



# Methodological Note - ITALY

## 1. INTRODUCTION

This note summarizes the methodology used in the preparation of the "disclosure" by Terumo Italia according to the Code of Ethics of Confindustria Medical Devices.

The data regarding transfers of value shall be published in the country where the beneficiary has established his/her domicile and the publication obligation in the case of groups of companies is also deemed extended to the parent companies of the member companies, and/or to other companies belonging to the group, in accordance with the relevant national codes and regulations.

## 2. DEFINITIONS

### HCP

The definition of an HCP varies from country to country and may include any member of the medical, healthcare, dental, pharmacy or nursing professions, or any other person, who in the course of his or her professional activities may prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve or supply healthcare services and/or medicinal products.

### HCO

An HCO is any legal person/entity:

- ) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as hospital clinic, foundation, university or other teaching institution or learned society (except for patient organisations)

or

- ) through which one or more HCPs provide services

Examples: hospitals, centralized purchasing offices, clinics, laboratories, pharmacies, research institutes, associations, foundations, universities, scientific societies or other educational or professional institutions (patient associations excluded).

### Third Party

It includes the subjects that propose, organize, manage, from a scientific, logistical and organizational point of view, events of any kind and type, aimed at satisfying an educational / training need of a scientific nature or of a different nature (as defined points 2.7.1 and 2.7.2 of the Confindustria Medical Devices Code of Ethics).

### Transfer of value (TOV)

Any direct or indirect Transfer of Value, whether monetary, in kind or otherwise, made, whether for promotional purposes or not, in connection with the development and/or sale of medical devices. This



includes, but is not limited to, payments of fees for services, registration fees, sponsorships, travel and the provision of hospitality.

#### **Transfers of Value to the individual healthcare professional (HCP)**

The transfers of value made by Terumo Italy during the previous year with reference to:

- expenses for participating in training, educational and promotional activities on company products organized by Terumo (*excluding meals and drinks*);
- fees for consultancy and professional services, including speaker activities as defined by a specific contract between Terumo and the Professional which indicates the type of service provided, including the related travel and hospitality costs (*excluding meals and drinks*).

If the Healthcare Professional does not give his consent to the processing of personal data, the data will be published on an aggregated basis.

#### **Value Transfers to the Healthcare Organization and with other Third Parties**

Transfers of value made to each Healthcare Organization or Third Party must be published on an individual basis.

They fall into this typology:

- ) contribution for the financing of events (eg sponsorship of conferences, congresses and scientific meetings) aimed at satisfying an educational / training need of a scientific or other nature in accordance with points 2.7.1 and 2.7.2 of the Code of Ethics of Confindustria Medical Devices;
- ) fees for consultancy and professional services, including the speaker activity defined by a specific contract between the Member and the Health Organization which indicates the type of service provided, including the related travel and hospitality costs;
- ) donations both in cash and in kind provided to the Health Organization.

#### **Transfer of value in aggregate form**

For transfers of value, which cannot be disclosed on an individual basis due to the absence of the relative consent, the amounts attributable to these transfers will be communicated on an aggregate basis.

In all cases in which it is necessary to publish the data on an aggregate basis for each of the categories identified in the previous points, it must be identifiable:

- ) the number of recipients on an absolute basis and as a total percentage of recipients;
- ) the aggregate data attributable to Healthcare Professionals who have not given consent to data processing;
- ) the percentage of transfers of value in aggregate form on the total of transfers.

The following transfers of value will also be published in aggregate form:

- ) all donations both in cash and in other goods to Third Parties, other than the Health Organization
- ) Expenses for Research and Development (R&D) activities
- ) Scholarships



### 3. PURPOSE OF THE DISCLOSURE

#### Transfers of value “excluded”

- ) supply of informative or educational materials and objects;
- ) meals and drinks;
- ) samples;

#### Date of transfer of value

The date of the transfer of value is the actual payment date to the recipient.

If the payment is made on different dates (for example, fee payment date and travel expenses date) the date to refer to is the date of payment of the fee.

In case of sponsorship of HCP / HCO to the participation of scientific conferences / events managed by third parties, the date of the event is taken as the date of transfer of value, if the effective date of payment of the fees, accommodation costs at the hotels, etc. they differ significantly from the date of transfer of value (= receipt of documents for the congress, the date of accommodation, etc.) to the beneficiary.

#### Transfer of value in the event of partial participation or cancellation

If no value has been transferred, the information on the transfer of value is not part of the disclosure.

#### Cross Border collaborations

In cases of transfers of value provided by entities of the Terumo Group which are based outside the national territory, these will be published by the country in which the main address of the beneficiary resides.

#### Types of Disclosure

##### a. Disclosure of individual data:

If in the contract the consent has been expressly given in writing and has not been revoked for at least one transfer of value in the reporting period, the transfers are made public as required by the Confindustria Medical Devices Code of Ethics.

##### b. Disclosure of aggregated data:

The declarations signed with the explicit indication of non-consent for a given event it will be disclosed as transfers of value in aggregate form in the reporting year, as required by the Confindustria Medical Devices Code of Ethics.

Transfers of value for beneficiaries for whom it was not possible to obtain the declaration of consent are shown on an aggregate basis.

### 4. SPECIFIC CONSIDERATIONS

#### Multi-year agreements and transfers of value for several years



In the case of multi-year agreements or other agreements based on which transfers of value have been made in several years, the information is included in the report relating to those actually paid in the reference year.

## **5. CONSENT MANAGEMENT**

### **Consent collection**

Terumo has requested the consent of the publication of the data from all HCPs in reference to each interaction in the reporting period.

Terumo will publish on an individual basis only the data of the individual recipients who have given their consent formally and positively, in compliance with the privacy legislation and applicable National Regulations. If one or more HCPs have not provided consent or have not sent a response to the request for consent, the relevant data will be published in aggregate form.

### **Management of withdrawal of consent by the recipient**

If the consent to the disclosure of individual data and the transfer of value is revoked, the individual data is removed from the published form within a period of 15 days after the submission of the written revocation.

### **Management of the recipient's request for revocation**

Requests and / or complaints from recipients can be submitted in writing to Terumo Italia at the following e-mail address [tit.transparency@terumo-europe.com](mailto:tit.transparency@terumo-europe.com)

## **6. DISCLOSURE MODULE**

### **Publication date**

The disclosure will be made within six months after the end of the calendar year of reference.

### **Disclosure platform**

Information reports will be published on the Company's website: <https://www.terumo-europe.com/en-emea/contact/terumo-italia-srl>

### **Disclosure Language**

The reports will be communicated in English and Local language, using a bilingual information model.

## **7. DIVULGAZIONE DEI DATI FINANZIARI E REGOLE DI CALCOLO**

### **Currency (local or otherwise, specify the exchange rate)**

The total of the transfers of value is indicated in the local currency after the conversion from foreign currencies for the exchange rates adopted on the day of the documentation of the actual payments in the electronic system.

Conversion rate is the EUR.

The basis for calculating the transfer of value is the internal Terumo Italia exchange rate table, updated monthly.



### **VAT included or excluded**

The transfer of value will be calculated based on the actual amount received by a certain recipient, whether in kind or in money.

The general approach is as follows:

- ) VAT included for transfers such as travel, accommodation, congress registration costs
- ) VAT excluded for transfers relating to contracts or fees for scientific consultancy services

### **Calculation rules**

The transfers of value made in the reference year are added together (both for individuals and for aggregates) based on the requirements of the subdivision of the form prepared by Confindustria Medical Devices.

Only the amounts of payments made within the (= reporting period) made during the year are considered for the calculation (see also the notes on transfers of value and the same over several years).

The calculation is performed in the same currency (see also the note on the currency).