

Grünenthal Pharma Ltd. - Methodological Note

Guidelines for Implementing the EFPIA Disclosure (Transparency) Code for the Reporting Year 2021

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 EFPIA and EFPIA member associations' decision to issue the EFPIA HCP/HCO Disclosure (Transparency) Code. This 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, other relevant decision makers, and healthcare organisations.

In Ireland, the EFPIA HCP/HCO Disclosure Code has been incorporated within the IPHA Code of Practice for the Pharmaceutical Industry (IPHA Code of Practice). The IPHA Code of Practice defines **Healthcare professionals (HCPs)** to include a person of the following classes: (i) Registered medical practitioners, (ii) Registered dentists, (iii) Registered pharmacists, (iv) Registered nurses. **Healthcare organisations (HCOs)** means any healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient associations within the scope of Annex III of the IPHA Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more healthcare professionals provide services. The term '**transfer of value**' means any direct and indirect transfers 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 exclusively for human use. Direct transfers of value are those made directly by a company for the benefit of a recipient. Indirect transfers of value are those made on behalf of a company for the benefit of a recipient, where the identity of such company is known to, or can be identified, by the recipient.

The reporting period in each case will be the previous calendar year and we agree to publish the relevant report by 1st July of the following year on the IPHA disclosure platform (www.transferofvalue.ie).

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 IPHA Code of Practice, 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 IPHA Code of Practice.



GRT IE ToV Disclosure Methodological Note for 2021 reporting year

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 IPHA Code of Practice.

Section1: 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. **(Consent is one of number of lawful basis, there are others like Legitimate Interest)** 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 these(?) 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 consent is revoked after publication of data, we will adjust the published report within 20 days if consent is revoked, and 40 days if notified of inaccuracies as supported by IPHA.

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, potential example is where the person concerned agrees to the publication one element of the fee for service but not another. We will be revising the consent management process next year, and looking towards Legitimate interest.

2.3 Our approach

If only partial consent to publication is given, the ToV for which consent to publication has been given is specified individually in our report, while any other ToV is included within the section detailing aggregate amounts.

For international activities with cross-border transactions, we will report the consents given by the associated affiliate.

3. Declaration of consent

3.1 Question

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

3.2 Our approach

All Irish HCPs who receive a ToV from Grünenthal are requested to provide consent to disclose details of each ToV they receive from us. This is done as part of a written agreement to which both parties agree. HCPs may withhold their consent at the point of request, or they may subsequently revoke their consent where previously granted.

4. Duration of publication

4.1 Question

For how long will the information be available on www.transferofvalue.ie?

4.2 Our approach

The IPHA Code of Practice stipulates that disclosure information must remain in the public domain for at least 3 years from the time of disclosure. We will amend the report accordingly in the event that any healthcare professional should revoke their consent during such period, or otherwise update the data as needed.

Section 2: 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 an Irish based subsidiary of the Grünenthal Group commission 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** in our capacity as an Irish subsidiary of the Grünenthal Group is 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 Euro?

2.2 Example

A doctor based in Ireland receives funding from us to take part in a healthcare convention in the UK, and the attendance fee is paid in GBP.

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 e.g. 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. exclusive of VAT.

4. ToV for product groups which do not solely comprise prescription pharmaceuticals

4.1 Question

If a ToV relates to a group of products which does not solely comprise prescription-only pharmaceuticals, how is this reported?

4.2 Background

Under the IPHA Code of Practice, ToVs must only 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

Not applicable for Grünenthal Pharma Ltd.

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 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 and fees are reported according to the year of the actual payment (even if this differs to the year in which the activity took place).

All meeting related costs (registration, travel and accommodation also in connection with a fee) are published according to the year in which the meeting 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 2015 to 31 December 2018, and which attracts a total consultancy fee of €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 of ToVs on an individual basis in accordance with the IPHA Code of Practice. 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. ToVs 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 provide ToVs to healthcare professionals ("pass-through costs"). In such cases, we publish the individual details of each of these ToVs, indicating the relevant recipient healthcare professional in each case.

9. Recording of ToVs 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 IPHA Code of Practice. We only publish details of such ToVs 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.

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 Our approach

In the event that we become aware that ToVs 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.

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

Grünenthal Pharma Ltd is committed to transparently disclosing as much information with regards travel as possible.

11.3 Our approach

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.

Section 3: 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 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, we will publish details of the donation and against the specific department. 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 our website www.grunenthal.ie. We additionally disclose other corporate donations to charitable organisations and our local community that are neither HCOs nor patient organisations on our website in the interest of transparency.

1.4 Question

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

1.5 Background

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

1.6 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.

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

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

3.2 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.

4. Continuous professional development events – travel and accommodation costs

4.1 Question

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

4.2 Our approach

We include all travel and accommodation costs in the report on a named 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.

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

5.1 Question

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

5.2 Our approach

If an event (convention, conference, symposium etc.) led by a HCO is organised by an events agency and associated ToVs are paid to that agency, we will publish details of such ToV against the name of the organising responsible body (HCO).

6. Continuous professional development events – costs for internal events

6.1 Question

How are costs for internal continuous professional development events published?

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 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.

7.3 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.

8. Service and consultancy fees – reimbursement of expenses

8.1 Question

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

8.2 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.

8.3 **Our approach**

All expense costs associated with a named individual are disclosed, and the average of aggregated costs are disclosed when more specific data is unavailable.

8.4 **Question**

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

8.5 **Our approach**

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

9. **R&D – definition**

9.1 **Question**

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

9.2 **Our approach**

In terms of the category "R&D", we only publish those ToVs investigator fees (without administrative costs related to the management of trials, e.g. by CROs) and meeting related costs (travel and accommodation) 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 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 of the 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.

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

10.1 **Question**

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

10.2 Our approach

In terms of publishing ToVs relating to "non-clinical health and environmental safety tests", we 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 publish the ToV, specifying the name of the recipient.

11. R&D – basic research

11.1 Question

When ToVs relate to basic research, how are these reported?

11.2 Our approach

We 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 publish the corresponding ToV under the category "monetary donations / donations in kind".

12 TOV website _ Rounding off numbers

12.1 Question

Where are the decimal places in 2020 ToV reporting

12.2 Our Approach

The www.transferofvalue.ie system previously rounded numbers to the nearest whole number for display purposes only - it stored the numbers in their original decimal form. For totals which were calculated by the system, the individual decimal numbers were summed, and the result was rounded. Now that decimal places are no longer permitted to be loaded, and to ensure consistency in the calculation for all members, we suggest that members only round numbers before loading rather than rounding when collecting the data.

Rounding each value to a whole number or only rounding the sum of the unrounded values results in different totals.

For example:

Values (€K) to be published: 11.3 / 32.6 / 10.6 / 7.7

- if each value is rounded from the start we obtain: 11 + 33 + 11 + 8 which is a total of 63

- if only the total of the unrounded values is rounded we obtain: $11.3 + 32.6 + 10.6 + 7.7$ which is a total of 62.2 and this becomes rounded to 62.

This results in a difference of one point between the two methods, which could become considerable depending on the amounts involved.