



2024 Methodological Note - Organon UK

Introduction

This note 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 in accordance with the ABPI Code of Practice.

I. 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 an 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. **Note:** 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.

II. Disclosure scope

Excluded ToVs. The following ToVs are expressly excluded under the ABPI 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, v) patient organisations and; 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. *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 given to institutions, organisations and associations for the purpose of supporting healthcare, scientific research or education. This type of support assumes no benefit in return for the funding, and no involvement by Organon to the activity in question;
- ii) Contributions towards the costs related to Events, paid to HCOs or to third parties managing events on their behalf such as:
 - Sponsorship agreements with HCOs 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). This type of support assumes Organon receives benefit in return for the funding; and
- iii) Fee for services and related expenses paid to the HCO for the contracted 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, 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).
- iii) Expenses reimbursed that relate to services provided under a service or consultancy agreement (e.g., travel and accommodation) are 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.

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.

III. Specific considerations

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

Package deals. According to ABPI code 19.1 and 28 commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration, the provision of training on its use or the services of a nurse to administer it. Such indirectly provided services, either to Patients or to HCPs, are included in the HCO section.

IV. Consent management

Organon UK is relying on Legitimate Interest as the legal basis for processing data related to transfer of value activities from January 2022 onwards and this is described in all contracts and letters of agreement with HCPs.

Individuals can object processing of their data by emailing privacyteam@organon.com. Organon shall seek to ensure a balance is struck between individuals' rights and freedoms and Organon legitimate interests. Organon will cease processing of data unless we can demonstrate compelling and legitimate grounds for the processing.

Organon does not allow for any "partial disclosure". In other words, HCPs and ORDMs can only consent to all (not some) of their ToVs being disclosed by Organon to the ABPI on an individually identifiable basis.

V. 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.

Taxes. Treatment of VAT depends on the type of TOV:

Indirect TOVs - Travel and Accommodation paid on behalf, or reimbursed to the HCP - will include VAT.

Direct payment TOVs will be excluding VAT, as that can be recovered by Organon.