

ORGANON Czech Republic Methodology Statement

Introduction

ORGANON Czech Republic s.r.o. (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. 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 Organisation (HCO) – any legal person (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 other teaching institution or learned society (except for patient organisations within the scope of the AIFP Code of Practice) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services. It also includes a company or other legal entity established by another healthcare professional who might also be its employee.

Healthcare Professional (HCP) - any person entitled to either prescribe or dispense a medicine. HCPs includes members of the medical, dental and pharmacy professions and any other persons, who in the course of their professional activities may



prescribe or dispense a medicine. It also includes any HCP – physical entity – who can be identified based on the registration number of the Czech Medical Chamber (such HCP is registered under this number as an HCP).

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

Transfers of Value (ToV's) – 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 generic or branded prescription-only medicinal products exclusively for human use.

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

Indirect ToV is one made on behalf of ORGANON for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.

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 collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

Disclosure's scope

Excluded ToVs. 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.
- v) patient organizations.
- vi) meals and drinks.

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 ToV's. The following types of ToV's to HCO's are disclosed by ORGANON:

- i) Donations, grants and benefits in kind provided to institutions, organisations and associations that support healthcare.
- ii) Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:
 - a. registration fees,
 - b. sponsorship agreements with HCO's 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 symposium at a congress, sponsoring of speakers, the costs of drinks or meals provided by the HCO if part of an inclusive package, and courses provided by an HCO where ORGANON does not select the individual HCPs that participate), and
 - c. travel and accommodations.
- iii) Fees for service and consultancy resulting from or related to contracts between ORGANON and institutions, organizations or associations of HCPs under which such institutions, organizations or associations provide any type of services to ORGANON, or any other type of funding not covered in the previous categories (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 ToV's. The following types of ToV's to HCP's 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 resulting from or related to contracts between ORGANON and HCPs under which such HCPs provide any type of services to ORGANON or any other type of funding not covered in the previous categories (examples include speakers' fees, speaker training, medical writing, data analysis, development of educational materials, general consulting and advising, 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 ToV's). 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.



ToVs in case of partial attendance 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 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.

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 the Czech Republic are reported by ORGANON.

Disclosing entities. This annual disclosure report covers all ToV's made to HCOs and HCPs in the Czech Republic, whether by ORGANON Pharma (CZ) Limited or by its affiliates including those based in other countries.

Specific considerations

Country unique identifier. In order to ensure disclosure of ToV's are allocated correctly, ORGANON has assigned a unique identifier to each HCP and HCO. In the Czech Republic, this is based on the company identification number (IČ) for HCOs and a national medical registration number (from the Czech Medical Chamber or Czech Chamber of Pharmacists) for HCPs.

Self-incorporated HCP. An HCP – physical entity – who can be identified based on the registration number of the Czech Medical Chamber will be registered under this number as an HCP. IČ (IN) does not turn a physical entity into a legal entity.

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.

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

Contributions provided to Events through Professional Congress Organisers (PCOs). ToVs through PCOs are reported in the name of benefitting HCO.

Consent management

All 2021 data published in our disclosure will be shown at aggregate level, consent collection for this data is not applicable.

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, ToV's for 2021 are reported no later than June 30, 2022). 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 via a company website www.organon.com/czech-republic-cz/

Disclosure language. ORGANON provides its annual disclosure in Czech and English.

Template. For consistency purposes, disclosures will be made using the structure set forth in the national Code on Disclosure, reflecting the requirements of the Code.

Disclosure financial data

Currency and VAT. All disclosed ToV's are reported in local currency and with VAT. ToV's paid in other currencies are converted to local currency at the exchange rate applicable on the date the cost is incurred. Disclosed ToV's to HCOs and HCPs reflect the amounts agreed in the contracts and on invoices submitted to ORGANON by HCOs or HCPs.