

Organon Methodology Statement

Introduction

Organon BioSciences S.R.L. (RO_9213) believe that interactions between pharmaceutical companies and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. Recently, there is a growing expectation that such interactions are transparent. As such, the European Federation of Pharmaceutical Industries and Associations adopted in 2014 the Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (“EFPIA Code”), requiring its members, including ORGANON, to disclose pre-defined types of transfers of value made to healthcare organizations and healthcare professionals on an annual basis. This Methodology Statement defines the relevant types of transfers to be disclosed, which transfers are excluded, and other relevant information to assist the reader understand how ORGANON collected, organized and reported the disclosed data.

Based on the provisions of EFPIA Code, at a national level, the Romanian Association of International Drug Producers (hereinafter referred to as “**ARPIM**”) adopted the *ARPIM code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals (HCP) and healthcare organizations (HCO)*, last updated in December 2017, applicable as of May 1st, 2018 (hereinafter referred to as “**ARPIM Disclosure Code**”) governing the transfers of value between pharmaceutical companies and healthcare professionals/healthcare organizations.

In addition, considering the national legal provisions referring to transfers of value, namely Ministry of Health’s Order No. 194/2015 on publicity of medicines for human use (“**Order No. 194/2015**”) this Methodology Statement aims to include these types of transfers as well for a general, complete view on the subject.

Definitions

Clinical Research Organization (CRO) – an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. A CRO is not a HCO.

Event – all promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies), organized or sponsored by or on behalf of ORGANON.

Healthcare Organization (HCO) – any legal person (i) that is a healthcare, medical or scientific organization such as a hospital, clinic, foundation, university or other teaching institution or learned society (but not a patient organization) or ii) through which one or more HCP’s provide services.

Healthcare Professional (HCP) - any natural person that is a member of the medical, dental, pharmacy or nursing professions.

Recipients – healthcare professionals, professional organizations, organizations of patients, and any other type of organizations which perform activities related to human health, medical or pharmaceutical care.

Transfers of Value (ToV's) – direct and indirect transfers of value, whether in cash, in kind or otherwise, made in connection with the development and sale of medicinal products for human use.

A Direct ToV is one made by directly ORGANON for the benefit of a Recipient.

An Indirect ToV is one made by a third party (such as a contractor, travel agent, partner or affiliate) on behalf of ORGANON for the benefit of a Recipient where the Recipient knows it is from, or can identify, ORGANON.

Research and Development ToV's are ToV's to an HCO or HCP 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 Regulation (EU) 536/2014); and iii) non-interventional studies that are prospective in nature and that involve the collection of patient data.

Disclosure's scope

ToVs excluded from ARPIM/EFPIA disclosure.

Considering the provisions of Order No. 194/2015 which comprise similar categories of ToVs to be disclosed as the ones included in ARPIM Disclosure Code, Romania was exempted (upon request) to report the transfers of values based on EFPIA Disclosure Code. This decision is captured in the Key Decisions of EFPIA Board meeting dated April 14, 2016.

However, disclosure under Order No. 194/2015 does not include expenses/costs for clinical studies performed in Romania, based on the explicit point of view of the National Agency for Medicines and Medical Devices (NAMMD) expressed in a letter addressed to ARPIM in June 2015 (as an answer to the express question launched by ARPIM after the entry into force of Order No. 194/2015).

In order to close the gap between the local legislation and EFPIA Code, ARPIM member companies will still have to disclose under ARPIM Disclosure Code, the Research & Development activities, on an aggregated basis, on top of the local legislation requirements.

As a consequence, ARPIM Disclosure Code makes express reference to the reporting under Order No. 194/2015 herein included the use of the predefined form of reporting, terms, publication etc. For the aggregate disclosure referring to Research & Development activities, the form to be used is expressly provided by ARPIM Disclosure Code.

The following ToV's are expressly excluded under the Code from disclosure: i) those solely related to over-the-counter medicines; ii) are part of ordinary course purchases and sales of medicines (for example, between ORGANON and a pharmacy); iii) medical samples, investigational compounds and biological samples for study; iv) informational or educational materials and items of medical utility and v) meals and

drinks (will be reported only those expenses which are mentioned in the agreements concluded with the healthcare professionals).

ToV Recognition/Payment Date. ToV's are disclosed on the basis of the date when the relevant payment order was submitted by ORGANON, not when the resulting income or benefit was received by the HCO/HCP.

ToV Value. TOV disclosures reflect the actual value or cost provided by ORGANON and not the resulting income or benefit to the HCO/HCP.

HCO/HCP ToV's. According to art. 35 para. (3) of Order No. 194/2015: *"(3) Manufacturers, MAHs or their representatives in Romania, wholesalers and retail distributors of drugs, medical devices and sanitary materials are obliged to report to ANMDM, until March 31st of the current year, all sponsorship activities and any other expenses borne in the year previous to reporting, for healthcare professionals, professional organizations, organizations of patients, and any other type of organizations which perform activities related to human health, medical or pharmaceutical care"*.

Based on the above legal provisions, on a more detailed basis, the following types of ToV's are disclosed by ORGANON:

- i) Sponsorships, donations and grants borne with the HCPs/HCOs/organizations of patients/any other organizations which perform activities related to human health, medical or pharmaceutical care;
- ii) Contributions to costs related to Events, including sponsorship of HCP's directly or indirectly through HCO's to attend Events, such as:
 - a. registration fees,
 - b. travel and accommodations (such as costs of flights, trains, car hire, tolls, parking fees, taxis and hotel accommodation); and
 - c. as regards meal expenses, will be reported only those expenses which are mentioned in the agreements concluded with the healthcare professionals.
- iii) Fees for services and consultancy (examples include speakers' fees, speaker training, medical writing, data analysis, development of educational materials, general consulting and advising via advisory boards/expert input fora, fees for participating in market research when the identity of the HCP is known to ORGANON, based on the services agreements concluded. To the extent incidental expenses incurred under a service or consultancy agreement are reimbursed (e.g., travel and accommodation), such ToV is disclosed in the relevant category and not as a fee for service or consultancy. As regards meal expenses, will be reported only those expenses which are mentioned in the agreements concluded with the healthcare professionals.
- iv) Any other expenses borne with the HCPs/HCOs.

Specific considerations

1. ToVs in case of partial attendances or cancellation.

ORGANON only reports the ToV amount actually received by a Recipient in case of a partial attendance, not the full amount paid by ORGANON. In case of a cancellation, since nothing is directly or indirectly received by a Recipient, no ToV is reported by ORGANON, even if amounts have been paid by ORGANON to the Event organizer.

2. Cross-border activities.

Regardless of which ORGANON entity contracts with and pays a Recipient, all HCO's or HCP's whose primary practice, main professional address or place of incorporation is in Romania are reported by ORGANON.

3. Disclosing entities.

This annual disclosure report covers all ToV's made to HCO's and HCP in Romania, whether by Organon BioSciences S.R.L. (RO_9213) or by its affiliates based in other countries.

4. Self-incorporated HCP.

Disclosure is made on the Recipient's name. So, a Fee for Service paid to a legal entity owned by a HCP is disclosed under the name of the legal entity (an HCO) and not the HCP's individual name as the HCO is the Recipient of the ToV.

5. Multi-year agreements.

Disclosure is made on the basis of the year the actual ToV's was provided, and not on the basis of a pro rata amount of the intended total ToV under the agreement. In addition, for situations where contracts have been concluded in one year but expenses were not effectively borne during the reporting time period (e.g., contracts concluded close to the end of 2019), the sponsorships and expenses made during another reporting time period, e.g. 2020, were not included; given that the expenses were not effectively borne in the respective year (e.g. 2019), such will be reported for the period in which the expenses were borne.

6. Consent management

Consent collection. Based on the applicable legal provisions on data privacy, the data subject's consent is not required when the processing is required in order to fulfill a legal obligation of the data controller. As such, since ORGANON is obliged to disclose transfers of value under Order No. 194/2015, the consent of the HCPs is not

mandatory to be obtained, an information notice being sufficient. However, since ORGANON may transfer such data outside the European Economic Area (e.g. in the United States), the consent of each HCP to disclose their personal information must be obtained prior to the processing. ORGANON has made its best effort to obtain such consent so as to be as transparent as possible about the nature and scale of its interactions with HCP's. The means by which ORGANON has obtained consent in Romania is by transfer of value consent form. Disclosure under ARPIM Disclosure Code is made on an aggregated basis.

Management of Recipient consent withdrawal. A Recipient has the right to withdraw their consent at any time. However, since ORGANON has a legal obligation to disclose the personal information referring to transfer of value, consent may be withdrawn only in respect of the transfer of personal data and not the effective publication on the authority's website. In such case, ORGANON shall not be allowed to transfer personal data as such, but may transfer an aggregate reporting, without naming the HCPs.

7. Disclosure Form

Date of publication. According to the applicable legal provisions (Order No. 194/2015), the reporting must be made no later than 31st of March for the ToV supported in the last year.

Under ARPIM Code, disclosure of expenses incurred by ORGANON for Research & Development activities shall be published not later than 6 months after the end of the relevant reporting period .

Disclosure platform. ORGANON provides its annual disclosure via its own web site www.ORGANON.ro and the platform of the National Agency for Medicines and Medical Devices (ANMMDM).

Disclosure language. ORGANON provides its annual disclosure in Romanian language.

8. Disclosure financial data

Currency and VAT. All disclosed ToV's are reported in local currency and exclusive of VAT. ToV's paid in other currencies than the local one, are disclosed in paid currency for an accurate reflection of the paid amounts.

How is VAT Managed?

Disclosed ToV's to HCO's and SCP's reflect the amounts agreed in the contracts and on invoices submitted to ORGANON by HCO's or HCP's and effectively paid by ORGANON.