

**ABPI Disclosure
Methodological Note**
March 2023



This note describes the methods used by Roche in the UK to meet its obligations and the requirements for disclosing payments and Transfers of Value (ToV) to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs) as outlined in the EFPIA HCP/HCO Code of Practice and reflected in the ABPI Code of Practice for the Pharmaceutical Industry.

Transfers of Value made to Patient Organisations will continue to be disclosed separately on the Roche website www.roche.co.uk.

Definitions.

Transfer of Value (ToV)

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.

Where a ToV is non-monetary in nature, the calculation of the ToV is explained in the relevant section below.

Healthcare Professional (HCP)

The term ‘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.

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.

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.

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>Roche pays fair market value (FMV) fees for the provision of services provided 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 and reimbursed for an event that is later cancelled (e.g. rail fare to attend a speaker meeting) will be disclosed.</p> <p>When Roche engages with an HCO to provide the services of an HCP, any fee for service is paid directly to the HCO, however expenses claimed by the HCP will be reported against the individual.</p>
<p>Payments made to consultants in relation to market research where the identity of those participants is known to Roche.</p>	<p>Roche did not make any ToV to HCPs/ORDMs for market research where the identity of such HCP/ORDMs was known to Roche in 2022</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>Roche UK and other Roche 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 Roche will reimburse expenses to attend Roche organised educational meetings and these are disclosed as such.</p>

Categories disclosed against HCOs for ToV made in 2022

Description of ToV	
Contributions towards cost of meetings paid to HCOs/third parties managing events on their behalf	<p>Roche discloses all payments made to medical associations, healthcare organisations, professional conference organisers, etc. in relation to meetings.</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.</p>
Collaborative Working (including Joint working)	<p>Collaborative Working is generally between pharmaceutical company(s), HCOs and other organisations and either enhances patient care or is of benefit to patients or alternatively benefits the NHS and at a minimum, maintains patient care Joint Working is a type of Collaborative Working.</p> <p>Where a Roche employee is working on a project and is included in the calculation of value, this value is calculated based on their daily rate according to their salary.</p> <p>Further information on Collaborative Working projects Roche is currently involved in can be found at www.roche.co.uk</p>
Donation	<p>In general these are physical items, services or benefits in kind which may be offered or requested by an HCO which are provided for the purpose of supporting healthcare, scientific research or education with no consequent obligation to the recipient organisation.</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>
Grants	<p>Roche may make a financial contribution in response to a request which is destined for an independent, specific activity or purpose, and which must benefit patients and/or public health, and must only be provided for the purpose of research, education and/or healthcare.</p> <p>Grants are only provided to HCOs and a clear arm's length arrangement is always in place.</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 fees for service.</p>

Roche does not include any Free of Charge Product or Service provided to an HCO under a commercial arrangement in its annual disclosure reporting .

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.)

Management of consent disclosure for HCPs/ ORDMs

In line with the requirements of applicable data protection laws and regulations (including the UK General Data Protection Regulation), where a transfer of value has been made to an individual HCP or ORDm by Roche, Roche will publicly disclose identifiable data in accordance with legitimate interests, unless an individual chooses to opt out of public disclosure.

We believe that there is a clear benefit in disclosing the individual, identifiable data of HCPs who have received payment from Roche for their services, not only in terms of the ABPI Code and ABPI members driving transparency, but also for society and patients in understanding those interactions.

Individuals can opt out of public disclosure at any time by emailing uk.disclosure@roche.com

If an individual chooses to opt out of public disclosure, Roche will treat this decision to opt out as enduring for all future reporting periods unless a subsequent email is sent to Roche stating that they wish to opt in again.

Roche will continue to work with HCPs/ORDMs who choose to opt out.

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

Roche 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 Roche to the ABPI on an individually identifiable basis.

Financial Considerations

Private companies

Where an HCP/ ORDM runs a private company (where he/she is the only employee of the corporation), Roche 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.

Payments to charity

On occasion, a UK HCP/ ORDM who has provided a service to Roche may ask for their fee to be paid to a charity. Roche's policy does not allow this and Roche 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

Roche discloses ToV based on the HCP's country of practice. If the HCP practices in more than one country, Roche will select one to be the primary country and disclose all ToV to him/her in that country.

ToVs made by affiliates of Roche for interactions with HCPs/ ORDMs in a different country are captured in a Roche Group system (iHCP) and will be disclosed by the Roche affiliate responsible for reporting in the HCP's primary country.

Co-promotion projects

Roche and Chugai Pharma UK Limited (Chugai) currently co-promote Prescription Only Medicines (POM). For this and any other situation where Roche jointly markets a product with another pharmaceutical company, Roche will only declare those ToVs made directly by Roche. ToVs made by any co-marketing partner (including Chugai) will be disclosed separately by that organisation.

Roche Group

The report for 2023 includes all relevant ToV paid to UK HCPs/ORDMs by Spark Therapeutics Inc (part of the Roche Group).

Handling of value-added tax (VAT) and withholding tax

In general, Roche defines ToV as “cost to Roche” and hence VAT is excluded from the reported ToVs.

Following the same principle, withholding taxes paid by Roche for ToVs provided to an HCP/ORDM/ HCO would be included.

Two exceptions from the above rule exist:

- For indirect payments related to events, VAT is typically not recoverable for Roche and the company’s systems do not capture VAT separately. In this instance the reported ToV will include VAT; and
- The same applies to actual cross-border spend captured in iHCP, for which no VAT is readily identifiable. In this instance, reported ToV will include VAT.

Transactions and currency conversions

All ToVs are disclosed in Roche’s local currency (£GBP). Any ToV made by an affiliate of Roche in foreign currency is converted using a single annual exchange rate for each currency, as embedded into the Roche transparency reporting systems and based on the average rate of the previous year.

Timing

Roche discloses to the ABPI all ToV it (and its affiliates) made between 1 January and 31 December of one year by 31 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 on 1 October 2021 but the payment is made on 15 January 2022, the disclosure will be treated as a 2022 ToV and disclosed to the ABPI by 31st March 2023 for publication by end of June 2023.
- In the case of a ToV 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.