# S.A. Grünenthal N.V. - Methodological Note

## Guidelines for Implementing the EFPIA Disclosure (Transparency) Code for the Reporting Year 2017 for Luxembourg

### Preamble

As a member company of the European Federation of Pharmaceutical Industry and Associations (EFPIA), we are obliged to ensure that the nature and scope of our cooperation with healthcare professionals and organisations is clear and transparent to the public. This is the reason behind the decision of EFPIA and EFPIA member associations to issue the EFPIA HCP/HCO Disclosure (Transparency) Code. The Code is intended to help avoid any suggestion of conflict of interest and to make the general public more aware of the importance and necessity of cooperation between pharmaceutical companies and healthcare professionals, other relevant decision makers and healthcare organisations.

In Luxembourg, the EFPIA HCP/HCO Disclosure Code has been incorporated within the APL Code of deontology for the Pharmaceutical Industry. The APLcode of deontology defines **Healthcare professionals (HCP)** as any natural person who is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. This definition of healthcare professional includes any official or employee of a government agency or other organisation (whether in the public or private sector) who may prescribe, purchase, supply, recommend or administer medicinal products and any employee of a pharmaceutical company whose primary occupation is that of a practising healthcare professional. All other employees of a pharmaceutical company and wholesalers or distributors of medicinal products are excluded from this definition.
**Healthcare organisations (HCO)** are defined as any association or organisation active in the field of healthcare or at the medical or scientific level, irrespective of the legal or organisational form, such as a hospital, foundation, university or other teaching institution or learned society, except for patient organisations whose business address, place of incorporation or primary place of operation is in Europe or any legal entity through which one or more healthcare professionals provide services.
The term '**transfer of value**' means any direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products for human use. A direct transfer of value is one made directly by a pharmaceutical company for the benefit of a healthcare professional or organisation. An indirect transfer of value is one made on behalf of a pharmaceutical company for the benefit of a healthcare professional or organisation, or made through an intermediate and where the pharmaceutical company knows or can identify the healthcare professional or organisation that will benefit from the transfer of value.
The reporting period in each case will be the previous calendar year and we agree to publish the relevant report by June of the following year on the corporate website.

The aim of this methodological note is to provide a clear and simple explanation of how we have recorded and are publishing this information in accordance with the APL Code of

deontology and to thereby provide a basic framework for interpreting our report. In particular, we would like to outline the underlying methodology we have applied and explain specific issues as to how this applies to our published information. In the event of any doubt over whether the details of any specific ToV need to be published, we have assumed in the interests of transparency that such details should be published. We have only refrained from publishing the details of those ToV where this is clearly not required under the APL Code of deontology.

This guideline is structured as follows: Each question is followed by an explanation and/or an example scenario and specific details of how we have complied with the requirements set out in the APLCode of deontology.

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# 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

Every individual person 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. Data protection legislation does not apply to organisations therefore consent to disclose has not been obtained from healthcare organisations.

### 1.3 Our approach

We require all healthcare professionals to indicate their consent for us to publish details of any ToV they receive from us within written contracts with the individuals. If consent is denied, we publish the total value of the ToV without specifying the name of the recipient as part of an aggregate disclosure. If a HCP's consent is revoked when the HCP provided legitimate consent for publication and comes back on it we will stop disclosing the relevant ToV on an individual basis going forward but information that was already disclosed on the platform will in principle not be amended or restated. However any information that was not yet disclosed on the platform will as from the revocation of the consent no longer be publicly disclosed on an individual basis. Any adjustments to the report will only be made beginning of October when the first update of the data takes place.

## 2. Partial consent

### 2.1 Question

***When a healthcare professional only agrees to publication of some of the relevant information, despite our efforts to obtain full consent, what is reported?***

### 2.2 Example

This situation may arise, for instance, where the healthcare professional agrees to the publication of details of having received funding to attend a professional congress or

seminar, but does not agree to the publication of the travel and accommodation costs associated with the trip. Another potential example is where the person concerned agrees to the publication of the expenses paid in connection with attending such an event, but not to the publication of any associated consultancy fee.

### 2.3 Our approach

Grünenthal N.V/S.A. decided to collect consent per individual and not per activity. This means that no partial consent to publication is possible. Each consent is applicable for all activities performed during 2017 and paid in 2017. If no consent is given, ToV are published under the aggregate disclosure.

For international activities with cross-border transactions we will respect the consent decision given per specific activity, even if the consent status for local activities is different.

## 3. Declaration of consent

### 3.1 Question

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

### 3.2 Our approach

All Luxembourg HCPs who receive a ToV from Grünenthal are requested to provide consent to disclose details of the ToV they received from us within a specific time frame (known as “consent per individual”). This is done as part of a written agreement that both parties agree to. This means that they provide consent to publicly disclose all ToVs made within a specific time frame which is specified in the written agreement.

## 4. Duration of publication

### 4.1 Question

***For how long will the information be available on the corporate website?***

### 4.2 Approach

The APL code of deontology stipulates that disclosure information must remain in the public domain for a period of at least 3 years from the time of disclosure. If needed, the data will be updated on specific time frames.

# II. GENERAL QUESTIONS

## 1. Cross-border issues

### 1.1 Questions

***When we provide ToVs to a healthcare professional or organisation based in another European state, how is this reported?***

### 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 subsidiary of the Grünenthal Group based in Belgium commission a consultancy agreement with a doctor based in Italy.

### 1.3 Our approach

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

The Grünenthal Group will publish the information of any country where there is no affiliate.

## 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 Luxembourg receives funding from Grünenthal 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 is published in the denomination of the local currency of the respective country. If the original payment was not made in local currency, we 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 held (related costs that means registration, travel and accommodation costs).

## 3. VAT

### 3.1 Question

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

### 3.2 Background

The EFPIA Disclosure Code permits publication of gross or net figures (i.e. including or excluding VAT).

### 3.3 Our approach

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

## 4. ToV for product groups which do not solely comprise prescription-only medicines, how is this reported?

### 4.1 Question

***What will we do if the ToV relate to a group of products which does not solely comprise prescription-only medecines?***

### 4.2 Background

Under the APL code of deontology, ToV only have to be disclosed when made in connection with prescription-only medicines. In practice, however, such ToV may relate to a group of products made up of a combination of prescription-only and non-prescription medicines and other products.

### 4.3 Our approach

As a Grünenthal affiliate who delivers non-prescription products as well as prescription-only products we will adopt an overall procedure for all our products and publish all ToV in the appropriate category even if a particular ToV is only related to a non-prescription product.

## 5. Reporting period

### 5.1 Question

***If more than one reporting period is applicable in association with a TOV, how is this reported?***

### 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 a ToV is granted in one reporting period, but relates to an event taking place in the next or previous reporting period.

### 5.3 Our approach

We publish ToV in according to the reporting period in which the ToV was actually granted / financially processed to the healthcare professional. All paid amounts related to grants and donations, fees and meeting related costs (registration, travel and accommodation also in connection with a fee) are reported according to the year of the actual payment (even if this differs to the year in which the activity took place).

If for any reason our internal accounting practices should change, we remain committed to ensuring all TOVs subject to publication are disclosed.

## 6. Publication of ToV relating to contractual arrangements lasting several years

### 6.1 Question

***When a ToV is made in relation to a contract stretching over several years, how is this reported?***

### 6.2 Example

This situation may arise, for example, in the event that we engage in a consultancy agreement with a doctor which has a term from 1 July 2017 to 31 December 2018 and which attracts a total consultancy fee of EUR 3,500.

### 6.3 Our approach

In any such case, the respective milestone payments are reported for the year of the actual payment(s).

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

### 7.1 Question

***When we have a sponsoring agreement with several healthcare organisations, how is this reported?***

### 7.2 Our approach

Generally, we publish details ToVs on an individual basis in accordance with the APL Code of deontology. If an individual ToV can be allocated *pro rata* to the known organisations, these shares are published under the name of the respective organisation.

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

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

### 8.1 Question

***In the event of a ToV being granted to a contract research organisation (CRO), how is this reported?***

### 8.2 Background

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

### 8.3 Our approach

Generally, we do not 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.

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

### 9.1 Question

***If ToVs are granted to universities and other educational establishments, how are these reported?***

### 9.2 Our approach

Generally speaking, any ToV we may grant to universities and other educational establishments are not covered by the APL Code of deontology. We will only publish details of such ToV in the event that they indirectly find their way to a healthcare organisation, such as a university hospital, or one or more healthcare professionals. In such cases, we publish the details of each of those ToV under the name of the university or other educational establishment to which they were granted unless the healthcare professionals who deliver the actual service for the University or educational establishment are known and have given consent for individual publication, in this case the ToV will be published under the name of the concerned healthcare professional.

## 10. Indirect payment of ToV to healthcare professionals

### 10.1 Question

***If ToVs are paid to healthcare professionals indirectly via third parties, how are these reported?***

### 10.2 Example

When an agreement is signed with a particular HCP to perform services for Grünenthal but the invoice related to this service is paid to a HCO e.g a hospital where HCP is employed.

### 10.3 Our approach

In the event that we are 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 if the healthcare professional has granted consent for individual publication. If the HCP has not given consent for individual disclosure, we disclose under the name of the HCO who is the first entity in the chain that is subject to the disclosure obligations.

## 11. Transport costs for joint transportation

### 11.1 Question

***When there are transport costs for the transportation of groups of healthcare professionals, how are these reported?***

### 11.2 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.

### 11.3 Our approach

Grünenthal N.V./S.A. is committed to transparently disclose as much information with regards to travel as possible. When exact costs can be assigned to an individual, this will be done so and reported against that individual. In the event that there is a group cost, and a breakdown of costs per individual cannot be determined, the aggregated cost will be divided amongst the group and the proportion of cost assigned to each individual; this will be disclosed accordingly.

## 12. Sponsoring of HCO in the form of catering costs

### 12.1 Question

***When catering costs are covered by Grünenthal to sponsor a HCO for the organisation of a scientific event, will this be reported?***

### 12.2 Background

According to APL code of deontology and the EFPIA HCP/HCO Disclosure code, meals and drinks do not fall within the scope of the transparency obligations and should thus not be disclosed. Local obligations and thresholds regarding meals and drinks should be followed.

### 12.3 Our approach

Costs related to meals and drinks offered to individual healthcare professionals within the framework of company-organised meetings or invitation to congresses for example, will not be published in our report. In some cases we agree to sponsor a HCO for the organisation of a scientific event and instead of a direct sponsoring to the HCO some HCOs prefer to receive an indirect sponsoring where Grünenthal pays the catering costs directly to the restaurant. For transparency reasons, this kind of catering

cost which are related to the sponsoring of HCOs will be included in our report under "Sponsorship agreements with HCOs".

## III. QUESTIONS ON THE DATA FORMS

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

1.1 Question

***When donations are made to hospitals or clinics, how are these reported?***

1.2 **Examples**

It is possible in this case that the donation will be made to a hospital or clinic as an entity 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, we will publish details of the donation against the specific department. If this specific department has no enterprise number of its own we will publish the details against the name of the hospital and mention the department or unit in the column 'Specification HCO'. In the event that the donation is made to the hospital as an entity, we will publish the details against the name of the hospital.

Grants and donations to patient organisations are disclosed separately on the Grünenthal Group website www.grunenthal.com.

### 2. Sponsoring - publication of ToV granted to HCOs

2.1 **Question**

***When TOVs are made in relation to sponsoring agreements, how are these reported?***

2.2 **Background**

When TOVs are made in relation to sponsoring of events, these are reported within the 'Sponsorship agreements with HCOs' section of the report.

2.3 **Our approach**

The related ToV is published in the reporting period when the payment was made, even if the related activity (i.e. sponsored event) took place in another year.

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

3.1 **Question**

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

3.2 **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.

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

4.1 **Question**

***How are the fees we have assumed for healthcare professionals or organisations to attend external continuous professional development events reported?***

4.2 **Our approach**

We 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 is published for each individual healthcare professional.

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

5.1 **Question**

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

### 5.2 Our approach

We include all travel and accommodation costs in the report on an individual basis unless they are related to group transfers and it is not possible to assign an individual ToV, in which case the total costs are averaged and assigned to each recipient. Accommodation costs for groups of healthcare professionals will be averaged across all supported attendees per night, and may not represent the exact cost of a specific room.

## 6. Continuous professional development events – organisation by an events agency

### 6.1 Question

***In the event that a continuous professional development event is organised by an events agency, what TOVs are published?***

### 6.2 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 against the name of the organising responsible body (HCO).

## 7. Continuous professional development events – costs for internal events

### 7.1 Question

***How are costs for internal continuous professional development events published?***

### 7.2 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.

## 8. Service and consultancy fees – definition

### 8.1 Question

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

8.2 **Background**

All fees associated with the provision of a service or other consultancy activities (other than those associated with R&D activities) are disclosed within the 'Fee for service and consultancy' section of the report.

8.3 **Our approach**

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

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

9.1 **Question**

***When expenses are reimbursed in connection with service and consultancy fees, how are these reported?***

9.2 **Background**

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

9.3 **Our approach**

All expense costs associated with a named individual are disclosed, and the average of aggregated costs is disclosed if more specific data is not available.

10. **R&D**

10.1 **Question**

***When TOVs are associated with R&D activities, how are these reported?***

10.2 **Our approach**

In the event that the ToV relate to any R&D activities, we will only publish the total ToV without specifying the name of the recipient.

10.3 **Question**

***Which ToVs are associated with "R&D" activities?***

10.4 **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.

11. **R&D – "non-clinical health and environmental safety tests"**

11.1 **Question**

***When TOVs relate to "non-clinical health and environmental safety tests", how are these reported?***

11.2 **Our approach**

Not applicable for Grünenthal S.A/N.V..

12. **R&D – basic research**

12.1 **Question**

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

12.2 **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 “Donations”