ARPIM CODE

APPLICABLE FROM JANUARY 1ST, 2023

https://arpim.ro/codul-de-etica/

ARPIM
INOVAȚIA SALVEAZĂ VIEȚI

The ARPIM Code constitutes the collection of ethical rules agreed by ARPIM members for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility. This Code applies to all types of communication and interaction (traditional and digital).

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DEFINITIONS

Definitions of capitalized terms are included to ensure their consistent understanding.

Applicable Codes:

- (i) in the case of Promotion or interaction that is undertaken, sponsored or organized by or on behalf of, or with, a Member Company located within Europe, the Member Association National Code of the country in which such Member Company is located; or

  (ii) in the case of Promotion or interaction that is undertaken, sponsored or organized by or on behalf of, or with, a Member Company located outside of Europe, the EFPIA Code; and

- the Member Association's National Code of the country in which the Promotion or the interaction takes place.

In case of international Event for which a Member Company sponsors the attendance of a HCP, if any funding is provided to such HCP in accordance with the provisions of Article 13, such funding is subject to the rules of the National Code where such HCP carries out his/her profession, as opposed to those in which the international Event takes place.

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

Contribution to Costs related to Events: is a support providing or covering the costs of meals, travel, accommodation and/or registration fees to support the attendance of an individual HCP or PO Representative to an Event organized or created by a Member Company and/or a Third Party.

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

RomanianAssociationofInternationalMedicineManufacturers(ARPIM): is the representative body of the innovative pharmaceutical industry in Romania.

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

EVENTS: All professional, promotional and non-promotional, scientific, educational meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organized or sponsored by or on behalf of a Member Company.

Healthcare Organization (HCO): any legal person/entity (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Romania or (ii) through which one or more HCPs provide services.

Healthcare Professional (HCP): any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Romania. For the purpose of this Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

DEFINITIONS

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

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

Item of Medical Utility: constitutes inexpensive item aimed directly at the education of HCPs enhancing the provision of medical services and patient care and that do not offset routine business practices of the HCPs.

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

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

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

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

Medicinal Product: has the meaning set forth in Article 1 of the Directive 2001/83/EC, namely: (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Member Company: as defined in the ARPIM Statutes, means research-based companies, developing and manufacturing Medicinal Products for human use.

Member Company Staff: personnel employed by a Member Company or retained by way of contract with Third Parties, who are concerned with any matter covered by this Code.

Non-Interventional Study (NIS): is a study where the Medicinal Product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the Medicinal Product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures must be applied to the patients and epidemiological methods must be used for the analysis of collected data .[1]

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

Patient Organization Representative: is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area.[2]

Personal Health Data: is any information related to the physical, mental health or to the inherited or acquired genetic characteristics of an identified or identifiable natural person, including the provision of health care services, which reveal information about his or her physiology or health status.[3]

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

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

Recipient: any HCP or HCO or PO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Romania.

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

DEFINITIONS

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

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

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

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

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

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

PREAMBLE

This document replaces previous codes issued by ARPIM, namely:

- ARPIM Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (effective date 31.03.2006);
- ARPIM Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations (effective date 3.04.2009);
- ARPIM Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (effective date 12.12.2013).

ETHICAL PRINCIPLES

As pharmaceutical companies, we work in collaboration with various stakeholders including HCPs, HCOs, POs and their Representatives, regulatory authorities, governments and the public to improve health and quality of life.

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

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

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

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

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

For ARPIM and its members, self-regulation means being fully committed to define, implement, comply with and enforce the highest ethical standards through the ARPIM Code, where breaches are not tolerated.

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

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

This demonstrates our commitment to the following ethical principles:

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

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

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

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

4. EFPIA Leadership statement on ethical practices -June 2010

INTRODUCTION

The Romanian Association of International Medicine Manufacturers was founded in 1996, with a view to facilitating Romanian patients' access to the best and latest pharmaceutical research and development.

Since 2004 ARPIM is affiliated to the European Federation of Pharmaceutical Industries and Associations (EFPIA), the representative organization of the European pharmaceutical industry.

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

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

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

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

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

ARPIM believes that interactions between Member Companies and HCPs have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. EFPIA recognizes that interactions between the industry and HCPs/HCOs can create the potential for conflicts of interest. Consequently, professional and industry associations, including ARPIM, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

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

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

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

ARPIM strongly supports public scrutiny and the understanding of these relationships and disclosure contributes to the confidence of stakeholders in the pharmaceutical industry.

In relation to working with HCPs and HCOs, since the introduction of the ARPIM Disclosure Code, ARPIM has worked to encourage Member Companies to always look to disclose. Member Companies will not be criticized for over-disclosure.

SCOPE OF THE ARPIM CODE

The ARPIM Code covers the following:

- Promotion of POMs to HCPs,
- interactions between Member Companies and HCPs, HCOs and POs;
- disclosure of ToVs from Member Companies to HCPs, HCOs and POs; and
- edural requirements of the ARPIM Code.

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

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

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

The ARPIM Code is not intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription Medicinal Products.

The ARPIM Code does not cover the following:

The ARPIM Code does not cover the following:

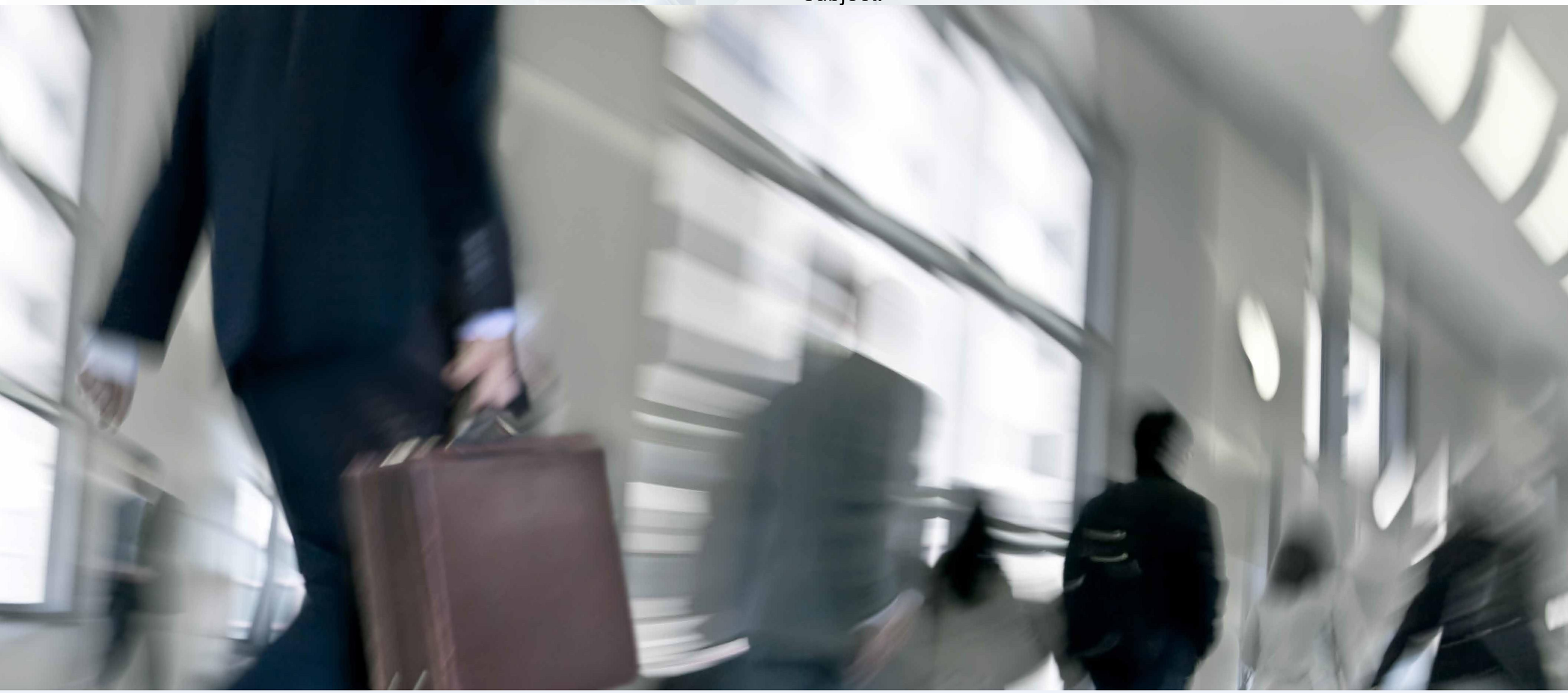
- the labelling of Medicinal Products and accompanying package leaflets,
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular Medicinal Product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- activities which relate solely to non-prescription Medicinal Products; or
- non-promotional, general information about Member Companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programs, and regulatory developments affecting a Member Company and its Medicinal Products.

Additional documents are developed to illustrate the provisions of the ARPIM Code and provide explanations for a consistent implementation, such as Annexes.

APPLICABILITY OF THE ARPIM CODE

The ARPIM Code sets out the minimum standards which ARPIM considers must apply. In a manner compatible with national laws and regulations, Member Companies must, at a minimum, adopt in their internal policy/procedures' provisions, no less rigorous than the provisions contained in the ARPIM Code.

Promotion and interactions which take place within Romania must comply with applicable laws and regulations. In addition, Promotion and interactions which take place within Romania must also comply with Applicable Codes. Member Companies must comply with any Applicable Codes and any laws and regulations to which they are subject.



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Promotion of POM to HCPS

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ARTICLE 1 MARKETING AUTHORIZATION

Section 1.01. A Medicinal Product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply or outside of its approved indications.

Section 1.02. Promotion must be consistent with the particulars listed in the Summary of Product Characteristics of the relevant Medicinal Product;

ARTICLE 2 INFORMATION TO BE MADE AVAILABLE

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

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

Section 2.02. Subject to applicable Romanian laws and regulations, where an advertisement is intended only as a reminder, the requirements of Section 2.01 above need not be complied with, provided that the advertisement includes no more than the name of the Medicinal Product or its international non-proprietary name, where this exists, or the trademark.

ARTICLE 3 PROMOTION AND ITS SUBSTANTIATION

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

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

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

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

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

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

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

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

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

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

ARTICLE 4 USE OF QUOTATIONS IN PROMOTION

Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with any Applicable Code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

ARTICLE 5 ACCEPTABILITY OF PROMOTION

Member Companies must maintain high ethical standards at all times. Promotion must: (a) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry; (b) be of a nature which recognizes the special nature of Medicinal Products and the professional standing of the intended audience; and (c) not be likely to cause offence.

ARTICLE 6 DISTRIBUTION OF PROMOTION

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

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

Section 6.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other digital communications for Promotion is prohibited except with the prior permission, or upon the request, of those who receive it.

ARTICLE 7 TRANSPARENCY OF PROMOTION

Section 7.01. Promotion must not be disguised.

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

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

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

ARTICLE 8 PROMOTIONAL INFORMATION PROVIDED DURING INTERNATIONAL EVENTS

Promotional information which appears on exhibition stands or is communicated to participants at international Events may, unless prohibited or otherwise regulated by local laws and regulations, refer to Medicinal Products (or uses) which are not registered in the country where the Event takes place, or which are registered under different conditions, as long as: (i) any such promotional material is accompanied by a suitable statement indicating the countries in which the Medicinal Product is registered and makes clear that the Medicinal Product or indication is not registered locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the Medicinal Product is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

ARTICLE 9 PERSONAL MEDICAL MATTERS

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

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Interactions with HCPS, HCOS and POS

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ARTICLE 10 EVENTS AND HOSPITALITY

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

Section 10.02. No Member Company may organize or sponsor an Event that takes place outside Romania unless:

- most of the invitees are from outside Romania and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country; or
- given the location of the relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country.

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

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

Section 10.05. Member Companies must not provide or offer any meal (food and beverages) to HCPs, HCOs' members or POs' Representatives, unless, in each case, the value of such meal does not exceed the monetary threshold set by the ARPIM Code.

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

Section 10.07. All forms of hospitality offered to HCPs, HCOs' members or POs' Representatives must be "reasonable" in level and strictly limited to the duration and main purpose of the Event. As a general rule, the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves.

ADDITIONAL INFORMATION- ARTICLE 10

It is prohibited to extend the hospitality, as defined above to any form of entertainment pre, during or post-event (e.g. but not limited to live music, shows, concerts, touristic tours, concerts, theatre, museum visits, sporting events).

Theatre or museum halls (or similar culture related venues): if no artistic event takes places during the period of the Event, respectively when access to exhibitions rooms is limited and if the use of such venues is justified by the required capacity for the Event; these venues are acceptable for organizing such Events.

ARPIM members must not organize Events, in Romania or abroad in 5-star hotels or sponsor independent 3rd Party Organized Events in Romania taking place at 5 star hotels, or using touristic resorts during the respective high seasons.

Venues with season related limitations for Romania are as follows, but not limited to well-known ski resorts during winter season (December-February), seaside resorts and Danube Delta resorts during summer season (June-August).

Sponsoring HCPs at independent events organized by medical scientific entities – or similar – outside Romania, taking place at 5-star hotels/locations: attendance of HCPs in the respective premises is acceptable but ARPIM member companies must ensure that accommodation for the entire period of such meeting is at maximum 4-star hotels. The same provisions apply to events organized by the Group Company of respective ARPIM member with and for Romanian HCPs.

The maximum limits for hospitality expenses are the following:

a)Airline travel (both domestic and international): economy class (coach). "Business" and higher classes are not allowed;

b)Meals: for domestic meals (food and drinks of any kind), the maximum amount is 250 RON for each person, for a main meal (lunch or dinner);

c)For "coffee breaks" (food and drinks of any kind), the maximum limit is 50 RON for each person.

For events where the duration (scientific agenda) exceeds 6 hours, two main meals can be offered as well as 2 "coffee breaks", for each day of the event.

In countries - "Host countries" - where local provisions do not set a limit for meals, the maximum limit is EUR 150 / day (or the relevant equivalent) for lunch plus dinner.

The above limits include VAT and „tip", if applicable, and apply individually, per main meal, respectively per „coffee break".

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

ARTICLE 11 PROHIBITION OF GIFTS

Section 11.01. Gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts) of HCPs, HCOs' members or POs' Representatives (either directly or indirectly) are prohibited.

Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the Recipient.

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

ADDITIONAL INFORMATION- ARTICLE 11

ARPIM member companies can only provide pens or paper pads exclusively during company-organized meetings, if they are non-product branded and inexpensive, considering monetary threshold specified in legislation.

ARPIM members are not allowed to distribute pens or paper pads during 3rd party Congresses, at exhibition booths or during satellite symposia.

ARTICLE 12 DONATIONS AND GRANTS TO HCOS AND POS

Section 12.01. Donations and Grants (in cash or in kind or otherwise) to HCOs and/or POs are only allowed if:

(i) they are made for the purpose of supporting healthcare, research or education;

(ii) they are documented and kept on record by the donor/grantor;

(iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products; and

(iv) are specifically based on an unsolicited request from the respective organization.

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

ARTICLE 13 CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP

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

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

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

ARTICLE 14 MEMBER COMPANY FUNDING

No Member Company may require that it be the sole funder or sponsor of a PO or HCO or any of its programs.

Member Companies welcome broad funding and sponsorship of POs and HCOs from multiple sources.

ARTICLE 15 CONTRACTED SERVICES

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

Section 15.02. It is permitted to contract HCPs or POs' Representatives as consultants, whether in groups or individually, for services such as speaking at and/orchairing meetings, consultancy, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or hospitality. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

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

b. a legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into arrangements;

c. the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular consultant meets those criteria;

d. the number of consultants retained, and the extent of the service are not greater than reasonably necessary to achieve the identified need;

e. the contracting Member Company maintains records concerning, and makes appropriate use of, the services provided by consultants;

f. the engagement of the consultant to provide the relevant service is not an inducement to recommend and/or prescribe, purchase, supply, sell or administer a particular Medicinal Product;

g. the remuneration for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating the HCPs or PO Representatives

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

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

Section 15.04. Limited market research, such as one-off phone interviews or mail/e-mail/ internet questionnaires are excluded from the scope of this Article 15, provided that the HCP, HCO's member or PO's Representative is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal, considering the requirement of art. 15- Additional Information.

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

ADDITIONAL INFORMATION- ARTICLE 15

Starting from the public information related to the activities carried out by the healthcare professionals within public and private practice, the ARPIM recommends as fair market value for Romanian HCPs the following limits for the gross hourly rates, VAT excluded, in case of services:

a) Up to 450 RON (four hundred fifty RON) /hour for the healthcare professionals found in the following situations: primary physicians ('medic primar') with or without academic title;

b) Up to 370 RON (tree hundred seventy RON) /hour for the healthcare professionals found in the following situations: specialized physicians ('medic specialist') with or without academic title;

c) Up to 285 RON(two hundred eighty-five RON) /hour for the healthcare professionals found in the following situations: pharmacists;

d) Up to 150 RON (one hundred fifty RON) /hour for the healthcare professionals found in the following situations: trainee physician ('medic rezident');

e) Up to 70 RON (seventy RON) /hour for the healthcare professionals found in the following situations: nurses.

For other healthcare related specialists but not limited to – psychologist; health-economist; medical device specialist – above limits for hourly rates may be applied according to their expertise and educational degree without exceeding the maximum amount per activity.

A total value for fees for services of **2 700 (two thousand seven hundred) RON per activity** will be considered for services during events, for example, but not limited to lecturing, chairman and respectively of **5 400 (five thousand four hundred) RON per activity** for services during events, for example but not limited to advisory board meeting, trainings. The total values for fees for services include preparation and service time.

No cap is to be foreseen for any consultancy services NOT event related (services not related to events and may require considerable time of preparation and/or service delivery). The company must assess the amount to be received based on the number of hours needed for the consultancy and the recommended maximum hourly fees, making sure that the amount received is at fair market value.

Transparent disclosure to the audience of the affiliation of the speaker/ chairman/advisor/consultants/trainer, etc with the ARPIM Member Company as beneficiary of the service should be made visible, disclosure of receiving a fee will be done in advance of the activity or event.

ARPIM member companies shall define internally a reasonable limit for the amounts paid for such services to an HCP per year.

3

Specific requirements for interactions with HCPS and HCOS

ARTICLE 16 MEDICAL EDUCATION

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

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

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

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

ARTICLE 17 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

Section 17.01. The provision of Informational or Educational Materials is permitted provided it is:

(i) "inexpensive";

(ii) directly relevant to the practice of medicine or pharmacy; and

(iii)directly beneficial to the care of patients.

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

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

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

ADDITIONAL INFORMATION- ARTICLE 17

The meaning of the term "inexpensive", is defined, as a value no more than 150 RON (one hundred -fifty RON), VAT included.

Items of medical educational utility might include anatomical models for examination rooms, inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject, reference guides or works and other informational/educational materials like but not limited to educational brochures on diseases, prescription manuals, patient self-assessment and tracking tools.

ARTICLE 18 NON-INTERVENTIONAL STUDIES

General Provisions

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

Section 18.02. Non-Interventional Studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study must comply with all of the following criteria:

a. There is a written study plan (observational plan/protocol);

b.In countries where ethics committees are prepared to review such studies, the study plan must be submitted to the ethics committee for review;

c.The study plan must be approved by the Member Company's scientific service and the conduct of the study must be supervised by the Member Company's scientific service as described in Section 20.01.a;

d.The study results must be analysed by or on behalf of the contracting Member Company and summaries thereof must be made available within a reasonable period of time to the Member Company's scientific service (as described in Section 20.01.a), which service must maintain records of such reports for a reasonable period of time. The Member Company must send the summary report to all HCPs that participated in the study and must make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing Applicable Codes upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority;[5] and

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

e. Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Member Company's scientific service that will also ensure that the Medical Sales Representatives are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Product.

Section 18.03. To the extent applicable, Member Companies are encouraged to comply with Section 18.02 for all other types of NIS, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Article 15.01.

ARTICLE 19 MEDICAL SAMPLES

Section 19.01. In principle, no Medical Samples should be given, except on an exceptional basis. Medical Samples must not be given as an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products, and must not be given for the sole purpose of treating patients.

Medical Samples are provided to HCPs so that they may familiarize themselves with the Medicinal Product and acquire experience in dealing with them.

In accordance with national and/or EU laws and regulations, a limited number of Medical Samples may be supplied on an exceptional basis and for a limited period. A reasonable interpretation of this provision is that each HCP should receive, per year, not more than 4 Medical Samples of a particular Medicinal Product he/she is qualified to prescribe for 2 years after the HCP first requested samples of each particular Medicinal Product (i.e. the "4x2" standard).

In this context, a new Medicinal Product is a product for which a new marketing authorization has been granted, either following an initial marketing authorization application or following an extension application for new strengths / dosage forms that include a new indication.

Extensions of the marketing authorization to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new Medicinal Product.

Without prejudice to the ban on medical sampling of Medicinal Product containing psychotropic and narcotic substances, Medical Samples can only be given in response to a written request from HCPs qualified to prescribe that particular Medicinal Product.

Written requests must be signed and dated by those who ask for the Medical Samples.

Section 19.02. Member Companies must have adequate systems of control and accountability for Medical Samples which they distribute and for all Medicinal Products handled by theirs Medical Sales Representatives. This system must also clearly establish, for each HCP, the number of Medical Samples supplied in application of the provisions in Section 19.01.

Section 19.03. Each Medical Sample must be no larger than the smallest presentation of that particular Medicinal Product in the relevant country.

Each sample must be marked as "free medical sample - no is intended for sale"or another form with this meaning and must be accompanied by a copy of the summary of product characteristics.

ARTICLE 20 MEMBER COMPANY STAFF

Section 20.01. All Member Company staff must be fully conversant with the relevant requirements of the Applicable Code(s) and laws and regulations.

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

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

a. Medical Sales Representatives must comply with all relevant requirements of the Applicable Code(s), and all applicable laws and regulations, and Member Companies are responsible for ensuring their compliance.

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

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

d. Medical Sales Representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their company's Medicinal Products, particularly reports of side effects.

e. Medical Sales Representatives must ensure that the frequency, timing and duration of visits to HCPs, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.

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

Section 20.03.

ARPIM members shall organize annually the Code training and knowledge assessment of their staff, using the ARPIM designated platform and using as reference the code and available training material.

ADDITIONAL INFORMATION- ARTICLE 20

ARPIM members' representatives may wish to attend events organized locally by other ARPIM members, such intention must always be communicated in advance, acceptable also directly at event site, before start of event and not interfering with its organization. In case of co-organized events by ARPIM members with non-ARPIM members, this principle will be applied

General principle:

- The visiting representative will be announced and identified before the event starts.
- No more than 1 (one) ARPIM member representative will attend, acceptable cases are in cases non-native speakers need translation
- Event in scope are considered any type of events
- Meetings having clearly a confidential nature, such as Advisory Boards, Confidential Expert Meetings, Investigator meetings are out of scope. Additionally, the symposiums organized by ARPIM member companies during congresses and conferences organized by professional medical societies, no restrictions shall be applicable.

The right to attend as observer during other ARPIM members events must be practiced in good faith and must never be abused. For the avoidance of doubt, such representative shall arrive in time, shall not cause any inconvenience, shall only have the right as observer, and shall in no way participate in discussions, Q&A sessions, nor shall influence any participants, nor interact during breaks with them.

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Specific requirements for interactions with POS

ARTICLE 21 INTERACTIONS WITH POS

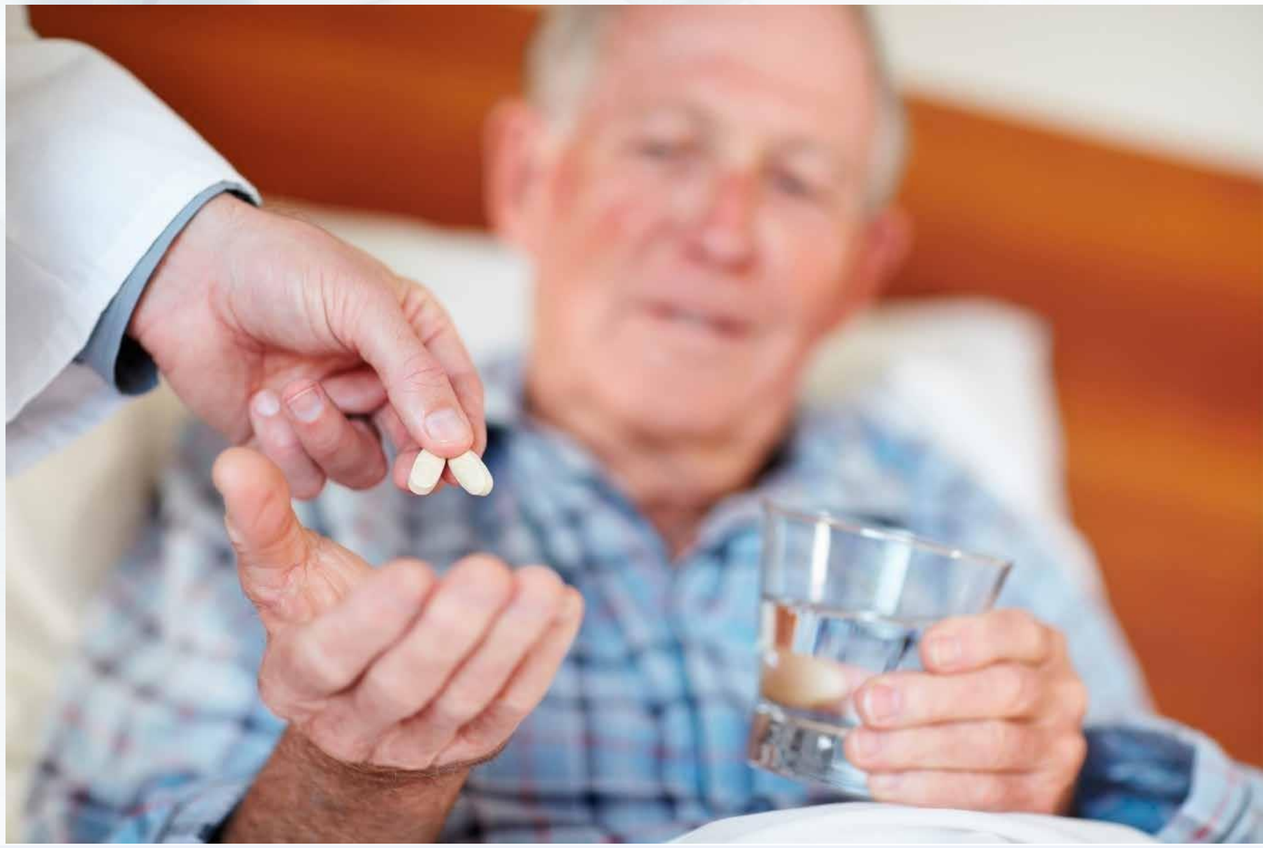
Section 21.01. Member Companies must comply with the following principles that EFPIA, together with pan-European POs, have subscribed to:

- The independence of POs, in terms of their political judgement, policies and activities, must be assured.
- 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 must not request, nor shall POs undertake, the Promotion of a particular POM.
- The objectives and scope of any collaboration must be transparent. Financial and non- financial support provided by Member Companies must always be clearly acknowledged.
- Member Companies welcome broad funding of POs from multiple sources.

Section 21.02. EU and national laws and regulations prohibit the advertising of POM to the general public.

Section 21.03. When Member Companies provide financial support, significant indirect support and/or significant non-financial support to POs, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency´s time and the nature of its involvement) and significant non-financial support. Will be considered as significant, financial or non-financial, any support of value above 150 RON.

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



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Disclosure of tov from member companies

ARTICLE 22. DISCLOSURE OF TOVS TO HCPS, HCOS, AND POS

Section 22.01. Time of Disclosure

Public disclosure must be made by each Member Company within **six (6) months** after the end of the relevant Reporting Period and the information disclosed must be required to remain in the public domain for a minimum of **tree (3) years** after the time such information is first disclosed.

The common reporting period for publication of ToVs to Recipients is set by the national legislation (Law 95/2006, ^814 and Ministerial Order no. 194/2015), publication will be made each year until end of June, covering all ToV for the past calendar year.

ARTICLE 23. DISCLOSURE OF TOVS TO HCPS AND HCOS

Section 23.01. Rationale

The following article provides for disclosures of ToVs to HCPs and HCOs, whether directly or indirectly. When deciding how a ToV must be disclosed, Member Companies should, wherever possible, identify and publish at the individual HCP (rather than HCO) level, as long as this can be achieved with accuracy, consistency and in compliance with applicable laws and regulations.

Section 23.02. Implementation and deviations

Romania has specific legislation, all ARPIM Member Companies are fully complying with this national legislation (Law 95/2006, ^814 and Ministerial Order no. 194/2015) that requires all ToV to be submitted to National Agency for Medicines and Medical Devices of Romania (NAMMDR) until end of March for the past calendar year. Publication of all Individual ToV will be done until end of June and on NAMMDR website and ARPIM Member company website.

Aggregate Disclosure, representing the R&D amounts, will be done by each ARPIM Member Company within **six (6) months** following the end of the relevant reporting period. The information shall be required to remain in the public domain for a minimum of **tree (3) years** after the first disclosure.

Section 23.03. Disclosure Obligation

General Obligation. Each Member Company must document and disclose ToVs it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 23.05.

Section 23.04. Form of Disclosure

ANNUAL DISCLOSURE CYCLE. Disclosures must be made on an annual basis and each Reporting Period must cover a full calendar year.

National legislation (Law 95/2006, ^814 and Ministerial Order no. 194/2015) provides the reporting period, submission date to National Medicines and Medical Devices Agency of Romania (NMMDAR) and disclosure date.

TEMPLATE. The individual disclosure will be made in RON/ payment currency using the standardized template as provided within Order no. 194/2015 of the Ministry of Health and as instructed by the law issuer.

PLATFORM OF DISCLOSURE. Disclosure of individual ToV is required by national law (Law 95/2006, ^814 and Ministerial Order no. 194/2015) to be done on National Medicines and Medical Devices Agency of Romania (NMMDAR) website and on ARPIM Member company website.

Aggregate R&D ToV will be done on ARPIM website and or ARPIM Member Company website.

LANGUAGE OF DISCLOSURE. Romanian

DOCUMENTATION AND RETENTION OF RECORDS. Each ARPIM Member Company must document all ToVs required to be disclosed pursuant to Section 23.03 and maintain the relevant records of the disclosures made under this article for a minimum of 5 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national laws or regulations.

Section 23.05. Individual and Aggregate Disclosure

Individual Disclosure. ToVs must be disclosed on an individual basis. Each ARPIM Member Company must disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to ToVs to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Romania has national legislation (Law 95/2006, ^814 and Ministerial Order no. 194/2015), requiring that all individual ToVs to be reportable to National Medicines and Medical Devices Agency of Romania (NMMDAR) and further all individual ToVs are disclosed on authority website and ARPIM Member website.

For ToV to a HCO, an amount related to any of the categories set forth below:

DONATIONS AND GRANTS. Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 12).

CONTRIBUTION TO COSTS RELATED TO EVENTS. Contribution to costs related to Events, through HCOs or Third Parties[6], including support to HCPs to attend Events, such as:

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

FEES FOR SERVICE AND CONSULTANCY. ToV resulting from or related to contracts between Member Companies and HCOs under which such HCOs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToV relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

For ToV to a HCP:

CONTRIBUTION TO COSTS RELATED TO EVENTS. Contribution to costs related to Events, such as:

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

FEES FOR SERVICE AND CONSULTANCY. ToVs resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

Aggregate Disclosure. All R&D ToV are reportable as aggregate amount according to disclosure principles.

NON DUPLICATION. Where a ToV required to be disclosed pursuant to Section 23.05 is made to an individual HCP indirectly via a HCO, such ToV must only be required to be disclosed once. To the extent possible, such disclosure must be made on an individual HCP named basis pursuant to Section 23.05.

RESEARCH AND DEVELOPMENT TOV Research and Development ToV in each Reporting Period must be disclosed by each ARPIM Member Company on an aggregate basis. Costs related to Events that are clearly related to activities covered in this section can be included in the aggregate amount under the "Research and Development Transfers of Value" category..

METHODOLOGY. Each Member Company must publish a note summarizing the methodologies used by it in preparing the disclosures and identifying ToV for each category described in Section 23.05. The note, including a general summary and/or country specific consideration, must describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amounts of ToV for purposes of this article, as applicable.

ARTICLE 24. DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO POS

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

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

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

This information must be disclosed on the Member Company website either on a national or European level on an annual basis and each Reporting Period shall cover a full calendar year.

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

6. cf. Guidance of indirect ToV through Third Parties - Support to/Sponsorship to Events through Professional Conference Organizers in Annex A

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Procedural requirements

ARTICLE 25. ENFORCEMENT

Section 25.01. Enforcement

ARPIM must, within current applicable laws and regulations enforce the provisions of the ARPIM Code. In the event that a breach is established pursuant to the procedures of its Code, ARPIM shall require from the offending company an immediate cessation of the offending activity and a signed undertaking by the company to prevent recurrence.

ARPIM adopts Implementation and Procedure Rules (as set forth in more detail in Article 28), which will be binding upon its members, and set forth the framework for the implementation of this Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other laws and regulations.

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

Section 26.01. Amendments to the ARPIM Code

Ethical Working Group (EEWG) of ARPIM shall regularly review ARPIM Code and any guidelines regarding compliance with ARPIM Code.

Proposed amendments to ARPIM Code will be submitted for the ARPIM Board assessment and the ARPIM General Assembly ratification. Proposed amendments to ARPIM Code shall be reviewed by the EEWG following consultation with ARPIM Member Companies.

ARTICLE 27. AWARENESS AND EDUCATION

ARPIM Member Companies must organize a training session every year to ensure that staff should remain informed with respect to ARPIM Code requirements. In this respect ARPIM Member Companies will organize Annual Knowledge Assessment for employees in scope, using the agreed ARPIM Knowledge Assessment Tool. ARPIM Member Companies must appoint **one (1) employee** responsible for the technical supervision and coordination of the Annual Knowledge Assessment.

ARTICLE 28. IMPLEMENTATION

Section 28.01. Reception of Complaints

Complaints may be lodged either with ARPIM or with EFPIA. Adjudication of complaints is a matter solely for the ARPIM.

Complaints received by EFPIA must be processed as follows:

a. EFPIA must forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant Member Association(s).

b. EFPIA must send an acknowledgement of receipt to the complainant, indicating the relevant Member Association(s) to which the complaint has been sent for processing and decision.

c. In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA must communicate these complaints to the Member Association either of the parent company or of the EU subsidiary designated by the parent company.

Section 28.02. Processing of Complaints and Sanctions by ARPIM

a. All complaints, whether originating from within the industry or not, are processed in the same manner, without regard to the origin of the complaint.

b. ARPIM will ensure, to the extent permissible, that any final decision taken in an individual case shall be published, excluding any confidential details concerning the decision and any personal data. The purpose of such publishing being to create awareness and prevent behavior/practices which have been found in breach of the ARPIM Code. The publishing of company's name(s) and/or details about the breach will be published in case of breach which has formed the object of a sanction by the Arbitration Committee.

c. The Arbitration Committee (AC) is the designated body of ARPIM to mediate complaints and to ensure that reported breaches of ARPIM Code are duly remediated. The AC prepares an annual report summarizing the work undertaken in connection with the implementation of the ARPIM Code and with the handled complaints and resolutions issued. The AC consists of **six (6) members, five (5) members** elected by EEWG, including the EEWG Leader that is an administrative coordinator (Leader of the Arbitration Committee), and **one (1) ARPIM staff** (Chair of the Arbitration Meetings). Any decision of the AC is adopted if the (simple) majority of this group participates and it shall be made based on the simple majority of the participants' votes. If there is a conflict of interests - for example the AC Leader or any of its member is also the representative of the plaintiff company or of the company subject of a complaint - this person will not participate in the assessment of the respective complaint. In such situations elected back-up members will step in. Leader and members of the AC are appointed by election every **two (2) years**.

<u>Processing Complaints and Sanctions</u>

Industry and/or non-industry complaints – should be submitted to the attention of the Leader of the Arbitration Committee at the following e-mail address office@arpim.ro. The AC Leader and Members shall maintain the complaint and its content strictly confidential towards any ARPIM member until final decision.

A valid complaint from ARPIM Company Member must be addressed in writing and must contain:

a. identification of the plaintiff company

b. identification of the person submitting the complaint

c. relevant details on which the complaint is based

d. proposed/requested corrective action

It is considered a valid complaint, any complaint with details deemed sufficient by the Arbitration Committee, received directly by any member company or directly by ARPIM office.

The AC may file a complaint on its own initiative, when a violation of the ARPIM Code is brought to its attention, such an example can be media monitoring.

Within maximum **twenty-four (24) hours** from receipt of the complaint - the AC Leader must contact – via e-mail the General Manager or the equivalent head of the ARPIM Member Company, hereinafter referred to as "General Manager" of the company subject of the complaint and request a written note containing the position of the company with respect to the complaint. The identity of the plaintiff company shall not be disclosed to the company subject of the complaint.

If a breach of the ARPIM Code is established and acknowledged by the company in breach, the General Manager must submit within **ten (10) working days** since receipt of the complaint, the corrective plan and timelines, to the attention of the AC Leader.

The AC will complete an assessment of complaint itself and of the corrective plan and timelines in maximum **ten (10) working days** from receipt of the written position from the company subject of the complaint and may request additional corrective action/s from the company in breach.

In the event that:

- a breach of the present Code is established by the AC but not acknowledged – partially or entirely - by the company in breach, thus no corrective plan was submitted, or
- a breach of the present Code is established by the AC and acknowledged - partially or entirely- by the company in breach and the additional corrective plan and timelines requested by the Arbitration Committee are not considered acceptable by the company in breach, or
- a breach of the present Code is established by the AC and acknowledged - partially or entirely- by the company in breach but no corrective action plan was submitted,

the General Manager of the company subject to the complaint must communicate disagreement with the elements of the complaint within a detailed position statement - within **ten (10) working days** from receipt of the information on the complaint – to the AC Leader.

In such cases the AC Leader will call upon an Arbitration Meeting within **ten (10) working days** from receipt of the position statement from the company in breach or within **twenty (20) working days** from the date of sending such letter to the company in breach. Any time before the Arbitration Meeting the Arbitration Committee will analyze all details received about the complaint and will consolidate a position.

Mandatory participants in the Arbitration Meeting are:

- General Manager of the company subject of the complaint
- Arbitration Committee Leader- Members should make all reasonable efforts to participate
- Executive Director of ARPIM (Chair of the AC)

The participants set forth above shall be bound by a strict obligation of confidentiality with respect to the subject-matter of the meeting, including for the avoidance of doubt, the identity of the company subject of the complaint.

Should the AC consider necessary to also convene the plaintiff company, such shall be done separately from the company subject of the complaint, or, if both parties agree, such convening can be done simultaneously.

Arbitration will be moderated by the Executive Director of ARPIM (Chair of the AC) and will conclude with an agreed upon corrective action plan if the case, and decision for sanction. Decision of the AC must be issued in maximum **tree (3) working days** from conclusion of the meeting unless differently agreed during the meeting and shall be immediately communicated to the plaintiff company and the company subject of the complaint.

All Arbitration Meetings will be documented by minutes protected by confidentiality.

In addition, the AC Leader will keep track of activities for remedy and their completion. The General Manager of the company in breach must report completion of all corrective actions as per the agreed upon corrective plan, within the timelines as set in the plan to the AC Leader.

Companies not complying with the corrective action plan as once accepted may be subject to sanctions.

Following the completion of a complaint, the AC shall propose workshops with all ARPIM Members Companies, aimed at increasing awareness about practices similar to the ones which have been found in breach of ARPIM Code and possible solutions for preventing any future breaches, without disclosing any confidential details about a particular case (such as the identity of the plaintiff company and the company subject of the complaint).

All Arbitration Meetings will be documented by minutes protected by confidentiality.

In addition, the AC Leader will keep track of activities for remedy and their completion. The General Manager of the company in breach must report completion of all corrective actions as per the agreed upon corrective plan, within the timelines as set in the plan to the AC Leader.

Companies not complying with the corrective action plan as once accepted may be subject to sanctions.

Following the completion of a complaint, the AC shall propose workshops with all ARPIM Members Companies, aimed at increasing awareness about practices similar to the ones which have been found in breach of ARPIM Code and possible solutions for preventing any future breaches, without disclosing any confidential details about a particular case (such as the identity of the plaintiff company and the company subject of the complaint).

<u>Other provisions</u>

a. If during the arbitration process new facts appear, likely to constitute a violation of the present Code, the AC shall acknowledge, notify and judge these facts without being required a separate complaint.

b. The interested parties may be assisted or represented by their consultants in front of the AC.

c. The decision of the AC shall be communicated in writing to the General Manager of the ARPIM member involved.

d. The decision of the AC cannot be overruled by the ARPIM Board.

e. The decision of the AC may include:

- Financial sanctions - during any **twelve (12) months period**

(ι) for the first violation: up to 5 000 (five thousand) EUR;

(ii) for the second violation: up to 10 000 (ten thousand) EUR;

(iii) for the third violation and each violation after the third: up to 15 000 (fifteen thousand) EUR;

- Administrative obligations as – not being limited to – retraining of the employees belonging the default company submitting the related documentation to the Arbitration Committee, update of the internal procedures of the company in breach, communication to HCP;
- Promptly informing the international headquarter of the company found in breach about the litigation;
- Promptly informing the National Medicines and Medical Devices Agency of Romania about such breach by an ARPIM member;
- Promptly informing the other ARPIM Members Companies about such breach by an ARPIM Member Company;
- Proposal to the General Assembly of ARPIM to suspend/terminate the membership of the ARPIM Member Company in breach.

f. If the resolution of the AC is not acceptable by one of the parties, such party may request a new assessment, only if there are additional elements in comparison with those previously presented. In this case, the process shall be performed as per the above-described procedure. In case that the decision of the AC is not acceptable to one of the parties and there are no additional elements to justify a new assessment by the AC, this party may make use of any recourse available under the law, such as address this issue to the National Medicines and Medical Devices Agency of Romania or, further on to a civil court.

g. The ARPIM office shall keep record of all cases and correspondence and ensure protection by confidentiality. The records shall be kept for ten (10) years from the date of the last recorded decision of the AC.

The process used by EFPIA is set out in a standard operating procedure (Annex D) of EFPIA code available on: https://www.efpia.eu/relationships-code/healthcare-professionals-hcps/.

ANNEX A

Guidance on disclosure of non-interventional studies

https://arpim.ro/codul-de-etica/

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THIS GUIDANCE PROVIDES A BASIS FOR DISTINGUISHING BETWEEN PROSPECTIVE VERSUS RETROSPECTIVE NIS AND AIMS AT ENSURING CONSISTENCY IN REPORTING OF TOVS RELATING TO NIS.

Background | Relevant Disclosure principles provision | Guidance

DISCLOSURE OF INDIRECT TRANSFERS OF VALUES (ToVs) THROUGH THIRD PARTIES SUPPORT TO / SPONSORSHIP TO EVENTS THROUGH PROFESSIONAL CONFERENCE ORGANISERS (PCOS)

Background | Relevant Disclosure principles provision | Guidance | Further recommendation

ADDITIONAL GUIDANCE ON TOVS THROUGH PCOS

SUPPORT TO / SPONSORSHIP TO EVENTS THROUGH PROFESSIONAL CONFERENCE ORGANISERS (PCOS)

Examples of possible scenarios in support of Events

Background

In application of the Disclosure principles to exemption on individual reporting of ToVs relating to non-interventional studies (NIS) is limited to NIS that are prospective in nature. The Code prescribes that retrospective NIS must be reported on an individual names basis, in line with applicable codes.

Member Companies informed EFPIA that it was not always possible to distinguish ToVs relating to prospective (included in the aggregated reporting of R&D ToVs) and retrospective (to be reported on an individual basis) NIS. The Ethics & Compliance Committee (E&CC) of EFPIA had considered that definitions in the new EU Clinical Trials Regulation 536/2014 could be used for reference when implementing the Disclosure requirements, thus anticipating and align with the regulatory change that will eventually take place.

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

ARPIM follows the guidance provided

7. Application Date of the new Clinical Trials Regulation 536/2014 is dependent on the development of the IT system “EU Clinical Trial Portal and Database”. At the moment, the “go-live date” is expected in second half of 2019. The effective implementation date of the Regulation will not change definitions, these definitions are considered as an appropriate reference for consistent implementation of provisions relating to the disclosure of ToVs relating to NIS.

Relevant Disclosure principles provision

Definition of Terms

Research and Development Transfers of Value - Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation N° 536/2014[8]); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the Code).

8. In the EFPIA HCP/HCO Disclosure Code, the definition of R&D ToVs refers to EU Directive 2001/20/EC on Clinical Trials. This legal instrument is replaced by EU Regulation N°536/2014. The definition under the EFPIA HCP/HCO Disclosure will refer to the update regulatory provisions.

Guidance

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

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

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

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

Background

Third parties[9] provide support to Member Companies in a variety of capacities, impacting more or less on the conduct of activities regulated by the Code. Such activities would be reported as indirect Transfers of Values (ToVs) following provisions of the Disclosure principles. When Member Companies provide support / sponsorship to PCOs involved in the organisation of scientific Events, it is understood that the Member Companies' intention is to provide support to HCPs/HCOs at arm's length.

Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or ToVs through an intermediate and where the Member Company knows or can identify the HCP/ HCO that will benefit from the ToV[10].

In consideration of the multiple ways collaboration with third parties can be contracted, it may not be straightforward to report in application of the ARPIM Disclosure Code in full. As this may lead to underreporting of ToVs through third parties, further Guidance aims at providing a consistent approach towards improved reporting wherever possible in compliance with applicable law and regulations.

This Guidance clarifies reporting of Indirect ToVs to HCOs made through Professional Congress Organiser (PCOs[11]).

In consideration of legal issues that may arise in the reporting of ToVs through Distributors on behalf of a Member Company, reporting of such ToVs are not within scope of this Guidance.

9.Third parties are entities or individuals that represent a company in the marketplace or interact with other third parties on behalf of a company or relating to the company's product. Among others, these thirds parties can be distributors, travel agents, consultants, contract research organisations. This Guidance applies to PCOs as third parties involved in Events involving HCOs.

10. Definition of an indirect ToV in EFPIA's HCP/HCO Disclosure Code Schedule 1

11.A PCO is a company/individual specialised in the organisation and management of congresses, conferences, seminars and similar events (all "Events"). For the application of this Guidance, commercial companies involved in organisation of travel (travel agencies) or accommodation (hotels, banqueting functions in hotels, etc.) are not considered PCOs.

Relevant Disclosure principles provision

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

- Registration fees;
- Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and
- Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code).

Definitions

Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

Guidance

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

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

- All ToVs to an HCO (either as Recipient or as Beneficiary) are reported in the relevant category under the name of the HCO
- ToVs through PCOs are reported:
  - either in the name of benefitting HCO (through include the name of Recipient PCO), if not included in direct ToVs to the HCO;
  - or in the name of Recipient PCO (to the benefit of include the name of benefitting HCO)

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

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

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

Further recommendation

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

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

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

Examples of possible scenarios in support of Events

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

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

ANNEX B

Questions submitted to ARPIM for clarification of code provisions

Background

Clarification and interpretation of Code provisions

Procedural steps

Background

The ARPIM Code sets out the minimum standards which ARPIM considers must apply to all ARPIM Member Companies operating in Romania. ARPIM transposes the EFPIA Code provisions into national code- named ARPIM Code, in line with applicable law or regulation. ARPIM, as well as ARPIM Member Companies may adopt stricter standards.

Member Companies shall be bound by the relevant EFPIA Member Association's code in each country in Europe in which they operate (whether directly or through its relevant operation in that country).

Clarification and interpretation of Code provisions

When questions are submitted to ARPIM office, the ARPIM will provide clarification of the ARPIM Codes provisions, which are minimum standards that must apply for all Company members. However, Company members may have stricter internal rules and procedures to comply with.

It should be noted that any clarification / interpretation provided cannot constitute a judgment of compliance with applicable codes. Decisions regarding compliance / breaches are the sole responsibility of Arbitration Committee.

When questions are submitted about the EFPIA Code, EFPIA will provide clarification, and - where applicable - may revert to the Member Association(s) concerned.

Procedural steps

Questions received by ARPIM

- ARPIM will acknowledge receipt of a question submitted by a Member or any other party within ten (10) working days;
- Responses will be prepared by EEWG members and EEWG Leader will draft the final response to be approved by ARPIM staff
- Reply to questions will be no longer that one (1) month
- Questions will be analyzed at least once per year by the EEWG and ARPIM staff and analysis with regards to ARPIM Code wording or ARPIM Code Training Material should be decided in case of future code revisions

Questions received by EFPIA- procedural steps are in the EFPIA Code available at: https://www.efpia.eu/relationships-code/the-efpia-code/

1. We keep PATIENTS AT THE HEART OF WHAT WE DO

2. We act with INTEGRITY

3. We act with RESPECT

4. We are TRANSPARENT regarding our actions

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

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

2. We act with INTEGRITY, therefore we:

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

3. We act with RESPECT, therefore we:

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

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

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

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ANNEX D

Aggregate (R&D) report template

report template

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