ARPIM CODE OF ETHICAL PRACTICE IN THE INTERACTION WITH PATIENT ORGANISATIONS

Adopted by the ARPIM Board in November 2017 and ratified by the ARPIM General Statutory Assembly in December 2017 (edition 2017) *

* Applicable from May 1st, 2018

CONTENTS

INTRODUCTION

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

We are the association that supports the common objectives of the most important 29 international innovative medicine manufacturers in Romania. Together, these companies represent 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 organisation 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. Most of these companies are currently operating in Romania as well.

The primary mission of EFPIA and, implicitly, of ARPIM (summarized by the motto "New medicinal products for better health") is promoting pharmaceutical research and development in order to discover better therapeutic solutions for improving human health.

The pharmaceutical industry has many common interests with patient organisations, which represent or support 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 Practice in the Interaction with Patient Organisations, with which member companies have to comply in their collaboration with patient organisations, in order to maintain the following high standards of ethics:

1. Ensuring the independence of patient organisations, in terms of their political judgment, strategies 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 (hereinafter referred to as "product/s");
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 patient organisations from multiple sources.

SCOPE

This ARPIM Code covers any interaction between ARPIM member companies, including 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

This ARPIM Code of Practice sets out the standards which ARPIM considers to be applicable to the relationship with patient organisations that operate in Romania, but not only.

The pharmaceutical companies that are ARPIM members must comply with the following codes, hereinafter 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 Romania, the industry code of the country in which said 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 office or in which the partnering subsidiary of a patient organisation has its location.

The provisions of these codes apply to activities or funding conducted 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, means any interaction covered by an Applicable Code, including the provision of funding.

The Applicable Codes to be complied with must be clearly 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 mentioned 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 funding or engages in activities with patient organisations covered by an Applicable Code, whether such entity is a parent company (e.g. the headquarters, main office/controlling enterprise of a trading company), a subsidiary 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, shall apply.

ARTICLE 2 WAYS OF INTERACTION

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

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

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

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

Indirect non-financial support consists in the services and goods provided by a third party/supplier to patient organisations, on behalf of pharmaceutical companies, or the time donated by a public relations agency in favour of a patient organisation.

ARTICLE 3 WRITTEN AGREEMENTS

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

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

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

Additional information:

The agreement must also stipulate the obligation of the patient organisation to provide the statements set under the relevant legislation in force, including those for the revenues resulting from such interactions with the company.

Each pharmaceutical company should have an approval procedure in place for such agreements.

ARTICLE 4 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 said organisation. In seeking such a permission, the specific purpose and the manner in which the logo and/or proprietary material will be used must be clearly stated.

Additional information:

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 organisation.

The company's logo can be used only with its consent.

ARTICLE 5 EDITORIAL CONTROL

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

Additional information:

At the request of the patient organisation, companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

The contribution to the drafting of a text should be explicitly declared and the reference should be clearly represented on the same page, in order to avoid any misunderstanding or misinterpretation, as the ARPIM member company is fully responsible under the terms of this code.

ARTICLE 6 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 may publish annually (on ARPIM's website) a list of all Patient Organizations interactions providing financial direct/indirect support and/or non-financial direct/indirect support.

This list will include a detailed description of the support provided to enable public to understand the activity. The description should contain the total amount and the invoiced consts. In case of non-monetary support which cannot be valuated as amount the description should clearly reflect the benefit for the Patient Association.

This information will be provided in Romanian and be updated at least once per year by 30 June current year for the previous year.

Additional information:

The monetary/non-monetary support provided to a Patient Association by a member company is public information.

The disclosure of the support must be published by the Association on a yearly bases and should contain all details to allow full understanding of the general public.

ARTICLE 7 SERVICE AGREEMENTS

Service agreements, under which patient organisations provide services to ARPIM member companies, are allowed only 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 attending advisory board meetings and providing speaker services. The agreements that cover consultancy or other services must meet the following criteria:

a) A written agreement, that specifies the nature of the services to be provided and, according to item g) below, the grounds for the payment of such services, shall be executed in advance by both parties.

b) A legitimate need for the services has been clearly identified and documented prior to requesting the services and entering into the agreement;

c) The criteria for selecting services are directly related to the identified need and the persons in charge of selecting the service have the expertise required for assessing whether said experts and advisors meet these criteria;

d) The extent of the service does not exceed the one reasonably necessary to meet the identified need;

e) The contracting company maintains records concerning the contracted services;

f) The contracting of patient organisations must not suggest in any way the recommendation/use of 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, consultancy agreements must not be used to justify compensating patient organisations;

h) In their written agreements with patient organisations, companies are strongly encouraged to include provisions regarding the obligation of the patient organisation to declare that they provide paid services to the company whenever they write or speak in public about a matter representing the subject of the agreement or any other issue related to that company;

i) Each company must disclose a list of the patient organisations with which it concluded service agreements – *see Article 6.*

ARTICLE 8 SINGLE-COMPANY FUNDING

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

ARTICLE 9 EVENTS AND HOSPITALITY

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

Pharmaceutical companies must not sponsor patient organisations for the purpose of attending medical congresses due to the commercial and promotional content thereof, except for the case in which the event includes a section dedicated to patients and / or when a patient organisation representative is invited to speak.

The hospitality extended in connection to such events shall be limited to covering travel, meals, accommodation and registration fees.

Hospitality may only be extended to persons who qualify as attendants, in their own right. In exceptional situations, in case of clear health needs (e.g. disability), the travel, meals, accommodation and registration fees may also be covered for an accompanying person deemed as the caregiver.

All forms of hospitality provided 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 organizing entertainment (e.g. sporting or leisure events). Social activities may be considered only if incidental to the main scope of the activity.

Exceptions (exclusively social activities) may be considered in the context of support programs mainly in such cases which target social integration of certain patients.

It is recommended to member companies to consider hospitality within the limits of the ARPIM HCP Code.

[1] Without exceeding the thresholds established for similar services in the ARPIM Code of Ethics on the Promotion of Prescription-only Medicines and on Interactions with Healthcare Professionals

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

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

   or

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

ARTICLE 10 ENFORCEMENT AND IMPLEMENTING REGULATIONS

The interactions of ARPIM member companies with the patient organisations must be separate from the promotional activities and, therefore, will be treated separately.

SCHEDULE I Implementation and Procedure Rules

SCHEDULE II Template for written agreements between ARPIM member companies and patient organisations

SCHEDULE I IMPLEMENTATION AND PROCEDURE RULES

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

ARPIM MEMBER STAFF

a) Each ARPIM member will ensure that its representatives, including the personnel retained by way of agreement with third parties) and any other ARPIM member representatives who, by the nature of their position, enter into contact with patient organisations, 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 that its relevant staff may be informed of the requirements of this Code. Each ARPIM member will implement a knowledge assessment system, tailored to the position of each employee. The training material should be reviewed and updated whenever necessary and whenever reference laws or regulations change.
c) Each ARPIM member company must have an employee in charge of ethics and compliance, who will be responsible for ensuring the implementation of this Code.
d) Furthermore, each ARPIM member should ensure an efficient system for monitoring the compliance of all employees or contractors with the ethical standards approved under this Code.

RECEPTION OF COMPLAINTS

The provisions of Art. 20 of the ARPIM Code on the promotion of prescription-only medicines to, and the interaction with HCPs, shall be applicable.

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

All parties are perfectly aware of the fact that the sponsorship must be disclosed in a transparent way from the outset.

Arrangements for disclosing the details of the activities representing the object of the agreement.

Applicable Code/s of practice:

Signatories to the agreement: Date of the agreement: