



Merz Pharmaceuticals GmbH

Methodological Note

Transfer of Value Disclosure Report as per National Legislation



I) Introductory note

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

Merz Pharmaceuticals GmbH is disclosing all transfers of value (ToVs) made in relation with Healthcare Professionals or Healthcare Organizations seated in Greece in accordance with:

- Law 4316/2014
- Circular 17702/19-02-2016 concerning scientific events

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

The 2018 Merz Pharmaceuticals GmbH Greece Disclosure Report covers direct and indirect ToVs made to HCPs/HCOs based in Greece. Disclosure is performed for the full calendar year 2017.

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.

ToVs might be e.g.:

- Donations, sponsorships, consulting fees, hospitality (excluding food & beverages), and every transfer of value made in relation to the promotion of products and in relation to scientific events
- Transfers of value made in relation to R&D activities and non-interventional clinical studies

HCP (Healthcare Professionals):



- Any natural person that is a member of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his professional activities, may prescribe, purchase, supply or administer a medicinal product;
- Any official or employee of a government agency or other organisation (whether public or private) that may prescribe, purchase, supply or administer medicinal products
- Any employee of a company whose primary occupation is that of a practicing HCP except private physicians with a permanent contractual collaboration with a company

HCO (Healthcare Organisation):

- Any legal person that is a healthcare, medical or scientific association (scientific society or an association of HCPs) such as a hospital, clinic, foundation, university or other educational institution or learned society of any type (e.g., NGOs) sponsored by pharmaceutical companies (except for patient associations)
- Any legal person through which one or more HCPs provide healthcare services

Cross-border situation:

Merz Pharmaceuticals GmbH is based in Frankfurt / Germany and does not have an affiliate in Greece. The disclosure report for Greece covers all ToVs made by the company headquarter and, if applicable, by other legal entities of the Merz group. Thus in general the ToVs contained in the Merz Pharmaceuticals 2017 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 Euro or other currencies. Yet the disclosure takes place in the country where the recipient has its primary practice address or place of incorporation.

III) Methodology for data collection

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

As events we define all scientific or promotional meetings, such as but not limited to conferences, congresses, symposia, training events (masterclasses) or advisory boards. All ToVs 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 category "sponsorship".

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 "service fees".

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.

For event-related expenses such as travel and accommodation the first day of the event will be the decisive date even though e.g. the booking of a flight will typically have occurred earlier.

For fees for service, grants or donations the date when the payments was actually financially processed will be decisive.

3) Amounts of ToV

The disclosed numbers are gross amounts. 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) Currency of publication:

All ToV specified in our report are published in Euro even if the ToVs 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).

5) Consent Collection:

For ToVs that will be individually disclosed under the name of the recipient proper consent has been gained by using a separate consent form.

IV) Research and Development

Transfers of value related to R&D will be reported as aggregate amount. These ToVs cover payments made in connection with

- 1) Non-clinical studies (as defined in OECD Principles on Good Laboratory practice)
- 2) Clinical trials (as defined in Directive 2001/20/EC)



- 3) Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study

V) Published Data

The Merz Pharmaceuticals disclosure report has been sent to the EOF in accordance with local transparency requirements. Publication will be made through the following transparency platform: EOF platform and Merz Pharmaceuticals website.

The data will remain in the public domain for three years and will be stored for a minimum of five years on record by the disclosing entity