



ARPIM

ASOCIAȚIA ROMÂNĂ A PRODUCĂTORILOR
INTERNAȚIONALI DE MEDICAMENTE

ARPIM CODE OF ETHICS IN THE PROMOTION OF MEDICINES

Adopted by ARPIM (Edition 2010)*

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INTRODUCTION

The European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”) is the representative body of the pharmaceutical industry in Europe. Its members are the national industry associations of over 20 pharmaceutical producing countries in Europe, including over 40 leading pharmaceutical companies. Most of the EFPIA member companies also operate in Romania. In Romania, EFPIA is represented by its Romanian affiliate, called ARPIM (Romanian Association of International Drug Manufacturers).

The primary mission of EFPIA and ARPIM is to promote the technological and economic development of the pharmaceutical industry in Europe and to assist in bringing to market medicinal products, which improve human health worldwide.

Promotion and dissemination of scientific and educational information ensure that the results of years of scientific work and huge investments in research and development will also be made available to the healthcare professionals and to the patients worldwide. 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 had become a EU member. In order to apply the same high ethical standards for promotional activities performed by the pharmaceutical industry in the EU, it is mandatory to implement in Romania a code of conduct similar to the one applied in the EU countries. The code should thus assist in judging if promotional practices related to medicinal drugs are in keeping 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. Considering that, ARPIM has adopted in May 2005 the ARPIM Code of Practice on the Promotion of Medicines (the “**ARPIM Code**”). The ARPIM Code reflects the requirements of the EFPIA Code and Council Directive 2001/83/EC¹, 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. 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 pharmaceutical companies conduct such promotion 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 their medicines 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 2007, applicable from July 1st 2008.

DEFINITIONS

- 1) The term “**promotion**” means 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 its medicinal product(s).

It includes:

- a) journal and direct mail advertising;
 - b) the activities of representatives including detail aids and other printed material used by any ARPIM member; the supply of samples;
 - c) the provision of objects which are costless and relevant for the medical and pharmaceutical practice;
 - d) the sponsorship of scientific or promotional meetings including payment of traveling and accommodation expenses in connection with these meetings;
 - e) the provision of information to the general public either directly or indirectly,
 - f) 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 any medicine or vaccine intended for human use, which requires a marketing authorization.
 - 4) The term “**healthcare professional**” includes members of the medical, dental, pharmacy and nursing professions and their assistants.
 - 5) The term “**appropriate administrative staff**” includes practice managers and hospital management of public or private institutions, as well as drug formulary members or directors.
 - 6) 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.
 - 7) The term “**representative**” means a representative calling on healthcare professionals and/or appropriate administrative staff in relation to the promotion of medicinal products, such as but not limited to medical representatives, district managers, area sales managers, sales managers, product managers, marketing managers, etc.
 - 8) The term “**sample**” means a free limited supply of a medicinal product provided to healthcare professionals so that they may familiarize themselves with it and acquire experience in dealing with it.

SCOPE OF THE ARPIM ETHICAL CODE OF PRACTICE

The ARPIM Code covers the promotion to healthcare professionals and administrative corresponding personnel of prescription-only medicinal products and interactions between healthcare professionals and pharmaceutical companies. The ARPIM Code is applicable not only for pharmaceutical companies but their subsidiaries, and any companies affiliated with ARPIM member companies or their subsidiaries if such affiliated companies have agreed to be bound by the ARPIM Code.

Member Companies shall be responsible for the obligations imposed under any relevant Applicable Code (defined below) 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 (defined below) 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 (defined below) but that do not act on behalf of the Member Company (e.g., joint ventures, licensees) comply with Applicable Codes (defined below).

The ARPIM Code includes all methods of promotion as described in the definitions above.

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 (OTC).

The ARPIM Code does not cover the following:

- 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 administrative staff 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, accurate, 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 they include no product claims;
- 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.

Attached to the ARPIM Code are: 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 and Annex B “Guideline for disclosure the study summary”

APPLICABILITY OF CODES

The ARPIM Code sets out the minimum standards, which ARPIM considers must apply.

ARPIM member companies must comply with ARPIM codes and all relevant Romanian laws and regulations to which they are subject. 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 “Monitorul Oficial” no. 372/28.04.2006);
- the European Federation of Pharmaceutical Industries and Associations (**EFPIA**) Code of Promotion Practices;
- the Council Directive no 2001/83/EC relating to medicinal products for human use amended by Council Directive 2004/27EC;
- the International Federation of Pharmaceutical Manufacturers Associations (“**IFPMA**”) Code of Pharmaceutical Marketing Practices where applicable;
- the Pharmaceutical Research and Manufacturers of America (**PhRMA**) Code on Interactions with Healthcare Professionals.

ARPIM member companies must willingly respect 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.).

PROVISION OF THE ARPIM ETHICAL CODE OF PRACTICE

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 National Medicines Agency or European Council Decision.

Section 1.03. The promotion of indications not covered by the marketing authorization for a medicinal product (“off-label indications”) is prohibited.

An ARPIM member, through its specialized departments, may provide information outside the indications specified in the marketing authorization, in response to an unsolicited request from a healthcare professional.

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. Such essential information should at least contain the following: brand name; active ingredient (INN); indication; dosage; method of use; statement of contraindications, precautions and side effects; name and address of ARPIM member promoting the medicinal product;
- b) the supply classification of the product;

When appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies may be included. The prescribing information for a medicinal product as required under Section 2.01 hereof does not have to be included on a promotional material if the promotional material includes no more than the trade name of a medicinal product, and/or an indication that the name of a medicinal product is a trademark, and/or the name and address of the company responsible for marketing the medicinal product.

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 administration way.

Section 2.03. Promotional posters must include the essential information presented in *Section 2.01*.

Section 2.04. Clinical data based on sources not published yet, 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 authorities, each ARPIM member must provide the reference source within a period of 30 (thirty) calendar days.

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 of the therapeutic value of the medicinal product concerned. It should be based on an up-to-date evaluation of all relevant evidence and 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 reasonable requests from healthcare professionals. In particular, promotional claims about side effects must reflect available evidence or must be capable of substantiation by clinical experience. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorization.

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

Section 3.04. When promotion refers to published studies, clear references 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 3.05. 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. Critical references to another medicinal product(s), which are accurate, balanced, and fair and can be substantiated, are acceptable. Use of promotional materials in which the products or activities of a competitor or healthcare professional are unfairly denigrated is prohibited. Also use of a competitor's brand name is not allowed. Only mentioning of non-proprietary (generic) names are allowed. The only exception allowed is a price comparison directly quoted from the official website of the Romanian health authorities.

Section 3.06. All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material should:

- a) clearly indicate the precise source(s) of the artwork;
- b) be faithfully reproduced; except where adaptation or modification is required in order to comply with any applicable code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.

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

Section 3.07. The words "safe" or "involving no-risks" must never be used to describe a medicinal product without proper substantiation.

Section 3.08. 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 3.09. It must not be stated that a product has no side effects, toxic hazards or risks of addiction or dependency.

Section 3.10. Adequate provisions should be made in co-promotion agreements and the like to ensure that the ARPIM Code is adhered to. Where companies jointly promote the same product and the promotional materials bear both company names, each company must certify the promotional material involved, as the companies concerned will be held jointly responsible under this Code.

Article 4. Use of Quotations In Promotion

Section 4.01. Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. For accurate and correct quotations, ARPIM members are requested to follow the guidelines set forth in “Quote-Unquote; Referencing in the Harvard Style”, or the Vancouver Referencing Style, or guidelines of similar high quality.

Article 5. Acceptability of Promotion

Section 5.01. ARPIM members must maintain high ethical standards at all times. Promotion must: (a) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry; (b) be of a nature which recognizes the special nature of medicines and the professional standing of the recipient(s); and Article 1 not be likely to cause offence to the competitors.

Article 6. Distribution of Promotion

Section 6.01. Promotion should only be directed at those persons 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 related to collection, use and disclosure of personal information. Requests by healthcare professionals to be removed or not be added from/in promotional mailing lists must be complied with.

Consent of healthcare professionals for their personal data to be stored and further used (by fax, e-mail, automated calling systems, text messages and other electronic data communication) by any ARPIM member must be obtained before any mailing list and/or database is created.

Section 6.04. In case international promotional materials produced outside of Romania are distributed during international congresses and symposia held in Romania for medicinal products, which are registered in countries outside Romania but not in Romania, suitable verbal or written explanations need to be provided on the registration status of such medicinal product by the ARPIM member staff present. Regarding materials which refer to the prescribing information (indications, warnings, precautions etc.) authorized in a country/countries other than Romania, a verbal or written statement indicating that registration conditions may differ internationally, needs to be provided by ARPIM member staff present.

Article 7. Transparency of Promotion

Section 7.01. Promotion must not be disguised. Any material relating to medicinal products and their uses, whether promotional in nature or not, which is sponsored by an ARPIM member must clearly indicate that it has been sponsored by the respective ARPIM member. The only exception to this is market research material, which need not reveal the name of the ARPIM member involved but must state that it is sponsored by the pharmaceutical industry.

Section 7.02. Non-interventional studies must not be disguised 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 company who ordered the article or the final beneficiary of the article. Such article must not resemble independent editorial matter.

Section 7.04. Every ARPIM member is responsible of informative materials referring to its medicinal products, no matter if they are or not of promotional nature, disseminated by public relations agencies under contract, and must insure that it is clearly indicated the dissemination was sponsored by the respective ARPIM member.

Article 8. Limitations regarding the 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 should be advised to consult a healthcare professional.

Article 9. Events and Hospitality

Section 9.01. In order to assist in the 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 9.02 below) provided that the following conditions are met:

- a) relevant and clear educational objectives are the principal focus of the event and entertainment and hospitality do not override and are not inconsistent with those objectives; and
- b) sponsorship of an event and/or of a healthcare professional's attendance at an event is openly disclosed (especially to the healthcare professional's employer). 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; and
- c) sponsorship of the event or of a healthcare professional at an event must not be conditional to any obligation to promote or purchase the products of the ARPIM member.

Section 9.02. 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 9.03. No ARPIM member may organize or sponsor an event that takes place outside Romania (an “**international event**”) unless:

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

Section 9.05. 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.

Section 9.06. All forms of hospitality offered to healthcare professionals shall be reasonable in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be willing to pay for themselves.

Section 9.07. 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". Any entertainment episode must be subsidiary in character and may be associated as hospitality only to a scientific event. By its contents and character, the entertainment episode must not be prejudicial to the image of the pharmaceutical industry.

The current section applies both to events initiated by an ARPIM member and to those organized by professional associations and sponsored by one or more ARPIM members.

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

Section 9.08. 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 9.09. ARPIM members must comply with guidance concerning the meaning of the term "reasonable", "extravagant", as used in this Article 9, as provided in, or in connection with the ARPIM code.

Section 9.10. 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 (six hundreds and seventy five RON) per night, breakfast included, in Bucharest
 - RON 520 (five hundreds and twenty RON) per night, breakfast included, outside BucharestHotel accommodation abroad: hotel should be of a class comparable to that mentioned above.

Note: For accommodation whether domestic or abroad, it is prohibited to use any accommodation and facilities, which are primarily associated by the public with sports, luxury, or exclusivity, regardless of their price. It is prohibited to use 5 star hotels, except for international events organized in such locations by the international scientific societies or by the respective international head office of the ARPIM member concerned.
- c) Meals: for domestic meals, the maximum limit is RON 150* (one hundred fifty) per meal for every person. For meals abroad the limits are 150* EUR (one hundred fifty) / day (or the relevant equivalent) for lunch and dinner; this limit does not apply for „gala dinner” organized as part of the international congresses (as described in the documentation of the event).
- d) For participation to national/international scientific events, the following expenses may be supported: participation tax, transport, meals, accommodation, in the limits presented at (a), (b) and (c). The support of other expenses for events additional to the scientific event is not allowed.

- e) Net speaker's fees (for domestic speakers) for events in Romania will be differentiated based on the event type: *local*, *regional* (limited to one up to a few counties), *national* (participants from all over the country), and also based on the professional and academic title.

Local or regional events

- for specialists, Professor Assistants, Lecturers - the maximum is EUR 300 (three hundreds EUR or the equivalent in RON)

- for senior physicians, Associate Professors, Professors, and for the chairperson - the maximum is EUR 400 (four hundreds EUR or the equivalent in RON)

National events

- for specialists, Professor Assistants, Lecturers - the maximum is EUR 400 (four hundreds EUR or the equivalent in RON)

- for senior physicians, Associate Professors, Professors, and for the chairperson - the maximum is EUR 500 (five hundreds EUR or the equivalent in RON)

For international speakers, the international speakers' fees will be respected (according to the internal procedure of the ARPIM member).

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

Section 9.11. In case a representative of an ARPIM member would like to attend the promotional event of another ARPIM member, this person should announce either in advance or at the site of the event to the company organizing the event the wish to participate. 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 will take all the reasonable steps to ensure the participation of the applicant. The visiting representative will 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, launches of major clinical trials, as well as other events with participation of at least 25 (twenty five) healthcare professionals where scientific findings are brought to the attention of the community. For the avoidance of doubts, meetings with less than 25 healthcare professionals or meetings of a clearly confidential nature (meetings of expert committees – advisory boards, marketing strategy meetings etc.) 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 will arrive in time, will not cause any inconvenience, will only have the right as observer, and will in no way participate in discussions, Q&A sessions, nor will 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 will be applicable as to participation. However, also in such cases, the visiting participants will respect the above-mentioned conditions relating to attitude.

Article 10. Gifts. Inducements. Sponsorship

Section 10.01. No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a healthcare professional as an inducement to prescribe, supply, sell or administer a medicinal product.

Section 10.02. Subject to *Section 10.01* above, when medicinal products are being promoted to healthcare professionals, gifts, pecuniary advantages or benefits in kind may be supplied or offered to such persons only if they are inexpensive (maximum 150 RON including VAT, before personalization) and relevant to the practice of medicine or pharmacy. Used as promotional objects,

objects of general use may include pens, agendas, calendars, office clocks and other similar stationary objects.

Section 10.03. Except where they carry all the information stipulated in *Section 2.01* above, promotional objects may bear no more than the name and logo of the ARPIM member and the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, and if possible, a simple statement of indications to designate the therapeutic category of the product or the way of administration.

Section 10.04. Gifts for the personal benefit of healthcare professionals (such as tickets to cultural event) should not be offered or provided. As an exception, traditional gifts for Christmas, Easter, women's day (or March 1st), birthday or anniversary are allowed, only if they are not costly under the terms of this Code (less than 150 RON, including VAT). The allowed traditional gifts are: flowers and/or sweets/pastry.

Section 10.05. Items for strictly medical use are allowed up to a value of RON 500 (five hundred RON) including VAT. These items should intend to cover the gaps of insufficient funding of social medicine, and could be items like peak flow meters, stethoscopes, thermometers, sphygmomanometers, otoscopes, ophthalmoscopes, laryngoscopes, reflex hammers, head mirrors, rhinoscopes, glucometers, tongue retractors, weight and height scales, etc. Any items exceeding this value, such as air conditioners, refrigerators, expensive medical equipment etc. should not be offered or provided.

Section 10.06. Items provided to a doctor, to a hospital or to a clinic, for more than 3-month loan, are subject to the requirements of this code.

Section 10.07. Items which are for use at home, or which have no use in the ordinary course of the practice of medicine or any other healthcare profession, such as domestic appliances, phones, computers, electronics, cars, which are not considered relevant items, are unacceptable.

Section 10.08. Payments in cash or cash equivalents (such as gift certificates or coupons) should not be offered or provided.

Section 10.09. Irrespective to the above statements, in order to support the efforts towards technical-medical and scientific development, donations or sponsorships for hospitals, clinics, public health institutions (except the private healthcare institutes) or the Non Governmental Organizations (affiliated to public healthcare institutes 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) for medical or technical equipment of general use, or for restoration and transformation of 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, which take place in the respective institute. For transparency purposes, all ARPIM members that have the intention to offer this type of donations or sponsorships shall inform the ARPIM Workgroup for Ethical Environment and shall act upon their intention after having received a preliminary approval. Also, the ARPIM members will include in their sponsorship contracts the interdiction of using the equipments in personal or for material benefits. The beneficiary obliged itself to use the sponsored objects exclusively in patients benefit for free. The infringement of this obligation may lead to the sponsorship revocation. The decision of the ARPIM Workgroup for Ethical Environment will be taken by at least fifty percent plus one of the members.

The sponsorships will be disclosed every year, in an adequate manner (name of the beneficiary institution, total amount of sponsorship per year and a listing of the objects donated), on ARPIM website and can also be disclosed – in the above mentioned way – based on internal decision of ARPIM, at any moment.

Section 10.10. Donations of medicines do not fall under the scope of this Code.

Article 11. Sponsorship of Healthcare Professionals and rendering of their services to the ARPIM members

Section 11.01. Companies must comply with criteria governing the selection and sponsorship of healthcare professionals to attend events as provided in, or in connection with the ARPIM Code. Funding must not be offered to compensate merely for the time spent by healthcare professionals in attending events. For the avoidance of doubt, this *Section 11.01* is not intended to prohibit the extension of hospitality to healthcare professionals in accordance with *Section 9.10* hereof.

Section 11.02. In order to obtain professional medical advice or consulting advisory arrangements can be entered into. It is appropriate for consultants or external advisors who provide these services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing services. Maximum level of reimbursement is mentioned under *Section 9.10* hereof. The following support the existence of a bona fide consulting arrangement:

- a) a written contract specifying the nature of the services to be provided and the basis for payment of those services;
- b) a legitimate need for the services has been clearly identified in advance;
- c) the criteria for selecting the consultants are related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professional meets those criteria;
- d) the number of healthcare professionals retained is not greater than the number reasonable necessary to achieve the identified purpose;
- e) documentation of the services provided is maintained by the ARPIM member;
- f) the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.

Section 11.03. No sponsorships or consultancy fees shall be provided or offered to a healthcare professional in exchange for prescribing medicinal products or for a commitment to continue prescribing medicinal products. Sponsorships or consultancy 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.

Section 11.04. The healthcare professionals may receive as sponsorship books and other educational materials, having a reasonable value, and also the payment of the membership taxes for belonging to national or international medical associations or the access fees to the internet specialty web pages, provided that they answer to a real educational purpose.

A reasonable value for books and other educational materials is less than 500 EUR per book. In special situation, this value can be bigger, but the ARPIM Workgroup for Ethical Environment should be informed.

Section 11.05. Sponsorships should not be conditional upon the promotion / advertisement / publicity or prescription / sale of products. Sponsorships should not stand as the counterpart / proceeds of some works, goods or services provided by the beneficiaries of sponsorship for the sponsor's benefit.

Note: the amounts in RON can be revised by the ARPIM Workgroup for Ethical Environment if the exchange rate will be modified more than 5% compare with the exchange rate used for this revision of the Code, i.e. 1 EUR = 4,5 RON. The time of this revisions and the future exchange rates will be approved during GAM

Article 12. Samples

Section 12.01. In accordance with current Romanian laws and regulations (Law 95/2006), a limited number of free samples of a particular medicinal product may be exceptionally supplied to healthcare professionals who are qualified to prescribe that medicinal product in order to familiarize them with the product; but only in compliance with the articles below.

Section 12.02. Samples may only be supplied in response to a written request, signed and dated, from the recipient. The solicitant may be only the physician abilitated to prescribe receipts.

Section 12.03. Samples distributed by medical representatives must be handed direct to the healthcare professionals requesting them or persons authorized to receive them on their behalf.

Section 12.04. Medicines that are sent by mail must be packed so as to be reasonably secured against being opened by young children. No unsolicited medicinal product may be sent through the mail.

Section 12.05. ARPIM members must have adequate systems of control and accountability for samples, which they distribute, and for all medicines handled by its representatives.

Section 12.06. Each sample shall be no larger than the smallest presentation on the market.

Section 12.07. Each sample must be marked ‘free medical sample– not for resale’ or words to that effect and must be accompanied by a copy of the summary of product characteristics.

Section 12.08. 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;
- b) any other medicinal products for which the supply of samples is inappropriate, as determined by competent authorities, from time to time.

Section 12.09. The number of samples yearly supplied for each prescription-only medicine is limited. The maximum number of samples according to Romanian laws and regulations is the number necessary for treatment of 10 (ten) patients per health professional and per year according with the dosage and way of administration approved through the Summary of Product Characteristics.

Article 13. ARPIM Member Staff

Section 13.01. Conduct of staff of ARPIM members

- a) 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.
- b) 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.
- c) Representatives must approach their duties responsibly and ethically.
- d) 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.

- e) Representatives must transmit to the medical department of their companies forthwith any information they receive in relation to the use of their company's medicinal products, particularly reports of adverse drug reactions.
- f) 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.
- g) 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 13.02. Internal measures of ARPIM members to insure compliance with the Code

- a) All ARPIM member staff, and any personnel retained 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 department in charge of scientific information about its medicinal products. This medical department must include at least a doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the ARPIM code and any Romanian advertising 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.
- c) Each ARPIM member must appoint at least one senior employee who shall be responsible for 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 14. Non-interventional studies

Section 14.01. Market research activities and observational studies and the like, must not be used as disguised promotion.

Section 14.02. Clinical trials whether pre-registration or phase IIIB or phase IV are subject to strict EU Directives 2001/20/CE, Low 95/2006 and/or other Romanian legislation effective at that time, and therefore do not fall under the scope of this Code.

Section 14.03. Observational studies are by definition of a non-comparative, non-experimental, and non-interventional nature. Observational studies are not meant to increase the number of prescriptions, but only to generate additional information on efficacy and safety in a real patient population in day-to-day practice. 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) 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.

- c) The scientific outcome of the observational study must be identified (i.e.: publication, generation and documentation of additional safety data).
- d) Observational studies, which, by definition, take place, only after a medicinal product is authorized have to follow the study descriptions sent to the National Medicines Agency prior to commencement of such studies.
- e) Observational studies should be documented by a study synopsis that includes 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 are by definition the indications resp. contraindications. Any changes to these eligibility criteria will be regarded as intervention, and will automatically transform the observational study into a clinical trial, which is subject to the strict rules as mentioned under section 14.02 hereof.
 - vi. Parameters to be measured.
 - vii. Proper statistical analysis plan.
 - viii. Responsibilities for completion of case report forms, spontaneous adverse event (AE) reporting and record retention.
- f) 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 from patients.
- g) With respect to observational studies, sales representatives of an ARPIM member should not:
 - i. Negotiate contracts with the investigator or site.
 - 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).
- h) 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.
- i) ARPIM members will disclose their observational studies on the ARPIM web site not later than 2 (two) weeks after initiation of the study, initiation being the date of “first patient in”. Minimum information required: study synopsis as described under point “e” hereof and in Appendix B.
- j) Within a period of 6 (six) months after completion of the study (meaning database lock), ARPIM members will publish the final report on the ARPIM website (confidential part, only accessible to ARPIM members), using the template from Appendix B.
- k) 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 custom considered, according with 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 the observational studies should not exceed 50 EUR (net value) per 1 visit / 1 patient; if the volume of activity for 1 visit is very important, based on study protocol, higher amount could be paid, but EEWG must be notified in advance. According to general practice, the number of study visits / patient should not exceed 12 / year.

Article 15. Sanctions

In the event that a breach of the present Code is established, the General Manager (or Country Manager or the equivalent head of the ARPIM member, hereinafter referred to as “General Manager”) of the plaintiff company will contact the General Manager of the company in breach and the responsible person within the company in breach will provide the plaintiff company within 2 (two) working days with an action plan with clear tasks and deadlines to stop the respective activity and to avoid any reoccurrence.

- a) The plaintiff company may file a complaint to the ARPIM Arbitration Committee (as defined below) in the following situations:
 - i. no active measures have been taken by the company in breach within 2 (two) working days from providing the action plan;
 - ii. the company in breach does not take sufficient actions to cease the unethical activities;
 - iii. the deadline established in the action plan is not complied with.
- b) The complaints should be in writing, addressed to the members of the Arbitration Committee and also to the president of ARPIM and should clearly specify the arguments of plaintiff and the breached norms from the Code.
- c) The Arbitration Committee will assemble to discuss and judge the complaint in maximum 3 (three) working days from the date the plaintiff filed the complaint.
- d) In the situation when complaints are received from third parties (non-ARPIM members) these complaints will be forwarded to the chief of the Arbitration Committee. If additional information is required, the Chief of the Arbitration Committee will contact the General Manager of the plaintiff company and the above-described procedure will be applied. If there is a conflict of interests (for example the Chief of the Arbitration Committee is also the representative of the plaintiff company), the complaint will be forwarded to the other members of the Arbitration Committee and the Chief of the Arbitration Committee will not participate to the concerned meetings, with the exception of the case when he is representing the company in breach.
- e) Before issuing any decision, the Arbitration Committee will consult involved parties/their representatives.
- f) If during the proceedings new facts appear, likely to constitute a violation of the present Code, the Arbitration Committee will acknowledge, notify and judge these facts without being required a separate complaint.
- g) The interested parties may be assisted or represented by their consultants in front of the Arbitration Committee.
- h) The decision of the Arbitration Committee will be issued in maximum 5 (five) working days after the complaint is officially registered at ARPIM - in attention of the Arbitration Committee.
- i) The decision will be communicated in writing to the General Manager of the ARPIM Members involved.
- j) The decision of the Arbitration Committee cannot be overruled by the ARPIM Board.
- k) 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. *Promptly informing the international headquarter of the company found in breach about the litigation;*
 - iii. *Promptly informing the National Medicines Agency about such breach by an ARPIM member;*
 - iv. *Promptly informing the media about such breach by an ARPIM member;*

- v. *Proposal to the General Assembly of ARPIM to suspend/terminate the membership of the ARPIM member in breach.*
- l) The Arbitration Committee will consist of all members of the Ethical Environment Working Group of ARPIM. If the complainant company and/or the company in breach belong to this Working Group, then these companies will not be allowed to participate in the Arbitration meetings.
 - m) Any decision by the Arbitration Committee can only be made if the majority of this Working Group is participating, and will be made based on majority of votes.
 - n) If the resolution of the Arbitration Committee is not acceptable by one of the parties, the plaintiff party may address this issue to the National Medicines Agency or further on to a civil court.
 - o) 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.

APPENDIX 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:

- a) the identity and physical and electronic addresses of the sponsor(s) of the website;
- b) the source(s) of all information included on the website, the date of publication of the source(s) and the identity and credentials (including the date credentials were received) of all individual/institutional providers of information included on the website;
- c) the procedure followed in selecting the content 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 website.

Section 2. Content of Websites.

- a) Information included in the website shall be regularly updated and shall 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. health education information;
 - iii. information intended for healthcare professionals (as defined in the ARPIM Code), including any promotion; and
 - iv. non-promotional information intended for patients and the general public about specific medicinal products marketed by the company.

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.

Health education information. Websites may contain non-promotional health education information 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 medicinal products, provided that the discussion is 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 health education information 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) (as defined in the ARPIM Code) and any other industry codes of practice governing the content and format of advertisement and promotion of medicinal products. Such information must be clearly identified as information for healthcare professionals, but need not be encrypted or otherwise restricted.

Non-promotional information for patients and the general public. Subject to any Romanian laws and regulations, websites may include non-promotional information for patients and the general

public on products distributed by the ARPIM member (including information on their indications, side-effects, interactions with other medicines, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each product that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the full, unedited copy of any public assessment report issued by the Committee for Medicinal Products for Human Use or a relevant national competent authority. Brand names should be accompanied by international non-proprietary names. The website may include links to other websites containing reliable information on medicinal products, including websites maintained by government authorities, medical research bodies, patient organizations, etc. The website must always advise persons to consult a healthcare professional for further information.

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. 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 that comply with these guidelines may be included in packaging of medicinal products.

Section 6. Scientific Review.

ARPIM members should ensure that 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 pursuant to those provisions of the applicable code that adapt the Section 13.03 of the ARPIM Code may perform this function, or 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.

APPENDIX B: Guideline for disclosure study summary

STUDY SUMMARY

1. Initiation of study

(fill in at max. 2 weeks after initiation of study)

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
	Treatment 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

(fill in after max. 1 month after data base was secured)

Number of enrolled patients		
Date of database closure		
Date of submission of study completion form on ARPIM's webpage		

3. Publication references (paper, poster, oral communication etc.)

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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 (PhEc, burden of illness, QoL), which involves HCPs as investigators.

*Art. 14 applies to all non-GCP studies, conducted only in Romania or also in other countries.

*Art. 14 does not apply to market research conducted by third parties, not involving individual evaluations of patients.