ARPIM HCP CODE

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

Adopted by the ARPIM Statutory General Assembly
of 27th of November 2014 (Edition 2014)*

* Applicable from January 1st , 2015.

Contents

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 28 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. Its members are the national associations of the pharmaceutical industry in 31 countries, as well as 38 of the most outstanding pharmaceutical companies. The majority of these companies are currently present in Romania.

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 in order 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. In order 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 drugs 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 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.

[1] Council Directive 2001/83/EC was amended in 2004 by Council Directive 2004/27/EC. The EFPIA Code was further revised in 2013, applicable from December 31st 2013.

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 stage 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.

Attached to the ARPIM Code are:

Implementation and Procedure Rules in the process of implementation of the requirements of ARPIM Code, Companies must follow the provisions of the "Implementation and Procedure Rules". Where ever the provisions of the Code are stricter related to the Rules, the provisions of the ARPIM Code will prevail.

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";

Annex C „Notification Form of the Workgroup for the Ethical Environment of ARPIM with respect to the requests of loans (commodatus) received by ARPIM members" according to section 11.03 from Implementation and Procedure Rules

Annex D: Information Form of the Workgroup for the Ethical Environment of ARPIM with respect to the medicines donations, according to section 11.04:

APPLICABILITY OF THE ARPIM CODE

The ARPIM Code sets out the minimum standards, which ARPIM members have committed to apply.

In the process of implementation of the requirements of ARPIM Code, Companies must follow the provisions of the "Implementation and Procedure Rules". Where ever the provisions of the Code are stricter related to the Rules, the provisions of the ARPIM Code will prevail.

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 Agency (NMA) 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":

(a) (i) in the case of promotion or interaction that is undertaken, sponsored or organiszed 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

(b) 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.).

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 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 Agency (NMA) or the European Medicines Agency (EMA).

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.

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, where an advertisement is intended only as a reminder, the requirements of *Section 2.01* above need not be complied with, provided that the advertisement includes no more than the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark, and a simple statement of indications to designate the therapeutic category of the product or the way of administration.

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 healthcare professional 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, in order 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.

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 in order to comply with any applicable code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.

Particular care must be taken to ensure that artwork included in 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.

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 in order to comply with any applicable code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources must be identified.

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 healthcare professionals 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.

Article 7. Transparency of Promotion

Section 7.01. Promotion must not be disguised.

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 healthcare professional.

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:

(i) "inexpensive";

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

(ii) directly beneficial to the care of patients.

Items of medical utility aimed directly at the education of healthcare professionals 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.

Article 10. Events and Hospitality

Section 10.01. All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (each, an "**event**"), including but not limited to visits to production sites or research laboratories, advisory board meetings, planning meetings, education (courses) or investigator meetings for clinical or non-interventional studies, organized or sponsored by an ARPIM member 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 invitees are from outside of Romania *and,* given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country, or

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**").

Section 10.03. Promotional information which appears on exhibition stands 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:

(i) any such promotional 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

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

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

It is not allowed to sponsor participation of healthcare professionals to independent or congress linked fashionable, sporting or cultural events.

Section 10.05. Member Companies shall not provide or offer any meal (food and beverages) to healthcare professionals, unless, in each case, the value of such meal (food and beverages) does not exceed the monetary threshold set within the Implementation and Procedure Rules of the ARPIM Code. 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.

Section 10.07. All forms of hospitality offered to healthcare professionals 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 healthcare professional recipients would normally be prepared to pay for themselves.

Section 10.08. In order not to influence the healthcare professional, ARPIM members should avoid using venues that are renowned for their entertainment or sporting facilities or for their "extravagance".

ARPIM members must comply with guidance concerning the meaning of the term "reasonable", "extravagant", as used in this Article, as provided in the Implementation and Procedure Rules of the ARPIM code.

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.

Section 10.10. Member companies must follow guidance on the meaning of the terms: "reasonable", "appropriate", "renowned" and "extravagant" as specifically detailed in the Implementation and Procedure Rules of the ARPIM Code.

Article 11 Sponsorship/Donations/Grants that Support Healthcare or Research

Section 11.01. Sponsorship/Donations and/or grants (in cash or in kind or otherwise) to public institutions, organizations or associations that are comprised of healthcare professionals 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:

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

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

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

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

Donations and grants to individual healthcare professionals are not permitted under this section. Company sponsorship of healthcare professionals to attend international events is covered by Article 13. Companies are encouraged to make available publicly information about donations and grants (in cash or in kind or otherwise) made by them covered in this Section 11.01.

ARPIM members are responsible to include in the sponsorship contracts the interdiction of using the equipment in personal interest or in order 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 the ARPIM Disclosure Code.

Article 12 Fees for Service

Section 12.01. Contracts between companies and institutions, organizations or associations of healthcare professionals 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):

i. are provided for the purpose of supporting healthcare or research; and

ii. 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 healthcare professionals 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 healthcare professionals in attending events. In the case of international events for which a company sponsors the attendance of a healthcare professional, if any funding is provided to such healthcare professional in accordance with the provisions of this Section 13.01, such funding is subject to the rules of the jurisdiction where such healthcare professional 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 healthcare professionals in accordance with Article 10 hereof.

Article 14. The Use of Consultants

Section 14.01. It is permitted that ARPIM members engage healthcare professionals 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, 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 agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;

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

c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;

d) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;

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

f) the hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and

g) 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 healthcare professionals.

Section 14.02. For services provided, external consultants shall be offered reasonable compensations, including the reimbursement of reasonable travel expenses, meals and accommodation (if the case). The limits considered reasonable (net hourly rates) are described in Implementation and Procedure Rules of the ARPIM Code and must be followed by ARPIM member companies.

Section 14.03. In their written contracts 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, healthcare professionals 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, provided that the healthcare professional 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. Member associations shall provide guidance on the meaning of "**minimal**" in connection with any Applicable Code(s).

Section 14.05. If a healthcare professional 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. 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

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.

In order 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 contracts between healthcare professionals 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 service 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 is reasonable and reflects the fair market value of the work performed;

d) Under no circumstance can the study be proposed or designed with the objective of rewarding healthcare professionals 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 healthcare professionals that participated in the study and should make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing Applicable Codes upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report 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 Agency of the National Medicine and Medical Devices (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 healthcare professional and with the same objective are not allowed.

m) Participating healthcare professionals 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.

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 given, except on an exceptional basis.

Medical samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products, and should not 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, for the products marketed after December **31st 2011.**

For products marketed under a Marketing Authorization issued before this date, no samples may be supplied.

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.

Article 17. Prohibition of Gifts.

Section 17.01. No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a healthcare professional.

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 healthcare professionals for editing medical literature is not permitted.

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 healthcare professionals, 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 hand in the healthcare professionals who come in contact with, 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 also 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 healthcare professionals, pharmacies, hospitals or other healthcare facilities, together with the manner in which 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.

Section 18.02.

a) 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.

b) 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 department must include at least a doctor 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.

c) 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 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. Additionally, 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. ARPIM members shall organize **annually the knowledge assessment** of the staff, using the ARPIM 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 Workgroup for ethical matters 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.

b) The training materials should be reviewed and approved by the Medical Department or other relevant Departments before being submitted to the staff.

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. 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 in its entirety or, where only selected details are published, including a level of detail that takes into account the seriousness and/or persistence of the breach as follows:

i. in cases of a serious/repeated breach, the company name(s) should be published together with details of the case;

ii. in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the company name(s).

Processing Complaints and Sanctions

Industry and/or non-industry complaints – should be submitted to the attention of the leader of the Arbitration Committee.

Complaints received by any other ARPIM member employee must be directed to the leader of the Arbitration Committee.

A valid complaint 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 actions

The leader of the Arbitration Committee must inform all members of the committee on the received complaint – within maximum 24 hours from receipt of the complaint.

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 potentially in breach and request a written position note containing: clarification, details, and argumentation in attention of the leader of the Arbitration Committee, the General Manager of the plaintiff company and cc to the members of the Committee.

In the event that a breach of the present Code is established and acknowledged by the company in breach the General Manager of the company in breach must submit within 3 (three) working days since receipt of the information on the complaint, the corrective plan and timelines, to the attention of the Manager of the plaintiff company, the leader of the Arbitration Committee and cc the members of the committee.

Based on the details received the General Manager of the plaintiff company may:

- consider complaint settled in case breach did not occur or

- request additional measures to be taken by the company in breach and/or
- request sanction

The Arbitration Committee will complete an assessment of the case and in maximum 2 (two) working days from receipt of the acknowledgement from the company in breach and may request additional corrective action/s from the company in breach.

In the event that:

- a breach of the present Code is established but not acknowledged – partially or entirely - by the company in breach, or
- the requested remedies are not considered acceptable by the company in breach, or
- no corrective action plan was submitted, or
- the submitted corrective action plan was not considered acceptable by the plaintiff company

the General Manager of the company in breach must communicate disagreement with the elements of the complaint within a detailed position statement - within 3 (three) working days from receipt of the information on the complaint – to the leader of the Arbitration Committee, the General Manager of the plaintiff company and cc the members of the Committee or

the General Manager of the plaintiff company must communicate disagreement with the proposed corrective actions - within 3 (three) working days from receipt, to the leader of the Arbitration Committee, the General Manager of the company in breach and cc the members of the Committee .

In such cases the Leader of the Arbitration Committee will call upon an arbitration meeting within 5 (five) working days from receipt of the position statement from the company in breach. Any time before the arbitration meeting the Arbitration Committee will analyze all details received on the "case" and will consolidate its position.

Mandatory participants in the arbitration meeting are:

- General Manager of the plaintiff company/or delegate
- General Manager of the company in breach/or delegate
- Leader of the Arbitration Committee – members of the Committee should make all reasonable efforts to participate.
- Secretary General of ARPIM

Each company involved may participate with additional two delegates.

Position of both companies will be heard as well as the position of the Arbitration Committee.

Arbitration will be moderated by the Secretary General of ARPIM and will conclude with an agreed upon corrective action plan and decision for sanction.

Decision of the Arbitration Committee must be issued in maximum 24 hours from conclusion of the meeting.

All complaints will be tracked and posted on the ARPIM intranet.

Update of the tracking log remains the obligation of the leader of the Arbitration Committee.

All Arbitration Meetings will be documented by minutes.

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 must report completion of all corrective actions according to 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.

The Arbitration Committee is the designated body of ARPIM to mediate complaints.

The ARPIM Arbitration Committee prepares and annual report summarizing the work undertaken by it 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 workgroup of an ethical environment, including the workgroup leader that is also coordinator 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 in breach - this person will not participate in the assessment of the respective case. 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 Members involved.

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

e) The decision of the Arbitration Committee may include:

   i. Financial sanctions - during any 12-months period
      - for the first violation: up to 5,000 (five thousand) EUR;
      - for the second violation: up to 10,000 (ten thousand) EUR;
      - for the third violation and each violation after the third: up to 15,000 (fifteen thousand) EUR;

   ii. administrative obligations as – not being limited to – retraining of the employees belonging the default company submitting the related documentation to the Arbitration Committee, the update of the domestic procedures of the company in breach, the transmission to a letter of apologize to the plaintiff company or a letter of the type „Dear doctor letter".

   iii. Promptly informing the international headquarter of the company found in breach about the litigation;

   iv. Promptly informing the Agency of the National Medicines and Medical Devices about such breach by an ARPIM member;

   v. Promptly informing the other ARPIM members about such breach by an ARPIM member;

   vi. 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, this 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 according to the above-described procedure. In case that the decision of the Arbitration Committee is not acceptable for one of the parties and there are no additional elements to justify a new assessment by the Arbitration Committee, this party may address this issue to the Agency of National Medicines and Medical Devices or, further on to a civil court.

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

Article 21. Amendments to the Code

Section 21.01. 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 Ethical Working Group of ARPIM following consultation with the ARPIM membership and the relevant ARPIM committees.

IMPLEMENTATION AND PROCEDURE RULES

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

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the ARPIM Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, the processing of complaints and the initiation or administration of sanctions by member associations.

The Implementation and Procedure Rules set forth herein are intended as a supplement to the provisions of the ARPIM Code and must be followed by member companies. The Implementation and Procedural Rules meet the local particular requirements and needs and are equally binding as the provisions of the ARPIM Code.

Wherever the provisions of the ARPIM Code are stricter related to the Rules, the provisions of the ARPIM Code will prevail.

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"** 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 drug/drugs 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;

INTERACTION WITH PUBLIC OFFICIALS (ROMANIAN FUNCTIONARI PUBLICI)

ARPIM members may interact for the performance of their activity with public officials (Romanian "functionari 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.

In order 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 Drug 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 Drug and Medical Devices Agency
g) Government Decision no. 734/2010 on the organization and functioning of the National Drug 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 (orientative, minimum content)

More general obligation:

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].

For Article 1. Marketing Authorization

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 its 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.

For Article 2. Information to Be Made Available

Section 2.01; a)

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)

The prescribing information for a medicinal product as required under Section 2.01 (a) hereof 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.

Additional Sections

Section 2.03. 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.

Section 2.04. 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 healthcare professional 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 healthcare professionals must include the note "This promotional material is addressed to healthcare professionals".

For Article 3. Promotion and Its Substantiation

Section 3.04

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.

Additional Section

Section 3.09. 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.

For Article 4. Use of Quotations In Promotion

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).

For Article 6. Distribution of Promotion
Additional Section

Section 6.04. 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.

For Article 7. Transparency of Promotion

Section 7.01 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.

For Article 9. Informational and/or Educational Materials and Items of Medical Utility.

Section 9.01 The meaning of the term "inexpensive", as defined by local association, is a value below **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.

For Article 10. Events and Hospitality
Additional General Provisions

In order to support the professional development of the healthcare professionals and to enhance their knowledge of the therapeutic areas in which they operate, ARPIM members may sponsor a variety of events (as described under *section 10.02*) provided that the following conditions are met:

a) Relevant and clear medical/scientific educational/informational objectives are the principal focus of the event and hospitality does not override and is not inconsistent with the limits set in the relevant section of this Code;

b) Sponsorship of an event and/or of a healthcare professional's attendance at an event is a public information. The meetings sponsored by (an) ARPIM member(s) must be disclosed in all of the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset

c) Sponsorship of the event or of the participation of healthcare professionals at an event must not be conditional to any obligation to promote, prescribe, recommend or purchase the products of the ARPIM member.

d) Sponsorship of events and/or sponsorship of the participation of healthcare professionals to attend an event must be disclosed by each ARPIM member. Provisions on technical aspects of disclosure and timelines to follow are subject of the relevant code.

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

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

For Section 10.02.

In the two exceptional situations as described in Section 10.02 – or other similar ones, considered exceptions from section 10.03 – the ARPIM member in question must notify the ethic work group of ARPIM with this respect, before the events occur.

The members of the EWG may communicate opposite opinion within 5 working days since the notification is received by the Ethical Working Group. If after elapsing of the 5 day period, the initiating ARPIM member may proceed.

For 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 the 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.

For Section 10.07

All forms of hospitality offered to healthcare professionals 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) and to the main purpose of the event.

For Section 10.08

For accommodation whether domestic or abroad, it is prohibited to use any location/or and facilities, which are primarily associated by the public with sports, luxury, or exclusivity, regardless of their price. It is prohibited using for accommodation 5 star hotels (note: the boarding houses are not integrated in this category).

It is not allowed to organize and/or sponsor events and/or sponsor the healthcare professionals' participation at events organized at five stars hotels for both events organized in Romania and/or abroad by the ARPIM members.

Additional Sections:

Section 10.11. 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 (incl. VAT):

- RON 675 per night, breakfast included, in Bucharest

- RON 520 per night, breakfast included, outside Bucharest

c) **Meals:** for domestic meals, the maximum limit is **RON 300*** (three hundred RON) per day for every person (coffee-break included), when the hospitality includes lunch, dinner and coffee-breaks or **RON 150*** (one hundred fifty RON) per person, when the hospitality includes only one main meal.

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

This limit does not apply for „*official dinner*" organized as part of the international congresses (as described in the documentation of the event).

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

Section 10.12. In case a representative of an ARPIM member would like to attend the promotional event of another ARPIM member, this person should communicate this intention either in advance or at the site of the event to the company organizing the event. In case of co-promotion events organized by one 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 organizers of the promotional event 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 events where other ARPIM members are allowed to take part are, in principle, all promotional or scientific events, such as – 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 the promotional 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.

For Article 11 Sponsorship/Donations/Grants that Support Healthcare or Research

Additonal Sections

Section 11.02. In order 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 healthcare professionals 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 drug 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 a unsolicited request from the respective organization

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

Section 11.03. In order to support the efforts towards technical-medical and scientific development in the benefit of patients, loans (commodatus) 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 healthcare professionals in their managing board) are allowed.

This type of support must be strictly unconditioned (no drug 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 (commodatus) are specifically based on a unsolicited request from the respective organization

Loans (commodatus) are subject to internal disclosure. Loans (commodatus) will be notified – using Annex C, attached to this Code - to the EEWG and it is the responsibility of the EEWG to ensure annually publishing on the intranet of ARPIM

Section 11.04. 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.

Section 11.05. The medicines donations to healthcare institutions shall be notified twice a year (July January) – according to annex D – to the ethical workgroup until the provisions on technical aspects of disclosure and timelines to follow from the relevant Code of Disclosure will become effective.

For Article 14. The Use of Consultants

Additional General Provisions

No service fee shall be provided or offered to a healthcare professional 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 healthcare professional's prescribing practice.

Additional Sections

Section 14.07. 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 the following **net hourly rates**:

i. 80 € net/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.
ii. 65 € net/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
iii. 50 € net/hour for the healthcare professionals found in the following situations: lecturers at events in the healthcare field, family physicians; university assistants; pharmacists
iv. 12 € net/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.

Section 14.08. Total value for fees for lecturing services should not exceed a maximum **net amount of 500 € per activities and event-day.**

Section 14.09. Fees for all other activities (consultative and or educational in nature) – as enumerated in section 14.01 should be calculated using reasonable hourly rates as presented above apply. Total value for fees for consulting and education services should not exceed a maximum **net amount of 1000 € per activity and event-day (for both preparation and delivery).**

Section 14.10. 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.

Section 14.11. In order to conclude a "bona fide" service and/or consulting agreements should fulfill all the following criteria:

a) a written contract specifying the nature of the services to be provided and the basis for payment of those services;
b) documentation of the services provided must be maintained by the ARPIM member;

Section 13.08. General considerations for ARPIM members when entering service engagement with healthcare or healthcare related professionals:

a) legitimate need for the services that has been clearly identified in advance;

b) clear criteria for selecting the consultants that must be related to the identified purpose

c) the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the particular healthcare professional meets those criteria;

d) the number of healthcare professionals retained must not be higher than the number reasonable necessary to achieve the identified purpose;

For Article 15. Non-interventional Studies of Marketed Medicines
Additional Sections

Section 15.02. 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.

Additional General Provisions

a) ARPIM members shall disclose their observational studies the relevant form (Annex B) on the ARPIM web site 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 at point (i).

b) Participating healthcare professionals 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. 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, according to the ARPIM standards. Also, a suitable contract covering the above should be entered into with the participating healthcare professional(s).

The amount paid to the healthcare professionals involved in an observational study should not exceed EUR **500 net value / 1 patient / study with no more than 12 visits per year and a limit of a maximum fee of EUR 50 net / patient / visit.**

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.

For Article 16. Samples
Additional Sections

Section 16.07. 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 healthcare professionals requesting them or persons authorized to receive them on their behalf.

Section 16.08. It is prohibited sending by regular mail the requested medicine products.

For Article 17. Prohibition of Gifts.
Additional Sections

Section 17.02. "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, as long as they are non-product branded and inexpensive.

ARPIM members are not allowed to distribute pens or paper pads at exhibition stands and pens or paper pads included in conference bags should not bear company or product logos.

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

The Guidelines for Internet Websites Available to Healthcare Professionals, 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:

b) the identity and physical and electronic addresses of the sponsor(s) of the website;

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

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

e) 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 APP and/or the medical practice and shall be submitted to ANMDM approval must clearly display, for each page and/or item, as applicable, the most recent date as of which such information was up-dated.

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

i. general information on the company;

ii. information for health education;

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

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

General information on 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, provided that 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 healthcare professional for further information.

Information for healthcare professionals. Any information on websites directed to healthcare professionals 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 healthcare professionals, but should not be accessible to the general public.

Section 3. **E-mail Enquiries.**
A website may invite electronic mail communications from healthcare professionals 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 post, telephone or other media. 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 a healthcare professional be consulted for further information.

Section 4. **Links From Other Websites.**
Links may be established to a company-sponsored website from websites sponsored by other persons, but ARPIM members should not establish links from websites designed for the general public to company-sponsored websites that are designed for healthcare professionals. In the same manner, links may be established to separate websites, including websites sponsored by the ARPIM member or by other persons. 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-sponsored 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). The scientific service 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 patients.		

ANNEX C: Form of information the ARPIM Workgroup for Ethical Environment with respect to the requests of loans (commodatus) received by ARPIM members according to the section 11.03 – Implementation and Procedure Rules

Compa y	Date sending EEWG	City/ District	Loan/commodat s beneficiary	Name of conta person	Object loaned	Value (RO with VA included)	Period Loan	Details/ Purpose
	DD/MM/AA	CHOOSE FROM TH LIST	CHOOSE FRO THE LIST AFTE SELECTING TH DISTRICT (SEARCH ALS UPWARD AN DOWNWARD). NOT FOUND, IT ADDED TO TH SHEET 2"BAZADATE" THE DISTRIC COLUMN, RESPECTIVELY ORDER			THE VALUE TURNED INT RON IRRESPECTIVE THE CURRENC AT TH EXCHANGE RATE TAKE INTO ACCOUN FOR OBTAININ THE INTERNA APPROVALS		

ANNEX D: Information Form of the Workgroup for the Ethical Environment of ARPIM with respect to the medicines donations according to section 11.04.

Company	Product name	INN	Concentration	Pharmaceutical form	Unit/package	Date donation	Beneficiary	Quantity	Value (RON with VAT included)