ARPIM HCP/HCO DISCLOSURE CODE

ARPIM CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS (HCP) AND HEALTHCARE ORGANISATIONS (HCO)

Adopted by ARPIM Board on 3 December 2013 and ratified by the ARPIM Statutory General Assembly of 12 December 2013 (Edition 2013)*

* Applicable from January 1st, 2015

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PREAMBLE

The Romanian Association of International Medicine Manufacturers was founded in 1995, with a view to facilitating access of Romanian patients 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 in Romania. They represent together 70% of the pharmaceutical industry business volume 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 operating in Romania.

Healthcare professionals and healthcare organizations with whom pharmaceutical companies collaborate provide the pharmaceutical industry with valuable, independent expertise derived from their clinical and management experience. This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and society at large. Healthcare professionals and healthcare organizations should be fairly compensated for the legitimate expertise and services they provide to the industry.

Prescription only medicines developed by the research and development industry are complex products designed to address the needs of patients and of healthcare professionals for the treatment of diseases. The pharmaceutical industry can provide a legitimate forum for the education of healthcare professionals regarding the new and innovative medicines as well as regarding latest discovery in the management of various diseases and for the exchange and sharing of knowledge among healthcare professionals and industry.

EFPIA and, implicitly, ARPIM believe that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe a medicine is one of the pillars of the healthcare system. ARPIM recognizes that interactions between the industry and healthcare professionals can create the potential for conflicts of interest. Consequently, ARPIM has adopted codes and guidelines to ensure that these interactions meet the high ethical standards of integrity that patients, governments and other stakeholders expect.

In order to continue to be successful, self-regulation needs to respond to the evolving demands of the society. In particular, there is a growing expectation that interactions between corporations and society are not only conducted with integrity but are also transparent. Following the EU Commission initiative on Ethics & Transparency in the pharmaceutical sector, a multi-stakeholders' platform – including, among others, EFPIA – has adopted a "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector" (the "Guiding Principles").

In line with these "Guiding Principles", ARPIM believes that it is critical to the future success of the pharmaceutical industry to respond to society's heightened expectations. ARPIM has therefore decided that its existing Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals and Decision Makers (the "ARPIM Code") and Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations (the "PO Code") should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organizations. ARPIM hopes that, by taking this step, it can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stakeholders in the pharmaceutical industry.

ARPIM believes that the interest of patients and other stakeholders in the transparency of these interactions is compelling. ARPIM recognizes that disclosure can raise data privacy concerns and seeks to work with healthcare professionals to ensure that these concerns are addressed. ARPIM nonetheless believes that transparency can be achieved without sacrificing the legitimate privacy interests of healthcare professionals and legislation should not therefore impose excessive restrictions on disclosure by the industry.

The following Code provides for disclosures of Transfers of Value to healthcare professionals, whether directly or indirectly. When deciding how a Transfer of Value should be disclosed, companies should, wherever possible, identify and publish at the individual healthcare professional (rather than healthcare organization) level, as long as this can be achieved with accuracy, consistency and compliance with applicable law.

The following code imposes obligations to disclose Transfers of Value to healthcare professionals and healthcare organizations commencing with reporting in 2016 in respect of Transfers of Value for the calendar year 2015.

APPLICABILITY OF THIS CODE

This Code governs disclosures regarding certain interactions with HCPs and HCOs. It is intended that this Code shall apply to interactions with HCPs and HCOs to the same extent as the existing HCP Code and PO Code. Therefore, this Code applies to Member Companies, including:

- Members: research-based pharmaceutical companies, developing and manufacturing medicinal products for human use, operating in Romania – called members;
- Separate, affiliate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization – shall be deemed to constitute a single company, and is as such committed to compliance with the ARPIM Codes.

This Code sets out the minimum standards which ARPIM considers must apply to all Member Companies.

This Code is not intended to apply to Transfers of Value the disclosure of which is already provided for under, or that are otherwise regulated by, the PO Code.

ARPIM Non-member companies that decide to voluntarily implement this Code shall comply with all of the provisions of this Code.

ARTICLE 1. DISCLOSURE OBLIGATION

Section 1.01 General Obligation

Subject to the terms of this Code, each Member Company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a recipient, as described in more detail in Article 3.

Section 1.02 Excluded Disclosures

Without limitation, Transfers of Value that

i. are solely related to over-the-counter medicines;
ii. are not listed in Article 3 of this Code, such as inexpensive items of medical educational utility (governed by ARPIM Code, Section 09.01), business meals (governed by ARPIM Code , Article 10, especially Section 10.05), medical samples (governed by ARPIM code Article 16); or
iii. are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and an HCP (such as a pharmacist) or an HCO

do not fall within the scope of the disclosure obligation described in Section 1.01.

Section 1.03 Schedules

Each of the attached Schedules forms part of this Code. Definitions of capitalized terms are included in Schedule 1 to ensure consistent understanding of such terms.

ARTICLE 2 FORM OF DISCLOSURE

Section 2.01 Annual Disclosure Cycle

Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the "Reporting Period"). The first reporting period shall be the calendar year 2015.

Section 2.02 Time of Disclosure

Disclosures shall be made by each Member Company within 6 months after the end of the relevant reporting period and the information disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed in accordance with Section 2.04, unless, in each case,

i. a shorter period is required under applicable national data privacy or other laws or regulations, or
ii. the Recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked.

Section 2.03 Template

Subject to Section 2.04, for consistency purposes, disclosures pursuant to this Code will be made in RON using a structure set forth in Schedule 2 for reference, reflecting the requirements of this Code.

Section 2.04 Platform of Disclosure

Disclosures will be made on the ARPIM's public website as a final report or as a link to company's website where the report is disclosed.

Section 2.05. Applicable National Code

Disclosures shall be made pursuant to this national code where the Recipient has its physical address. If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its physical address, the Member Company shall disclose such Transfer of Value in a manner consistent with the national code to which it is subject.

Section 2.06 Language of Disclosure

Disclosures shall be made in Romanian language.

Section 2.07 Documentation and Retention of Records

Each member company shall document all Transfers of Value required to be disclosed pursuant to Section 1.01 and maintain the relevant records of the disclosures made under this Code for a minimum of 5 years after the end of the relevant reporting period, unless a shorter period is required under applicable national data privacy or other laws or regulations.

Section 2.08 Cross-border payments

As a general principle, Transfers of Value that fall within the scope of this Code have to be disclosed in the country where the recipient has its principal practice, whether the Transfer of Value occurs in or outside of Romania.

ARTICLE 3 INDIVIDUAL AND AGGREGATE DISCLOSURE

Section 3.01 Individual Disclosure

Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis. Each Member Company shall disclose, on an individual basis for each clearly identifiable recipient, the amounts attributable to Transfers of Value to such recipient in each reporting period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemized disclosure shall be made available upon request to

i. the relevant recipient, and/or
ii. the relevant authorities.

1. For Transfers of Value to an HCO, an amount related to any of the categories set forth below:

a. Sponsorships/ Donations/ Grants to HCOs that support healthcare, including sponsorships, medicines donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 11 of ARPIM Code);

b. Contribution to costs related to events, through HCOs or third parties, including sponsorship to

HCPs to attend events, such as:

i. Registration fees;
ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an event;
iii. Travel and accommodation (to the extent governed by Article 10 of the ARPIM Code)

c. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between member companies and institutions, organizations or associations of HCPs under which such institutions, organizations or associations provide any type of services to a member company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

2. For Transfers of Value to an HCP:

a. Contribution to costs related to events, such as:

i. Registration fees; and
ii. Travel and accommodation (to the extent governed by Article 10 of the ARPIM Code)

b. Fees for Service and Consultancy. Transfers of Value resulting from, or related to contracts between Member Companies and HCPs, under which such HCPs provide any type of services to a member company or contracts related to any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts. Fees for service and Consultancy should be established according to fair market value of such services as recommended by the provisions of the ARPIM Code.

Section 3.02 Aggregate Disclosure

For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 3.01, cannot be disclosed on an individual basis for legal reasons, a member company shall disclose the amounts attributable to such Transfers of Value in each reporting period on an aggregate basis. Such aggregate disclosure shall identify, for each category,

i. the number of recipients covered by such disclosure, on an absolute basis and as a percentage of all recipients, and
ii. the aggregate amount attributable to Transfers of Value to such recipients.

Section 3.03 Non Duplication

Where a Transfer of Value required to be disclosed pursuant to Section 3.01 or 3.02 is made to an individual HCP indirectly via an HCO, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual HCP named basis pursuant to Section 3.01(2).

Section 3.04 Research and Development Transfers of Value

Research and development Transfers of Value in each reporting period shall be disclosed by each member company on an aggregate basis. Costs related to events that are clearly related to activities covered in this section can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

Section 3.05 Methodology

Each member company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 3.01. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

ARTICLE 4 ENFORCEMENT

Section 4.01 Written Agreements

When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, companies are encouraged to include provisions relating to the recipients' consent to disclose Transfers of Value in accordance with the provisions of the ARPIM HCP/HCO Disclosure Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.

Section 4.02 Sanctions

For violation of the provisions of the Code – as reported by a Member Company by a non-member company or by any non-industry reporter, this noncompliance will be handled in accordance to Article 20. Complaints and Sanctions, of the ARPIM Code.

If the applicable national law or regulation prescribes equivalent or more stringent disclosure requirements, the relevant member company shall comply with such equivalent or more stringent requirements in a manner as consistent as possible with the substantive disclosure requirements of this Code.

ARTICLE 5 AMENDMENTS TO AND GUIDANCE REGARDING COMPLIANCE WITH THE CODE

Section 5.01 Code Compliance

The ARPIM Ethical Environment Working Group (EEWG) shall assist member companies to comply with their obligations under this Code. The key tasks of the EEWG are set forth in Schedule 3 attached to this Code.

Section 5.02 Amendments to the Code

The ARPIM EEWG 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`s Board decision and the ARPIM General Assembly ratification. Proposed amendments to this Code shall be reviewed by the EEWG following consultation with the ARPIM membership and the relevant ARPIM working groups.

Schedule 1 Definition of Terms Used in the ARPIM HCP/HCO Disclosure Code

Sponsorships/donations/Grants
Sponsorships/ donations/Grants, collectively, means those sponsorships, donations and grants (either cash or benefits in kind) within the scope of Article 11 of the ARPIM code

Sponsorship Agreements
Agreements formalized in contracts that describe the purpose of the sponsorship and the related Transfers of Value. If the contract includes "Registration fees" and "Travel and Accommodation", such Transfers of Value should, in principle, be disclosed separately in the relevant categories.
Examples of activities that should as a minimum be covered under "Sponsorship Agreements":

- Rental of booths at an "Event";
- Advertisement space (in paper, electronic or other format);
- Satellite symposia at a congress;
- Sponsoring of speakers;
- If part of a package, drinks or meals provided by the organizers (included in the "Sponsorship Agreement") etc.

Events
All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "Event") organized or sponsored by or on behalf of a company (as described in article 10 of the ARPIM Code)

HCO
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, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the ARPIM PO Code) whose business address, place of incorporation or primary place of operation is in Romania or

(ii) through which one or more HCPs provide services.

HCP
Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Romania. For the avoidance of doubt, the definition of HCP includes:

(i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and

(ii) any employee of a member company whose primary occupation is that of a practicing HCP, but excludes

(x) all other employees of a Member Company and

(y) a wholesaler or distributor of medicinal products.

Fee for Service and Consultancy agreements
Examples of that could be covered under fee for service and consultancy agreements:

- Speakers' fees;
- Medical writing;
- Data analysis;
- Development of education materials;
- General consulting / advising.

HCP Code – ARPIM Code
ARPIM Code on the Promotion of Prescription-only Medicines to, and interactions with Healthcare Professionals as adopted by the Board of Directors and the General Meeting of ARPIM – 12 December 2013

Medicinal Products
Medicinal Products as used in the ARPIM HCP/HCO Disclosure Code has the meaning set forth in Article 1 of the Directive 2001/83/EC, including: medicinal products, immunological medicinal products, radiopharmaceuticals, medicinal products derived from human blood or human plasma, for which a marketing authorization has been delivered in application of Directive2001/83/EC.

PO Code
ARPIM Code of Interaction with Patient Associations

Recipient
Any HCP or HCO as applicable, in each case, who`s primary practice, principal professional address or place of incorporation is in Romania.

Research and Development Transfers of Value
Transfers of Value to HCPs or HCOs related to the planning or conduct of

i. non-clinical studies (as defined in OECD Principles on Good Laboratory Practice*);
ii. clinical trials (as defined in Directive 2001/20/EC**); or
iii. non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study***.

*The OECD Principles on Good Laboratory Practice (as latest revised in 1997) define non-clinical studies as follows (Section I – 2. Definitions of Terms; section 2.3.1): Non-clinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities. For complete reference, see: www.oecd.org

**The EU Directive 2001/20/EC (Article 2(a) defines clinical trials as: any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmaco-dynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. For complete reference, see: EUR-lex.europa.eu.

***The EU Directive 2001/20/EC (Article 2(c)) defines non-interventional trials as: Studies where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the 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.

Transfers of Value
Direct and indirect Transfers of Value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products exclusively for human use. Direct Transfers of Value are those made directly by a member company for the benefit of a recipient. Indirect Transfers of Value are those made on behalf of a member company for the benefit of a recipient, or Transfers of Value made through an intermediate and where the member company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

Schedule 2 Model of a Standardized Template


Model of a
standardized templat

Schedule 3 Implementation and Procedure Rules

Section 1 ARPIM Obligations

ARPIM will ensure that:
a. The ARPIM Disclosure Code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its national code on its website; and
b. The it's Ethical Working Group will prepare, and provide to the EFPIA Codes Committee an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the applicable year.

For Section 3.01 Individual Disclosure

2. For Transfers of Value to an HCP:

a. Contribution to costs related to events, such as:

i. Travel and accommodation (to the extent governed by Article 10 of the ARPIM Code)

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

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.

b. Fees for Service and Consultancy:

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.

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

Fees for all other activities (consultative and or educational in nature) 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 2. 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.
Reception of Complaints; Processing of Complaints and Sanctions will follow the provisions as set forth in the ARPIM Code – Article 20

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 plaintiff company 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 workgroup participate and it shall be made based on the simple majority of the assistants' 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.