with the intention of guaranteeing that these activities are carried out in compliance with the strictest 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 terms are included to ensure their consistent understanding.

Applicable codes:

- ((i) in the case of a promotion or interaction carried out, sponsored or organised by a Member Company located in Europe, when done on its behalf or together with it, the National Code of the Member Association of the country in which such a Member Company is located; or (ii) in the case of a promotion or interaction carried out, sponsored or organised by a Member Company not located in Europe, when done on its behalf or together with it, the EFPIA Code; and
- National Code of the Member Association of the country in which the promotion or interaction takes place.

In the case of an international Event for which a Member Company sponsors the presence of an HCP, if any funding is provided to such an HCP in accordance with the provisions of Article 13, such funding is subject to the rules of the National Code in the country where that HCP pursues their profession, rather than the one where an international Event is taking place.

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

Contribution to the cost of Events: is support that provides or covers the costs of meals, travel, accommodation or registration fees to support the presence of an individual representative of an HCP or PO at the Event organised or designed by a Member Company or a Third Party.

Donations and grants: together involve the provision of funds, assets or services that are freely provided for the purpose of supporting health care, scientific research or education, without any obligation to the recipient to return goods or services for the benefit of donors.

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 the Annexes that are expressly stated as binding and which form part of this Code.

Europe: includes countries where the National Codes of the EFPIA Member Associations apply.[1]

1 As of June 2019, these countries include: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Northern Macedonia, Norway, Poland, Portugal,

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 production facilities, and meetings for planning, training or gathering of researchers for clinical and non-interventional studies) organised or sponsored by or on behalf of the Member Company.

Healthcare Organisation (HCO): any legal person/entity(ies) that is a health, medical or scientific association or organisation (regardless of legal or organisational form) such as a hospital, clinic, foundation, university or other educational institution, or a scientific society (other than a patient organisation within the meaning of Article 21) whose business address, place of establishment or primary place of business is in Europe, or (ii) through which one or more HCPs provide services.

Healthcare Professional (HCP): any natural person who is a member of the medical, dental, pharmaceutical or nursing/technician professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer the Medicines and whose primary practice, main professional address or place of establishment is in Europe. For the purposes of this Code, the definition of HCP includes:

(i) Any official or employee of a government, government agency or other organisation (whether in the public or private sector) who may prescribe, purchase, supply, recommend or administer Medicines; and (ii) any employee of a Member Company whose primary occupation is an HCP, but excludes (x) all other employees of the member company and (y) wholesalers or distributors of Medicines.

Host Country Principle: refers to the primacy of the monetary threshold for meals (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 take precedence.

Informational or educational material: an inexpensive material directly relevant to medical or pharmaceutical practice and directly useful for patient care.

Item of medical utility: is an inexpensive item that is directly aimed at the education of HCPs, which improves the provision of medical services and patient care and that does not compensate for the routine business practices of HCPs.

Location: refers to the geographical location where the event is organised (e.g. city, town).

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

Medical Sales Representative: staff employed by a Member Company or retained through a contract with a Third Party, which interacts with HCPs and HCOs, in connection with the promotion of Medicines.

Medical sample: has the meaning given in Directive 2001/83/EC, i.e. a free sample of a Medicine given to persons qualified to prescribe or supply, so that they can become acquainted with new products and gain experience in working with them.

Medicine: has the meaning set out in Article 1 of Directive 2001/83/EC, as follows:

(a) any substance or combination of substances with properties for treating or preventing disease in humans; or (b) any substance or combination of substances that can be used or administered to humans in order to restore, correct or modify physiological functions by performing pharmacological, immunological or metabolic action, or to make a medical diagnosis.

Member Association: an organisation representing pharmaceutical manufacturers at the national level whose members include, but are not limited to, research companies. Together, the national Member Associations or their constituent members, as the context requires, are bound by the EFPIA Code.

Member Company: means companies engaged in the research, development and production of Medicines in Europe for human use.

Member Company Staff: staff employed by or retained by a Member Company by contract with Third Parties, dealing with any matter covered by this Code.

National Code: Code of Practice of a Member Association.

Non-interventional study (NIS): a study in which the Medicine(s) are prescribed in the usual way in accordance with the conditions of the marketing authorisation. The inclusion of the patient in a certain therapeutic strategy is not determined in advance by the study protocol, but belongs to the existing practice, and the prescribing of the Medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures should be applied to patients and epidemiological methods must be used to analyse the data collected.[2]

Patient Organisation (PO): a non-profit legal person/legal entity (including the umbrella organisation to which it belongs), mainly composed of patients or carers, which represents or supports the needs of patients or carers and whose business address, place of establishment or primary place of business is in Europe.

Patient Organisation Representative: a person who has a mandate to represent and express the collective views of the PO regarding a particular issue or disease area.[3]

Personal Health Data: all information relating to the physical, mental health or inherited or acquired genetic characteristics of an identified or identifiable individual, including the provision of health services that discloses information about his or her physiological or health status.[4]

2 - Article 2 of Directive 2001/20/EC
3 - EUPATI Definition
4 - Definition based on the definitions of “personal data”, “genetic data” and “health data” in Article 4 of the EU General Data Protection Regulation

Prescription-Only Medicines: Medicines that require a medical prescription issued by a qualified professional.

Promotion: includes any activity carried out, organised or sponsored by the Member Company, or done under its authority, where the prescribing, supply, sale, administration, recommendation or consumption of its Medicines is promoted.

Recipient: any HCP, HCO or PO, as applicable, in any case, whose primary practice, main professional address or place of establishment is in Europe.

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

Research and Development Transfers of Value: Transfers of value to HCPs and HCOs related to the planning or implementation of (i) non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice); (ii) clinical trials (as defined in EU Regulation 536/2014); or (iii) NISes that are prospective in nature and involve the collection of patient data from or on behalf of individuals or groups of HCPs specifically for the study.

Sponsorship: support provided by a Member Company or someone on its behalf, when permitted by law, as a contribution to support an activity (including the Event) performed, organised or created by the HCP, PO or a Third Party.

Third Party: a legal person/legal entity or a natural person representing the Member Company or interacting with other Third Parties on behalf of the Member Company or in connection with the Member Company's Medicine, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contractors, market research companies, advertising agencies, Event service providers, public relations service providers, non-clinical, non-intervention study management service providers.

Transfers of Value (ToV): direct and indirect ToVs, in cash, in kind or otherwise, for promotional purposes or otherwise, in connection with the development and sale of Prescription-Only Medicines solely for human use. Direct ToVs are those directly entered into by the Member Company for the benefit of the Recipient. Indirect ToVs are those performed on behalf of the Member Company for the benefit of the Recipient, or those performed through a Third Party and where the Member Company knows or can identify the Recipient who will benefit from the Transfer of Value.

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

INTRODUCTORY CLAUSE

THis document replaces the previous codes issued by INOVIA, as follows:

- CODE OF CONDUCT FOR THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES AND COMMUNICATION WITH HEALTHCARE PROFESSIONALS, JULY 2014
- THE INOVIA CODE OF CONDUCT FOR RELATIONS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS, DECEMBER 2014

ETHICAL PRINCIPLES

As pharmaceutical companies, we work with a variety of stakeholders, including HCPs, HCOs, POs and their representatives, regulators, governments and the public to improve health and quality of life.

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

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

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

Our goal is to create an environment in which stakeholders and the public consider pharmaceutical companies to be reliable partners.

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

For INOVIA and its members, self-regulation means that it is fully committed to defining, applying, respecting and enforcing the highest ethical standards through the EFPIA Codes and National Codes, where violations are not tolerated.

Self-regulation involves the concept of a constant challenge for us to exceed society's expectations and openness to suggestions from others on how we can further strengthen confidence in our industry and our conduct.

Stakeholders who share the values and principles contained in this self-regulation are invited to adhere to these rules and guidance.[5]

This demonstrates our commitment to the following ethical principles:

First of all, **PATIENTS ARE AT THE HEART OF WHAT WE DO**. We strive to ensure that everything we do will ultimately benefit patients. Our primary contribution to society is that we produce high-quality Medicines and encourage their appropriate and rational use in the field of care.

We work with **INTEGRITY**, interact responsibly and strive to ensure that our communication with healthcare professionals is accurate, legitimate and balanced. We are responsible for our decisions, actions and interactions and encourage others to follow the same high ethical standards.

We interact with all our stakeholders with **RESPECT**. We are committed to approaching our stakeholders in an open way, with an appropriate, constructive attitude, a desire to learn and with mutual respect. We appreciate the importance of independent decision-making by stakeholders, based on evidence and including patient interest. When it comes to society, we listen to what is expected of us and adjust the way we work accordingly. We follow applicable laws and make ethical judgments when processing personal health data.

We are committed to ensuring respect for **TRANSPARENCY**. We are open concerning our activities and interactions and encourage stakeholders to act with the same openness.

5 - EFPIA Management Statement on Ethical Practices - June 2010.

INTRODUCTION

INOVIA*[6] *members include:

- Pharmaceutical companies involved in the production, marketing and promotion of innovative medicines, whose activity is based on research and that are active in the development of new chemical compounds and/or biotechnological medicines; and
- EFPIA members.

Separate entities belonging to the same multinational company - which could be a parent company (e.g. headquarters, head office or controlling company of a commercial company), a subsidiary or any other form of company or organisation - are considered to form one company and as such are committed to compliance with the **INOVIA** Code.

INOVIA and its members[7] are aware of the importance of (i) providing accurate, fair and objective information on Medicines in order to make rational decisions regarding their use, (ii) ensuring that interactions with HCPs, HCOs and POs, which are crucial for the exchange of knowledge in order to improve the quality of patient care, take place in an ethical manner and (iii) greater transparency in the interaction of the pharmaceutical industry with HCPs, HCOs and POs.

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

INOVIA encourages competition among pharmaceutical companies. The **INOVIA** Code is not intended to restrict the Promotion of Medicinal Products to HCPs, or to limit interactions with HCPs, HCOs and POs in a way that is detrimental to fair competition. Instead, it seeks to ensure that pharmaceutical companies conduct such Promotions and Interactions in a truthful manner, avoiding deceptive practices and potential conflicts of interest with stakeholders, and in accordance with the applicable laws and regulations.

Therefore, the **INOVIA** Code aims to foster an environment in which the public can be confident that their choices regarding Medicines are based on the merits of each product and the healthcare needs of patients.

HCPs and HCOs provide the pharmaceutical industry with valuable, independent and professional 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 as a whole. HCPs and HCOs should be fairly paid for the legitimate expertise and services that they provide to the industry.

6 - Article 6 of the INOVIA Statute
7 - Find an updated list of INOVIA members at www.inovia.rs

INOVIA believes that the interactions between Member Companies and HCPs have a profound and positive impact on the quality of patient care and the value of future research. At the same time, the integrity of an HCP's decision to prescribe a Medicine is one of the pillars of the healthcare system. INOVIA recognizes that interactions between the industry and HCPs/HCOs can create the potential for conflict of interest. Consequently, professional and industry associations, including INOVIA and its Member Companies, have adopted codes and guidance to ensure that these interactions meet the high standards of integrity expected by patients, governments and other stakeholders.

In order to continue to be successful, self-regulation needs to respond to the growing demands of society. In particular, INOVIA recognizes the increasing expectation that interactions with society are not only conducted with integrity, but also that they are transparent.

In the same way, the pharmaceutical industry works with POs to learn from their knowledge and experience of a patient's condition, which can provide a true picture of what it is like to live with a specific condition, how care is provided, how it affects patients, their careers and families and how medicines and other treatments can change their lives and meet their needs.

POs play a key role as they help shape, develop and define the outcomes that most impact patients. Member Companies disclose the amounts provided to POs as part of these interactions.

INOVIA strongly supports public scrutiny and understanding of these relationships and the publication of data contributes to stakeholder confidence in the pharmaceutical industry.

In relation to working with HCPs and HCOs, since the introduction of the INOVIA Code, this association has worked to encourage Member Companies to always strive to disclose and encourage HCPs (and POs where relevant) to agree to individual disclosure. Member Companies will not be criticized for over-disclosure.

THE SCOPE OF THE INOVIA CODE

The INOVIA Code covers:

- Promotion of prescription-only medicines to HCPs,
- Interactions between Member Companies and HCPs, HCOs and POs;
- Disclosure of ToVs from Member Companies to HCPs, HCOs and POs; and
- Procedural requirements of the **INOVIA** Code.

Member Companies are responsible for the obligations imposed in accordance with any relevant Applicable Code, even if they engage a Third Party to design, implement or participate on their behalf in activities covered by the Applicable Code. In addition, Member Companies must take reasonable steps to ensure that all parties engaged in designing, implementing or participating in activities covered by the Applicable Code but not acting on behalf of the Member Company (e.g. joint ventures, licensees) comply with the Applicable Codes.

The **INOVIA** Code covers all methods of Promotion, including, but not limited to, oral and written promotional activities and announcements, advertising in magazines and by direct mail, 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 includes the provision of Informational or Educational Materials, Items of Medical Utility, hospitality in relation to Events and Medical Samples.

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

The **INOVIA** Code does not cover:

- The labelling of Medicinal Products and accompanying materials, which are subject to the provisions of Chapter V of Directive 2001/83/EC;
- Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a particular question about a particular Medicinal Product;
- Factual, informational announcements and reference materials relating, for example, to changes in packaging, adverse reaction warnings as part of general precautions, trade catalogues and price lists, provided that they include no product complaints;

- Activities related solely to non-prescription Medicinal Products; or
- Non-promotional, general information about Member Companies (such as information intended for investors or current/future employees), including financial information, descriptions of research and development programmes, and regulatory developments affecting the Member Company and its Medicines.

The following documents are attached to the **INOVIA** Code and are binding for **INOVIA** members:

- Annex A — Standardised Disclosure **Template**;
- Annex B — **INOVIA** Guidance;
- Annex C — Guidance Obligations for Member Associations under the EFPIA Code; and

- **Annex F - Implementation and procedure rules**
- **Annex G - Guidance on the meaning of the term**

Additional documents are designed to illustrate the provisions of the **INOVIA** Code and provide explanations for its consistent implementation, namely:

- **INOVIA** Recommendations;
- Examples of ethical principles

THE INOVIA CODE APPLICATION

The **INOVIA** Code sets out the minimum standards that this association considers mandatory.

Member Companies must comply with the Applicable Codes and all laws and regulations in force in the Republic of Serbia.

Non-member associations and companies that choose to voluntarily apply the **INOVIA** Code must require that each of their members, affiliates and subsidiaries, as applicable, comply with all provisions of the **INOVIA** Code.

As a member of the EFPIA, **INOVIA** must establish adequate procedures to ensure that each of its Member Companies meets the requirements of this National Code and any other National Code that may be applicable to its business.

The spirit must be respected, as well as the provisions of the **INOVIA** Code. **INOVIA** also encourages compliance with the document and the spirit of the provisions of the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA") Code, where applicable.

CHAPTER 1
PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO HCPs

ARTICLE 1 MARKETING AUTHORISATION

Section 1.01. The Medicine must not be promoted before obtaining a marketing authorisation that allows sale or supply, or outside the approved indications.

Section 1.02. Promotion must be in accordance with the information given in the summary of the product characteristics.

ARTICLE 2 PUBLICLY ACCESSIBLE INFORMATION

Section 2.01. In accordance with the applicable national laws and regulations, all promotional material must clearly and legibly contain the following information:

- Essential information in accordance with the summary of product characteristics. The required minimum includes the following information: trademark, international non-proprietary name (INN), name and address of the marketing authorisation holder, date of the last revision of the summary of product characteristics, including the sentence that detailed information is available in the full summary of product characteristics, the sentence that promotional material is intended only for the professional public, reference number and date of approval of the promotional material (for materials that require the approval of the Agency for Medicines and Medical Devices of Serbia);
- An updated, relevant and accurate list of references;
- Where appropriate, the selling price or indicative price of different formulations and the conditions for reimbursement from compulsory health insurance funds.

Section 2.02. In accordance with the applicable national laws and regulations, where the purpose of advertising is to serve only as a reminder, the requirements of Section 2.01 above need not be met, provided that the promotional material contains only the trademark or its international non-proprietary name (INN), and the name of the company/ marketing authorisation holder.

ARTICLE 3 PROMOTION AND SOURCES OF INFORMATION

Section 3.01. Promotion must be accurate, balanced, fair, objective and complete enough to enable HCPs to form their opinion on the therapeutic value of the Medicine in question. It must be based on an updated assessment of all relevant evidence and clearly reflect that evidence. It must not mislead by distorting information, exaggerating, unnecessarily emphasizing, omitting or in any other way.

Section 3.02. Promotion must be such that it can be argued and quickly made available at the request of the HCP. In particular, promotional claims concerning adverse reactions must reflect the available evidence or be justified by clinical experience. However, no justification is required as to the validity of the information approved in the marketing authorisation.

Section 3.03. Promotion must encourage the rational use of Medicines by presenting them objectively and without exaggeration. Claims must not imply that the Medicine, or active ingredient, has special properties, qualities or characteristics, unless it can be proven.

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

Section 3.05. Any comparison between different Medicines must be based on relevant and comparable aspects of the given Medicines. Comparative advertising must not lead to a wrong conclusion or be offensive.

Section 3.06. All visual material, including graphs, illustrations, photographs and tables taken from published studies and included in promotional material must: (a) clearly indicate the exact source(s) of that material; (b) be faithfully reproduced, except where it needs to be adapted or modified to comply with the Applicable Code(s), in which case it must be clearly stated that the visual material has been adapted and/or modified.

Special care must be taken to ensure that the visual material included in the Promotion does not mislead about the nature of the Medicine (for example, whether it is suitable for use in children) or to lead to an erroneous conclusion based on a claim or comparison (for example, using incomplete or statistically irrelevant information or unusual scales).

Section 3.07. The word “safe” should never be used to describe a Medicine without proper qualifications.

Section 3.08. The word “new” should not be used to describe any Medicine or Medicine formulation that is available in principle, or any therapeutic indication being promoted, for more than one year.

Section 3.09. It should not be stated that the Medicine has no side effects, toxic hazards or risk of addiction or dependency.

ARTICLE 4 USE OF QUOTATIONS IN PROMOTION

Quotations from medical and scientific literature or from personal communication must be faithfully reproduced (except in cases where they need to be adapted or modified to comply with each Applicable Code(s), in which case it must be clearly stated that the quotation has been adapted or modified) with precise source identification.

ARTICLE 5 ACCEPTABILITY OF PROMOTION

Member Companies must maintain high ethical standards at all times. Promotion:

(a) Must never discredit or diminish confidence in the pharmaceutical industry;

(b) Must respect the special nature of Medicines and the professional title of those for whom they are intended; and

(c) must not be offensive.

ARTICLE 6 DISTRIBUTION OF PROMOTIONAL MATERIAL

Section 6.01. A promotion must only be directed at those HCPs whose need or interest in certain information can be logically assumed.

Section 6.02. The list of mail recipients must always be updated. Requests for deletion from the list of mail recipients must be respected.

Section 6.03. In accordance with the applicable national laws and regulations, the use of fax, e-mail, automated calling systems, text messages and other digital communication for promotional purposes is prohibited, except with prior permission or at the request of those receiving it.

ARTICLE 7 TRANSPARENCY OF PROMOTION

Section 7.01. Promotion must not be disguised.

Section 7.02. Clinical assessments, post-marketing surveillance programmes and post-marketing experience and studies (including those of a retrospective nature) must not constitute disguised promotion. Such assessments, programmes and studies must be conducted primarily for scientific or educational purposes.

Section 7.03. When a Member Company pays for or otherwise provides or organises the publication of promotional material in journals, such promotional material must not resemble independent editorial material.

Section 7.04. Material relating to Medicines and their use, whether promotional or not, sponsored by a Member Company must clearly indicate that it is sponsored by that Member Company.

ARTICLE 8 PROMOTIONAL INFORMATION PROVIDED DURING INTERNATIONAL EVENTS

Promotional information that appears on exhibition stands or is communicated to participants in international Events may, unless prohibited or otherwise regulated by local laws and regulations, refer to Medicines (or their use) that are not registered in the country where the Event takes place, or that are registered under different conditions, provided that: (i) each such promotional material is accompanied by an appropriate statement indicating the countries in which the Medicine is registered and clearly stating that the Medicine or indication is not registered locally, and (ii) any such promotional material refers to information on prescribing (indications, warnings, etc.) that is approved in the country or countries in which the Medicine is registered must be accompanied by an explanation indicating that the conditions of registration vary from country to country.

ARTICLE 9 PERSONAL MEDICAL MATTERS

In case of requests from individual members of the general public for advice regarding personal medical matters, the person asking the question must be advised to contact the HCP.

CHAPTER 2
INTERACTION WITH HCPs, HCOs and POs

ARTICLE 10 EVENTS AND HOSPITALITY

Section 10.01. All Events must be held at "appropriate" Locations and Venues that are suitable for the main purpose of the Event, avoiding those that are "renowned" for their entertainment or are "extravagant".

Section 10.02. No Member Company may organise or sponsor an Event held outside its country unless:

- The majority of the invited participants are outside their country and if, taking into account the countries of origin of the majority of the invited, it is logistically reasonable to hold the Event in another country; or
- Taking into account the Location or expertise that is the goal or subject of that meeting, it makes more logistical sense to hold the Event in another country.

Section 10.03. Member Companies may only offer hospitality when that hospitality is appropriate and otherwise complies with the provisions of the Applicable Codes.

Section 10.04. Hospitality in connection with the Events must be limited to travel expenses, meals, accommodation and registration fees.

Section 10.05. Member Companies may not provide or offer any meals (food and drink) to HCPs, members of HCOs or representatives of POs, unless, in any case, the value of such a meal exceeds the monetary threshold set by the relevant Member Association in its National Code (according to the "Host Country Principle"). In the Republic of Serbia, the maximum value is set at 60 euros (including VAT), in the local currency, at the middle exchange rate of the National Bank of Serbia on the day of the transaction.

Section 10.06. Hospitality can only apply to persons who qualify as participants in the meeting. In exceptional cases of identified health needs (e.g. disability or injury), it is also permitted to cover the costs of travel, food, accommodation and registration fees of an accompanying person.

Section 10.07. All forms of hospitality offered to HCPs, members of HCOs or representatives of POs must be "reasonable" at the level of the Event and strictly limited to the main purpose of the Event. As a general rule, the hospitality provided should not exceed what these individuals would normally be willing to pay for themselves.

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

ARTICLE 11 PROHIBITION OF GIFTS

Section 11.01. Gifts for the personal benefit (such as tickets for sports or entertainment activities, gifts as a result of social courtesy) of HCPs, members of HCOs or representatives of POs (directly or indirectly) are prohibited.

It is also forbidden to give or offer cash, cash equivalents or personal services. For these purposes, personal services are any type of service that is not related to the profession and that provides personal benefit to the Recipient.

Section 11.02. A promotional aid is a non-monetary item given for promotional purposes (which does not include promotional materials as defined in Chapter 1). The provision or offer of such items to HCPs, members of HCOs or representatives of POs in connection with the promotion of Prescription-Only Medicines 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 or POs are only permitted if: (i) given for the purpose of supporting health, research or education; (ii) documented and recorded by the donor/grantor; and (iii) not providing an incentive to recommend, prescribe, purchase, procure, sell or administer certain Medicines.

Section 12.02. Donations and grants to individuals are not allowed. The Contribution to Costs Related to Events for HCPs that will attend the international Events is covered by Article 13.

ARTICLE 13 CONTRIBUTION TO THE COST OF EVENTS AND SPONSORSHIP

Section 13.01. Member Companies must adhere to the criteria for the selection and support of HCP or PO representatives who will attend the Events as provided, or in connection with any Applicable Code. No payment may be offered to compensate only for the time spent by an HCP or a PO representative attending the Events.

Section 13.02. Public use of the HCO or PO logo or protected material by a Member Company requires the written permission of that organisation. In requesting such permission, the specific purpose and manner of use of the logo or protected material must be clearly indicated.

Section 13.03. Member Companies must ensure that their Sponsorship of HCOs and POs is always clearly recognised and obvious from the outset.

ARTICLE 14 MEMBER COMPANY FUNDING

No Member Company may claim to be the sole funder or sponsor of a PO or HCO or any of their programmes.

Member Companies support the 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 and PO Representatives under which they provide any type of services to Member Companies (not otherwise covered by the Code) are only permitted if those services are: (i) provided for the purpose of providing support to health, research or education; (ii) such that they do not provide an incentive to recommend or prescribe, purchase, procure, sell or administer certain Medicines.

Section 15.02. It is permitted to contract HCP or PO Representatives as consultants, either in groups or individually, for services such as speaking at meetings or conducting meetings, engaging in medical/scientific studies, clinical trials or training services, participating in advisory board meetings, and participation in market research where such participation includes compensation or hospitality. Projects covering these actual consulting or other services must, to the extent relevant to the arrangement, meet all of the following criteria:

a. A written contract must be signed in advance before the start of the services setting out the nature of the services provided and, in accordance with Item (g) below, the basis for payment for those services;
b. A legitimate need for services must be clearly identified and documented before seeking services and making arrangements;
c. The criteria for selecting consultants must be directly related to the identified need, and the persons responsible for selecting consultants must have the expertise necessary to assess whether a particular consultant meets those criteria;
d. The number of consultants and the scope of the service may not exceed what is reasonably necessary to achieve the identified need;
e. The company must keep records relating to the services provided by the consultants and use them appropriately;
f. Hiring a consultant to provide a relevant service should not be an incentive to recommend or prescribe, purchase, procure, sell or administer a particular Medicine;
g. The fee for the services must be reasonable and reflect the fair market value of the services provided. In this regard, the undertaken consulting arrangements must not be used to justify compensation for HCPs or PO Representatives.

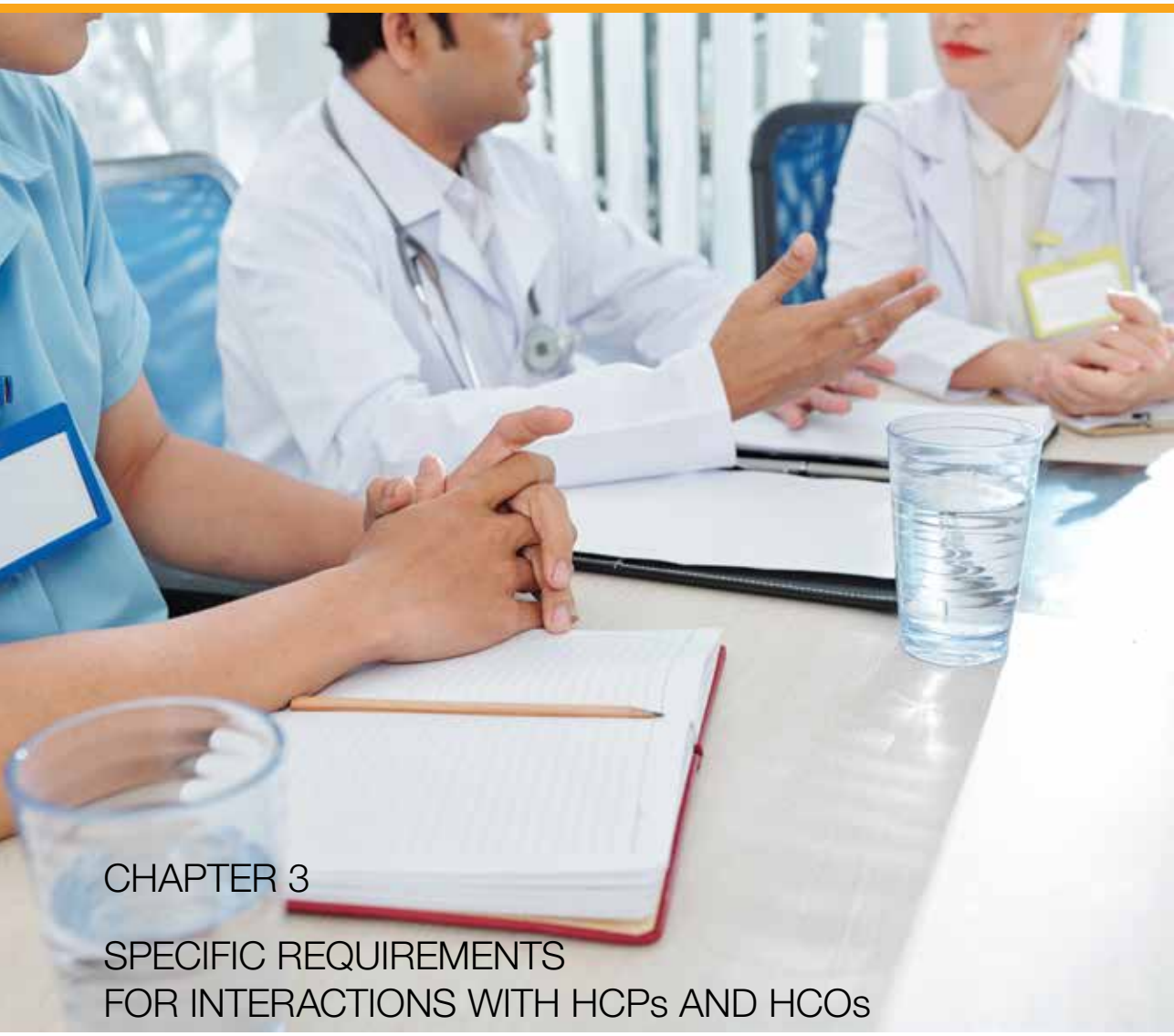
Section 15.03. In their written contracts with consultants, Member Companies are strongly encouraged to include provisions relating to the obligation of consultants to declare that they are consultants to a Member Company whenever they write or speak in public about the subject of the contract or any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

Similarly, Member Companies that employ, on the basis of contracts, HCPs who are still practising their profession, are strongly encouraged to ensure that such persons have an obligation to disclose their employment contracts in the Member Company whenever they write or speak in public about the subject of employment or any other matter relating to that Member Company. The provisions of this Section 15.03 apply even though the INOVIA Code does not cover otherwise non-promotional, general information about Member Companies (as explained in the "INOVIA Code Scope" section).[8]

Section 15.04. Limited market research, such as one-off telephone interviews or questionnaires by mail/e-mail/internet, is excluded from the scope of this Article 15, provided that the HCP, HCO member or PO Representative is not consulted repeatedly (either with respect to call frequency in general or to calls related to the same research) and that the remuneration is minimal.

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

8 - Companies are strongly encouraged to include such provisions in any contracts covered by this Section 15.03.



CHAPTER 3

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HCPs AND HCOs

ARTICLE 16 MEDICAL EDUCATION

Medical education aims to increase the scientific knowledge and competencies of HCPs in order to improve medical practice and improve the outcome of treatment of patients.

Member Companies may be engaged in different types of Medical Education, but such activities may not constitute a Promotion.

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

When organising Medical Education activities in which Member Companies participate in the preparation of 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 different 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 if the material is: (i) "inexpensive"; (ii) directly relevant to medical or pharmaceutical practice; and (iii) directly useful for patient care.

Section 17.02. Items of Medical Utility that are directly focused on HCP education and patient care can be provided if they are "inexpensive" and do not compensate for the routine business practices of those who receive them.

Section 17.03. The nature of Informational or Educational Materials and Items of Medical Utility may not constitute a circumvention of the prohibition on giving gifts as defined in Article 11 of this Code. The provision of such materials or items should not be an incentive to recommend or prescribe, purchase, procure, sell or administer a particular Medicine.

Section 17.04. Informational or Educational Materials and Items of Medical Utility may include the name of the Member Company, but may not be product branded, unless the name of the Medicine is necessary for the proper use of the material or item by the patient.

ARTICLE 18 NON-INTERVENTIONAL STUDIES

Section 18.01. Non-interventional studies must be conducted primarily for scientific purposes and must not constitute a disguised Promotion.

Section 18.02. Non-interventional studies that are prospective in nature and involve the collection of patient data from or on behalf of individuals or groups of HCPs specifically for the study must meet all of the following criteria:

a. There must be a written study plan (protocol);

b. The study protocol must be submitted to the ethics committee for approval;

c. The study protocol must be approved by the scientific department of the Member Company and the conduct of the study must be supervised by the scientific department of the Member Company, as described in Section 20.01.a;

d. The results of the study must be analysed by or on behalf of the Member Company and a summary of the results must be available within a reasonable period of time to the scientific department of the Member Company (as described in Section 20.01.a), which must keep records of such reports. The Member Company must send a summary report to all HCPs that participated in the study and must submit a summary report to the industry self-regulatory bodies or boards in charge of

monitoring or implementing the Applicable Codes at their request. If the study shows results that are relevant to the benefit-risk assessment, the summary report must be forwarded immediately to the relevant competent authority;[9] and

e. Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be supervised by the scientific department of the Member Company, which will also ensure that Medical Sales Representatives are adequately trained. Such participation must not be associated with the Promotion of any Medicine.

Section 18.03. To the extent possible, 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 in exceptional cases. Giving Medical Samples should not be an incentive to recommend or prescribe, purchase, procure, sell or administer a particular Medicine, and they should not be given solely for the purpose of treating patients.

Medical Samples are given to HCPs in order to get acquainted with the Medicine and gain experience in working with it.

In accordance with national law, a limited number of Medicines may be delivered in exceptional cases and for a limited period. In the Republic of Serbia, the provision of free samples is limited to one of the smallest packages of a Medicine during one calendar year, solely to HCPs who prescribe or administer such a Medicine.

Section 19.02. Member Companies must have adequate control and accountability systems for the samples they distribute and for all the Medicines handled by their Medical Sales Representatives. This system must also clearly determine, for each HCP, the number of Medical Samples submitted, applying the provisions of Section 19.01.

Section 19.03. Each sample must be marked “free medical sample - not for sale” and must be accompanied by a copy of the summary of product characteristics. The Healthcare Professional is obliged to sign the receipt of the sample.

ARTICLE 20 MEMBER COMPANY STAFF

Section 20.01. All Member Company Staff must be fully familiar with the relevant requirements of the Applicable Codes and laws and regulations.

a. Each Member Company must establish a scientific department in charge of information concerning its Medicines and the approval and supervision of NISes. Member Companies are free to decide how best to establish such departments in accordance with this Section 20.01 (i.e. whether there will be one department

9 - Member companies are encouraged to disclose the summary data and results of NISes in the way they are required to do in relation to interventional clinical studies

in charge of both obligations or separate departments with clearly delineated obligations), taking into account their own resources and organisation. The scientific department must include a doctor of medicine or, where appropriate, a pharmacist who will be responsible for approving any promotional material prior to publication. Such a person must certify that they have examined the final form of the promotional material and that, in his/her opinion, it complies with the requirements of the Applicable Codes and all the relevant laws and regulations, complies with the summary of product characteristics and represents a fair and true account of the Medicine. In addition, the scientific department must include a doctor of medicine or, where appropriate, a pharmacist who will be responsible for supervising any NIS (including an overview of all responsibilities relating to such studies, in particular with regard to any responsibilities assumed by Medical Sales Representatives). Such a person must certify that they have examined the NIS protocol and that, in his/her opinion, it complies with the requirements of the Applicable Codes and all relevant laws and regulations.

b. Each Member Company must appoint at least one senior official who must be responsible for overseeing the Member Company and its subsidiaries to ensure that the standards of the Applicable Codes are met.

Section 20.02. Each Member Company must ensure that its Medical Sales Representatives are familiar with the relevant requirements of the Applicable Codes and all applicable laws and regulations, and that they are adequately trained and have sufficient scientific knowledge to be able to provide accurate and complete information on the Medicines they promote.

a. Medical Sales Representatives must comply with all the relevant requirements of the Applicable Codes and all applicable laws and regulations, and Member Companies are responsible for ensuring their compliance.
b. Medical Sales Representatives must fulfil their duties responsibly and ethically.
c. During each visit, in accordance with the applicable laws and regulations, the Medical Sales Representative must give the persons visited, or have available for them, a summary of the product characteristics for each Medicine that they represent.
d. Medical Sales Representatives must immediately submit to the scientific departments of their companies all information that they receive regarding the use of their company's Medicines, especially reports of side effects.
e. Medical Sales Representatives must ensure that the frequency, time and duration of visits to health centres, pharmacies, hospitals or other healthcare institutions, together with the manner in which they are conducted, do not interfere with their work.
f. Medical Sales Representatives must not use any incentive or excuse to get an interview. In an interview, or when seeking an appointment for an interview, Medical Sales Representatives must, from the outset, take reasonable steps not to mislead anyone about their identity or the identity of the Member Company they represent.

CHAPTER 4
SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs

ARTICLE 21 INTERACTIONS WITH POs

Section 21.01. INOVIA Member Companies must respect the following principles adopted by the EFPIA together with the pan-European POs:

- The independence of POs must be ensured, in terms of their political views, guidance and activities.
- All interactions between POs and Member Companies must be based on mutual respect, with the views and decisions of each partner having equal value.
- Member Companies may not request, nor will POs conduct, the Promotion of a particular Prescription-Only Medicine.
- The objectives and scope of any cooperation must be transparent. Financial and non-financial support provided by Member Companies must always be clearly identified.
- Member Companies support the broad funding of POs from multiple sources.

Section 21.02. The EU and national laws and regulations prohibit the advertising of promotions of Prescription-Only Medicines in public.

Section 21.03. When Member Companies provide financial support, significant indirect support or significant non-financial support to POs, they must have a written agreement. It must indicate the amount of funding and the purpose (e.g. unlimited grant, special meeting or publication, etc.). It must also include a description of significant indirect support (e.g. a donation from a public relations agency and the nature of its participation) and significant non-financial support.

Section 21.04. Member Companies must not influence the text of PO materials that they sponsor in a way that suits their commercial interests. This does not prevent Member Companies from correcting inaccuracies in the facts. In addition, at the request of the PO, Member Companies may contribute to the production of the text from a fair and balanced scientific perspective.

CHAPTER 5
DISCLOSURE OF TRANSFERS OF VALUE FROM MEMBER COMPANIES

ARTICLE 22 Disclosure of ToVs to HCPs, HCOs and POs

Time of disclosure

Disclosure shall be made by each Member Company within 6 months of the end of the relevant Reporting Period and the information to be disclosed must remain in the public domain for at least 3 years after such information was first disclosed, except, in any case, if (i) a shorter period is required under applicable national laws or regulations, or (ii) the relevant legal basis for data protection (e.g. legitimate interests, legal obligation or consent of the Recipient in connection with a particular disclosure) is no longer applicable.

The usual reporting period for reporting on ToVs to Recipients is set in the time interval from 20 to 30 June each year.

ARTICLE 23 DISCLOSURE OF ToVs TO HCPs AND HCOs

Section 23.01. Rationale

The following article provides for the disclosure of ToVs to HCPs and HCOs, either directly or indirectly. When deciding how to disclose ToVs, Member Companies should, whenever possible, identify and publish data for each individual HCP (not HCO), as long as this can be achieved with precision, consistency and in accordance with the applicable laws and regulations.

Section 23.02. Disclosure obligation

General obligation. In accordance with the provisions of this Article, each Member Company must document and publish information on the ToVs it performs, directly or indirectly, to or for the benefit of the Recipient, as described in more detail in Article 23.04.

Exceptions to disclosure Without limitation are ToVs that (i) relate solely to over-the-counter Medicines; (ii) are not listed in Section 23.04 of this Article, such as Items of Medical Utility (in accordance with Article 17), meals (in accordance with Article 10, especially Section 10.05) or Medical Samples (in accordance with Article 19); or (iii) are part of the usual purchases and sales of Medicines by and between the Member Company and HCPs (such as a pharmacist) or HCOs do not fall within the scope of the disclosure obligation described above in the “General Obligation” section.

Section 23.03. Form of disclosure

Annual disclosure cycle. Disclosures must be made on an annual basis and each Reporting Period must cover a full calendar year.

Template Subject to the "Platform of Disclosure", for the sake of consistency, disclosures in accordance with this Article shall be made through the structure listed in Annex A as a reference, reflecting the requirements of this Article.

Platform of Disclosure. Disclosure may be made in one of the following ways, provided that it is unrestricted and publicly available:

- On the website of the relevant Member Company in accordance with the section "Applicable National Code"; or
- On a central platform, such as that provided by the relevant government, regulatory or professional body or authority or the Member Association, provided that disclosure made on a central platform developed at the initiative of the Member Associations is carried out as far as possible using the structure set out in the Annex A as a reference

Applicable National Code. Disclosure must be in accordance with the National Code of the country in which the Recipient has their professional address. If the Member Company is not a resident or does not have a subsidiary or affiliate in the country where the Recipient has their physical address, the Member Company must disclose the ToVs in a manner consistent with the relevant National Code.

Language of Disclosure. Disclosure must be in the language(s) prescribed by the National Code by the relevant Member Association. Member Companies are invited to disclose in English in addition to the mandatory disclosure in the local language (if not English). In the Republic of Serbia, disclosure is done in Serbian.

Documentation and Retention of Records. Each Member Company shall document all ToVs required to be disclosed in accordance with Section 23.02 and keep relevant disclosure records in accordance with this Article for at least 5 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national laws or regulations.

Section 23.04. Individual and Aggregate Disclosure

Individual Disclosure. Except as expressly provided in this Article, ToVs must be disclosed on an individual basis. Each Member Company shall disclose, on an individual basis, for each clearly identified Recipient, the amounts attributed to the ToVs for that Recipient in each Reporting Period that may reasonably be allocated to one of the categories below. Such ToVs may be aggregated on the basis of categories, provided that the said disclosures must be made available upon request to (i) the relevant Recipient or (ii) the competent authorities.

- For ToVs to HCOs, the amount relating to any of the following categories:

Donations and grants. Donations and grants to HCOs that support health care, including donations and grants (either in cash or in kind) to institutions, organisations or associations that consist of HCOs or provide health care (in accordance with Article 12).

Contribution to the cost of Events. Contribution to the cost of Events, through HCOs or Third Parties[10], including support for HCPs to attend the Event, as follows:

- Registration fees;
- Sponsorship Agreements with HCOs or with Third Parties appointed by the HCO to manage the Event; and
- Travel and accommodation (to the extent regulated by Article 10).

Fees for services and consultancy. ToVs arising from or in connection with contracts between Member Companies and HCOs, under which the HCO provides any type of service to a Member Company or any other form of financing not covered by the preceding categories. Fees, on the one hand, and, on the other, ToVs relating to costs agreed in a written contract providing for an activity, will be disclosed as two separate amounts.

◊ For ToVs to HCPs:

Contribution to the cost of Events. Contribution to the cost of Events, such as:

- Registration fees; and
- Travel and accommodation (to the extent regulated by Article 10).

Fees for services and consultancy. ToVs arising from or in connection with contracts between Member Companies and HCPs, under which the HCP provides any type of service to a Member Company or any other form of financing not covered by the preceding categories. Fees, on the one hand, and, on the other, ToVs relating to costs agreed in a written contract providing for an activity, will be disclosed as two separate amounts.

Aggregate Disclosure. For ToVs where certain information, which can otherwise reasonably be attributed to one of the categories listed in Section 23.04, cannot be disclosed on an individual basis for legal reasons, the Member Company must disclose the amounts attributable to such ToVs in each Reporting Period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such a disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the total amount attributable to ToVs to such Recipients.

Non-duplication. When a ToV that must be disclosed in accordance with Section 23.04 is made to an individual HCP indirectly through the HCO, that ToV must be disclosed only once. To the extent possible, such a disclosure must be made at the level of the individual designated HCP in accordance with Section 23.04.

Research and Development Transfers of Value. ToVs in the field of research and development must be disclosed by all Member Companies on an aggregate basis.

10 - Compare Guidance of Indirect ToVs through Third Parties - Support for / Sponsorship of Events through professional conference organisers in Annex B

Costs related to Events that are clearly related to the activities covered by this section may be included in the total amount under the category "Research and Development Transfers of Value".

Methodology. Each Member Company must publish a note summarising the methodologies it used in preparing the disclosure and identifying the ToVs for each category described in Section 23.04. The note, which includes a general summary 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 amount of ToVs for the purposes of this Article, as applicable.

ARTICLE 24 DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO POs

Each Member Company must publish a list of POs to which it provides financial support or significant indirect/non-financial support or that it has engaged to provide contracted services to that Member Company.

This disclosure must include a description of the nature of the support or services provided that is comprehensive enough to enable the average reader to understand the nature of the support or arrangement without the need to disclose confidential information. In addition to the PO name, the following elements must be included:

◊ For support:
- The monetary value of financial support and invoiced costs.
- Non-monetary benefit received by a PO when non-financial support cannot be attributed to significant monetary value.

◊ For contracted services: the total amount paid per PO during the Reporting Period.

This information must be published on the website of the Member Company or at national or European level on an annual basis and each Reporting Period covers the entire calendar year.

Methodology. Each Member Company must publish the methodologies it has used in preparing the disclosure and identifying the support and services provided.

CHAPTER 6
LEGAL REQUIREMENTS

ARTICLE 25 APPLICATION

Application in Member Associations

Member Associations must, in accordance with the applicable laws and regulations, implement the provisions of the EFPIA Code. If a violation is established in accordance with the procedures of its National Code, INOVIA will require the company that violated the provision to immediately cease the offending activity and to sign and undertake to prevent a recurrence.

INOVIA has adopted Implementation and Procedure Rules (as detailed in Article 28), which are binding on its members, and has established a framework for the implementation of this Code, the handling of complaints and the enforcement of sanctions, in a manner consistent with the applicable laws and regulations on data protection, competition and others.

ARTICLE 26 AWARENESS AND EDUCATION

Member Associations must, in accordance with the applicable laws and regulations, raise the awareness and education of companies about the EFPIA Code, including by providing guidance to companies in order to prevent violations of National Codes.

ARTICLE 27 IMPLEMENTATION AND PROCEDURE RULES

The implementation and procedure rules set out herein set the framework for the implementation of the INOVIA Code, the handling of complaints and the initiation or application of sanctions by Member Associations.

Implementation by Member Associations. Each Member Association is obliged to:

a. Establish national procedures and structures for receiving and processing complaints, establish sanctions and publish appropriate details in this regard, including, at a minimum, the national body of the Member Association designated to deal with complaints, consisting of a non-industry chair and, in addition to industry, membership composed of other stakeholders;

b. Ensure that its National Code, together with administrative procedures and other relevant information, is easily accessible through, at a minimum, the publication of the National Code on its website;

c. Prepare and submit to the EFPIA Code Committee (hereinafter defined) an annual report summarising the work it has done in relation to the implementation, development and enforcement of its National Code during the year.

ANNEX A - STANDARDISED

	Full name *(Article 1.01)*	**HCP:** City of principal practice HCO: city where registered *(Article 3)*	Country of principal practice *(Schedule 1)*	Principal practice address *(Article 3)*	Unique country identifier *OPTIONAL* *(Article 3)*	Donations and grants to HCOs *(Article 3.01.1.a)*	C S a HCO appo man
HCP	***INDIVIDUAL DISCLOSURE BY NAME - one line per HCP*** *(i.e. all transfers of value during the year for an individual HCP will be*						
	Dr A					N/A	
	Dr B					N/A	
	etc.					N/A	
	OTHER, NOT INCLUDED ABOVE - where inform						
	Aggregate amount attributable to transfers of value to such Recipients - *Article 3.02*					N/A	
	Number of Recipients in aggregate disclosure - *Article 3.02*					N/A	
	% of the number of Recipients included in the aggregate disclosure of data in the total number, by category, of Recipients disclosed - *Article 3.02*					N/A	
HCO	***INDIVIDUAL DISCLOSURE BY NAME - one line per HCO*** *(i.e. all transfers of value during the year for an individual HCO will be*						
	HCO 1					*Annual amount*	*An*
	HCO 2					*Annual amount*	*An*
	etc.					*Annual amount*	*An*
	OTHER, NOT INCLUDED ABOVE - where inform						
	Aggregate amount attributable to transfers of value to such Recipients - *Article 3.02*					*Aggregate HCOs*	
	Number of Recipients in aggregate disclosure - *Article 3.02*					*Number*	
	% of the number of Recipients included in the aggregate disclosure of data in the total number, by category, of Recipients disclosed - *Article 3.02*					%	

R & D	***AGGREG***
	Transfers of Value for Re as defined - Article 3.04 anc

Latest update: 27 June 2019

DISCLOSURE TEMPLATE

ontribution to the costs of Events *(Articles 3.01.1.b & 3.01.2.a)*			Fees for service and consultancy *(Article 3.01.1.c & 3.01.2.c)*			
Sponsorship greements with Os/Third Parties ointed by HCO to nage the Event	Registration fees	Travel and accommod ation	Fees	Related expenses agreed in the fee for service and consultancy, including travel and accommoda tion relevant to the contract		**TOTAL** *OPTIONAL*
e summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)						
N/A	*Annual amount*	*Annual amount*	*Annual amount*	*Annual amount*		
N/A	*Annual amount*	*Annual amount*	*Annual amount*	*Annual amount*		
N/A	*Annual amount*	*Annual amount*	*Annual amount*	*Annual amount*		
mation cannot be disclosed on an individual basis for legal reasons						
N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*		*Optional*
N/A	*Number*	*Num ber*	*Num ber*	*Number*		*Optional*
N/A	%	%	%	%		N/A
summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)						
nual amount	*Annual amount*	*Annual amount*	*Annual amount*	*Annual amount*		*Optional*
nual amount	*Annual amount*	*Annual amount*	*Annual amount*	*Annual amount*		*Optional*
nual amount	*Annual amount*	*Annual amount*	*Annual amount*	*Annual amount*		*Optional*
mation cannot be disclosed on an individual basis for legal reasons						
Aggregate HCOs	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*		*Optional*
Number	*Number*	*Num ber*	*Num ber*	*Number*		*Optional*
%	%	%	%	%		N/A
ATE DISCLOSURE						
					TOTAL AMOUNT	*OPTIONAL*

ANNEX B (binding)
INOVIA Guidance

GUIDANCE ON THE DISCLOSURE OF NON-INTERVENTIONAL STUDIES

Background

In the application of the **INOVIA** HCP/HCO Disclosure Code, the exemption on the individual reporting of ToVs related to non-interventional studies (NISes) is limited to NISes that are prospective in nature. The Code stipulates that retrospective NISes must be reported on the basis of individual names, in accordance with the applicable codes.

Member Companies have informed the EFPIA that it is not always possible to distinguish between ToVs relating to prospective (included in the aggregate reporting on ToVs in the field of R&D) and retrospective (reported on an individual basis) NISes.

The Ethics and Compliance Committee believes that the definitions in the new EU Clinical Trials Regulation 536/2014[11] can be used as a reference for the implementation of disclosure requirements, anticipating regulatory changes over time and achieving alignment with them.

On 13 June 2017, the EFPIA Board approved the Guidance on the disclosure of all NISes on an individual basis if ToVs relating to prospective and retrospective non-interventional studies cannot be distinguished.

This Guidance provides a basis for distinguishing between prospective and retrospective NISes and aims to ensure consistency in the disclosure of NIS-related ToVs.

Relevant provision of the INOVIA Disclosure Code

Schedule 1: Definition of terms

Research and Development Transfers of Value - Transfers of value to HCP and HCO related to the planning or implementation of (i) non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice); (ii) clinical trials (as defined in Regulation No. 536/2014[12]); or (iii) **non-interventional studies that are prospective in nature** and involve the collection of patient data from or on behalf of individuals or groups of HCPs specifically for the study (Section 15.01 of the HCP Code).

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11 - The date of application of the new Clinical Trials Regulation 536/2014 depends on the development of the IT system "EU Clinical Trial Portal and Database". At this moment, the "start date of implementation" is expected in the second half of 2019. The date of the effective implementation of the Regulation will not change the definitions, and these definitions are considered an appropriate reference for the consistent application of the provisions related to the disclosure of ToVs related to NISes.
12 - In the INOVIA HCP/HCO Disclosure Code, the definition of Research and Development ToVs refers to the EU Directive 2001/20/EC on Clinical Trials. This legal instrument has been replaced by EU Regulation No. 536/2014. The definition in the INOVIA HCP/HCO Disclosure Code will refer to the updated regulatory provisions.

Guidance

Transfers of values related to non-interventional studies (NISes) that are not within the definition of R&D ToVs according to the **INOVIA** Disclosure Code must be reported on an individual basis by name. In this regard, prospective and retrospective NISes will be considered in accordance with the classification in the table below:

PROSPECTIVE NIS	RETROSPECTIVE NIS
Prospective cohort studies in which Medicine prescribing is independent of patient inclusion in the study A retrospective study in which a prospective element is subsequently introduced Long-term extension studies with patient follow-up after a certain period of time for the purpose of observation and the active collection of additional data	Review or research of the database only for the purposes of observation A retrospective review of records where all events of interest have already occurred ◊ e.g. case control, cross-sectional and purely retrospective cohort studies Studies in which the person prescribing the Medicine later becomes an Investigator, provided that the prescription has already taken place ◊ e.g. retrospective collection of data from individual medical records at the investigator's site

For the sake of clarity, activities that do not fall within the definition of R&D ToVs, including NISes that are not carried out to maintain a marketing authorisation (in application and following the definition of the Clinical Trials Regulation 536/2014), will be reported as "service/consultancy fees".

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

This Guidance will apply to the 2018 ToVs at the latest (reported in 2019).

DISCLOSURE OF INDIRECT TRANSFERS of VALUE THROUGH THIRD PARTIES SUPPORT TO / SPONSORSHIP OF EVENTS THROUGH PROFESSIONAL CONFERENCE ORGANISERS (PCOs)

Background

Third parties[13] provide support to Member Companies in various capacities, more or less influencing the performance of activities regulated by the INOVIA Codes. Such activities may be disclosed as indirect transfers of value (ToVs) in accordance with the provisions of the INOVIA Disclosure Code. When Member Companies provide support for / sponsorship of PCOs involved in the organisation of scientific Events, it is understood that the intention of the Member Companies is to provide support to HCP/HCO at arm's length.

Indirect ToVs are those performed on behalf of the Member Company for the benefit of the Recipient, or ToVs performed through an intermediate and where the Member Company knows or can identify the HCP/HCO who will benefit from the ToV[14].

Given the multiple ways in which cooperation with third parties can be contracted, it may not be exactly easy to fully disclose this information using the INOVIA Disclosure Code. As this may lead to insufficient ToV disclosure through third parties, additional Guidance aims to provide a consistent approach to improved disclosure wherever possible in accordance with the applicable laws and regulations.

This Guidance clarifies the process of reporting on Indirect ToVs to HCOs made through the Professional Congress Organiser (PCO[15]).

Given the legal issues that may arise in the process of reporting ToVs through the Distributor on behalf of the Member Company, reporting such ToVs is not within the scope of this Guidance. Where appropriate, INOVIA may consider further Guidance for this category (and other categories of third parties involved) of ToVs.

Relevant provision of the INOVIA

Disclosure Code Section 3.01.1.b

Contribution to costs related to Events, through HCOs or third parties, including the sponsorship of HCPs to attend the Events, must be reported individually under the name of the Recipient; such costs may relate to:

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13 - Third parties as legal entities or individuals that represent the company on the market or interact with other third parties on behalf of the company or in relation to the company's product. Among other things, these third parties may be distributors, travel agencies, consultants and contract research organisations. This Guidance applies to PCOs as third parties involved in Events involving HCOs.

14 - The definition of an indirect ToV in INOVIA's HCP/HCO Disclosure Code Schedule 1

15 - PCO is a company/individual specialised in organising and managing congresses, conferences, seminars and similar events (under the common name "Events"). For the application of this Guidance, commercial companies involved in the organisation of travel (travel agencies) or accommodation (hotels, banquet departments in hotels, etc.) are not considered PCOs.

◊ Registration fees;
◊ Sponsorship Agreements with HCOs or with Third Parties appointed by the HCO to manage the Event; and
◊ Travel and accommodation (to the extent regulated by Article 10 of the **INOVIA** HCP Code).

Schedule 1: Definitions

Indirect Transfers of Value are those performed on behalf of the Member Company for the benefit of the Recipient, or Transfers of Value performed through an intermediate and where the Member Company knows or can identify the HCP/HCO who will benefit from the Transfers of Value.

Guidance

Contribution to Events through the PCOs that would therefore be the Recipient of the ToV must be considered as an indirect ToV.

When a Member Company participates in costs related to Events through the PCO, the following reporting approaches are considered in accordance with the **INOVIA** reporting requirements:

◊ All ToVs for HCOs (either as a Recipient or as a Beneficiary) are classified in the relevant category called HCO.

◊ ToVs through PCOs are reported:

- Either in the name of the benefitting HCO (through including the name of the Recipient PCO), if it is not included in the direct ToVs to HCOs;
- Or in the name of the Recipient PCO (include the name of the benefitting HCO)

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

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

For further clarification, the attached table provides an overview of the support/ sponsorship scenarios for Events through PCOs that can help prepare the reporting process in accordance with this Guidance.

As a reminder, the contribution of costs related to Events paid through third parties in favour of individual HCPs that the Member Company knows must be reported on an individual basis by name, as an Indirect ToV to the HCP.

Further recommendation

INOVIA recommends that Member Companies confirm support/sponsorship for Events through PCOs in written agreements, and encourages them to include provisions regarding the information that PCOs must provide to a Member Company to ensure an appropriate ToV reporting process under the **INOVIA** Disclosure Code.

Member Companies are encouraged to describe the process of collecting information in their Methodological Note, where it must also be stated that the full value of the ToV for the PCO will not be of benefit (in cash or in kind) to the HCO as the PCO may retain a “service fee”.

Further guidance adopted at the national level or required by national laws may supplement this INOVIA Guidance (in such cases, Article 4.03 of the INOVIA Disclosure Code applies).

This Guidance will apply to the 2018 ToVs at the latest (reported in 2019).

Further guidance on ToVs through PCOs

SUPPORT TO / SPONSORSHIP OF EVENTS THROUGH PROFESSIONAL CONFERENCE ORGANISERS (PCOs)

For further clarification, the attached table provides an overview of support/sponsorship scenarios for Events through PCOs that can help prepare the reporting process in accordance with this INOVIA Guidance.

Examples of possible scenarios for support Events

These examples are offered to assist Member Companies in preparing their disclosure reports in the perspective of the optimal reporting on the Events that they sponsor/ support.

Recipient PCO receiving ToV	BENEFICIARY HCP/HCO	DISCLOSURE
PCO on behalf of/in collaboration with HCO	Where the Member Company knows the beneficiary HCP/HCO	Individual disclosure in line with guidance
PCO on behalf of/in collaboration with HCO	**Where the Member Company does not know the beneficiary HCP/HCO**	**When it comes to the disclosure on the basis of an individual named HCP/HCO, the Member Company may consider disclo-sure under the PCO's name with an indication of the area of spe-cialty.**
PCO with the HCO scientific com-mittee	HCO(s) is (are) known to the Member Company	Individual disclosure in line with guidance
PCO with the HCP scientific committee	**HCP(s) is (are) known to the Mem-ber Company**	**Individual disclosure in line with relevant provisions of the INOVIA HCP/HCO Disclosure Code**
PCO developing/organising an Event at its own initiative (inde-pendent event)	Where the Member Company knows the HCP/HCO participating in the Event	Individual disclosure in line with guidance
PCO developing/organising an Event on its own initiative (in-dependent event)	**Where the Member Company does not know the HCP/HCO participating in the Event**	**When it comes to disclosure on the basis of an individual named HCP/HCO, the Member Company may consider disclo-sure under the PCO's name with an indication of the area of specialty.**

Disclosure on the basis of individual names is subject to obtaining appropriate consent; where such consent cannot be obtained, the corresponding ToV will be disclosed at the aggregate level.

ANNEX C (binding)

Guidance Obligations for Member Associations under the EFPIA Code

Member Companies must adhere to the relevant guidance in this Annex or in connection with any Applicable Code.

Article 10 Events and hospitality

The Member Association must establish a monetary threshold in its National Code because otherwise the EFPIA will establish such a threshold instead of the Member Association.

Member Associations must provide guidance on the meaning of the term “reasonable”, as used in Article 10. Member Associations must also provide guidance on “appropriate”,

“renowned” and “extravagant” venues, as used in Article 10.

Article 15 Contracted services

Member Associations must provide guidance on the meaning of the term “minimal”, in accordance with Section 15.03 or in relation to any Applicable Code.

Article 17 Informational or educational materials and items of medical utility

Member Associations must provide guidance on the meaning of the term “inexpensive”, as used in Article 17.

Article 21.03

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

ANNEX D
INOVIA Recommendations

DISCLOSURE "GATEWAY" ON THE WEBSITES OF MEMBER ASSOCIATIONS

Background

In the application of the INOVIA Disclosure Code, ToVs to HCPs/HCOs are reported (in accordance with the applicable laws and regulations) in one of the following forms:

- On the websites of individual Member Companies;
- Through the Association platform, which functions as a "gateway" for individual companies' websites;
- On a multi-stakeholder platform;
- On a government platform.

ANNEX E
Examples of ethical principles.

1. PATIENTS ARE AT THE HEART OF WHAT WE DO, therefore:

- We continue to improve existing treatments and deliver innovative new medicines
- We support the common goal of timely access to medicines
- We maintain a dialogue to better understand the needs of patients
- We work with stakeholders, including research communities, to address healthcare challenges
- We continue to work appropriately with HCPs and others to support their role in treating patients

2. We act with INTEGRITY, therefore:

- We only work with HCPs/HCOs/POs when there is a legitimate need
- We consider the role and responsibilities of the stakeholders we communicate with to avoid conflicts of interest or undue influence
- We review the values, standards, procedures and decision-making processes of other stakeholders
- We support evidence-based decision making
- We provide access to medical education and support the rapid dissemination of scientific information

3. We act with RESPECT, therefore:

- We are aware of the importance of providing accurate, fair and objective information on medical devices so that rational decisions can be made regarding their proper use
- We support the independence of HCP decisions in prescribing medicines
- We ensure mutual respect and independence, in terms of political judgments, strategies and activities, in all partnerships with patient organisations
- We promote the attitude and environment of mutual respect towards other stakeholders, taking into account differences in culture, attitudes and ways of working

4. We are TRANSPARENT about our activities, therefore:

- We share clinical data in a responsible manner
- We publish details on HCP and HCO transfers of value
- We publish details on financial support and significant non-financial support to patient organisations
- We clearly indicate the sponsorship of pharmaceutical companies for any materials related to medical products and their use
- We publish activities through other relevant registers (such as the European Institutions' Transparency Register).

Annex F
Implementation and procedure rules

1. It is recommended that INOVIA members strive to resolve all cases of possible violations of the Code amicably, in direct contact. The application of the principle of agreed dispute resolution is also advised in cases of disputes between INOVIA members and pharmaceutical companies that are not INOVIA members. If an amicable solution is not possible, a report of a violation of the code should be filed.
2. A report on the Code violation shall be filed in writing/electronically to the INOVIA Executive Director, who shall also inform the person in charge of compliance with the Code (hereinafter: Code Compliance Officer).
3. The report must contain the following:

   a) Information on the identity of the person filing the report (name, address, identification number, tax identification number, etc.).

   b) Information on activities deemed to have violated the Code and appropriate evidence thereof (the report must contain an accurate and detailed description of the activities, documentation and arguments by the person filing it, as well as relevant data and facts).

   c) The cited provision of the Code that, in the opinion of the person filing the report, has been violated.
4. If the report does not contain all the necessary elements under Art. 3 of the Code, the Executive Director shall notify the person filing it in writing within 8 days. The person filing the report then has 15 days from the receipt of this written notice to complete their report. If the person filing the report does not complete the report within this deadline, the report is rejected, by a decision made by the Executive Director.
5. If the report is filed in accordance with Article 3, the Executive Director shall inform the accused member thereof within 8 days from the date of receipt of the report and shall request their written response. A scanned or electronically signed document sent via the official e-mail addresses of the Member Companies will also be considered a written answer.
6. The accused member has 15 days from the receipt of such a notification to submit a written response. This answer must include one of the following:

   a) Recognition that the Code has been violated, with the obligation to immediately cease all activities that violate the Code and refrain from all future activities that may violate the Code;

   b) Disputing the allegations in the report with an explanation that defends this position.

7. The Code Compliance Officer shall, within 30 days from the day of receipt of the response referred to in Art. 6 of the Code, schedule an oral hearing, which will be held at the INOVIA premises, for which they will send a written invitation to the person who filed the report and the accused member.

   This hearing is attended by the authorised representatives of the person who filed the report and the accused member. The representative of the person who filed the report at the hearing shall present and explain in detail the allegations in the report, while the representative of the accused member shall present and explain in detail the allegations in the response to the report.

   The hearing is attended by the Code Compliance Officer, the executive director of the association (as a record keeper), a representative of the person who filed the report and a representative of the accused member. The presence of the representative of the person who filed the report at this hearing is mandatory.

   If the representative of the accused member does not appear at the hearing, the hearing will be held in their absence.

   If the representative of the person who filed the report does not attend the duly scheduled oral hearing, it will be considered that they have withdrawn the report.

   The hearing is conducted by the Code Compliance Officer and a record is made of it.

8. After the end of the hearing under Art. 7 of the Code, the Code Compliance Officer shall make a decision in writing within 30 days.

   This decision must contain a brief written explanation and instructions on the right to appeal. The Code Compliance Officer may decide:

   a) That the accused member has violated the Code;

   b) That the accused member has not violated the Code;

   The decision establishing that the code has been violated must also contain a decision on the sanctions imposed on the accused in accordance with Art. 13.

9. If the decision under the previous article determines that the accused member has violated the Code, they may give a statement under Art. 6., Paragraph a), Item 1, in which case the proceedings are suspended and the Code Compliance Officer imposes the sentence referred to in Article 13.

10. The accused member has the right to appeal the decision finding that the Code has been violated. The person who filed the report has the right to appeal against the decision establishing that the accused member has not violated the Code.

    The appeal shall be filed within 15 days from the date of receipt of the decision, to the INOVIA Board of Directors (BD).

    The INOVIA Board of Directors decides on the appeal, together with the Code Compliance Officer. Each member of the Board has the right to one vote. The Code Compliance Officer has the right to one vote. Representatives of the companies

directly involved in the case in question may participate in the second-instance proceedings but do not have the right to vote when deciding.

The decision in the second-instance procedure is reached by the majority of votes of the present members. Voting must be attended by at least 50% of the members of the Board and the Code Compliance Officer.

If there is no required majority after the vote to make a decision, and the vote is equal, the decision voted for by the Code Compliance Officer (golden vote) will be adopted.

11. The INOVIA Board of Directors, together with the Code Compliance Officer, may make the following decisions on the appeal:

a) To reject the appeal and confirm the first-instance decision

b) To annul the first-instance decision or reverse that decision in part or in full.

The decision on the appeal is final and there is no right to file an appeal or any other legal remedy. The decision must be delivered to the parties in writing, by mail or electronically, within 15 days from the date of the decision.

12. If the person who filed the report succeeds in the proceedings, the accused member must bear all the costs of the proceedings. The accused member shall bear the costs of the proceedings even if they acted in accordance with Art. 6, Paragraph a) Item 1.

If the person who filed the report does not succeed in the proceedings, they must bear all the costs of the proceedings.

13. The Code Compliance Officer and the INOVIA Board of Directors may impose one of the following sanctions:

a) Publication of the decision on the INOVIA website.

b) Suspension of an association member for 3, 6 or 12 months. During the suspension, a member of the association on whom it is imposed has the obligation to respect all their duties towards the Association, but has no right to participate in the daily work of the Association.

c) Exclusion of a member from membership in the Association.

Sanctions may be imposed individually or cumulatively.

14. The Code Compliance Officer is elected from the general or professional public and cannot be employed in a Member Company or INOVIA.

Annex G
Guidance on the meaning of the term

Inovia issues the following guidance on the meaning of terms appearing in this Code:

Terms under Article 10:

"Reasonable" - in accordance with the nature of the **"Event"** and the place of its holding

"Appropriate" - a place that has adequate space for the organisation of professional events such as conference rooms and meeting rooms. Restaurants will only be considered "appropriate" if they provide a separate meeting space, i.e. when access by the general public is completely disabled during the event.

"Renowned for entertainment facilities" - places that are known for providing special types of entertainment as the predominant activity (which is not related to congress activities), such as casinos, spa and golf hotels, ski resorts in the period between 20 December and 1 March and the like

"Extravagant" - all five-star hotels in the Republic of Serbia according to the published categorisation of the Tourism Sector, the Ministry of Trade, Tourism and Telecommunications of the Republic of Serbia at the link: http://mtt.gov.rs/sektori/sektor-za-turizam/korisne-informacije-turisticki-promet-srbija-kategorizacija/

Term under Article 15.4

"Minimal" - in the maximum amount of 20 EUR in local currency, according to the middle exchange rate of the National Bank of Serbia on the day of the transaction

Term under Article 17

"Inexpensive" - in the maximum amount of 30 EUR in local currency (VAT included), according to the middle exchange rate of the National Bank of Serbia on the day of the transaction.

Term under Article 21

"Significant" - an amount exceeding 5% of the total project value.

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