Grünenthal Norway AS - Methodological Note

Guidelines for Implementing the EFPIA Disclosure (Transparency) Code for the Reporting Year 2016

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' 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 Norway, the EFPIA HCP/HCO Disclosure Code has been incorporated within the Ethical Rules for the Pharmaceutical Industry in Norway, as written and provided by The Association of the Pharmaceutical Industry in Norway (LMI). LMI define **Healthcare professionals (HCPs)** in Section 13-7 of the Medicinal Products Regulation or in the Health Personnel Act. All other employees of a pharmaceutical company or employees of a distributor of medicinal products are excluded from the definition of healthcare personnel. **Healthcare organisations (HCOs)** mean any legal person who provides healthcare assistance or patient treatment, such as health authorities, medical offices, etc. The term '**transfer of value**' means any direct or indirect transfer of a benefit with a financial value. The reporting period in each case will be the previous calendar year and we agree to publish the relevant report by 30th June of the following year on Grünenthal Norway AS's website (www.grunenthal.no).

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 LMI's Ethical Rules for the Pharmaceutical Industry in Norway, 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 by EFPIA / LMI.

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 LMI's Ethical Rules for the Pharmaceutical Industry in Norway.

Contents

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 when engaging services from said 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 a reasonable timeline.

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 some consultancy fees but not others.

2.3 Our approach

If only partial consent to publication is given, all TOVs provided to that individual in the stated reporting period are disclosed as an aggregate disclosure.

For international activities with cross-border transactions we 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 Norwegian 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 that both parties agree to. 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 publicly available?

4.2 Our approach

LMI 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.

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 Norwegian-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 a Norwegian 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 NOK?

2.2 Example

A doctor based in Norway receives a consultancy fee for providing services in Germany, and the fee is paid in Euros.

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). When it hasn't been operationally possible to link the exchange rate of the day in which payment was made, the exchange rate in use on 31st December of the reporting period has been used.

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 ToVs paid to individuals after any applicable deductions have been made, and TOVs paid to healthcare organisations as gross amounts, i.e. inclusive 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

According to EFPIA and LMI, 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 Norway AS.

5. ToV for non-prescription pharmaceuticals

5.1 Question

When a ToV relates to a group of products which includes non-prescription medicines, how is this reported?

5.2 Background

Following LMI's Ethical Rules for the Pharmaceutical Industry in Norway, ToVs may only be paid in connection with prescription medicines. In practice, however, such ToVs may relate to a group of products made up of a combination of prescription-only and non-prescription medicines and other products.

5.3 Our approach

In Norway, Grünenthal do not have any non-prescription medicines therefore this is not applicable. However, should this change, we will allocate the full amount of ToV as relating to prescription-only medicines, and will publish it in the appropriate category.

6. Reporting period

6.1 Question

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

6.2 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.

6.3 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.

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

7.1 Question

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

7.2 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 42,500 NOK.

7.3 Our approach

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

8. Sponsoring payments made to more than one organisation

8.1 Question

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

8.2 Our approach

Generally, we publish details of ToVs on an individual basis in accordance with LMI's Ethical Rules for the Pharmaceutical Industry in Norway. 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.

9. ToVs to contract research organisations (CROs)

9.1 Question

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

9.2 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.

9.3 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.

10. Recording of ToVs granted to universities and other educational establishments

10.1 Question

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

10.2 Our approach

Generally speaking, any ToV we may grant to universities and other educational establishments are not covered by EFPIA / LMI. 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.

11. Indirect payment of ToV to healthcare professionals

11.1 Question

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

11.2 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.

12. Transport costs for joint transportation

12.1 Question

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

12.2 Background

Grünenthal Norway AS are committed to transparently disclosing as much information with regards travel as possible

12.3 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.

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 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.no. 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 interests 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**

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

8.5 **Question**

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