

Methodological Note 2021 Disclosure

Introduction

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice 2021 requires all companies to document and publicly disclose certain transfers of value (TOVs) made directly or indirectly to healthcare professionals (HCPs), other relevant decision makers (ORDM) and healthcare organisations (HCOs) located in Europe (Clause 24.1).

Each company providing TOVs must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of TOV (Clause 24.10).

The term 'transfer of value' (TOV) means a direct or indirect TOV, 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 a company for the value of the recipient. An indirect TOV is one made on behalf of a company 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 TOV (Clause 24.1).

The term '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 (Clause 1.4).

The term 'other relevant decision makers' (ORDM) particularly includes 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 HCPs (Clause 28.1 (24.1)).

The term 'healthcare organisation' (HCO) means either 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 HCPs or ORDMs provide services (Clause 28.1 (24.1)).

Camurus Ltd discloses all TOVs to HCPs, ORDMs and HCOs in accordance with its commitment to the ABPI Code of Practice which is aligned with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on Disclosure on Transfers of Value.

All required TOVs made in the UK from January 1st, 2021 to December 31st 2021 are disclosed on the ABPI central platform.

This document summarises the approach taken by Camurus in calculating the figures provided.

Definitions

HCPs and ORDMs

Camurus Ltd regards all employees of the NHS or any non-statutory (3rd sector) or private HCO as HCPs/ORDMs regardless of their professional status.

Payments made to HCPs are disclosed by category type (see below) and reflect the total annual amount of TOV made for each category.

There are no Non-UK HCP disclosures for 2021.

HCOs

Camurus Ltd regards all hospitals, Clinical Commissioning Groups (CCGs), General practitioner (GP) practices and other places of work for HCPs treating patients or providing associated advice or management services related to the treatment of patients as HCOs. In addition, all medical societies (national or local) and all "networks" of HCP associations are regarded as HCOs.

Payments made to HCOs are disclosed by category type (see below) and reported on a per activity basis.

TOVs

Payments have been disclosed under the following TOV category types:

Collaborative Working (which includes Joint Working) (clauses 20 & 28): six joint working projects have been disclosed on the ToV for 2021.

Donations and Grants to HCOs (Clauses 23 & 28): On occasion, Camurus Ltd is asked by a HCO to provide a financial grant. Grants are funds given for a specific purpose without any obligations undertaken by the HCO other than to utilise the funds in accordance with the grant. Grants may include, but are not limited to support to research, patient education and independent scientific meetings and healthcare professional education. The grant is declared against the named HCO.

Contribution to costs of Events (Clauses 10 & 28)

Sponsorship agreements with HCOs / third party organisations appointed by HCOs to manage an Event. Sponsorship of meetings organised by HCOs: Camurus Ltd discloses all payments made to medical associations, HCOs, etc. in relation to support for third party meetings. This category includes funding provided via sponsorship packages with associated benefits such as brand visibility, speaking slots, etc.

Sponsorship for HCPs to attend medical meetings: Camurus Ltd supports the attendance of HCPs at medical meetings, including conferences and congresses. Camurus Ltd discloses the associated TOVs against the individual attendee. Where costs are not individually itemised (e.g. the cost of a taxi transferring multiple HCPs from an airport to a conference venue), the total cost is split equally between all those receiving the benefit. Costs declared include registration fees, travel and accommodation.

Fees for service and consultancy, and related expenses: Camurus Ltd discloses all payments made to HCPs and ORDMs for their services provided to Camurus Ltd in the form of service and consultancy fees; any related expenses agreed in the fee for service

or consultancy contract, including transport and accommodation, are disclosed as related expenses.

On occasion, a HCO may require that any services provided by its HCP employees cannot be contracted with the individual HCP but must be a service contracted through the HCO. In those instances the full amount paid by Camurus Ltd is disclosed against the HCO as a fee for service plus any related expenses.

R&D

Research and Development (R&D) ToVs are disclosed at an aggregate level (i.e. total spend with all involved HCPs/ ORDMs/HCOs added together without specifying individuals who have been paid).

Items included:

- Pre-clinical research and clinical research (includes Investigator Sponsored Research (ISR))
- Advisory boards and consultancy services in relation to clinical research
- Fees for service to HCPs, ORDMs and HCOs in relation to study sites (including where these fees have been made by CRO on behalf of Camurus)
- Travel and accommodation in relation to a fee for service contract.

Items not included:

- Overhead cost (including CRO fees) and Materials (such as study medication, injection kits, testing etc.).

Scope of disclosure

Recipients

All TOVs made to HCPs/ORDMs and HCOs practicing in the United Kingdom (England, Scotland, Wales and Northern Ireland) have been disclosed.

Excluded TOVs

The following TOVs have not been disclosed:

Hospitality costs: the cost of subsistence (food & drinks) is generally not disclosed, unless it forms an integral and inseparable part of the cost of an event, e.g. sponsorship of a third party HCO event.

Informational and educational materials: any information or educational materials provided to HCPs/ORDMs or HCOs have not been disclosed.

Donations to Patient Organisations: any financial support and/or any significant indirect/non-financial support made to Patient Organisations are reported separately on the Camurus company website.

Donations to charitable organisations: all TOV made to charitable organisations are outside the scope of disclosure.

Data Privacy

The Data Privacy law requires that Camurus Ltd obtains permission from individual HCPs/ORDMs to publicly disclose their personal data such as their name, address and

individual TOVs. Camurus Ltd has made every effort to secure and retain a record of the necessary permissions prior to disclosing their data. This has been achieved by asking individual HCPs/ORDMs to sign a disclosure agreement form and consent has been obtained from all HCPs/ORDMs for TOVs during the reporting period.

Camurus Ltd fully supports the principles of transparency and privacy. Information disclosed must remain in the public domain for at least three years from the time of disclosure (Clause 24.5) and Camurus Ltd will document all disclosures and retain the records for at least five years after the end of the calendar year to which they relate (Clause 24.6).

Private companies

Where a HCP runs a private company for the purposes of their private income, any payments to that organisation is regarded, for disclosure purposes, as a payment to the HCP directly.

Similarly, organisations where the majority of employees or contracted suppliers are comprised of HCPs, the full value of payments made to such organisations associated with the services of a named or identifiable individual is regarded as if it was a direct payment to the HCP.

Payments to third party agencies for services provided by individual HCPs

Camurus Ltd may contract with advertising agencies and logistics agencies, etc., for services related to its business. On occasion, the work commissioned by Camurus Ltd might be contracted out to an individual HCP/ORDM. Camurus Ltd requires that all such services must be disclosed to Camurus Ltd by the contracted service agency. Where the individual HCPs/ORDMs are identifiable, Camurus Ltd discloses any payments made to those HCPs/ORDMs by the service agency as if the payments had been made directly by Camurus to those HCPs/ORDMs.

Payments to UK HCPs or HCOs by other Camurus affiliates

Payments made to HCPs practising in the UK or to UK-based HCOs by Camurus's overseas operations are disclosed, regardless of the source of funding.

Tracking and collation of disclosures

All TOV data is collated on a single TOV spreadsheet based on contracts, agreements and invoice information, agency submitted TOV information, other Camurus affiliate submitted TOV information, and data privacy consent responses. This TOV spreadsheet is utilised to complete the ABPI template for disclosure. The completed ABPI template is uploaded to the ABPI central platform.

Other considerations

Reporting date

There is an inevitable delay between the date on which a payment is approved within Camurus and the date on which the payment is made. Camurus discloses the details of the payment on the date the transfer of value is made.

VAT and other tax considerations

Where payments were made and VAT was applicable, the VAT has been excluded for the purposes of disclosure. Therefore, all values provided are exclusive of VAT.



There are no other tax considerations.

Multi-year contracts

Camurus discloses the details of the payment on the date the transfer of value is made and not for the full value of the contract.

Co-marketing projects

Camurus Ltd does not jointly market any products with any other pharmaceutical companies.