



Merz Pharma UK Ltd Methodological Note

**On the Disclosure of Transfers of Value made to Healthcare Professionals and
Healthcare Organisations in 2018**



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List of abbreviations

ABPI	Association of the British Pharmaceutical Industry
BIK	Benefits in kind
CCGs	Clinical Commissioning Groups
EFPIA	European Federation of Pharmaceutical Industries and Associations
HCO	Healthcare organisation
HCP	Healthcare professional
GP	General practitioner
ORDM	Other relevant decision maker
TOV	Transfer of value



Introduction

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice 2016 requires all companies to document and publicly disclose certain transfers of value (TOVs) made directly or indirectly to healthcare professionals (HCPs) and healthcare organisations (HCOs) located in Europe (Clause 24.1)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)¹.

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 1.10)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)¹.

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 1.5)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 1.9)¹.

Merz 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 Value².

All required TOVs made in the UK from January 1st 2018 to December 31st 2018 are disclosed on the ABPI central platform.

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

[1] ABPI Code of Practice for the Pharmaceutical Industry 2016. Available from: <http://www.pmcpa.org.uk/thecode/Pages/default.aspx> [last accessed 03/2019].

[2] EFPIA Code of Practice 2014. Available from: <https://efpia.eu/relationships-codes/disclosure-of-payments-to-hcps/> [last accessed 03/2019].



Definitions

HCPs and ORDMs

Merz regards all employees of the NHS or any private HCO as HCPs/ORDMs regardless of their professional status. In addition, Merz regards all registered or qualified HCPs as within the scope of disclosure regardless of their NHS status. Part-time employees of Merz who are also an employee of a HCO fall within the scope of disclosure for all payments made by the company.

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

HCOs

Merz 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:

Joint Working with HCOs: Merz is not currently involved in or a partner of any joint working projects with HCOs.

Donations, Grants and Benefits in Kind (BIK) to HCOs: On occasion, Merz is asked by a HCO to provide a financial grant or BIK. The grant or BIK is declared against the named HCO. Where it is a BIK (e.g. an item of medical equipment) then the recommended retail price of the item is the amount declared against the named HCO.

Contributions towards the costs of meetings organised by HCOs: Merz discloses all payments made to medical associations, HCOs, etc. in relation to support for third party meetings. This includes direct funding such as sponsorship fees or the right to erect an exhibition stand.

Sponsorship for HCPs to attend medical meetings: Merz supports the attendance of HCPs at medical meetings, including conferences and congresses. Merz 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: Merz discloses all payments made to HCPs and ORDMs for their services provided to Merz 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 Merz is disclosed against the HCO as a fee for service plus any related expenses.

Research and Development: All payments to HCPs and HCOs related to research and development are disclosed as an aggregate figure in accordance with the ABPI Code of Practice.



Scope of disclosure

Recipients

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

Products concerned

Merz markets both prescription-only medicines, as well as medical devices. Consequently, all TOVs relating to those products have been disclosed. Merz does not market any over-the-counter products in the UK.

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 have been reported separately on the Merz 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 Merz obtains permission from individual HCPs/ORDMs to publicly disclose their personal data such as their name, address and individual TOVs. Merz 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.

Where consent has been obtained, Merz has declared the TOV against the individual HCP's/ORDM's names.

Where permission has not been obtained, Merz has declared the total TOV as an aggregate figure for all anonymous TOVs made to HCPs (so not against their individual names).

Merz 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 Merz 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)¹.

[1] ABPI Code of Practice for the Pharmaceutical Industry 2016. Available from: <http://www.pmcpa.org.uk/thecode/Pages/default.aspx> [last accessed 03/2019].



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

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

Cross border activities

Payments to UK HCPs or HCOs by other Merz affiliates

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

Currency

Where payments were made in a currency other than UK sterling, the exchange rate on the 25^h of March 2019 was used (e.g. for conversions from Eur to GBP a conversion rate of 0.85 was used).

Tracking and collation of disclosures

All activities and payments related to TOV are pre-approved according to Merz standard operating procedures (SOPs). All direct payments are captured via the Merz accounting software. All indirect payments are captured via contracted agencies and the TOV information provided to Merz post event.

All TOV data is collated on a single TOV spreadsheet based upon the Merz accounting software and invoice information, agency submitted TOV information, other Merz 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 Merz and the date on which the payment is made. Merz discloses the details of the payment on the date the transfer of value is actually made. This means that some projects which took place at the end of 2018 have not been disclosed as part of the 2018 annual reporting period, because the invoice has not been received and settled until in 2019, and will therefore be reported in the 2018 annual reporting period.

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

Where contracts run for several years, Merz declares the amount paid relevant to the year in which each part of the payment was made. Thus a project which spans 2 calendar years and includes several individual TOVs during that time, it will have two associated disclosures; one for each calendar year showing the value of the transfer made in that specific calendar year.

Co-marketing projects

Merz does not jointly market any products with any other pharmaceutical companies.