ARPIM HCP CODE

ARPIM CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS

Adopted by ARPIM Board on November 2017 and ratified by the ARPIM Statutory General Assembly of December 2017 (Edition 2017)*

* Applicable from May 1st 2018.

CONTENT

INTRODUCTION

The Romanian Association of International Medicine Manufacturers was founded in 1995, with a view to facilitating Romanian patients' access to the best and latest pharmaceutical research and development.

We are the association that supports the common objectives of the most important 29 international innovative medicine manufacturers operating in Romania. They represent together 70% of the pharmaceutical industry business in Romania.

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

The primary mission of EFPIA and implicitly of ARPIM summarized by the motto "new medicinal products for better health" is to promote the pharmaceutical research and development to discover better therapeutic solutions for greatly improve human health.

Dissemination of scientific and educational information ensures that the results of years of scientific work and huge investments in research and development shall also be made available to the healthcare professionals and to the patients. In all healthcare-related activities the representatives of the pharmaceutical industry believe that high standards should be defined and observed and are convinced that, as far as its marketing activities are concerned, self-discipline is the process which best serves the public interest. Ethical criteria for promotion of medicinal products are regarded as the foundation for proper behavior, consistent with the search for truthfulness and righteousness.

In January 2007 Romania became an EU member. To apply the same high ethical standards for promotional and non-promotional activities performed by the pharmaceutical industry in the EU, it is mandatory to implement in Romania a code of conduct aligned to the one applied in the EU countries. Considering that, ARPIM has adopted in May 2005 the ARPIM Code.

The ARPIM Code on the Promotion of Prescription–only Medicines to, and Interaction with, Healthcare Professionals (hereafter "ARPIM Code") shall represent a reference that should thus assist in judging if promotional practices related to medicinal Medicines are in alignment with acceptable ethical standards.

ARPIM is conscious of the importance of providing accurate, fair and objective information about medicinal products so that rational decisions can be made as to their use.

The ARPIM Code reflects the requirements of the EFPIA Code and Council Directive 2001/83/EC[1], as amended, relating to medicinal products for human use (the "**Directive**"). The ARPIM Code fits 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 operating in Romania. The ARPIM Code is not intended to restrain the promotion of medicinal products or to limit the interaction with professionals from healthcare field in a manner that is detrimental to fair competition. Instead, it seeks to

[1] Council Directive 2001/83/EC was amended in 2004 by Council Directive 2004/27/EC. The EFPIA Code was further revised in 2013, Approved by the General Assembly of 6 June 2014.

ensure that the promotional activities and other related activities are performed in a truthful manner, avoiding deceptive practices and potential conflicts of interest with healthcare professionals, and in compliance with Romanian laws and regulations. The ARPIM Code thereby aims to foster an environment where the general public can be confident that choices regarding the medicines prescribed for their treatment are being made on the basis of the merits of each product and the healthcare needs of patients.

SCOPE OF THE ARPIM ETHICAL CODE OF PRACTICE

The ARPIM Code covers the promotion of prescription-only medicinal products and interactions of ARPIM member pharmaceutical companies with healthcare professionals. The ARPIM Code is applicable not only to pharmaceutical companies but their subsidiaries, and any companies affiliated with ARPIM member companies or their subsidiaries.

Member Companies shall be responsible for the obligations imposed under any relevant Applicable Code (defined below in APPLICABILITY OF THE ARPIM CODE) even if they commission other parties (e.g., contract sales forces, consultants, market research companies, advertising agencies) to design, implement or engage in activities covered by the Applicable Code on their behalves. In addition, Member Companies shall take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Applicable Code but these third parties do not act on behalf of the ARPIM Member Company (e.g., joint ventures, licensees) comply with Applicable Codes.

The ARPIM Code is not intended to restrain or regulate the provision of non-promotional medical, scientific and factual information nor is it intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription only medicines.

The ARPIM Code covers all methods of promotion as described in the definitions above and all other interactions with HCPs and healthcare institutions considering exceptions below:

- The summaries of product characteristics as provided by the relevant legislation, the labeling of medicinal products and accompanying package leaflets, insofar as they are not promotional in nature;
- Correspondence, possibly accompanied by materials of non-promotional nature, made in response to individual enquiries from healthcare professionals or appropriate decision makers or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry and are not promotional in nature;
- Factual, informative announcements and reference material concerning licensed medicinal products and relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided that they include no promotional statement in relation with the product;
- Non-promotional information relating to human health or diseases, provided there is no reference either direct or indirect to specific medicinal products;
- activities which relate solely to non-prescription only medicinal products;
- Non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programs, and discussion of regulatory developments affecting the company and its products.

- Interventional clinical studies, no matter if they are pre-authorization or Phase IV studies, making the object of EU directives 2001/20/CE and the complements thereof, Law 95/2006 and/or the Romanian legislation valid when drawing up the study.

Annex A**,** the "Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU" which provide guidance with respect to the content of websites containing information on medicinal products subject to prescription;

Annex B "Guideline for disclosure the summary of a non-interventional study";

APPLICABILITY OF THE ARPIM CODE

The ARPIM Code sets out the minimum standards, which ARPIM members have committed to apply and gives guidance for implementation.

The provisions of the ARPIM Code are applicable to each and all partnering companies which jointly promote the same product(s) and each will be held responsible for compliance with all provisions of the code.

ARPIM member companies must comply with the ARPIM Code and all relevant Romanian laws and regulations. In the event of a conflict between the provisions of the applicable code, law and regulations set forth above, the more restrictive of the conflicting provisions shall apply.

ARPIM also encourages compliance with the letter and spirit of the provisions of:

- The law no. 95/2006 regarding the reform in healthcare field (published in Part I of "Official Journal" no. 372/28.04.2006) with all subsequent amendments;
- Decisions, guidelines, provisions of the National Medicines and Medical Devices Agency (NMMDA) regulating the activity of medicine products promotion released based on medical prescription;
- Code of Promotion Practices of the European Federation of Pharmaceutical Industries and Associations (EFPIA);
- The Council Directive no 2001/83/EC relating to medicinal products for human use amended by Council Directive 2004/27EC and amended by Directive 2010/84/CE;
- Code of Pharmaceutical Marketing Practices, International Federation of Pharmaceutical Manufacturers Associations (IFPMA) where applicable;
- Code of Interactions with Healthcare Professionals, Pharmaceutical Research and Manufacturers of America (PhRMA).

Promotion and interaction which take place within Europe must comply with applicable laws and regulations. "Europe" as used in the EFPIA HCP Code includes those countries in which the EFPIA member associations' codes of practice apply. In addition, promotion and interaction which take place within Europe must also comply with each of the following "Applicable Codes":

1. (i) in the case of promotion or interaction that is undertaken, sponsored or organized by or on behalf of, or with, a company located within Europe, the member association national code of the country in which such 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 company located outside of Europe, the EFPIA HCP Code; and

2. the member association's national code of the country in which the promotion or interaction takes place.

In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions shall apply (unless otherwise covered by section 13.01), 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") shall prevail.

ARPIM member companies must in good faith observe the requirements set forth by the code, and they shall be bound to it with regard to both their direct and indirect actions when they operate by means of third party contractors (for instance distributors, agents, foundations etc.).

DEFINITIONS

1. The term "**promotion"** means all activities of the Representatives of a company and any activity organized or sponsored by any ARPIM member, or undertaken with the authority of an ARPIM member, which promotes the prescription, supply, sale, administration, recommendation or consumption of a medicinal product(s).

   It includes:

   a) oral and written promotion and communication;

   b) journal and direct mail advertising;

   c) supply of samples;

   d) provision of objects relevant for the medical and pharmaceutical practice;

   e) sponsorship of scientific or promotional meetings, including payment of the expenses related to the participation at such meetings;

   f) provision of information to the general public either directly or indirectly;

   g) and all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, radio, television, the internet, electronic media, interactive data systems and the like.

2. The term "promotional material" means any tool used for promotional purposes, as defined under "promotion" above.

3. The term "**medicinal product"** means (a) any substance or any combination of substances presented of 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, which requires a marketing authorization.

4. The term "**healthcare professional" (HCP)** includes members of the medical, dental, pharmacy and nursing professions and their assistants.

5. **Healthcare Institution** means any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a **hospital, clinic, public health institutions or the Non-Governmental Organizations (affiliated** to public healthcare institutes or which have healthcare professionals in their managing board), medical society, university or other teaching institution or learned society (except for patient organizations within the scope of the ARPIM PO Code) whose business address, or primary place of operation is in Romania and (ii) through which one or more HCPs provide healthcare or conduct research.

6. The term **"decision makers**" includes representatives of the staff of the public and private institutions, as well as but not limited to persons that hold a function or a mandate in a government authority with connection with health policies and regulations, members or presidents of consultative Commissions, members or presidents of National Committee for Coordination of specialized commissions, members or presidents of expert commissions.

7. The term "**market research"** means the collection and analysis of information and must be unbiased and non-promotional. The use of the statistics or information could be done with promotional purposes. The two phases must be kept distinct. Market research should not collect individual patient data.
8. The term "**representative"** means a representative calling on healthcare professionals and/or appropriate decision makers in relation to presenting promotional and non-promotional information on medicinal products, such as but not limited to medical representatives, district managers, area sales managers, sales managers, product managers, marketing managers, medical scientific liaisons etc.
9. The term "**sample"** means a medicinal product, supplied for free, labeled as free sample, provided to healthcare professionals so that they may familiarize themselves with it and acquire experience in dealing with it.
10. The term **observational/non-interventional study** refers to the study within which:
    - the medicine/medicines is/are prescribed in compliance with the terms of their marketing authorization;
    - the use for the patient of a determined therapeutic strategy is not pre-established by the study protocol, but it is submitted to the current practice,
    - the decision of prescribing the medicine is clearly separated from that of including the patient into the study;
    - no additional diagnostic or supervision procedure is required, and
    - the analysis of the gathered data, is based on epidemiologic methods;

Additional information

INTERACTION WITH PUBLIC OFFICIALS (ROMANIAN "FUNCŢIONARI PUBLICI")

ARPIM members may interact for the performance of their activity with public officials (Romanian "funcţionari publici") including healthcare professionals holding position of decision makers.

For this type of interactions which are not regulated by the provisions of this Code, other than in this chapter, ARPIM members will have the following obligations:

1. In any interaction with public officials, ARPIM members shall observe a proper conduct and ethical practices. ARPIM members will not participate and/or initiate any activity or relation that can affect the public official's integrity or the reputation of the pharma industry, of ARPIM or of other ARPIM members.
2. Interactions between ARPIM members and public officials should be conducted under the highest standards of ethics and professionalism and ARPIM members should avoid any perception of conflict of interest.
3. The ARPIM members will not provide any misleading, false, injurious and/or discriminatory information to the public official.

To increase transparency ARPIM members may include in the agreements concluded with healthcare professionals and decision makers, references to the obligation of the healthcare professionals and of the decision makers to respect all legal provisions regulating incompatibility and/or conflict of interest, if applicable. For the purpose of supporting ARPIM members, a non-exhaustive list of legislation in the healthcare field that comprises provisions on HCP/decision-makers' incompatibilities and/or conflict of interests is included.

In addition, for the support of the members an example of a contractual provision that can be included by ARPIM members in the agreements concluded with the HCP/decision makers is presented below.

The list and the model clause provided are only an example and should be regarded as a minimum protection recommended to the ARPIM members to which they can add as they see fit, without any acknowledgement by ARPIM on the degree of compliance granted by such clause.

List of main legislation containing provisions on incompatibility or conflict of interests of HCP/decision makers

a) Law no. 95/2006 on the healthcare reform;

b) Law no. 188/1999 on the Statute of the public officers;

c) Law no. 161/2003 for certain measures for ensuring transparency in the exercise of public dignities. of public functions and in the business environment, prevention and sanctioning of corruption,

d) Order no. 632/2006 for the approval of the format of the declaration of interest, of the declaration concerning the incompatibilities and of the declaration of property,

e) Order no. 398/2013 for the set-up of consultative commissions of the Ministry of Health.

f) Decision of the Scientific Council of the National Medicines and Medical Devices Agency no. 33/31.12.2010 on the approval of the Regulation for the organization and functioning of the Scientific Council of the National Medicines and Medical Devices Agency

g) Government Decision no. 734/2010 on the organization and functioning of the National Medicines and Medical Devices Agency

h) Government Decision no. 972/2006 for the approval of the Statute of the National Health Insurance House

Example of contractual clause

More general obligation (minimum content):

The [HCP/decision maker] declares that he/she is not under a state of incompatibility, as provided by the applicable legislation. The [HCP/decision maker] declares and undertakes that he/she will observe the obligations regarding the conflicts of interests prescribed by any applicable legislation.

More detailed obligations (a new paragraph can be added to the first paragraph):

The [HCP/decision maker] declares that he/she is not under a state of incompatibility, as provided by the applicable legislation. The [HCP/decision maker] declares and undertakes that he/she will observe the obligations regarding the conflicts of interests prescribed by any applicable legislation.

The [HCP/decision maker] guarantees that he/she shall fill and submit to the unit where he/she carries out his/her activity or to any other competent or interested authorities and entities all the declarations indicated in any applicable legal provisions stipulating the submission of declarations of interests, declarations concerning the incompatibilities**, declarations of property or any other similar obligations for the [HCP/decision maker].**

PROVISIONS OF THE ARPIM CODE

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 and supply. A medicinal product must not be promoted outside of its approved indications.

Section 1.02. Promotion must be consistent with the particulars listed in the Summary of Product Characteristics (SPC) of the relevant medicinal product and must be in accordance with the terms of its marketing authorization as issued by the Decision of either the National Medicines and Medical devices Agency (NMMDA) or the European Medicines Agency (EMA).

The promotion by using information not covered by the Marketing Authorization terms for a medicinal product ("off-label promotion") is prohibited.

The ARPIM members, through their specialized (MEDICAL/SCIENTIFIC) departments, may provide information outside the indications specified in the Marketing Authorization ("off label"), exclusively in response to an unsolicited and explicit request from a Healthcare Professional or an entitled Healthcare Organization.

ARTICLE 2. INFORMATION TO BE MADE AVAILABLE

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

a) Essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised.

   (i) Such essential information should at least contain the following: brand name; active ingredient (INN = international nonproprietary name); indication; dosage; method of use; contraindications, precautions and adverse reactions; name and address of the Marketing Authorization Holder; for these pieces of information, the font size 10 shall be used, whichever might be the font type).

   (ii) The prescribing information for a medicinal product does not have to be included on a promotional material if the promotional material includes no more than the name and address of the company responsible for marketing the medicinal product.

b) The supply classification of the product and the type of prescription based on which it is released/sold;

c) 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 relevant Romanian laws and regulations, if an advertisement is intended only as a reminder, the requirements of *Section 2.01* above need not be complied with, if the advertisement includes no more than the name of the medicinal product or its international non-proprietary name, when available, or the trademark, and a simple statement of indications to designate the therapeutic category of the product or the way of administration.

Additional information

The posters, promotional panels, banners, booths – and the variants thereof - must include the essential information presented in Section 2.01 when they contain more than the name of the medicinal product or the international common name (if available) or the brand.

Clinical data based on sources not in the public domain, must be accompanied by the following standard phrase "Data on file at [add name of ARPIM member concerned]. Data are available on request". At the request of a HCP or relevant health authority, the ARPIM member must provide the reference source within a period of 30 (thirty) calendar days.

Any advertising printed material destined to the HCPs must include the note "This promotional material is addressed to healthcare professionals".

ARTICLE 3. PROMOTION AND ITS SUBSTANTIATION

Section 3.01. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion on the therapeutic value of the medicinal product concerned. It should be based on an up-to-date assessment of all relevant evidence and it should reflect that evidence clearly. It must not mislead by distortion, exaggeration, and 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 a request from a HCP or to a request of an ARPIM member. In particular, promotional claims about adverse reactions must reflect available evidence or must be capable of substantiation by clinical experience. Substantiation needs not to be provided, however, in relation to elements approved in the marketing authorization.

Section 3.03. When promotion refers to published studies, clear references should be given. Also, if the referred data is the result of an investigation in animals (e.g. *in vivo*) or *in vitro*, this should be clearly stated and the reference should be clearly presented in this way on the same page, to avoid any misunderstanding or misinterpretation.

Section 3.04. Any comparison made between different medicinal products must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.

Within comparative advertising it is not allowed:

a. To denigrate the products of another pharmaceutical company.

b. To use the brand (trademark) name of another pharmaceutical company, being only permitted to mention the non-proprietary (generic) name. The only exception allowed is a price comparison directly quoted from the official website of the Romanian health authorities.

c. To compare products which have different indications.

Section 3.05. All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material should:

a) clearly indicate the source(s) of the artwork;

b) be faithfully reproduced; except where adaptation or modification is required 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 any promotional material does not mislead about the nature of a medicinal product (for example use illustration presenting children in a promotional material for a product not indicated for children) or mislead about a claim or comparison (for example by using incomplete or statistically irrelevant information or unusual scales).

Section 3.06. The words “safe”, “involving no risks” or similar wording must never be used to describe a medicinal product without proper substantiation.

Section 3.07. The word “new” must not be used to describe any 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 3.08. It must not be stated that a product has no side effects, toxic hazards or risks of addiction or dependency.

Additional Information

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.

ARTICLE 4. USE OF QUOTATIONS IN PROMOTION

Section 4.01. Quotations from medical and scientific literature or from public communications must be faithfully reproduced (except where adaptation or modification is required 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 must be identified.

For accurate and correct quotations, ARPIM members are requested to follow relevant guidelines (e.g. but not limited to "Quote-Unquote; Referencing in the Harvard Style", or the Vancouver Referencing Style).

ARTICLE 5. ACCEPTABILITY OF PROMOTION

Section 5.01. ARPIM members must maintain high ethical standards in the promotion process. 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 medicines and the professional standing of the recipient(s) of the promotional act; c) not be likely to cause offence to the competitors.

ARTICLE 6. DISTRIBUTION OF PROMOTION

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

Section 6.02. Promotional material for a prescription-only medicinal product should only be sent or distributed to healthcare professionals. It is prohibited to leave such promotional materials in places that are accessible to the general public such as, but not limited to, pharmacies, waiting rooms, corridors of hospitals and clinics, etc.

Section 6.03. Mailing lists must be kept up-to-date and to respect the law no. 677/2001 with all subsequent amendments, related to collection, use, processing and disclosure of personal data. Requests by HCPs to be removed or not be added from/in promotional mailing lists must be complied with.

The use of fax, e-mail, automated calling systems, text messages and other electronic data communication for the promotion is prohibited except for the cases in which it is performed with the previous agreement of the recipient or on the request thereof.

Additional Information

In case that international promotional materials produced outside Romania are distributed during international congresses and symposia held in Romania for medicinal products which are registered in other countries but not in Romania and/or for medicinal products registered in Romania under different indications, suitable, clear written statement need to be provided on the registration status in Romania of that medicinal product and/or the respective indication. These should be attached to the respective material, by the ARPIM member.

Regarding materials which refer to the prescribing information (warnings, precautions etc.) authorized in a country/countries other than Romania, and different from the Romanian label a written statement indicating that registration conditions may differ internationally, needs to be attached by ARPIM member to the respective material.

ARTICLE 7. TRANSPARENCY OF PROMOTION

Section 7.01. Promotion must not be disguised.

Additional Information

Any material relating to medicinal products and their uses, whether promotional in nature or not, which is issued under the sponsorship of an ARPIM member must clearly indicate that it has been sponsored by the respective ARPIM member. The only exception to this may be certain market research material, which need

not reveal the name of the ARPIM member involved to avoid influencing responders. Such market research materials must disclose that the research is sponsored by the pharmaceutical industry.

Section 7.02. Non-interventional studies, post marketing surveillance or any other data collection must not be used to disguise promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose.

Section 7.03. When promotional materials are published in the press following services engaged by an ARPIM member, its subsidiary or a related company (i.e. the PR company of the ARPIM member) such promotional material should clearly reveal the ARPIM member, beneficiary of the publication service. Such article must not resemble independent editorial matter.

Section 7.04. Every ARPIM member is accountable for all informative materials referring to its medicinal products, no matter if they are or not of promotional nature. In case such materials are disseminated by public relations agencies under contract, sponsorship by the respective ARPIM member and its nature must be clearly/visibly disclosed.

ARTICLE 8. NO ADVICE ON PERSONAL MEDICAL MATTERS

Section 8.01. 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.

ARTICLE 9. INFORMATIONAL AND/OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY.

Section 9.01. The transmission of informational or educational items and items of medical utility is permitted provided these are:

a) "inexpensive";

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

c) directly beneficial to the care of patients.

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 the recipient.

The scope of informational and educational materials and items of medical utility considered may not constitute a circumvention of the prohibition of gifts defined under Article 17 of this Code.

The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.

Additional Information

The meaning of the term "inexpensive", as defined by local association, is a value up to 150 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 10. EVENTS AND HOSPITALITY

General Provisions

ARPIM members may sponsor independent events organized by 3rd parties with the purpose to allow the continuing professional development and clinical performance of HCPs and improve patient care and patient outcome.

ARPIM member companies should never make attempts to control or to influence such events or their content or to condition the meeting on any particular agenda or set of topics.

ARPIM members may sponsor a variety of events (as described under section 10.02) if the following conditions are met:

a) Information about the meeting – including the **agenda** - is publicly available within a reasonable timeframe prior to the meeting date, offering equal opportunity for all HCPs to participate.

b) Relevant and clear medical/scientific educational topics are the main focus of the event and the associated hospitality is reasonable and is aligned to the scope of the event;

c) Sponsoring independents event and/or HCPs to attend independent events is public information. The sponsorship by any ARPIM member must be disclosed by the event organizer in all the materials relating to the event and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset

d) Sponsoring independent events and /or HCPs to attend independent events must not be conditional to any obligation to promote, prescribe, recommend or purchase the products of the ARPIM member.

e) The companies are encouraged to follow criteria that govern selection for granting such sponsorship, as provided in the ARPIM Code.

f) Sponsoring independent events and /or HCPs to attend independent events must be disclosed by each ARPIM member in accordance with the ARPIM Transparency Code.

g) The companies should follow the criteria that govern the selection and the sponsorship of HCPs to participate at the events, as provided in the ARPIM Code or with respect to the ARPIM Code.

h) Organizing any entertainment in connection to an independent event, or sponsoring participation to entertainment during or in connection to an independent event organized by any third party is prohibited.

Section 10.01. All promotional, scientific or professional meetings, with HCPs (including residents) organized by an ARPIM member (such as but not limited to educational satellite symposia, advisory board, investigators meeting) as well as independent meetings, sponsored by ARPIM members (such as but not limited to congresses, conferences, symposia, continuous medical education courses) must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of the ARPIM Code.

Section 10.02. No ARPIM member may organize or sponsor an event that takes place outside Romania, with the following exceptions:

a) most of the attendees are from outside of Romania *and,* given the countries of origin of most of the attendees, it makes greater logistical sense to hold the event in another country, or

b) given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "**international event**").

Additional Information

In the two exceptional situations as described in Section 10.02 – or other similar ones, considered exceptions from section 10.02 – the ARPIM member in question must notify the ARPIM Ethical Environment Working Group (EEWG) with this respect, before the events occur.

EEWG members may communicate opposite opinion within 5 working days since the notification is received. If after elapsing of the 5-day period, no opposite opinion was raised the initiating ARPIM member may proceed.

Section 10.03. Promotional information which appears on exhibition booths or is distributed 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, so long as:

a) any such material (excluding promotional aids) has attached a suitable statement indicating countries in which the product is registered and makes clear that the product or use is not registered locally, and

b) any such material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the medicinal product is registered should have attached an explanatory statement indicating that registration conditions differ internationally.

Section 10.04. Hospitality extended in connection with company organized events with HCPs attending and with sponsored independent events shall be limited to travel, meals, accommodation and genuine registration fees.

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).

It is prohibited to sponsor HCPs to attend independent 3rd party meetings or congresses linked fashionable, sporting and/or cultural events.

Section 10.05. Member Companies shall not provide or offer any meal (food and beverages) to HCPs, unless, in each case, the value of such meal (food and beverages) does not exceed the monetary threshold set within the ARPIM Code. For independent events outside Romania the monetary threshold set in the country where the event takes place (i.e. the "host country") shall prevail.

Section 10.06. Any kind of hospitality may only be extended to persons who qualify as participants in their own right, meaning with a bona fide scientific professional relationship to the topics discussed at such event. Spouses and other accompanying persons, unless qualified as above, are not allowed to attend neither ARPIM member organized meetings nor benefit from the sponsorship of an independent event and should not receive any associated hospitality at the company's expense; the entire costs, which their presence involves, are the responsibility of those they accompany.

Section 10.07. All forms of hospitality offered to HCPs shall be reasonable in level and strictly limited to the duration of the event. As a general rule, the hospitality provided must not exceed what HCP recipients would normally be prepared to pay for themselves.

All forms of hospitality offered to HCPs shall be reasonable in level and strictly limited to the duration of the event (arrival at earliest the day before the opening and departure latest the day after its conclusion, according to the agenda of the event and reasonable flight schedules).

Section 10.08. To avoid inappropriate influence of the HCPs, ARPIM members should avoid using venues that are renowned for their entertainment or sporting facilities or for their "extravagance" or touristic designation for company organized meetings.

Additional Information

Venues with season related limitations for Romania are but not limited to: well-known ski resorts during winter season (01 Dec. -28/29 Feb.), sea side resorts and Danube Delta resorts during summer season (15 Jun. -31 Aug.).

With respect to theatre or museum halls (or similar) if no artistic event is held 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; these might be considered acceptable venues for such events.

ARPIM members must comply with guidance concerning the meaning of the term "reasonable", "extravagant", as used in this Article.

Domestic or abroad, it is prohibited to ARPIM members to sponsor events or to organize their own events that use as meeting facility, venues which are primarily associated by the public with: leisure (e.g. spa, wellness, beauty or balnear treatments etc.), sports, luxury, gambling or exclusivity, regardless of their price.

Therefore, it ARPIM members should not organize events with HCPs, in Romania or abroad using 5 star hotels or to sponsor independent 3rd party events organized in Romania taking place at 5 star hotels or in touristic resorts during the respective high seasons, i.e. during the summer season (15 Jun. -31 Aug.) and during the winter season (01 Dec. -28/29 Feb.).

With respect to sponsorship of HCPs for participation 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 while ARPIM member companies should ensure accommodation the entire period of such meeting at maximum 4 star hotels for the sponsored HCPs. The same provisions apply to events organized by the Group Company of respective ARPIM member with and for Romanian HCPs.

Section 10.09. Any document issued to invitees, which places undue emphasis on the luxury or ambience of the location or the accommodation, restaurants, or any social activity is not allowed.

Additional Information

The maximum limits for hospitality expenses are:

a) Airline travel (both domestic and abroad): economy (coach) class. Business class or beyond is not allowed;

b) Hotel accommodation (domestic) maximum budget:

- RON 675 per night, breakfast included, in Bucharest;

- RON 520 per night, breakfast included, outside Bucharest.

c) Meals: for domestic meals, the maximum amount is RON 300* (three hundred RON) per day for every person when the hospitality includes two main meals and RON 150* (one hundred fifty RON) per person per main meal, when the hospitality includes only one main meal;

d) For coffee break the maximum limit is RON 35 (thirty-five RON) per person. For full day events, not more than 2 coffee breaks per event day are acceptable.

Amounts include VAT.

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

ARPIM member companies shall not provide or offer any meal (food and beverages) to individual HCPs, unless the value of such meal (food and beverages) complies with the monetary threshold set hereby.

In case a representative of an ARPIM member would like to attend an event organized by another ARPIM member, this person should communicate the intention either in advance or at the site of the event to the company organizing the event. In case of co- organized events by an ARPIM member (which appears as

organizer or sponsor of the event) with a non-ARPIM member, the first one shall take all reasonable steps to ensure the participation of the applicant.

- The visiting representative shall identify him/herself to the organizer before the event starts.
- No more than 1 (one) representative of each ARPIM member can attend another ARPIM member's event. It is only when a foreign representative wishes to attend to an event, that he/she may be accompanied by a second representative of the ARPIM member for the justified purpose to assure the translation.
- Promotional and/or non-promotional events, other ARPIM members may attend are, in principle, but not limited to – launch and re-launch events, events dedicated to major published clinical studies and events where scientific studies are presented.
- Any meetings having clearly a confidential nature; meetings of expert committees – advisory boards, marketing strategy meetings, investigator meetings are closed to the participation of other ARPIM members.

The right to take part at events of ARPIM members should be practiced in good faith and should never be abused by any of the ARPIM members. For the avoidance of doubt, such visiting person 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 he/she influence any participants. For any sponsored symposia (luncheon events, satellite symposia, etc.) organized during congresses and conferences organized by professional medical associations or societies, no restrictions shall be applicable as to participation. However, also in such cases, the visiting participants shall respect the above-mentioned conditions relating to attitude.

ARTICLE 11 SPONSORSHIP/DONATIONS/GRANTS THAT SUPPORT HEALTHCARE OR RESEARCH

Section 11.01. Sponsorship/Donations and/or grants (monetary/in kind or otherwise) to public institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare or conduct research (that are not otherwise covered by the ARPIM HCP Code or the ARPIM PO Code) are only allowed if:

a) the sole purpose is of supporting healthcare or research;

b) are documented and kept on record by the sponsor/donor/grantor; and

c) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products;

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

Donations and grants to individual HCPs are not permitted. Sponsorship of HCPs to attend international events is covered by Article 13. Companies are encouraged to make available publicly information about donations and grants (monetary/ in kind or otherwise) made by them covered in this Section 11.01.

ARPIM members are responsible to include in the sponsorship/donation contracts the interdiction of using the donated equipment in personal interest or to obtain material advantages by the recipient's employees, and the recipient commits himself to use the object obtained by such donation, sponsorship, exclusively to the free benefit of the patients, and will complete disclosure of these activities as regulated by Romanian law.

Additional Information

To support the efforts towards technical-medical and scientific development in the benefit of patients, donations or sponsorships, for hospitals, clinics within the public health sector (except the private healthcare

institutes) or to the Non-Governmental Organizations (affiliated to public healthcare institutions or which have HCPs in their managing board) are allowed in the following cases:

Donations or sponsorships specifically destined (and proven by means of official contracts) as medical or technical equipment of general use, or for renovation and adaptation of the hospital/clinic locations.

This type of support must be strictly unconditioned (no medicines prescriptions or other types of commitment should be performed in exchange) and it must be directly connected to the medical activities, and to be directly or indirectly in benefit of the patient.

Are specifically based on an unsolicited request from the respective organization.

This kind of support is subject of disclosure for which provisions of the relevant laws and ARPIM Code must be followed.

To support the efforts towards technical-medical and scientific development in the benefit of patients, loans/lease of medical and/or technical equipment of general/medical use for hospitals, clinics within the public health sector (except the private healthcare institutes) or to the Non-Governmental Organizations (affiliated to public healthcare institutions or which have HCPs in their managing board) are allowed.

This type of support must be strictly unconditioned (no medicines prescriptions or other types of commitment should be performed in exchange) and it must be directly connected to the medical activities, and to be directly or indirectly in benefit of the patient.

Loans/lease are specifically based on an unsolicited request from the respective organization.

Items for strictly medical use, may be provided to public institutions only (not to individual HCPs). These items should intend to cover the gaps of insufficient funding of healthcare system (for example, but not limited to items like peak flow meters, stethoscopes, thermometers, sphygmomanometers, othoscopes, ophthalmoscopes, laryngoscopes, reflex hammers, head mirrors, rhinoscopes, glucometers, tongue retractors, weight and height scales, etc.). These items should not bare neither company nor product logo.

ARTICLE 12 FEES FOR SERVICE

Section 12.01. Contracts between companies and institutions, organizations or associations of HCPs under which such institutions, organizations or associations provide any type of services to companies (or any other type of funding not covered under Article 11 or not otherwise covered by the ARPIM HCP Code) are only allowed if such services (or other funding):

a) are provided for the purpose of supporting healthcare or research; and

b) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

ARTICLE 13 SPONSORSHIP OF HEALTHCARE PROFESSIONALS

Section 13.01. Companies must comply with criteria governing the selection and sponsorship of HCPs to attend training or events as provided in, or in connection with, any Applicable Code(s). Funding must not be offered to compensate merely for the time spent by HCPs in attending events. In the case of international events for which a company sponsors the attendance of a HCP, if any funding is provided to such HCP in accordance with the provisions of this Section 13.01, such funding is subject to the rules of the jurisdiction where such HCP carries out his/her profession, as opposed to those in which the international event takes place. For the avoidance of doubt, this Section 13.01 is not intended to prohibit the extension of hospitality to HCPs in accordance with Article 10 hereof.

ARTICLE 14. THE USE OF CONSULTANTS

General Provisions

No service fee shall be provided or offered to an HCP in exchange for prescribing medicinal products or for a commitment to continue prescribing medicinal products. Service fees cannot be offered or provided in a manner or on conditions that would interfere with the independence of a HCP's prescribing practice.

Section 14.01. It is permitted that ARPIM members engage HCPs for services such as but not limited to: lectures, consulting and/or advising (participation in but not limited to advisory board meetings), and involvement in medical/scientific activities and studies, training services (medical training for ARPIM member companies), and participation in market research whether in groups or individually.

The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

a) a written contract or agreement is signed 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) documentation of the services provided must be maintained by the ARPIM member;

c) a legitimate need for the services has been clearly identified in advance of requesting the services and entering into any agreement with the prospective consultants;

d) the criteria for selecting consultants must be clear and are directly related to the identified need;

e) the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the particular HCP meets those criteria;

f) the number of HCPs retained is not greater than the number reasonably necessary to achieve the identified need;

g) the contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;

h) contracting HCPs to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and

i) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating HCPs.

Section 14.02. For services provided, external consultants shall be offered reasonable compensations, including the reimbursement of reasonable travel expenses, meals and accommodation related to the provision of the service. The limits considered reasonable (hourly rates) are described in Additional Information below and must be followed by ARPIM member companies.

*Section 14.03***.** In their written agreements with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company, whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, 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 his/her employment arrangement with the company whenever he/she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company. The provisions of this Section 14.03 apply even though the ARPIM Code does not otherwise cover non-promotional, general information about companies (as discussed in the "Scope of the ARPIM Code" section).

Section 14.04. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Article 14, if the HCP is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal.

Section 14.05. If an HCP attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of Article 10 shall apply.

Section 14.06. Reasonable maximum gross hourly rates for such services that can be paid to any individual HCP are provided below.

Additional Information

Starting from the public information related to the activities carried out by the healthcare professionals within private clinics or pharmacies, the ARPIM members recommend as fair market value for Romanian HCPs the following **gross amounts (hourly rates) VAT excluded**:

a) **450 RON/hour** for the healthcare professionals who can be found in the following situations: lectors or moderators at meetings in the healthcare field; presidents of medical societies or professional associations at national level; university professors or lecturers, primary physicians.

b) **370 RON/hour** for the healthcare professionals found in the following situations: lecturers at events in the healthcare field, presidents of medical societies or professional associations at local level; head of works (university lecturers); specialized physicians; main pharmacists

c) **285 RON/hour** for the healthcare professionals found in the following situations: lecturers at events in the healthcare field, family physicians; university assistants; pharmacists

d) **70 RON/hour** for the healthcare professionals found in the following situations: lecturers at events in the healthcare field: other categories of professionals not included in one of the above categories.

Note: if a speaker has both professional and academic title, the highest one shall be take into consideration.

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

- Total value for fees for lecturing and moderating services should not exceed a maximum **gross amount of** 2,700 **RON per activity and event-day.** Transparent disclosure to the audience of affiliation of the speaker with the ARPIM member company as beneficiary of the service should be made visible.
- Fees for all other activities (consultative and or medical training of ARPIM member employees) – as enumerated in section 14.01 should be calculated using reasonable hourly rates as presented above, as apply, and should not exceed a maximum **gross amount of 5,400 RON per activity and event-day (for both preparation and delivery).**

Based on efforts for the preparation, duration of event and level of expertise, ARPIM member companies shall define internally reasonable maximum net amounts for such services that can be paid to any individual HCP in a fiscal year.

ARTICLE 15. NON-INTERVENTIONAL STUDIES OF MARKETED MEDICINES

General Provisions

a) ARPIM members shall disclose their observational studies using the relevant form (Annex B) on the ARPIM website not later than 1 (one) month after the initiation of the study, initiation being the date of “first patient in”.

Within a period of 1 (one) year after completion of the study (meaning database lock), ARPIM members shall document publication/communication of study results (confidential part, only accessible to ARPIM members), using the same form as mentioned at point a).

b) Participating HCPs can be compensated for their work, taking into consideration factors such as their experience level, expertise in the therapeutical area concerned, and actual time and efforts spent on the study-related tasks. Overall, the amount should be reasonable, meaning that it should reflect the actual time and efforts spent as a supplement to professional routine work, and not exceed what is usually considered, per the ARPIM standards. Also, a suitable contract covering the above should be concluded with the participating HCP(s).

The amount paid to the HCPs involved in an observational study should not exceed the value for 10 (ten) visits, i.e. **2 850 RON gross value/ 1 patient / study, with no more than 12 visits per year and a limit of a maximum fee of 285 RON gross / patient / visit. Amounts are VAT excluded.** The aforementioned maximum amounts are indicative and constitute a common perception of all ARPIM members for fairness and reasonableness of the maximum possible compensation for HCP services as defined herein.

In case of extraordinary situations – appropriately documented – exceeding this limit can be taken only after 5 (five) working days since the notification of the ARPIM ethical group if within this period the ethical group did not formulate and send to the applicant a different resolution – recommendation.

Section 15.01. Observational studies are by definition of a non-comparative, non-experimental, and non-interventional nature and the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of their 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 medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.

Observational studies can supply information related to the clinical evolution of the patient included in the study, the safety in a real patient population in day-to-day practice and not only. The observational studies are not meant to increase the number of prescriptions.

To have better control on these kinds of studies, observational studies must be performed according to current legislation and in compliance with the following:

a) The observational study must be scientifically sound and yield relevant data and information on the ARPIM member's own medicinal product(s). The sponsor must not offer medicinal products used in the study. Generation of increased interest in or awareness of, the ARPIM member's medicinal products is not an acceptable objective of an observational study.

b) There is a written study plan (protocol) and there are written agreements between HCPs and/or the institutes at which the study will take place, on the one hand, and the company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to clause (c) immediately below, the basis for payment of those services;

   The study protocol must be approved by the company's scientific service which also must ensure supervision of the conduct of the study

   Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific department that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

c) Any remuneration provided must be reasonable and must reflect the fair market value of the work performed;

d) Under no circumstance can the study be proposed or designed with the objective of rewarding HCPs for using, purchasing, recommending or prescribing the medicinal products of the ARPIM member, or to persuade them to do so by participating in such study;

e) Specific local laws, rules and regulation including those on personal data privacy (including the collection and use of personal data) must be followed;

f) The scientific outcome of the observational study must be identified (i.e.: publication, generation and documentation of additional safety data).

The study results must be analyzed by or on behalf of the sponsor or contracting third party and summaries thereof must be maintained as records by the scientific service of the ARPIM member for a reasonable period of time. The company should send the summary report to all HCPs that participated in the study and should make the summary report available to industry self-regulatory bodies and/or committees that oversee 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 should be immediately forwarded to the relevant competent authority

g) Observational studies, which, by definition, take place only after a medicinal product is authorized, have to follow the study descriptions sent to the National Medicine and Medical Devices Agency (ANMDM).

h) The observational study can be started after following the procedures required by the laws in force.

i) Observational studies should be documented by a study synopsis that includes in their turn at least the following elements:

i. Scientific rationale.

ii. Objective of the study.

iii. Duration of the study.

iv. Target number of patients and number of physicians/sites planned for the study.

v. Inclusion and exclusion criteria. These must be within the indications limits, respectively contraindications of the involved medicine product. Any changes to these eligibility criteria out of the current practice for the pathology in question and the prescription information (RCP) shall be regarded as intervention, and shall automatically transform the observational study into a clinical trial, which is subject to the strict rules as mentioned under section 15.01 hereof.

The treatment with the medicine product should be decided by the physician based on his medical judgment and irrespective of the patient's inclusion into the study, not being decided by the study protocol.

vi. Parameters to be measured: the used scales, scores, questionnaires must be validated.

vii. Proper statistical analysis plan.

viii. Responsibilities for completion of case report forms, reporting of adverse events (AE) and retention (conservation/archiving) of the written materials of the study.

j) In all observational studies the sponsor (ARPIM member) must comply with the requirements of law 677/2001 concerning the collection, use and exposure of personal information gathered from the patients.

k) With respect to observational studies, sales representatives of an ARPIM member should not:

i. Negotiate contracts with the investigator or study center.

ii. Make payments to, or discuss payments with, the investigator or site.

iii. Encourage enrollment of patients in the study.

iv. Conduct medical or scientific discussions about the study (e.g. sample size, eligibility criteria).

l) Observational studies may be conducted only for a limited period of time. Successive renewals with the same HCP and with the same objective are not allowed.

m) Participating HCPs can be compensated for their work, taking into consideration factors such as their experience level, expertise in the therapeutics area concerned, and actual time and efforts spent on the study-related tasks.

The epidemiological research activities, observational studies and any other type of non-interventional research project carried out after the record of a medicine product must not be used as disguised promotion.

ARTICLE 16. SAMPLES

Section 16.01. In accordance with current Romanian laws and regulations and in accordance with the EU Directive 2001/83/CE, in principle, no medical samples should be provided, except on an exceptional basis.

- Medical samples must not be provided as an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products, and should be given for the sole purpose of treating patients.

- Medical samples are provided to health professionals so that they may familiarize themselves and acquire experience with the medicines.

In accordance with national and/or EU laws and regulations, a limited number of medical samples – of new medicinal products - may be supplied on an exceptional basis and for a limited period in compliance with the articles below.

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

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

Section 16.02. The number of samples yearly supplied for each medicine sold based on prescription is limited to maximum **4 units** of the smallest form available on the local market, per physician, per year, for 2 years since the reception of the first request**.**

Section 16.03. ARPIM members must have adequate systems of control and accountability for samples, which they distribute, and for all medicines given as samples by its representatives.

Section 16.04. Each sample shall be no larger than the smallest marketed presentation.

Section 16.05. Each sample must be marked '**free medical sample – not for sale**' or words to that effect and must be accompanied by a copy of the summary of product characteristics.

Section 16.06. No samples of the following medicinal products may be supplied:

a) medicinal products which contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971 and the national law

b) those for which the supply of samples is inappropriate, as determined by competent authorities, from time to time.

Additional Information

Samples may only be supplied in response to a written request, signed and dated, from the recipient. The solicitant may be only the physician habilitated to prescribe such medicine. Samples must be handed directly to the HCPs requesting them or persons authorized to receive them on their behalf.

It is prohibited sending by regular mail the requested medicine products.

ARTICLE 17. PROHIBITION OF GIFTS

Section 17.01. No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to an HCP.

Payments in cash or cash equivalents (such as gift certificates or coupons) are prohibited.

Payment of membership taxes in domestic or international medical association or support of the HCPs for editing medical literature is not permitted.

Additional Information

"Leave behinds" are considered gifts unless they fall into a category of items that are otherwise permitted under the ARPIM Code (i.e. informational or educational items or items of medical utility) and may not be provided to HCPs by ARPIM members.

Promotional objects, objects of general use (such as pens, agendas, calendars, office clocks and other similar stationary objects) are not permitted.

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

ARPIM members are not allowed to distribute pens or paper pads at exhibition booths.

In case, pens or paper pads are part of the sponsorship package to be included in conference bags these should not bear company or product logos.

ARTICLE 18. ARPIM MEMBER STAFF

Section 18.01. Each ARPIM member shall ensure that its representatives, including personnel retained by way of contract with third parties, and any other ARPIM member representatives who call on HCPs, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicinal products (each, a "representative") are familiar with the relevant requirements of the ARPIM Code, and all relevant Romanian 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) Representatives must comply with all requirements of the ARPIM code, and all relevant Romanian laws and regulations, and each ARPIM member is responsible for ensuring their compliance.

b) Representatives must approach their duties responsibly and ethically.

c) During each visit, representatives must provide to HCPs visited, or have available for them, a summary of the product characteristics for each medicinal product they present, as well as details on the price and reimbursement of such medicinal product.

d) Representatives must transmit immediately to the relevant department of their companies (medical, pharmacovigilance, quality assurance) any information they receive in relation to the use of the medicines out of the indications approved in Romania or with respect to their use during pregnancy and the reports related to the side effects or reports of quality deficiencies of their company's medicinal products.

e) Representatives must ensure that the frequency, timing and duration of visits to HCPs, pharmacies, hospitals or other healthcare facilities, together with the way they are made, do not generate inconvenience.

f) Representatives must not use any subterfuge to gain a call. No fee may be paid or offered for the grant of an interview. In an interview, or when seeking an appointment for an interview, representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the ARPIM member they represent.

g) ARPIM member representatives should preserve independence of the relationship patient physician, and should never interfere. Representatives should under no circumstance come in contact with, intend to gain access to or manipulate in any way and purpose – neither proactive nor in response to a request from an HCP - any document that contains medical information or medical record related to patients – such as, but not limited to: observation sheet, hospital discharge sheet, medical letter, laboratory test results.

h) It is prohibited to ARPIM member's representatives to assist, observe or take part in the process of medical consultation and therapeutic decision provided by the HCPs to the patients during the routine clinical practice.

Specific activities such as, but not limited to: adverse events collection and reporting; activities related to clinical research which either fall under specific regulations or are carried out based on patient informed consent are exempted from provisions under art 14 g) and h).

Section 18.02. All ARPIM member staff, and any personnel employed by way of contract with third parties, who are concerned with the preparation or approval of promotional material or activities must be fully conversant with the requirements of the ARPIM code and relevant Romanian laws and regulations.

Every ARPIM member must establish a medical and/or scientific department in charge of scientific and promotional information about its medicinal products and the approval and supervision of non-interventional & epidemiological studies. This medical/scientific department must include at least a physician or, where appropriate, a pharmacist who shall be responsible for approving any promotional material before release, who will be responsible as well for the oversight of non-interventional studies, including the review of any responsibility relating to such studies. Such person must certify that protocol has undergone revision and approval that all requirements of relevant regulations and codes are complied with. Such person must certify that he or she has examined the final form of the promotional material and the protocols of specified research activities and that in his or her belief it is in accordance with the requirements of the ARPIM code and any Romanian laws and regulations, is consistent with the summary of product characteristics and is a fair, equal and truthful presentation of the proofs about the medicinal product and has scientific value.

Each ARPIM member should implement a training program for all the employees - both on employment and whenever there are significant changes of the ARPIM Codes or in the Romanian laws and regulations in force.

ARTICLE 19. AWARENESS AND EDUCATION

a) Each ARPIM member shall organize training **at least every two years** so that the staff should remain informed with respect to the requirements of the ARPIM Code and the Romanian law and regulations in force.

b) ARPIM members shall organize **annually the knowledge assessment** of the staff, using the ARPIM designated platform and using as reference the training material published on ARPIM site. Each employee will be randomly assigned 20 questions for the knowledge testing and satisfactory score is achieved with 17 correct answers.

   The periodical review and update of this material is performed by the EEWG at least every 2 (two) years and/or whenever the reference law or regulations are amended.

   Each ARPIM member company must have in place a responsible employee for the technical supervision and coordination of the knowledge assessment.

c) Each ARPIM member must appoint/to establish at least one senior/managing employee who shall be responsible of assuring the observance of the ethical and compliance norms and to notify to the ARPIM secretary office the name of the person in charge with the ethics in promotion at the level of the organization in question within at most 30 days since his appointment/replacement. This employee shall be responsible for the implementation of the provisions of this code and of effective

legislation and who shall supervise that the demands and the standards of this code are respected. Each ARPIM member shall ensure an efficient control system by which all employees or contractors should respect the ethical standards established by this code.

ARTICLE 20. MARKET RESEARCH

Section 20.1. Market research refers to any organised effort to collect information about the market and consumers of products or services.

Section 20.2. Market research is a valid method for recording the data and characteristics of the pharmaceutical market.

Section 20.3. Market research can be conducted:

- either through questionnaires to which subjective answers are given by a sample that is representative of the reference population, i.e. the HCPs; or
- through questionnaires given to groups comprising a representative sample of the population under examination (focus groups - qualitative market research), i.e. the HCPs, in order to obtain a synthesis of answers.

Section 20.4. Market research must be unbiased, must not be focused on promoting sales, and must not aim at influencing the opinion of the participants.

Section 20.5. In each market research, care must be taken to ensure the random and representative selection of the participants.

Section 20.6. Market research may be retrospective/prospective; or a snapshot.

Section 20.7. Information and statistical results of market research may be used for promotional purposes, if the identity of the research (who, when, where, which sample) is clearly stated. In any case, the collection and the use of research data must be clearly distinct processes.

Section 20.8. Market research must be conducted in a manner that does not affect the credibility and reputation of the pharmaceutical industry.

Section 20.9. Market research must be conducted by certified market research companies, which must abide by the principles of ESOMAR/ EphMRA (European Society of Market Research, http://www.ephmra.org).

Section 20.10. Any communication between a patient and his familiars and the market research companies dealing with the trade/ allocation/ promotion of a medicines, is forbidden within the framework of these market research activities – as described above.

Section 20.11. ARPIM Member Staff must not perform or directly conduct market research.

Section 20.12. When ARPIM Member enters into an agreement with market research companies, they may grant to HCPs a reasonable compensation, which may not in any case exceed rates - as enumerated in section 14.

ARTICLE 21. COMPLAINTS AND SANCTIONS

Reception of Complaints

Complaints may be lodged either with ARPIM or with EFPIA.

Complaints received by EFPIA shall be processed as follows:

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

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

c. In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar matter(s) lodged from outside the industry against several subsidiaries of any company), EFPIA will communicate these complaints to the Member Association either of the parent company or of the European subsidiary designated by the parent company.

Adjudication of complaints shall be a matter solely for ARPIM.

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.

The purpose of such publishing being to create awareness, and prevent behavior/practices which have been found in breach of the ARPIM HCP 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.

Processing Complaints and Sanctions

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……. The leader and the members of the Arbitration Committee shall maintain as strictly confidential the complaint and its content towards any ARPIM member and publishing the convening of the Arbitration Committee (as such is detailed below) also towards the members of the Arbitration Committee.

A **valid complaint** from a 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 sent to ARPIM Executive Director's office.

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

Subsequently – within maximum 24 hours from receipt of the complaint - the leader of the Arbitration Committee must contact – via e-mail - the General Manager (or the equivalent head of the ARPIM member, 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 such complaint. The identity of the plaintiff company shall not be disclosed to the company subject of the complaint.

In the event that a breach of the present Code is established and acknowledged by the company in breach, the General Manager or its designated representative of the company in breach must submit within 10 (ten) working days since receipt of the information on the complaint, the corrective plan and timelines, to the attention of the leader of the Arbitration Committee.

The Arbitration Committee will complete an assessment of the corrective plan and timelines and in maximum 10 (ten) working days from receipt of the written position note 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 Arbitration Committee 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 Arbitration Committee 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 Arbitration Committee 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 or its designated representative must communicate disagreement with the elements of the complaint within a detailed position statement - within 10 (ten) working days from receipt of the information on the complaint – to the leader of the Arbitration Committee.

In such cases the leader of the Arbitration Committee will call upon an Arbitration Meeting within 10 (ten) working days from receipt of the position statement from the company in breach or within 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 or its designated representative
- Leader of the Arbitration Committee – members of the Committee should make all reasonable efforts to participate.
- Executive Director of ARPIM

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 Arbitration Committee 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 and will conclude with an agreed upon corrective action plan if the case, and decision for sanction.

Decision of the Arbitration Committee must be issued in maximum 72 hours 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 leader of the Arbitration Committee will keep track of activities for remedy and their completion. The General Manager of the company in breach or its designated representative must report completion of all corrective actions as per the agreed upon corrective plan, within the timelines as set in the plan to the leader of the Arbitration Committee.

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

Following the completion of a complaint, the Arbitration Committee shall propose workshops with all ARPIM members, 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).

The Arbitration Committee is the designated body of ARPIM to mediate complaints and to ensure that reported breaches of ARPIM Code are duly remediated.

The Arbitration Committee 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 Arbitration Committee consists of 5 (five) members elected of the ARPIM EEWG, including the workgroup leader that is also coordinator (leader) of the Arbitration Committee. Any decision of the Arbitration Committee is adopted if the (simple) majority of this group participates and it shall be made based on the simple majority of the participants' votes.

Conflict of interest

If there is a conflict of interests - for example the leader or any member of the Arbitration Committee 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.

Other provisions

a) If during the investigation new facts appear, likely to constitute a violation of the present Code, the Arbitration Committee 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 Arbitration Committee.

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

d) The decision of the Arbitration Committee cannot be overruled by the ARPIM Board.

e) The decision of the Arbitration Committee may include:

- Financial sanctions - during any 12-months period
    i. 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 about such breach by an ARPIM member;
- Promptly informing the other ARPIM members about such breach by an ARPIM member;
- Proposal to the General Assembly of ARPIM to suspend/terminate the membership of the ARPIM member in breach.

f) If the resolution of the Arbitration Committee 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 Arbitration Committee is not acceptable to one of the parties and there are no additional elements to justify a new assessment by the Arbitration Committee, 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 or, further on to a civil court.

g) The Arbitration Committee shall keep record of all cases and correspondence and ensure protection by confidentiality. The records shall be kept for 5 (five) years from the date of the last recorded decision of the Arbitration Committee.

ARTICLE 22. AMENDMENTS TO THE CODE

Section 22.01. The Ethical Working Group of ARPIM shall regularly review this Code and any guidance issued regarding compliance with this Code.

Any proposed amendments to the Code will be submitted for the ARPIM Board assessment and the ARPIM General Assembly ratification. Proposed amendments to this Code shall be reviewed by the ARPIM EEWG following consultation with the ARPIM membership and the relevant ARPIM committees.

ANNEX A: GUIDELINES FOR WEBSITES AVAILABLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND THE PUBLIC IN THE EU

The Guidelines for Websites Available to HCPs, Patients and the Public in the EU set forth herein are intended as a supplement to the provisions of the ARPIM Code of Practice on the Promotion of Medicines (the "**ARPIM Code**").

***Section 1*. Transparency of Website Origin, Content and Purpose.**

Each website shall clearly identify:

a) the identity and physical and electronic addresses of the sponsor(s)/owner(s) of the website;

b) full references related to the source(s) of all medical information included on the website;

c) the target audience of the website (e.g., HCPs, patients and the general public, or a combination thereof); and

d) the purpose or objective of the websites.

***Section 2.* Content of Websites.**

a) Information included in the website shall be regularly updated whenever there appear significant amendments of Marketing Authorization and/or the medical practice and shall be submitted to ANMDM approval, if the case.

b) Must clearly display, for each page and/or item, as applicable, the most recent date as of which such information was up-dated.

c) Examples of information that may be included in a single website or in multiple websites are:

   i. general information of the company;

   ii. information for health education;

   iii. information intended for HCPs (as defined in the ARPIM Code)

   iv. disclosure of transfers of value to healthcare professionals (HCP) and healthcare organizations (HCO)

General information of the company. Websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programs, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising law.

Information for health education. Websites may contain non-promotional information for health education about the characteristics of diseases; methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to therapeutic medicine options, if the discussion should be balanced and accurate. Relevant information may be given about alternative treatments, including, where appropriate, surgery, diet, behavioral change and other interventions that do not require use of medicinal products. Websites containing information for health education must always advise persons to consult a HCP for further information.

Information for HCPs. Any information on websites directed to HCPs that constitutes promotion (as defined in the ARPIM Code) must comply with applicable code(s) and with the regulations in force (as defined in the ARPIM Code) and any other regulations governing the content and format of advertisement

and promotion of medicinal products. Such information must be clearly identified as information for HCPs, but should not be accessible to the general public.

Section 3. **E-mail Enquiries.**

A website may invite electronic mail communications from HCPs and patients or the general public seeking further information regarding the ARPIM member's products or other matters (e.g., feedback regarding the website). The ARPIM member concerned may reply to such communications in the same manner as it would reply to enquiries received by mail, phone or other mean. In communications with patients or members of the general public, discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that an HCP to be consulted for further information.

Section 4. **Links from Other Websites.**

Links may be established to a company owned website from websites qwned by other persons, but ARPIM members should not establish links from websites designed for the general public to company owned websites that are designed for HCPs. In the same manner, links may be established to separate websites, including websites owned by the ARPIM member or by other entity. The "Links" should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

Section 5. **Website Addresses on Packaging.**

Subject to any applicable Romanian laws and regulations, uniform resource locators (URLs) of company owned websites addresses that comply with these guidelines may be included in packaging of medicinal products.

Section 6. **Scientific Review.**

ARPIM members should ensure that the scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the ARPIM code(s) and local laws and regulations. The medical/scientific department established within the company according to *Section 13.02b* of the ARPIM Code must perform this function, or – in extraordinary situations – it may be entrusted to other appropriately qualified persons.

Section 7. Privacy.

The website must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information.

ANNEX B: GUIDELINE FOR DISCLOSURE STUDY SUMMARY

STUDY SUMMARY

1. Initiation of study

(fill in at max. 1 month after initiation of study) (FPFV)

Sponsor Company		
Contact Person		
Title of study		
Substance		
Type of study (check one)	NIS (Non-interventional / observational study)	
	Epidemiological Study	
Indication		
Objectives	primary:	
	secondary:	
Scheduled times	First patient first visit	Year/Month
	Last patient last visit	Year/Month
	Follow-up period in protocol per patient	Weeks/Months
	Database closure	Year/Month
Number of patients to enter study		
Number of involved investigators / institutions		
Target population (demography, epidemiology)		
Data of submission to ARPIM		

2. Completion of study & publication (fill in after max. 1 year after data base lock)	
Publication references (paper, poster, oral communication etc.)	
Details : Date and publication or scientific event for publication/communication. Link to publication or detailed refrece	
NB: Art. 14 applies to all non-GCP studies, i.e.: *NIS (non-interventional studies), as defined by EU Directive 20/2001 EC and local regulations (involve treatment) – prospective and retrospective *Epidemiological studies (usually do not involve treatment, collect other data) - prospective and retrospective *Results of research (pharmaco-economy, burden of illness, quality of life) involving healthcare investigators. *the provisions shall apply to all non-GCP studies, conducted only in Romania or also in other countries. *the provisions shall not apply to market research conducted by third parties, not involving individual evaluations of patients.	