

ARPIM HCP/HCO DISCLOSURE CODE

ARPIM CODE ON THE DISCLOSURE OF SPONSORSHIPS AND OTHER TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS (HCP) AND HEALTHCARE ORGANISATIONS (HCO) (HEREINAFTER REFERRED AS THE “ARPIM DISCLOSURE CODE”)

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



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PREAMBLE

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 33 countries, as well as 40 of the most outstanding pharmaceutical companies. Most of these companies are currently operating in Romania as well.

The healthcare professionals and organisations with which 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 the society at large. Healthcare Professionals (HCP) and Healthcare Organisations (HCO) are entitled to fair compensation for the legitimate expertise and services they provide to the pharmaceutical industry.

Prescription-only medicines developed by the research and development industry are complex products designed to address the needs of patients and 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 the latest discovery in the management of various diseases and for the exchange and sharing of knowledge among healthcare professionals and the pharmaceutical 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 admits that the interactions between the industry and healthcare professionals may create potential 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 remain 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's 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 for the future success of the pharmaceutical industry to respond to the 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 (the "ARPIM HCP Code") and Code of Ethical Practice in the Interaction with Patient Organisations

(the “ARPIM PO Code”) should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals/organisations.

ARPIM hopes that, by taking this step, it can facilitate the close 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 admits that disclosure can raise data privacy concerns and, therefore, 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, so that the legislation is not required to enforce excessive restrictions for disclosure in the pharmaceutical industry.

The following Code provides for the disclosure of the 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 organisation) level, as long as this can be achieved with accuracy, consistency and compliance with the applicable law.

The following code enforces obligations for disclosing the Transfers of Value to healthcare professionals and healthcare organisations, commencing with 2016 in relation to the Transfers of Value for the calendar year 2015.

APPLICABILITY OF THIS CODE

This Code governs the disclosure regarding interactions with HCPs and HCOs. It is intended for this Code to apply to the interactions with HCPs and HCOs in the same extent as the existing ARPIM HCP Code and ARPIM 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 organisation – 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 the PO Code or that otherwise regulated by said 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 the Transfers of Value it performs, 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 representing a limitation, the Transfers of Value that:

- i. refer to medicines released without a medical prescription;
- ii. are not listed in Article 3 of this Code, such as inexpensive items of medical educational utility (governed by ARPIM HCP Code, Section 09.01), business meals (governed by the ARPIM HCP Code, Article 10, especially Section 10.05), medical samples (governed by ARPIM HCP Code Article 16); or
- iii. are part of the regular commercial practice for the purchase and sale of medicines 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 an integral part of this Code.

ARTICLE 2 FORM OF DISCLOSURE

SECTION 2.01 ANNUAL DISCLOSURE CYCLE

Disclosure shall be made on an annual basis and each reporting period shall cover the previous calendar year in full (the “Reporting Period”).

SECTION 2.02 TIME OF DISCLOSURE

Individual Disclosures will be made by each ARPIM Member towards the National Medicines and Medical Devices Agency (ANMDM), within 3 months following the end of the relevant reporting period, and on the own (public) website, within 6 months following the end of the relevant reporting period, in accordance with the provisions of Order no. 194/2015 of the Ministry of Health, and the disclosed information shall be required to remain in the public domain for a minimum of 3 years following the disclosure date, in accordance with the legal obligation.

Aggregate Disclosures will be made by each Member Company within 6 months following the end of the relevant reporting period and the disclosure will take place in accordance with Section 2.04.

The information shall be required to remain in the public domain for a minimum of 3 years after the first disclosure.

SECTION 2.03 DISCLOSURE TEMPLATE

The individual disclosure will be made in RON, using the standardized template as provided within Order no. 194/2015 of the Ministry of Health.

Subject to Section 2.04, for consistency purposes, Individual and Aggregate disclosures pursuant to this Code will be made in RON using a structure set forth in the Reporting template as set by Order 194/2015 of the Ministry of Health and Schedule 2 for reference, reflecting the requirements of the EFPIA Disclosure Code for aggregate disclosure.

SECTION 2.04 DISCLOSURE PLATFORM

Individual Disclosure shall be made on the National Medicines and Medical Devices Agency (ANMDM) website and each ARPIM member's website, in accordance with the provisions of the Order no. 194/2015 of the Ministry of Health, without any restrictions. The reports of the ARPIM member companies must be disclosed by ANMDM, in the second quarter of each year, on the ANMDM website.

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

SECTION 2.05 APPLICABLE NATIONAL CODE

Disclosure shall be made pursuant to the national legislation and the national code of the country on the territory of which the Recipient has its physical address. If a member company does not have its residence or a subsidiary or an affiliate in the country on the territory of which the Recipient has its physical address, said member company shall disclose such Transfers of Value in a manner consistent with the national legislation and national code to which it is subject.

SECTION 2.06 DISCLOSURE LANGUAGE

Disclosure shall be made in the Romanian language.

SECTION 2.07 DOCUMENTATION AND RETENTION OF RECORDS

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

SECTION 2.08 CROSS-BORDER TRANSFERS OF VALUE

As a general principle, the Transfers of Value that fall within the scope of this Code have to be disclosed in the country on the territory of which the recipient conducts its main activity, 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 specified by this Code, the Transfers of Value shall be disclosed on an individual basis, following the implementing regulations of Order no. 194/2015 of the Ministry of Health. Each member company shall disclose, on an individual basis for each clearly identified Recipient, the amounts attributable to Transfers of Value to said Recipient in each reporting period, which can be reasonably allocated to one of the categories set out below.

1. For the 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, medicine donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare services (governed by Article 11 of ARPIM HCP Code);

b. Contribution for covering event-related costs. Contribution to event-related costs, through HCOs or third parties, including the sponsorship for HCPs to attend events, such as:

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

c. Service Fees: Speaking, Consultancy and Other. Transfers of Value resulting from or related to agreements between member companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services to a member company or any other type of funding not covered in the previous categories. The Fees, on the one hand, and the Transfers of Value related to expenses corresponding to such fees accepted under written agreements, on the other hand, that cover the activity, will be disclosed as separate amounts.

When a Fee for a provision of Services: speaker, consultancy or other services, is provided to a legal entity that is owned by an HCP or when a payment is provided to a legal entity where an HCP is employed, the Service Fee paid to this legal entity should be disclosed on behalf of said legal entity (considered an HCO under the Code), as this is the recipient of the payment. Furthermore, the *“travel and accommodation costs associated with the activity”* agreed by means of a Service Fee under an agreement should be disclosed on an individual basis (on behalf of the HCO), in the relevant category – i.e. the amount of the fee will be shown separately from the corresponding expenses, accepted under the Service agreement.

2. For the Transfers of Value for the benefit of an HCP:

a. Contribution to event-related costs, such as:

- i. Registration fees; and
- ii. Travel and accommodation, to the extent provided under Article 10 of the ARPIM Code

b. Fees for Services and Consultancy. Transfers of Value resulting from, or related to the agreements concluded between member companies and HCPs, under which such HCPs provide any type of services to a member company, or related to any other type of funding not covered in the previous categories. The Fees, on one hand, and the Transfers of Value related to expenses corresponding to such fees accepted under written agreements, on the other hand, that cover 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 NON-DUPLICATION

When a Transfer of Value that must be disclosed pursuant to Section 3.01 or 3.02 is performed to the benefit of a certain HCP indirectly, via an HCO, said Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual basis (referring to the receiving HCP), pursuant to Section 3.01(2).

SECTION 3.03 TRANSFERS OF VALUE FOR RESEARCH AND DEVELOPMENT

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

SECTION 3.04 METHODOLOGY

Each ARPIM member company shall publish its individual Transfers of Value following the implementing regulations provided under Order no. 194/2015 of the Ministry of Health. For the disclosure under section 3.03, the disclosure shall be accompanied by a note on the general and/or country-specific considerations that describe the methodology applied, VAT and other tax-related aspects, currency-related aspects and other issues concerning the timing and amount of the Transfers of Value, for purposes of this Code, as applicable. The note must be attached to the disclosure document.

ARTICLE 4 ENFORCEMENT

SECTION 4.01 WRITTEN AGREEMENTS

When performing a Transfer of Value to an HCP/HCO - for the purpose of emphasizing and increasing transparency and disclosure awareness - companies are encouraged to include, in the written agreements concluded with the HCP/HCO, contractual terms on the compliance with the legislation in force on personal data protection, such as provisions related to the consent of the Beneficiaries, lectors, consultants for the disclosure of the Transfers of Value, under the provisions of the ARPIM HCP/HCO Disclosure Code. As applicable, companies are encouraged to renegotiate the existing agreements in order to include notifications on the disclosure obligation, including, if applicable, on the consent for disclosure.

SECTION 4.02 SANCTIONS

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.

If the applicable national law or regulations prescribe 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 THE COMPLIANCE WITH THE CODE

SECTION 5.01 CODE COMPLIANCE

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

SECTION 5.02 AMENDMENTS

The ARPIM EEWG shall regularly review this Code and any guidance issued regarding the compliance with this Code. Any proposed amendments to this Code shall be subject to the decision of the ARPIM Board and the ratification by the ARPIM Statutory General Assembly. The 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 THE TERMS USED IN THE ARPIM HCP/HCO DISCLOSURE CODE

Sponsorships/donations

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

Agreements on the organisation of/attendance to scientific events

These agreements describe the activities and the related Transfers of Value. The Transfers of Value concerning “Registration fees” and “Travel and Accommodation expenses” should be, in principle, reported separately.

Examples of activities related to the participation to a scientific event, without limitation to the following, are:

- Rental of booths;
- Advertisement space (in paper, electronic or other format);
- Satellite symposia at a congress;
- Sponsoring the expenses of the speakers involved in the „Event“;
- Covering the expenses of other attendees;

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 HCP Code).

HCO

Any legal entity

- (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or another teaching institution or healthcare professional association or society (except for patient organisations within the scope of the ARPIM PO Code) that has its registered office, place of incorporation or primary place of operation 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 medicine and whose primary practice, main professional address or place of registration is in Romania. For the avoidance of doubt, the definition of HCP includes:

- (i) any official or employee of a government institution or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicines 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 retailer of medicinal products.

Service agreements

Examples of elements that could be covered by service agreements:

- Speakers’ service;
- General consultancy service;

- Employee training services;
- Consultancy service (Medical Writing);
- Data analysis (statistical analysis);
- Development of education materials;
- Consultancy services during expert meetings (“Advisory Board”).

ARPIM HCP Code

ARPIM Code of Ethics on the Promotion of Prescription-only Medicines to and interactions with Healthcare Professionals, as adopted by the ARPIM Board of Directors and the General Statutory Assembly.

Medicinal Products

The term “Medicinal Products”, as used in the ARPIM HCP/HCO Disclosure Code, has the meaning set forth in Article 1 of 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 Directive 2001/83/EC.

ARPIM PO Code

ARPIM Code of Ethical Practice in the Interaction with Patient Organisations.

Recipient

Any HCP or HCO, as applicable, that conducts its main activity or has its main place of business or place of incorporation in Romania.

Transfers of Value for Research and Development

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 (according to the latest revision in 1997) define non-clinical studies as follows (Section 1 – 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](http://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 either those made on behalf of a member company for the benefit of a

recipient, or those 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 STANDARDIZED REPORTING FORMS

The reporting forms are those published in Official Gazette no. 168 - March 11th, 2015 (Order 194-2015), with subsequent amendments, as published on the ANMDM website.

SECTION 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 on the ARPIM website; and
- b. The ARPIM Ethical Working Group will prepare and provide, to the EFPIA Codes Committee, upon request, details on the annual reporting of the Transfers of Value.

SECTION 2. COMPLAINTS AND SANCTIONS

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