

**ABPI Disclosure
Methodological Note**
March 2017



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 Health Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs) as outlined in the EFPIA HCP/HCO Disclosure Code 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 Europe 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.

Categories disclosed against HCOs for ToV made in 2016

Description of ToV	
Contributions towards cost of meetings paid to HCOs/third parties managing events on their behalf	Roche discloses all payments made to medical associations, healthcare organisations, etc. in relation to meetings. 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.
Joint working	<p>Joint working arrangements are situations where, for the benefit of patients, one or more pharmaceutical company and the NHS pool skills, experience and/or resources for the joint development and implementation of patient-centred projects, and share a commitment to successful delivery.</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 Joint Working projects Roche is currently involved in can be found at www.roche.co.uk</p>
Fees for Service	Fees paid to HCOs for the provision of a service e.g. consultancy fees, are reported as fee for service against the relevant HCO.
Donations/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 information.</p> <p>Grants are only provided to HCOs and a clear arm's length arrangement is always in place.</p>
Medical and Educational Goods and Services ("MEGS")	This term covers the non-promotional provision of goods and/or services which directly enhance patient care, or benefit the NHS and maintain patient care. These would be disclosed as a benefit in kind to the relevant HCO.

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 who have been paid).

Items included:

- Pre-clinical research and clinical research (includes 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 CRO on behalf of Roche)
- 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.)

Management of consent disclosure for HCPs and ORDMs

In line with the requirements of the Data Protection Act 1998 and the rights of data subjects thereunder, Roche 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 or ORDM concerned.

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 DPA applies to the protection of personal data only.

Roche sets a high standard for consent by asking those HCPs and ORDMs engaged or sponsored by any member of the Roche Group to consider signing and returning to Roche a *Declaration of Consent to Disclosure of Personal Data* (Declaration). Once returned to Roche, a signed Declaration is held valid for three (3) calendar reporting periods unless such HCP or ORDM notifies Roche of their wish to subsequently withdraw their consent during this time.

From June 2016, where consent to disclosure had not previously been obtained (or had previously been withdrawn or withheld) for the 2016 reporting year, each HCP or ORDM engaged or sponsored by a member of the Roche Group was sent a Declaration for their consideration as standard business practice.

In February 2017, for those HCPs and ORDMs who had not yet consented to disclosure, a Declaration was sent for their further consideration.

Each HCP and ORDM is entitled to withdraw their consent to disclosure at any time. In such cases, HCPs and ORDMs are asked to send an email to uk.disclosure@roche.com notifying Roche's UK Transparency Team that they wish to withdraw their consent for the current calendar reporting period. Following publication of Roche's ToV data, HCPs and ORDMs are also able to contact the ABPI via the ABPI platform to withdraw their consent. Where consent is withdrawn, Roche will adjust its disclosure to ensure that the total amount of all ToVs applicable to that HCP or ORDM forms part of the disclosed aggregate figure and is no longer identifiable against the individual HCP or ORDM.

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 a HCP or 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 or 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 or 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 or ORDM concerned and hence classed as a ToV to the individual UK HCP or 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 or 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 a Prescription Only Medicine (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.

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 in foreign currency is converted using the daily exchange rate rates embedded into the Roche accounting systems at the time the ToV is applied.

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 2015 but the payment is made on 15 January 2016, the disclosure will be treated as a 2016 ToV and disclosed to the ABPI by 31st March 2017 for publication by end of June 2017.
- 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 are disclosed by reference to the year the payment or benefit was provided to the HCP/ORDM/HCO