# Grünenthal Italia S.r.l. - Methodological Note

## Guidelines for Implementing the EFPIA Disclosure (Transparency) Code for the Reporting Year 2024

### Preamble

As a member company of the European Federation of Pharmaceutical Industry and Associations (EFPIA), we feel obliged to ensure that the nature and scope of our cooperation with healthcare professionals and organisations should be clear and transparent to the public. This is the reason behind the EFPIA´s and EFPIA member association´s decision to issue its Transparency Code. The Code is intended to help avoid any suggestion of conflicts of interest and to make the general public more aware of the importance and necessity of cooperation between pharmaceutical companies and healthcare professionals and organisations.

**Healthcare professionals (HCP)** include every person that carries out his activity in the medical and dental sector, public, private and hospital pharmacy, nurses, General and Health Directors of Local Health Authorities/Hospital Authorities, technical and administrative staff of public and private organizations and any other person that can prescribe, source, purchase or supply medicinal specialties and that carries out his activity mainly in Europe. Intermediate medicinal distributors are excluded.

**Healthcare organisations (HCO)** include every entity that is an Association or medical, scientific, health or research Organization (notwithstanding its legal form) such as Hospitals, Clinics, Foundations, Universities, Training and Graduate Schools (Patient Associations are not included) that have their legal office or principal office in Europe, or through which a HCP provides services. In order to comply with the requirements of the EFPIA Disclosure (Transparency) Code as approved at the EFPIA General Assembly on the 24th of June 2013, we agree to document and publish details of any Transfer of Value (ToV) we may provide directly or indirectly to any healthcare professionals or organisations. The reporting period in each case will be the previous calendar year and we agree to publish the relevant report by the **end of June** of the following year.

The aim of these guidelines is to provide a clear and simple explanation of how we intend to record and publish this information in accordance with the Trade Association Code of Ethics (i.e. Codice Deontologico Farmindustria) and to thereby provide a basic framework for interpreting our report. In particular, we would like to outline the underlying methodology we intend to apply and to explain specific issues as to how we will apply this in publishing the relevant information. In the event of any doubt over whether the details of any specific ToV need to be published, we will assume in the interests of transparency that such details should be published. We will only refrain from publishing the details of those ToV where this is clearly not required under the Trade Association Code of Ethics Codice Deontologico Farmindustria.

These guidelines are structured as follows: Each question will be followed by an explanation and/or an example and specific details of how we intend to comply with the requirements set out in the EFPIA Transparency Code.

## Contents

# I. DATA PROTECTION

## 1. Consent to publish information

### 1.1 Question

***How important is the permission from the healthcare professionals or organisations concerned in terms of publishing the information?***

### 1.2 Legal background

Everyone is entitled by law to protection of data relating to them. This basic right covers the recording, processing and dissemination of any personal information, whereby any of these shall require the specific consent of the person affected. There are strict requirements for any such consent – it must be explicit, it needs to be visually highlighted in any contractual texts or similar documents and must be clearly and transparently worded.

### 1.3 Our approach

We made the maximum effort to obtain healthcare professionals' consent to publish details of any ToV they receive from us. If this consent is denied, we will only publish the total value of the ToV without specifying the name of the recipient. If the consent is refused after publication of data we will adjust the report within 10 working days.

## 2. Declaration of consent

### 2.1 Question

***What sort of declaration of consent is our data processing based on?***

### 2.2 Our approach

We use the specimen data privacy declaration contained in our contracts templates or in the events invitations for all healthcare professionals and organisations.

## 3. Duration of publication

### 3.1 Question

***How long do we make the information available for on our www.transparency.grunenthal.com platform and the respective country website https://www.grunenthal.it/chi_siamo/la_nostra_responsabilita/compliance/codice_di_transparenza_efpia?***

### 3.2 Our approach

Our report is generally available for a period of 3 years. We will amend the report accordingly in the event that any healthcare professional should withdraw their consent during such period or update the data as needed.

## II. GENERAL QUESTIONS

### 1. Cross-border issues

### 1.1 Questions

***What will we do in the case of cross-border issues where we provide ToV to a healthcare professional or organisation based in another European state?***

### 1.2 Examples

A cross-border situation exists when the pecuniary ToV is granted in a country other than the country in which the healthcare professional or organisation is based, has their practice or main office. This sort of situation includes those cases where we, as a UK-based subsidiary of the Grünenthal Group conclude a consultancy agreement with a doctor based in Italy.

### 1.3 Our approach

Any pecuniary ToV which we grant to healthcare professionals or organisations based in another ***European member state*** shall be published by our affiliated company based in that country. In the example given above, this would be our Italian affiliate. In the event that we do not have a local affiliate in the country that a recipient healthcare professional is based, we will publish the information on our international website (www.transparency.grunenthal.com).

### 2. Publication of ToV granted in a foreign currency

### 2.1 Question

***What do we do when the ToV is granted in any currency other than euros?***

### 2.2 Example

A doctor based in Italy receives funding from us to take part in a healthcare convention in the US and the attendance fee is paid in US dollars.

2.3 **Our approach**

All ToV specified in our report will be denominated in the local currency of the respective country. If the original payment was not made in local currency, we will convert the amount using the average exchange for the month in which the ToV was paid (applicable for grants and donations as well as fees) or for the month when the meeting was hold (related costs that means registration, travel and accommodation costs).

3. **VAT**

3.1 **Question**

***Will the figures we publish indicate VAT?***

3.2 **Legal background**

The EFPIA Disclosure Code essentially allows us to publish gross or net figures (i.e. including or excluding VAT).

3.3 **Our approach**

We will publish the ToV paid as net amounts, i.e. excluding VAT.

4. Publication of ToV relating to contractual arrangements lasting several years

4.1 **Question**

***What will we do in the event of publishing details of a ToV granted in relation to a contract stretching over several years?***

4.2 **Example**

This situation may arise, for example, in the event that we conclude a consultancy agreement with a doctor which has a term from 1 July 2015 to 31 December 2018 and which attracts a total consultancy fee of EUR 3,500.

4.3 **Our approach**

In such case, we will report the respective milestone payments for the year of the actual payment.

5. **Reporting period**

5.1 **Question**

***What will we do if more than one reporting period needs to be considered when publishing details of ToV?***

5.2 **Example**

This situation may arise in the event that a healthcare professional agrees during one reporting period to appear as a guest speaker at an event, but this event then actually takes place in the following reporting period. Another potential example is where ToV is granted in one reporting period, but relates to an event taking place in the next reporting period.

5.3 **Our approach**

We will publish ToV in accordance with our internal accounting regulations in the reporting period in which ToV was actually granted to the healthcare professional or to the third party, in the event that the ToV has been passed from it to healthcare professional and recorded in our accounts. All paid amounts related to grants and donations and fees will be reported with the year of the actual payment. All meeting related costs (registration, travel and accommodation also in connection with a fee) will be published for the year when the meeting takes place.

In the event that our internal accounting regulations should change, meaning that a ToV which would have been published in the latter reporting period under the previous regulations would, under the amended regulations, be published in the earlier reporting period, we will continue to publish ToV in the latter reporting period. This means that any changes to our internal regulations will not result in any failure to publish details of any ToV subject to a publication requirement.

## 6. Sponsoring payments made to more than one organisation

6.1 **Question**

***What will we do in cases where we have a sponsoring agreement with several healthcare organisations?***

6.2 **Our approach**

We will generally publish details ToV on an individual basis in accordance with the EFPIA Disclosure Code. If an individual ToV can be allocated *pro rata* to the relevant organisations, these shares will be published under the name of the respective organisation.

If such an allocation is not possible, we will assume that each organisation receives an equal share and will publish this accordingly.

## 7. ToV to contract research organisations (CROs)

### 7.1 Question

***What will we do in the event of ToV being granted to contract research organisations (CROs)?***

### 7.2 Background

Contract / clinical research organisations are research organisations which provide clinical study planning and execution services to companies in the pharmaceutical sector in return for payment.

### 7.3 Our approach

We will not generally publish details of any ToV granted to any CROs whose services we retain. The exceptions are those cases where

- the CRO is comprised of healthcare professionals or has links to a medical institution (like a university hospital or a publicly-run organisation). In such case, the CRO is considered to be an organisation and details of any ToV granted to it will be published by us individually in accordance with the general regulations.

- the CRO is used to indirectly grant ToV to healthcare professionals ("pass-through costs"). In such case, we will publish the individual details of each of these ToV, indicating the relevant healthcare professional in each case.

## 8. Recording of ToV granted to universities and other educational establishments

### 8.1 Question

***What will we do in terms of the publication of ToV granted to universities and other educational establishments?***

### 8.2 Our approach

Generally speaking, any ToV we may grant to universities and other educational establishments are not covered by the EFPIA Disclosure Code. We will only publish details of such ToV in the event that they indirectly find their way to an organisation, such as a university hospital, or one or more healthcare professionals. In such case, we will publish the details of each of those ToV under the name of the university or other educational establishment to which they were granted.

## 9. Indirect payment of ToV to healthcare professionals

### 9.1 Question

***What will we do in the event that ToV are paid to healthcare professionals indirectly via third parties?***

### 9.2 Our approach

In the event that we become aware that ToV granted by us to a third party have been passed on to healthcare professionals, or those persons have benefitted from such, we will generally publish the details of each of those ToV under the name of the relevant healthcare professional. Our contractual arrangements with third parties include the data protection provision that third parties require the consent of their own contracting partner for the publication of details relating to ToV and must demonstrate such to us.

## 10. Transport costs for joint transportation

### 10.1 Question

***What will we do about publishing details of transport costs for joint transportation or for the transportation of groups of healthcare professionals?***

### 10.2 Legal background

It is not necessary under the EFPIA Disclosure Code to allocate ToV paid in the form of transport costs for a group of healthcare professionals to individual healthcare professionals within that group.

### 10.3 Our approach

These costs will not be broken down according to the particular individuals involved and excluded from the reports

# III. QUESTIONS ON THE DATA FORMS

## 1. Donations – publication of ToV granted to hospitals or clinics

### 1.1 Question

***What will we do about the publication of donations to hospitals or clinics?***

1.2 **Examples**

It is possible in this case that the donation will be made to a hospital or clinic as a whole or to a department or unit within that institution, such as the oncology unit.

1.3 **Our approach**

In the event that the donation is clearly intended for a specific department or unit within a hospital and this department is a legal entity in its own right, we will publish details of the donation and give the name of the department. In the event that the donation is made to the hospital as a whole, we will publish the details thereof and given the name of the hospital.

2. **Continuous professional development events – definition**

2.1 **Question**

***What do we understand by continuous professional development events?***

2.2 **Our approach**

We classify any conventions, conferences, symposia etc. with a medical or scientific focus or serving to further the training of healthcare professionals as continuous professional development events.

3. **Continuous professional development events – registration fees**

3.1 **Question**

***What will we do about the publication of the fees we have assumed for healthcare professionals or organisations to attend external continuous professional development events?***

3.2 **Our approach**

We will generally publish the payment of registration fees as a ToV to the relevant healthcare professionals in the section devoted to " registration fees". The total amount of such fees assumed during the reporting period will be published for each individual healthcare professional.
If the healthcare professional for whom we paid the registration fee does not show up at the event, we will publish the expense incurred in the aggregate amount. The healthcare professional who has not benefited from the ToV will not be included in the total number of recipients.

4. **Continuous professional development events – travel and accommodation costs**

4.1 **Question**

***Which costs will we publish when we assume travel and accommodation costs relating to continuous professional development events?***

4.2 **Our approach**

We will include all travel and accommodation costs in the report unless they are related to group transfers.
If the healthcare professional for whom we paid travel and accommodation costs does not show up at the event, we will publish the expense incurred in the aggregate amount. The healthcare professional who has not benefited from the ToV will not be included in the total number of recipients.

5. **Continuous professional development events – organisation by an events agency**

5.1 **Question**

***What will we do about publishing details of TOV in the event that a continuous professional development event is organised by an events agency?***

5.2 **Our approach**

If an event (convention, conference, symposium etc.) is organised by an events agency and the ToV is paid to that agency, but the event has a clear relevance to a HCO, we will publish details of such ToV and specify the name of the HCO.

6. **Continuous professional development events – costs for internal events**

6.1 **Question**

***What will we do about publishing costs for internal continuous professional development events?***

6.2 **Our approach**

In the event that we charge a registration fee for one of our own internal continuous professional development events ~~and waive it for certain healthcare professionals~~, we will publish this as a ToV granted to the relevant professional. In the event that we assume the travel and accommodation costs for those persons attending our internal continuous professional development events, details of such will be published specifying the name of the relevant healthcare professional in the category provided for this purpose.

7. **Service and consultancy fees – definition**

7.1 **Question**

***Which TOV do we record as service and consultancy fees?***

7.2 **Legal background**

Service and consultancy fees are due under corresponding service and consultancy agreements.

7.3 **Our approach**

Under the category service and consultancy fees, we record all fees unless they are related to R&D which will be disclosed in an aggregate form.

8. **Service and consultancy fees – reimbursement of expenses**

8.1 **Question**

***What will we do about the publication of any expenses reimbursed in connection with service and consultancy fees?***

8.2 **Legal background**

In terms of ToV falling under the category "service and consultancy fees", the data record template provides for any expenses reimbursed being published in addition to and separately from the fee itself. These expenses may include travel and accommodation costs.

8.3 **Our approach**

8.4 Costs for joint transportation of a number of healthcare professionals, will not be respected in the report

9. **R&D – definition**

9.1 **Question**

***Which ToV come under "R&D"?***

9.2 **Our approach**

In terms of the category "R&D", we will only publish those ToV relating to "regulatory necessary" studies. These are any studies which are required in order to obtain approval for a pharmaceutical product or for post-marketing surveillance. We would consider this to include the planning and implementation of non-clinical studies (in accordance with the OECD Principles on Good Laboratory Practice), Phase I to IV clinical studies (pursuant to Directive 2001/20/EC) and non-interventional studies within the meaning of Article 15 EFPIA Code. We also include those studies which are necessary to demonstrate the additional benefit of a pharmaceutical product and to demonstrate or maintain that the expenses involved should be reimbursed. The TOV published in the report is related to an amount paid by Headquarter for a cross-border activity.

## 10. R&D – "non-clinical health and environmental safety tests

### 10.1 Question

***What will we do about publishing TOV relating to "non-clinical health and environmental safety tests"?***

### 10.2 Our approach

In terms of publishing ToV relating to "non-clinical health and environmental safety tests", we would only publish the total value of these for the category "R&D" in the event that the tests they relate to are suitable for submission to an approval authority. In all other cases, we will publish the ToV, specifying the name of the recipient. Can be stated as “Not applicable” in the local note (if true)

## 11. R&D – basic research

### 11.1 Question

***What will we do about publishing TOV relating to basic research?***

### 11.2 Our approach

We will publish the total value of ToV for basic research under the category "R&D ".

In the event that we support basic research in the form of donations to a university hospital, for example, we will publish the corresponding ToV under the category "monetary donations / donations in kind".

## Glossary

| Term | Section |
|---|---|
| accommodation costs | III. 4. |
| basic research | III. 11. |
| clinical research organisation (CRO) | II. 9. |
| cross-border issues | II. 1. |
| currency, foreign | II. 2. |
| declaration of consent | I. 3. |
| donations | III. 1. |
| events agency | III. 5. |
| events, internal | III. 6. |
| expenses | III. 8. |
| health and environmental safety tests | III. 10. |
| sponsoring | II. 6. |
| transport costs | II. 10. |
| travel costs | III. 4. |
| universities, ToV to | II. 8. |
| VAT | II. 3. |