



Merz Pharma GmbH & Co. KGaA

Methodological Note

**Transfer of Value Disclosure Report Belgium for the Calendar Year
2018**



I) Introductory note

Merz supports laws and obligations which promote transparency around the relationships between healthcare companies, healthcare professionals (HCPs) and healthcare organizations (HCOs).

The disclosure report published via the betransparent platform covers all transfers of value (ToVs) made in relation with Healthcare Professionals, Healthcare Organizations or Patient Organisations seated in Belgium in accordance with:

- Sunshine Act: chapter 1 of title 3 of the Law of 18 December 2016 regarding various provisions on health, Belgian official Journal 27 December 2016.
- RD Sunshine Act: Royal Decree of 14 June 2017 executing the Sunshine Act, Belgian official Journal 23 June 2017.

This Methodological Note is intended to serve as supporting documentation for the Merz 2018 Disclosure Report. It summarizes the disclosure recognition methodologies applied by Merz in order to identify, collect and report ToVs for each disclosure category.

The 2018 Merz Disclosure Report for Belgium covers direct and indirect ToVs made to HCPs, HCOs and patient organizations based in Belgium. Disclosure is performed for the full calendar year 2018.

The report is disclosed as consolidated report under Merz Pharma GmbH & Co. KGaA. Merz legal entities which have made transfers of value to recipients covered by the Belgian Sunshine Law during 2018 are:

- Merz Pharmaceuticals GmbH (Germany)

Please note that Merz Pharma Benelux B.V. publishes a separate transparency report.

II) Relevant Definitions

ToV (Transfers of Value):

Direct or indirect transfers of value, whether payments, in kind or otherwise, made in connection with the development, the promotion and the sale of medicinal products exclusively for human use and medical devices. Direct transfers of values are made directly by the company to the recipient. Indirect transfers of value are made through an intermediary third party where the benefitting HCP / HCO can be identified.



HCP (Healthcare Professional):

Any natural person practicing medical, dental, pharmaceutical, veterinary or nursing art or who, in the course of his professional activities, may prescribe, purchase, deliver, recommend, lease, use or administer medicines or medical devices and whose practice is established in Belgium (Art. 1, 4°, RD Sunshine Act).

HCO (Healthcare Organisation):

Any association or organisation active in health, medical or scientific care, whatever its legal or organisational form, as well as any legal entity through which one or more healthcare professionals provide services (Art. 41, §1, 2°, Sunshine Act).

Patient Organisation:

A healthcare organisation that is responsible for patient representation (Art. 1, 5°, AR Sunshine Act)

III) Methodology for data collection

1) Transfer of Values Related to Contribution of Costs of Events

As events we define all scientific meetings, such as but not limited to conferences, congresses, symposia, training events (masterclasses) or advisory boards. All ToVs that can be classified as sponsorship such as registration fees and costs for travel & accommodation which are made to HCPs or HCOs in connection with these events will be disclosed under the respective categories “registration fees” and “travel and accommodation”.

If the HCP/HCO did receive a fee for the provision of a service (e.g. speaker agreement, consultancy services) all ToVs made to him will by contrast be disclosed under the category “fees”. Related expenses within the frame of the provision of service will be disclosed under the category “expenses for service and consultancy”.

2) Date of Transfer of Value

The ToVs are disclosed according to the reporting period in which the ToV was actually granted to the HCP. All paid amounts related to fees or grants are reported for the calendar year of the actual payment even though this might differ from the year the event took place.

By contrast all related costs for the meeting such as travel and accommodation or registration costs are published according to the year in which the meeting took place. This means that the situation can occur that meeting-related travel and accommodation costs will be reported in one calendar year but the service fee provided will be reported in the following calendar year.



3) Amounts of ToV

Whenever individual costs can be clearly assigned to an HCP / HCO these will be reported against the individual HCP / HCO. There might be situations in which the individual costs cannot be clearly assigned because of group costs e.g. for bus transfers. In these cases the total amount of the ToV will be divided by all persons benefitting from it and the per pax amount will be reported against each individual.

4) Cross-border situation

All Merz companies covered by this report are located outside of Belgium. Thus in general the ToVs contained in the Merz disclosure report are cross-border ToVs. This means that the ToV occurred outside the country where the recipient's primary practice or its place of incorporation is located. The original ToVs may thus have been made in other currencies than Euro. Yet the disclosure takes place in the country where the recipient has its primary practice address or place of incorporation.

5) Currency of publication

All ToVs specified in our report are disclosed in Euro although the ToVs may have been made in another currency. If the original payment was not made in Euro, we convert the amount using the average exchange for the month in which the ToV was paid (applicable for fees, grants and donations), or for the month when the meeting was held (related costs as e.g. travel and accommodation costs).

IV) Research and Development

We disclose as aggregate amount only all ToVs related to the planning or conduct of

- 1) experiments as referred to in Article 2, 11°, of the Law of 7 May 2004 on experiments on human persons
- 2) non-clinical studies as defined in the OECD Principles on Good Laboratory Practice and
- 3) clinical trials referred to in Article 6 of the Law of 25 March 1964 on medicinal products (Art. 1, 3°, RD Sunshine Act and Art. 42, §1, paragraph 2, Sunshine Act)

V) Transfers of Value made to Patient Organisations



The transfers of value which were made to patient organisations or umbrella organisations cover donations as well as sponsorship of events or financial support of publications as well as cooperation in patient awareness campaigns.