ARPIM CODE OF ETHICAL PRACTICE IN THE INTERACTION WITH PATIENT ORGANIZATIONS

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

Adopted by ARPIM*

ARPIM
ASOCIAȚIA ROMÂNĂ
a Producătorilor Internaționali de Medicamente

* Applicable from April 1st 2014.

Contents

Introduction

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

We are the association that supports the common objectives of the most important 28 international innovative medicine manufacturers operating in Romania. They represent together 70% of the pharmaceutical industry business in Romania.

Since 2004 ARPIM is affiliated to the European Federation of Pharmaceutical Industries and Associations (EFPIA), the representative organization of the European pharmaceutical industry. Its members are the national associations of the pharmaceutical industry in 31 countries, as well as 38 of the most outstanding pharmaceutical companies. The majority of these companies are currently present in Romania.

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

The pharmaceutical industry has many common interests with patient organizations representing or supporting the needs of patients and caregivers.

In order to ensure that the relations between the pharmaceutical industry and patient organisations are conducted in an ethical and transparent manner, ARPIM has adopted the Code of Ethical in Interaction with Patient Organisations – basic standard ARPIM member companies have to align with in their collaboration with patient organizations to maintain the following high standards of ethics:

1. Ensure the independence of patient organizations, in terms of their political judgment, policies and activities

2. All partnerships between patient organisations and the pharmaceutical industry shall be based on mutual respect, with the views and decisions of each partner having equal value;

3. The pharmaceutical industry shall not request, nor shall patient organisations undertake the promotion of a particular prescription-only medicine;

4. The objectives and scope of any partnership shall be transparent. Financial and non-financial support provided by the pharmaceutical industry shall always be clearly acknowledged;

5. The pharmaceutical industry encourages funding of patient organisations from multiple sources.

Scope

This ARPIM Code covers any interaction between ARPIM member companies and their contracted third parties and patient organisations which operate in Romania, but not only.

Patient organisations are defined as non-profit organisations (including umbrella organisations to which they belong). Their members are mainly patients and/or caregivers, people that represent and/or support the needs of patients and/or caregivers.

Applicability

The ARPIM Code of Practice sets out the standards which ARPIM considers must apply in the relationship with patient organisations that function in Romania, but not only.

ARPIM member companies must comply with the following codes, further referred to as "Applicable Codes" and any laws and regulations to which they are subject:

a) ARPIM Code of Practice
b) EFPIA Code of Practice outside Romanian territory
c) In the case of partnerships and activities taking place in a particular country within Europe, other than the industry code of the country in which the activity takes place;
d) In the case of cross-border partnerships and activities, the industry code of the country in which the patient organisation has its main European location, or in which the partnering affiliate of a patient organization has its location.

The requirements apply to activities or funding within Europe. 'Europe' as mentioned in the ARPIM Code, includes those countries in which the EFPIA member associations' codes of practice apply.

"Activity" as used above, shall mean any interaction covered by an Applicable Code, including the provision of funding.

The Applicable Codes that will apply must be specified in a written agreement between the company and the patient organisation. In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions shall apply.

For the avoidance of doubt, the term 'company' as used in this ARPIM code, shall mean any legal entity that provides funds or engages in activities with patient organisations covered by an Applicable Code whether such entity be a parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation. 'Activity' as used above, shall mean any interaction covered by an Applicable Code, including the provision of funding.

Provisions

Article 1 Non-promotion of Prescription-only Medicines

The relevant EU and national legislation **as well as** the codes of practice prohibiting the advertising of prescription-only medicines to the general public, apply.

Article 2 Written Agreements

When pharmaceutical companies provide patient organisations with financial or non-financial support, directly or indirectly, it must be done under a contract or written agreement.

The document must state the amount and purpose of financing (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of direct or indirect non-financial support, (e.g. the donation of public relations agency's time), and the nature of supplier involvement.

A template of a written agreement is available in Annex II.

Article 3 Use of Logos and Proprietary Materials

The public use of a patient organisation's logo and/or proprietary material by a pharmaceutical company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

Article 4 Editorial Control

Pharmaceutical companies must not seek to influence the text of patient organisation material they sponsor in a manner favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies.

Article 5 Transparency

a) Each company must make publicly available a list of patient organizations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description must include the monetary value of financial support and of invoiced costs. For significant nonfinancial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit that the patient organization receives. This information will be provided on annual basis on the ARPIM website.
b) Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.
c) Each company must make publicly available a list of patient organizations that it has engaged to provide significant contracted services. This should include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Companies must also make public the total amount paid per patient organization over the annual reporting period.

Article 6 Contracted Services

Contracts between companies and patient organizations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research.

It is permitted to engage Patient Organisations as experts and advisors for services such as participation at advisory board meetings and speaker services. The agreements that cover consultancy or other services must fulfil all the following criteria:

a) A written contract or agreement shall be executed in advance. The agreement should specify the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
b) A legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into the agreement;
c) The criteria for selecting services are directly related to the identified need and the persons responsible for selecting the service have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria;
d) The extent of the service is not greater than is reasonably necessary to achieve the identified need;
e) The contracting company maintains records concerning the contracted services;
f) The engaging of Patient Organisations is not an inducement to recommend a particular medicinal product;
g) The compensation for the services is reasonable and does not exceed the fair market value[1] of the services provided. In this regard, token consultancy agreements must not be used to justify compensating patient organisations;
h) In their written contracts with Patient Organisations, companies are strongly encouraged to include provisions regarding the obligation of the Patient Organisation to declare that they have provided paid services to the company whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company;
i) Each company must make publicly available a list of patient organisations that it has engaged to provide paid-for services – *see Article 5c.*

Article 7 Single-company Funding

No company may require that it be the sole funder of a patient organisation or any of the major programmes initiate by it.

Article 8 Events and Hospitality

The events sponsored or organised by or on behalf of a company must be conducted in an appropriate venue that is conducive to the main purpose of the event, avoiding those that are 'renowned' for their entertainment facilities or are 'extravagant'.

All forms of hospitality provided by the pharmaceutical industry to patient organisations and their members shall be reasonable in level and secondary to the main purpose of the event, whether the event is organised by the patient organisation or the pharmaceutical industry.

[1] Not to exceed the maximum amounts established for similar services in the **ARPIM CODE OF ETHICS ON THE PROMOTION OF PRESCRIPTION ONLY MEDICINAL PRODUCTS AND ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS**

Pharmaceutical companies must not sponsor patient organizations to participate in medical congresses due to commercial and promotional content, except the case when the event contains a section dedicated to patients and / or when there is a speaker invited from the patient organization.

Hospitality extended in connection with events shall be limited to travel, meals, accommodation and registration fees.

Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases, in case of clear health needs (e.g. disability), the travel meals, accommodation and registration fees cost of an accompanying person considered to be a caregiver can be taken.

All forms of hospitality offered to patient organisations and their representatives shall be "reasonable" in level and strictly limited to the purpose of the event.

Hospitality shall not include sponsoring or organising entertainment (e.g. sporting or leisure events).

No ARPIM member company – the entity operating in Romania - may organise an event that takes place outside Romania unless:

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

or

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").

Article 9 Enforcement

ARPIM member companies' interactions with the patient organizations must be separate from the promotional activities and therefore they will be treated separately from these ones.

ANNEX I Implementation and Procedure Rules
ANNEX II Model template for written agreements between ARPIM member companies and patient organisations

ANNEX I Implementation and Procedure Rules

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the ARPIM Code on Relationships between the Pharmaceutical Industry and Patient Organisations (the "**ARPIM Code**"), the processing of complaints and the initiation or administration of sanctions by member associations.

Ways of Interaction

In the current context where patient organizations have limited funds to finance their activities, the support of patient organizations may be represented by the general financing (by covering the daily operational costs of the organization) or projects financing (dedicated specifically for a project or a series of projects included into organization objective) or contracted services / costs of services related to providing resources / time by the patient organization or its representative for pharmaceutical companies (press event, advisory board).

Direct financial support consists in the payment made directly by a pharmaceutical company to a patient organization.

Indirect financial support consists in the payment made by a third party / supplier on behalf of a pharmaceutical company to a patient organization.

Direct non-financial support consists in: provision of goods and / or scientific/educational support periodically provided by pharmaceutical companies / volunteers from pharmaceutical companies.

Indirect non-financial support consists in services and goods provided by a third party / supplier to patient organizations on behalf of pharmaceutical companies or time donation of a public relations agency in favour of a patient organization.

Additional Provisions:

Article 2 Written Agreements

The contract must also stipulate the patient organizations' liability to declare under the relevant legislation in force the revenues come from these interactions with the company.
Each pharmaceutical company should have an approval process in place for these agreements.

Article 3 Use of Logos and Proprietary Materials

Pharmaceutical companies will not ask and will not allow the use of the product logos in connection with any event or activity of a patient organization.
The company's logo can be used only with its consent.

Article 4 Editorial Control

Contribution to the drafting of a text should be explicitly declared and the reference should be clear represented on the same page to avoid any misunderstanding or misinterpretation; ARPIM member company being fully responsible under the terms of this code.
At the request of Patient Organizations companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

Article 5 Transparency

The provided direct / indirect, financial / non-financial support to a patient association by an ARPIM company member is public information.

The declaration must be made by the association in a clear and complete manner so that the public can be informed at any time about the existence of this interaction.

Each company has the liability to publish annually (on ARPIM's website) a list of all interaction with patient organisations to which it provides financial direct/indirect support and/or non-financial direct/indirect support.

This list should include at least the following information:

- name of the organisation;
- a brief description of the organisation;
- a description of the nature of the interaction with the patient organisation;
- the date or period of support;
- the total amount and/or the percentage of the support given by the company of the total income of the patient association at the end of the previous financial year or non-monetary benefit.

This information will be provided in Romanian and be updated at least once per year by 31 March current year for the previous year.

Template for
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Article 8 Events and Hospitality

The maximum travel expenditure / hospitality related to the participation in events are:

a) **Flights** (both domestic and international): economy class (*economy* or *coach*). Business class or higher is not allowed;

b) Hotel accommodation:

i. Internal: maximum budget for Bucharest 675 RON (six hundred seventy five RON) per night and breakfast, VAT included, and maximum budget 520 RON (five hundred twenty RON) per night and breakfast, VAT included, outside Bucharest.

ii. Outside Romania: the budget will depend on each country.

iii. It is forbidden to use for accommodation, whether internal or external, any location and facility that is mainly associated by the public with sport, luxury or exclusivity, regardless of their cost. It is forbidden to use 5 star hotels

c) Meals:

i. For internal meals: the maximum amount where the hospitality includes lunch, dinner and coffee breaks is of 300 RON (three hundred RON) per day/per person (coffee-break included) or 150 RON (one hundred and fifty RON) per person where the hospitality includes one main meal.

ii. For meals outside the country: the limit per person is of 150 euro/day (a hundred and fifty Euros or the equivalent) for lunch plus dinner.

ARPIM Member Staff

a) Each ARPIM member will ensure that its representatives, including the personnel retained by way of contract with third parties, and any other ARPIM member representatives who by the nature of their position get into contact with patient organizations, and not only them, are familiar with the requirements of this code.

b) Each ARPIM member should implement a training program for all employees – so as its relevant staff be informed of the requirements of this Code. Each ARPIM member will implement an evaluation system of the employees' knowledge tailored on their position. The review and updating of the training material should be made whenever necessary and whenever reference laws or regulations change.
c) Each ARPIM member company must have an employee responsible for ethics and compliance who will be responsible for ensuring the implementation of this Code.
d) Each ARPIM member should ensure an effective system of monitoring the compliance with the ethical standards approved through this Code by all employees or contractors.

Reception of Complaints

Complaints may be lodged either with ARPIM or with EFPIA.

Complaints received by EFPIA shall be processed as follows:

a. EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant Member Association(s).
b. EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant Member Association(s) to which the complaint has been sent for processing and adjudication.
c. In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar matter(s) lodged from outside the industry against several subsidiaries of any company), EFPIA will communicate these complaints to the Member Association either of the parent company or of the European subsidiary designated by the parent company.

Adjudication of complaints shall be a matter solely for ARPIM.

ARPIM will ensure, to the extent permissible, that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, including a level of detail that takes into account the seriousness and/or persistence of the breach as follows:

i. in cases of a serious/repeated breach, the company name(s) should be published together with details of the case;
ii. in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the company name(s).

Processing Complaints and Sanctions

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

Complaints received by any other ARPIM member employee must be directed to the leader of the Arbitration Committee.
A valid complaint must be addressed in writing and must contain:

a) identification of the plaintiff company
b) identification of the person submitting the complaint
c) relevant details on which the complaint is based
d) proposed/requested corrective actions

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

Subsequently – within maximum 24 hours from receipt of the complaint - the leader of the Arbitration Committee must contact – via e-mail - the General Manager (or the equivalent head of the ARPIM member, hereinafter referred to as "General Manager") of the company potentially in breach and request a written position note containing: clarification, details, and argumentation in attention of the leader of the Arbitration Committee, the General Manager of the plaintiff company and cc to the members of the Committee.

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

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

- consider complaint settled in case breach did not occur or
- request additional measures to be taken by the company in breach and/or
- request sanction

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

In the event that:

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

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

ANNEX II Model template for written agreements between ARPIM member companies and patient organisations

When pharmaceutical companies provide patient organisations with financial or non-financial support, directly or indirectly, they must have in place a written agreement, signed in advance.
Below is a model template, which may be used in its entirety or adapted as appropriate, setting out key points of a written agreement. It is intended as a straightforward record of what has been agreed, taking into account the requirements of ARPIM' s Code of Ethical Practice in the Interaction with Patient Organisations.

- Name of the activity;
- Names of partnering organisations (pharmaceutical company, patient organisation, and where applicable, third parties that will be brought in to help, as agreed by both the pharmaceutical company and the patient organisation);
- Type of activity (e.g. whether the agreement relates to unrestricted grant, specific meeting, publication, etc.);
- Objectives;
- Agreed role of the pharmaceutical company and patient organisation;
- Time frame of the agreement;
- Total amount of funding;
- The obligation of the patient organisation to declare the support provided by the company in the terms of the relevant legislation in force;
- Description of direct or indirect /non-financial support (e.g. the donation of public relations agency's time, free of charge training courses, etc).

All parties are perfectly aware that sponsorship must be made known in a transparent way from the outset.

The disclosure arrangements

Code/s of practice that apply:

Signatories to the agreement: Date of agreement: