

Organon Methodology Statement

Introduction

Organon Austria GmbH (Organon) believes 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 (Code), requiring its members, including Organon, to disclose pre-defined types of transfers of value 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.

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 an 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 or any other person who as part of their professional activities may prescribe, purchase supply or administer a medicinal product and whose primary practice or principal professional address is in Austria. For clarity, an HCP includes: i) any official or employee of a governmental 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 Organon whose primary occupation is that of a practicing HCP, but excludes: x) all other employees of Organon and y) a wholesaler or distributor of medicinal products.

Recipients – any HCO or HCP whose primary practice, main professional address or place of incorporation is Austria.

Transfers of Value (ToVs) – 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 ToVs are ToVs 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

Excluded ToVs. The following ToVs 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 and iv) informational or educational materials and items of medical utility

ToV Recognition Date. ToVs are disclosed on the basis of the date Organon made the ToV, 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 ToVs. The following types of ToVs to HCOs are disclosed by Organon:

- i) donations and grants that support healthcare (including charitable product donations and logistic assistance to people in emergency need);
- ii) contributions to costs related to Events, including sponsorship of HCPs directly or indirectly through HCOs to attend Events, such as:
 - a. registration fees,
 - b. sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event (examples include hiring a booth or stand space, acquiring advertising space (in paper, electronic or other format), arranging a satellite symposia at a congress, sponsoring of speakers or faculty, the costs of drinks or meals provided by the HCO if part of an inclusive package, and courses provided by a HCO where Organon does not select the individual HCPs that participate), and
 - c. travel and accommodations; and
- iii) fees for service and consultancy (examples include retrospective non-interventional clinical studies and epidemiological studies). 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.

HCP ToVs. The following types of ToVs to HCPs are disclosed by Organon:

- i) contributions to costs related to Events such as:
 - a. registration fees, and
 - b. travel and accommodations (such as costs of flights, trains, car hire, tolls, parking fees, taxis and hotel accommodation); and

- ii) fees for service 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, and investigator-initiated studies that do not meet the definition of Research & Development ToVs). 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.
- iii) If ToVs under point i) of this chapter have been allocated indirectly to HCPs nominated by an HCO, Organon will disclose these ToVs via the HCO. This is according to Article 9.4 last sentence Pharmig Code of Conduct.

ToVs in case of partial attendances or cancellation. Since ToVs are reported on the basis of what Organon paid, and not what the Recipient received, the full amount paid by Organon shall be reported in case of a partial attendance. In case of an HCP cancellation, no ToV will be disclosed.

Cross-border activities. Regardless of which Organon entity contracts with and pays a Recipient, all HCOs or HCPs whose primary practice, main professional address or place of incorporation is in Austria are reported by Organon.

Disclosing entities. This annual disclosure report covers all ToVs made to HCOs and HCPs in Austria, whether by Organon Austria GmbH or by its affiliates based in other countries.

Specific considerations

Reporting Period 2022. The disclosure covers all TOVs in the period from 1st of January 2022 until 31st of December 2022.

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 HCPs individual name as the HCO is the Recipient of the ToV.

Multi-year agreements. Disclosure is made on the basis of the year the actual ToV was provided, and not on the basis of a pro rata amount of the intended total ToV under the agreement.

Non-interventional studies. In those circumstances where Organon is unable, despite its best efforts, to determine whether ToV is made to a HCP by a CRO, on behalf of Organon, are prospective or retrospective in nature, such ToVs are treated as prospective and allocated in the aggregate to Research and Development.

Contributions provided to Events through PCOs. ToVs through Professional Conference Organizations (PCO) are reported in the name of benefitting HCO, if not included in direct ToVs to the HCO; PCOs are obliged to indicate the name of the benefitting HCO in their offers.

Consent management

Consent collection. Unless disclosure is mandated by local legislation, data protection legislation in force in Austria, as reflected by the more stringent requirements contained in the General Data Protection Regulation (EU) 679/2016, requires Organon to obtain the consent of each HCP and HCO to disclose their personal information. 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 HCPs. The means by which Organon has obtained consent in Austria is a stand-alone agreement covering all interactions with the HCP for an entire year.

Management of Recipient consent withdrawal. A Recipient has the right to withdraw their consent at any time. If this occurs prior to Organons publication of the ToV, then the Recipients ToVs shall be reported on an aggregate basis only with no disclosure of the Recipients name. If consent is withdrawn by a Recipient after the publication of the relevant years ToVs, then the Recipients name and ToVs shall be removed and the corresponding amount of ToVs will be added to the aggregate reporting for the remainder of the 3year period for which the publication remains available.

Partial consent. In the event an HCP consents to disclosure of only a portion of the ToVs they have received (which is not in the interest of Organon or EFPIA), Organon will disclose the entire amount of the HCPs ToVs in the aggregate without naming the HCP. Partial disclosure under the individual disclosure category would be misleading with respect to the nature and scale of the interaction between Organon and the HCP.

Disclosure Form

Date of publication. Organon publishes the ToV for the preceding calendar year no later than 6 months after the end of the relevant reporting period (for example, ToVs for 2022 are reported no later than June 30, 2023). The information disclosed shall remain available for three (3) years thereafter, subject to individual disclosures being shifted to aggregate disclosure in the event of after-the-fact revocation of consent by the Recipient.

Disclosure platform. Organon provides its annual disclosure its own web site.

Disclosure language. Organon provides its annual disclosure in German.

Disclosure financial data

Currency and VAT. All disclosed ToVs are reported in local currency and exclusive of VAT. ToVs paid in other currencies are converted to local currency at the exchange rate applicable on the date the cost is incurred.

How is VAT Managed?

Disclosed ToVs to HCOs and HCPs reflect the amounts agreed in the contracts and on invoices submitted to Organon by HCOs or HCPs. The data collection and reporting is by guidance to all data providers based on “net amounts”. If VAT cannot accurately be excluded, the full ToV amount is disclosed exceptionally.

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