



Methodological Note for Disclosure of Transfer of Values in 2022

Published March 2023

Chugai Pharma UK Ltd.
&
Chugai Pharma Europe Ltd.

Introduction

Transparency is fundamental in encouraging positive and constructive working relationships between the pharmaceutical industry and healthcare providers and stakeholders, across the UK and Ireland.

The ABPI and IPHA Codes of Practice require Chugai to disclose certain transfers of value (ToVs) to healthcare professionals (HCPs), healthcare organisations (HCOs), other relevant decision makers (ORDMs) patients, carers, members of the public and journalists.

This methodological note describes the methods used by Chugai in the UK to meet its obligations and the requirements for disclosing Transfers of Value (ToV) to Health Professionals (HCPs), Other Relevant Decision Makers (ORDMs), Healthcare Organisations (HCOs), Patients, Carers, Members of the public and journalists, as outlined in the EFPIA Code of Practice and reflected in the ABPI Code of Practice and the IPHA Code of Practice for the Pharmaceutical Industry.

Transfers of Value made to Patient Organisations, patients, carers, members of the public and journalists are disclosed separately on the Chugai website
<https://www.chugai.eu/responsibility/transparency/>

Definitions

Transfer of value

The term 'transfer of value' 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.

Healthcare Organisation (HCO)

The term 'healthcare organisation' 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 the UK, or an organisation through which one or more health professionals or other relevant decision makers provide services.

Health Professional or Healthcare Professional (HCP)

The term 'Health professional' or 'healthcare professional' 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 any employee of a pharmaceutical company whose primary occupation is that of a practicing health professional.

Other Relevant Decision Maker (ORDM)

The term 'other relevant decision makers' 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 health professionals.

Contracted services provided by members of the public, including patients, carers and journalists

These services include speaking at meetings, assistance with training, writing articles and/or publications, participating in advisory boards; advising on a design etc. of a clinical trial and participating in market research where such participation involves remuneration and/or travel.

Transfers of value

Categories disclosed against individual HCPs or ORDMs for ToV made in 2022

Description of ToV	
<p>Fees for service and consultancy and associated related expenses agreed in the fee for service or consultancy contract.</p>	<p>Chugai pays fair market value (FMV) fees for the provision of services by HCPs/ORDMs. These types of services may include, but are not limited to; chairing or speaking at meetings and participating in advisory boards. This service provision is documented and agreed via a consultancy agreement and the fees and associated expenses documented in the agreements are disclosed.</p> <p><i>Note:</i> If a meeting was cancelled after an HCP/ORDM had already spent time preparing for the meeting then this preparation time would be reimbursed and hence disclosed.</p> <p>Associated expenses may include: travel expenses, accommodation rates (may include dinner, bed and breakfast or room only depending on the engagement) and other associated expenses claimed by the service provider, for example parking.</p> <p><i>Note:</i> Expenses already incurred for an event that is later cancelled by the HCP and are not able to be reclaimed by Chugai (e.g. rail fare to attend a speaker meeting) will be disclosed.</p> <p>When Chugai engages with an HCO to provide the services of unknown to Chugai HCPs, ORDM, patient etc, any fee for service is paid directly to the HCO and disclosed against the HCO, however expenses claimed by the HCP will be reported against the individual provided consent is given.</p>
<p>Payments made to consultants in relation to market research where the identify of those participants is known to Chugai</p>	<p>Chugai discloses such payments against the individual, provided consent is given.</p>

<p>Sponsorship of HCPs/ORDMs for attendance at meetings. This includes registration fees and associated expenses in the form of travel and accommodation.</p>	<p>Chugai UK and other Chugai affiliates may provide sponsorship for individual HCPs/ORDMs to attend third party organised meetings.</p> <p>All associated registration fees, accommodation rates and travel expenses are disclosed accordingly.</p> <p>In certain circumstances Chugai will reimburse expenses to attend Chugai organised educational meetings and these are disclosed as such.</p>
<p>Over-the-counter (OTC) medicines</p>	<p>As per the PMCPA code of practice, the term ‘over-the-counter medicine’ means those medicines or particular packs of medicines which are primarily advertised to the public for use in self-medication.</p> <p>This does not apply to Chugai, as we do not provide over the counter medicines and therefore no ToVs are disclosed.</p>

Categories disclosed against HCOs for ToV made in 2022

Description of ToV	
<p>Contributions towards cost of meetings paid to HCOs/third parties for managing events on their behalf</p>	<p>Chugai discloses all payments made to medical associations, healthcare organisations, professional conference organisers, etc. in relation to meetings. In addition, all medical societies (national or local) and all “networks” of associations for HCPs are regarded as HCOs.</p> <p>This includes direct funding such as sponsorship fees for the right to have an exhibition stand, and indirect support e.g. providing a logistics agency. This does not cover any costs towards catering.</p>
<p>Collaborative working</p>	<p>Collaborative Working is where Chugai works in partnership with a healthcare organisation on large projects, typically involving situations where, for the benefit of patients,</p>

	<p>one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centered projects and share a commitment to successful delivery. Chugai discloses all payments relating to Collaborative Working.</p>
Fees for Service	<p>Fees paid to HCOs for the provision of a service e.g., consultancy fees, are reported as fee for service against the relevant HCO.</p>
Donations and Grants (DAG)	<p>Donations and grants collectively mean providing funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return.</p> <p>Donations are physical items, services or benefits in-kind which may be offered or requested. Grants are the provision of funds. Grants and Donations to individuals (HCPs, patients, etc.) are not provided.</p> <p>Chugai publicly discloses all donations and grants on an annual basis.</p>
Medical and Educational Goods and Services (“MEGS”)	<p>This term includes the non-promotional provision of goods and/or services which directly enhance patient care or benefit the NHS and maintain patient care.</p> <p>All MEGS will fall under either under Grants, Donations or Collaborative working as per ABPI Code 2021, and would be disclosed as an in kind ToV to the relevant HCO.</p>
Provision of patient support service or package deals involving the delivery of services delivered by an HCP	<p>ToV for any part of the service delivered by an HCP e.g. nurse infusion support will be disclosed as fee for service.</p>

Categories disclosed against contracted services provided by members of the public, including patients and journalist for ToV made in 2022

Description of ToV	
Fee for service and expenses including travel related to contracted services with individual(s)	<p>ToV required for contracted services provided by members of the public, including patients, carers and journalists.</p> <p>ToV will be disclosed as fee for service as well as expenses, these items will be disclosed separately. A breakdown of the total payments to each group of individuals, i.e. the public, patients and journalists, per calendar year and a description of the types of services provided</p>

Disclosure of Research and Development Transfers of Value

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 or organisations who have been paid).

Items included:

- Pre-clinical research and clinical research, including Investigator Sponsored Research (ISR)
- Non-interventional studies
- Advisory boards and consultancy services in relation to clinical research
- Real world data studies and Health Outcomes research
- Fees for service to HCPs, ORDMs and HCOs in relation to study sites (including where these fees have been made by CROs on behalf of Roche)
- Travel and accommodation in relation to a fee for service contract

Items not included:

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

It is common practice for a pharmaceutical company to engage a clinical research organisation (CRO) to manage specific research projects and clinical trials. In these circumstances the CRO may make payments to HCPs and HCOs on behalf of Chugai. Such indirect payments are captured on a quarterly basis and provided to Chugai or processed through a business partner, Roche and subsequently disclosed by Chugai

Management of consent disclosure for HCPs/ ORDMs

In line with the requirements of the Data Protection Act 2018 and the EU General Data Protection Regulation 2016/679 (the “Data Protection Legislation”) and the rights of data subjects thereunder, Chugai will only make a disclosure of an individual HCP’s or ORDM’s personal data to the ABPI with the prior written consent of the HCP/ ORDM concerned.

Chugai is not required to obtain consent from UK HCOs engaged or sponsored by members of the Chugai Pharma UK Ltd to make an identifiable HCO disclosure to the ABPI as the Data Protection Act applies to the protection of personal data only.

Contracted services provided by members of the public including patients, carers and journalists will be disclosed on an aggregate basis. Please note ToV to UK individuals representing patient organisations will be disclosed against the patient organisation and not individually.

Chugai does not allow for any partial disclosure.

2020 Data Disclosed

- 36 individuals provided consent to disclose and agreed to some transfers of value being disclosed individually.
- 39 individuals did not provide consent and were disclosed in aggregate.

2021 Data Disclosed

- 37 individuals provided consent to disclose and agreed to some transfers of value being disclosed individually.
- 32 individuals did not provide consent and were disclosed in aggregate.

2022 Data Disclosed

- 55 individuals provided consent to disclose and agreed to some transfers of value being disclosed individually.
- 36 individuals did not provide consent and were disclosed in aggregate.

Financial Considerations

Private companies

Where an HCP/ ORDM runs a private company (where he/she is the only employee of the corporation), Chugai has treated this as if it were an individual HCP/ ORDM and has disclosed against the individual.

Where an organisation is principally made up of a group of HCPs, but where the ToV cannot be reasonably ascribed to an individual HCP within the organisation, this organisation has been designated an HCO and the ToV disclosed accordingly.

In lieu payments to charity

On occasion, a UK HCP/ ORDM who has provided a service to Chugai may ask for their fee to be paid to a charity. Chugai's policy does not allow this, and Chugai insists that all payments are made directly to the UK HCP/ ORDM concerned and hence classed as a ToV to the individual UK HCP/ ORDM concerned.

Cross Border Payments

Chugai discloses ToV based on the HCP's country of practice. If the HCP practices in more than one country, Chugai will select one to be the primary country and disclose all ToV to him/her in that country. Chugai's intention is to always disclose on a named individual basis once the HCP has provided written consent. Where this has not been granted then the payment is disclosed in an aggregated form.

Co-Marketing projects

Where Chugai jointly markets a product with another pharmaceutical company, Chugai will only declare those ToVs made directly by Chugai. ToVs made by any co-marketing partner (including Roche) will be disclosed separately by that organisation.

Tax and VAT considerations

It is the responsibility of the receiving HCP to settle local tax requirements. The contract for each engagement should be agreed and signed by both parties prior to any work being undertaken and there is a clear statement regarding tax payment responsibilities. Where a payment has been made to a HCO or third party vendor then where VAT has been included this has been settled by Chugai and where this has occurred this has been highlighted in the disclosure per line. There are occasions where VAT is added as part of an invoice but was not stated in the fully executed Agreement. Chugai may need to settle VAT as a separate and subsequent payment. The amount disclosed against HCOs is not inclusive of VAT.

Transactions and currency conversions

Chugai uses a finance system that gives an automated currency conversion based on the date of payment. This process is used for all TOV. For payments made prior to 2017, Chugai calculated currency conversion based on an average rate over the year.

Timing

Chugai discloses to the ABPI, all ToV it, and its affiliates, made between 1 January and 31 December of one year by 30 March the following year (for publication by the ABPI by end of June of the same year).

A ToV is considered to be made when the transfer is complete (e.g. when an amount is paid or a benefit received). For example:

- If a contract is signed in October 2021 but the payment is made in January 2022, the disclosure will be treated as a 2022 ToV and disclosed to the ABPI by 30 March 2023 for publication by end of June 2023.
- In the case of any cross-border ToVs captured in iHCP, the attendance/ activity date will be classed as the date of the transfer of value.

For any multi-year contracts, the ToV is disclosed by reference to the year the payment or benefit was provided to the HCP/ ORDM/ HCO/ Members of the Public, Patients, Carers and Journalists.

Useful links

LINK TO EFPIA CODE

<https://www.efpia.eu/relationships-code/the-efpia-code/>

LINK TO IPHA DISCLOSURE PORTAL <https://www.transferofvalue.ie/>

LINK TO ABPI CODE OF PRACTICE <https://www.pmcpa.org.uk/the-code/>

LINK TO ABPI DISCLOSURE PORTAL <https://www.abpi.org.uk/our-ethics/disclosure-uk/>

LINK TO IPHA CODE AND SUPPORTING DOCUMENTS

<https://www.ipha.ie/ipha-codes/>

Contact information

For inquiries regarding Chugai's disclosure of ToVs and to request further information or corrections should be directed via email: disclosure@chugai-pharm.co.uk or telephone +44 208 987 5680.

Healthcare Compliance Team
Chugai Pharma Europe Ltd. & Chugai Pharma UK Ltd.