



Organon UK Methodology Statement

Introduction

This Methodology Statement defines the relevant types of transfers to be disclosed, which transfers are excluded, and other relevant information to assist the reader to understand how Organon collected, organised and reported the disclosed data.

Organon is a global healthcare company formed through a spinoff from MSD on the June 3rd, 2021. Organon will disclose TOVs from June 3rd 2021 onwards. Any TOVs that occurred prior to this date, will be disclosed by MSD.

Definitions

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

Event – scientific meetings, promotional meetings, 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), organised or sponsored by or on behalf of Organon.

Healthcare Organisation (HCO) – a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.

Health Professional (HCP) - includes members of the medical, dental, pharmacy and nursing professions and any other persons, who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. It also includes 'other relevant decision makers', particularly those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals. It also includes any employee of Organon whose primary occupation is that of a practicing health professional. If a healthcare organisation consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the ABPI Code regarding individual health professionals.

Recipients – any HCO or HCP whose primary practice, main professional address or place of incorporation is in the United Kingdom.

Transfers of Value (ToVs) – means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines.

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



An 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 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 Directive 2001/20/EC); and iii) noninterventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study.

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 the ordinary course of business 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.

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. *Indirect ToVs concerning travel and accommodation are disclosed on the basis of the date that the event took place; Direct ToVs are disclosed on the basis of the date the ToV is posted to our finance systems.*

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 HCO's are disclosed by Organon:

- i) Donations, grants and benefits in kind provided to institutions, organisations and associations that support healthcare;
- ii) contributions towards the costs related to Events, paid to HCOs or to third parties managing events on their behalf, which may include sponsorship of HCP's 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, arranging a satellite symposium at a congress, sponsoring of speakers or faculty,); and
 - c. travel and accommodations
- iii) Fees for service and related expenses paid to a HCP or to their employer on their behalf
- iv) Joint Working
- v) Contracts between companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services on behalf of Organon; provided for the purpose of supporting research or medical and educational goods or services.

HCP ToVs. The following types of ToVs 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 (examples include speaker 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 as related expenses and not as a fee for service or consultancy.

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 a HCP cancellation, no ToV will be disclosed.

ToVs in case of cancelled events and participations. For third-party events that are cancelled by the third party independent of the will of Organon and, where the invited HCP does not attend or cancels late when they have accepted to attend, the ToV is disclosed equal to the amount of the costs Organon have not recovered.

Cross-border activities. Regardless of which Organon entity contracts with or pays a Recipient, all HCO's or HCP's whose primary practice, main professional address or place of incorporation is in the United Kingdom are reported by Organon.

Disclosing entities. This annual disclosure report covers all ToVs made to HCO's and HCP in the United Kingdom, whether by Organon Pharma (UK) Limited or by its affiliates based in other countries.

Specific considerations

Multi-year agreements. Disclosure is made on the basis of the year the actual ToV was provided. The amount that will be disclosed, will be the total amount paid by Organon in each year.

Non-interventional studies. In those circumstances where Organon is unable, despite its best efforts, to determine whether ToVs made to an 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.

Consent management

Consent collection. Data Protection legislation in the United Kingdom requires Organon to obtain the consent of each HCP to disclose their personal information. Organon has made reasonable efforts 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 the United Kingdom is through the



completion of a due diligence certification prior to the provision of any ToV. Excluded from this are circumstances where only travel within the UK has been provided.

Management of Recipient consent withdrawal. A Recipient has the right to withdraw their consent at any time for activities in 2021. Please note that Organon UK will be relying on Legitimate Interest as the legal basis for processing data related to transfer of value activities from January 2022.

Partial consent. Organon UK will not report partial disclosure as 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 2021 are reported no later than June 30, 2022). The information disclosed shall remain available for three (3) years thereafter.

Disclosure platform. Organon provides its annual disclosure via a central platform called the AGS 360 Portal organised by the ABPI.

Disclosure financial data

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

VAT. VAT is included when relevant.

Working with other Pharmaceutical Companies

Transfers of Value are divided between each of the pharmaceutical companies participating in the project.