

# **ABPI Disclosure Methodological Note**

*July 2020*



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.com](http://www.roche.com)

### **Statement for the disclosure of 2019 data during the COVID-19 pandemic in 2020**

As part of the pharmaceutical industry's annual disclosure of transfers of value to HCPs, ORDMs and HCOs via the Disclosure UK platform and in order to ensure accuracy of the published data, the ABPI writes to all of the HCPs, ORDMs and HCOs named in companies' disclosure data ahead of its publication on Disclosure UK at the end of June. (Over 20,000 in June 2019.)

Given the unprecedented pressure on the NHS and health care professionals in responding to the COVID-19 pandemic, in April 2020 the ABPI and PMCPA agreed that it would not be appropriate for industry to write to HCPs, ORDMs or HCOs to request that disclosure data be reviewed. Doing so would have added additional work for NHS professionals at that time. To avoid this, and in-line with guidance provided by the ABPI, Roche's 2019 transfer of value data was published on Disclosure UK in aggregate.

Following updated guidance from the ABPI, Roche's 2019 transfer of value has now been published on Disclosure UK in disaggregated format as appropriate.

# 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 2019

| Description of ToV                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Fees for service and consultancy and associated related expenses agreed in the fee for service or consultancy contract</p> <p>Associated expenses</p>      | <p>Roche pays fair market value (FMV) fees for the provision of services provided by HCPs/ORDMs. These types of services may include; 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><b>Notes:</b></p> <p>1) If a meeting was cancelled after an HCP or 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 and any additional and appropriate subsistence.</p> <p><b>Notes:</b></p> <p>1) 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>2) 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 providing consent is given.</p> |
| <p>Payments made to consultants in relation to market research where the identify 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 2019.</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 2019

| Description of ToV                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
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| 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, professional conference organisers, 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 <a href="http://www.roche.co.uk">www.roche.co.uk</a></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")                                               | <p>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.</p> <p>These would be disclosed as a in kind ToV to the relevant HCO.</p>                                                                                                                                                                                                                                                                                                                                                                                                         |
| Provision of patient support service                                                              | This term covers the provision of a patient support service. ToV for any part of the service delivered by an HCP e.g. nurse infusion support will be disclosed as fees for service.                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

## 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 2018 and the EU General Data Protection Regulation 2016/679 (the “Data Protection Legislation”) 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 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 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 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.

## 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.

## 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 2018 but the payment is made on 15 January 2019, the disclosure will be treated as a 2019 ToV and disclosed to the ABPI by 31st March 2020 for publication by end of June 2020.
- 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





## **EFPIA Disclosure Code 2020 Self-Certification Scheme**

Healthcare professionals (HCPs) and healthcare organisations (HCOs) with whom F. Hoffmann – La Roche (hereinafter “Roche”) works provide the Pharmaceutical Industry with valuable, independent and expert knowledge derived from their clinical and management experience. As owners of scientific knowledge and experts in medicinal products, pharmaceutical companies can be a unique resource to the healthcare systems and providers, which will ultimately benefit the patients.

Throughout the medicines life cycle pharmaceutical companies work with scientists and HCPs. These collaborations are essential in addressing patient needs. Industry and HCPs collaborate in a range of activities from clinical research to sharing best clinical practice and exchanging information on how new medicines fit into the patient pathway.

EFPIA and its member associations have adopted codes and guidelines to ensure that the interactions of their member companies with HCPs and HCOs meet the high standards of integrity and transparency. Building greater transparency to the relationships between pharmaceutical companies and HCPs/HCOs aims to build understanding of the collaboration and recognition of its value to patient care.

EFPIA and its members are fully committed to implement and apply the highest ethical standards. Despite the exceptional circumstances related to COVID-19, Member Companies made their best efforts to disclose the relevant information for 2019.

Except in countries where disclosure is prescribed by laws, Roche hereby confirms that its disclosures of transfers of value (ToVs) to HCPs and HCOs made in 2019 have been reported in application of the EFPIA Disclosure Code following key principles:

### **Disclosure quality**

Roche certifies that:

- its disclosures are made in each country where it operates;
- its disclosures include direct and indirect ToVs, as defined in the codes and associated guidance issued by EFPIA;
- its Methodological Note describes the process it has followed in order to compile the data hereby disclosed.

### **Methodology used for the collection and organisation of ToVs is in line with the EFPIA Disclosure Code’s requirements and applicable codes**

Roche certifies that:

- data collection complies with the requirements of the EFPIA Disclosure Code;
- actions are taken to ensure individual disclosure for HCPs and HCOs’ transfers of values (each as defined in the EFPIA Disclosure Code).



**Aggregate disclosures are limited to Research and Development ToVs and such ToVs that cannot be disclosed on an individual basis for legal reasons**

Roche certifies that aggregate disclosure is limited to the following topics:

- Research and Development Transfers of Value (as defined in the EFPIA Disclosure Code);
- Transfers of Value to Recipients that have opposed to the publication on grounds of the protection of their private data;
- if an HCP or HCO (where applicable) has provided consent to individual disclosure only in respect of part of the Transfers of Value he/she/it received, all Transfers of Value to such HCP or HCO (where applicable) are being disclosed in the aggregate.

#### **Ensuring compliance with Data Privacy Obligations**

Roche certifies that its disclosure complies with the Data Privacy obligations.

Date: *May 27, 2020*

Name of signatory: Bill Anderson

Position: CEO Roche Pharmaceuticals

Signature:

Date: *June 9, 2020*

Name of signatory: Padraic Ward

Position: Head of Roche Pharma International

Signature: