

CSL Behring AG

Guidelines for Abiding by the EFPIA Transparency Code as of the 2019 Reporting Year

Preamble

CSL Behring is a global leader in the plasma protein biotherapeutics industry. We research, develop, manufacture and market biotherapies that are used to treat serious and rare conditions. Users of our therapies rely on them for their quality of life and, in many cases, for life itself.

Our commitment to saving lives and improving the quality of life for people with serious and rare conditions is evident in everything we do. Whether we are manufacturing and marketing safe and effective products or researching and developing innovative biotherapies, we are first and foremost focused on fulfilling our patients' needs.

As a responsible pharmaceutical enterprise committed to serving our patients' best interests, we feel obliged to ensure that the nature and scope of our cooperation with healthcare professionals and organisations should be clear and transparent. It is the policy of CSL Behring to ensure that all of its activities comply with all applicable national disclosure requirements and marketing laws.

Most of the CSL Behring European affiliates belong to countries or associations that have incorporated the EFPIA code into the governing transparency code for reporting 2016 data as of 2017. These include Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom and Switzerland.

Transparency 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 and organizations are defined according to the EFPIA Transparency Code or official country specific definitions.

In order to establish transparency as intended in EFPIA Transparency Code as completed December 2013, for validity on January 1st 2014 for reporting as of 2016, we want to document and publish details of any Transfer of Value (ToV) we may provide directly or indirectly to any healthcare professionals or organisations according to the commitments we entered into in the different countries or according to laws as applicable in the country

applicable. 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 and to thereby provide a basic framework for interpreting our disclosed data. 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 and/or consent has not been provided.

These guidelines are structured as follows: The most critical and frequently asked question will be addressed within the appropriate context. 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 respective applicable country transparency code or at earlier intervals if required so by law.

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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 in terms of publishing the information?

1.2. Legal background

Everyone is entitled by law to the 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 require all healthcare professionals and organisations to provide their consent to us for publishing 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.

2. Partial consent

2.1. Question

What will we do if a healthcare professional or organization only agrees to the publication of some of the relevant information, despite our efforts to obtain full consent?

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 publish the expenses paid in connection with attending such an event, but not to the publication of any associated consultancy fee.

2.3. Our approach

If only partial consent to publication is given, the amount of all ToVs to the healthcare professional or organization concerned will be aggregated completely - included in the column indicating total amounts.

3. Declaration of consent

3.1. Question

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

3.2. Our approach

Before disclosure, all healthcare professionals and -organisations will be informed of the transparency policy and requested to provide consent. Only allowed data will be collected according to data privacy law, or is explicitly provided by healthcare professionals or -organisations for disclosure purposes.

4. Duration of publication

4.1. Question

How long do we make the information available on www.cslbehring.ch?

4.2. Our approach

Our report is generally available for a period of 4 years. We will amend the report accordingly in the event that any healthcare professional or –organisations should withdraw their consent during such period. This means that on a regular basis, every year the oldest entry will be removed from the report page and a new entry will be added. For example, if the report covers 2015, 2016, 2017, 2018 – then for 2019 submission, 2015 will be removed from the report page.

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 Switzerland-based subsidiary of the CSL Group conclude a consultancy agreement with a healthcare professional based in another European Country that is required to disclose according to the EFPIA code, country law or association.

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 subsidiary of the CSL Group shall be published by our affiliated company based in that country, where the healthcare professional or organisation is based. We will publish the information ourselves in any country where we do not have an affiliate (e.g. Finland).

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 CHF?

2.2. Example

A healthcare professional based in Switzerland 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 CHF. If the original payment was not made in CHF, we will convert the amount into CHF using the exchange rate of the 01.04.2019.

3. VAT

3.1. Question

Will the figures we publish indicate VAT?

3.2. Legal background

The EFPIA Transparency 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 excluding VAT.

4. Reporting period

4.1. Question

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

4.2. Example

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

4.3. Our approach

We will publish ToV in accordance with our internal accounting regulations in the reporting period in which the ToV was actually granted to the healthcare professional or organisation and recorded in our accounts.

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.

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

5.1. Question

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

5.2. Example

This situation may arise, for example, in the event that we conclude a consultancy agreement with a healthcare professional which has a term from 1 July 2016 to 31 December 2019 and which attracts a total consultancy fee of CHF 3'500.-

5.3. Our approach

In this case we would publish the amount that was actually paid in the relevant reporting period.

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 Transparency Code and/or the applicable Swiss pharmacopoeia 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 a healthcare professional or –organization. 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 unless the work falls under the category of research and development, in which case it will be provided as an aggregated sum.
- 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, unless the work falls under the category of research and development, in which case it will be provided as an aggregated sum.

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 Transparency 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, or if the organisation falls into the healthcare organisation category according to the Swiss Pharma-Cooperation Code. 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 enter into agreements with healthcare professionals and healthcare organisations indirectly, e.g. when there are third parties involved in congress or meeting organization, or 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, if possible. Our contractual arrangements with third parties include provisions that the third party will provide us with all ToV information, subject to applicable transparency codices and that the third party will also be committed to obtain in cooperation with us the required consent declarations of the respective health care professionals and -organisations for the disclosure. Requirements of Law, especially privacy law regulations, will be fulfilled. In cases where consent for disclosure is not given, the third party will provide us with the data in an aggregated manner.

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 Transparency Code to allocate ToV paid in the form of transport costs for a group of healthcare professionals to individual healthcare professionals within that group. For example, only the total amount of the costs for a bus shuttle for a group of healthcare professionals would be published and would not be

broken down according to the particular individuals involved.

10.3. Our approach

We will only publish such transport costs in an aggregated amount, without specifying names of the individual healthcare professionals, unless the transport cost can be broken down to individual healthcare professionals or allocated without disproportional effort.

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

We will disclose the name of the organisational unit that has provided the billing address (if the billing address is different from the recipient address in the contract, then the latter is to be disclosed), unless it has been requested by the contract partner to disclose to hospital or clinic as a whole. Company unique identifier is that of the contractual recipient.

1.4. Question

Which ToV will we publish relating to sponsoring agreements?

1.5. Legal background

In terms of sponsoring agreements, we understand an agreement in which CSL Behring is granted the possibility of performing marketing activities on an educational scientific event (e.g. conventions, conferences, symposia) in consideration of paying an adequate amount of money. Within the scope of sponsoring are agreements in which marketing activities are granted within other projects, e.g. compilation of brochures or other educational activities like compilation of websites, e-learning- tools.

1.6. Our approach

We will disclose sponsoring fees and travel and accommodations as required by the Swiss Pharma-Cooperation Code. As far as we do not have influence on how the financial contribution is distributed, the total sponsorship will be disclosed as provided to healthcare organisation. When there is a contribution to a specifically designated healthcare professional, the corresponding amount and name will be disclosed.

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 event e.g. conventions, conferences, symposia, scientific training events 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 registration 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 registration fees assumed during the reporting period will be published for each individual healthcare professional.

3.3. Financial contribution

The registration fees mentioned above will be published without the 33.3% financial contribution the relevant healthcare professionals have to pay according to the Swiss Pharmacoooperation Code.

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 understand travel and accommodation costs to be any transportation to and from the event and/or transportation required within the event agenda. This includes hotel accommodations, but not meals.

4.3. Financial contribution

The travel and accommodation costs mentioned above will be published without the 33.3% financial contribution the relevant healthcare professionals have to pay according to the Swiss Pharmacoooperation Code.

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 event agency?

5.2. Our approach

If an event (e.g. convention, conference, symposium etc.) is organised by a third party (event agency) and the ToV is paid to that event 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. Our contractual arrangements with third parties (event agency) include provisions that the third party (event agency) will provide us with all ToV information, subject to applicable transparency codices and that the third party (event agency) will also be committed to obtain in cooperation with us the required consent declarations of the respective healthcare professionals and organisations for the disclosure. Requirements of Law, especially privacy law regulations, will be fulfilled. In cases where consent for disclosure is not given, the third party (event agency) will provide us with the data in an aggregated manner.

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 healthcare professional. We will also publish refunds of travel or accommodation expenses to the healthcare professional for attending in our internal continuous professional development events.

6.3. Financial contribution

The registration fees as well as the travel and accommodation costs mentioned above will be published without the 33.3% financial contribution the relevant healthcare professionals must pay according to the Swiss Pharmacoooperation Code.

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. We understand these to be service agreements for speakers, experts, trainers and health care organisations.

7.3. Our approach

Under the category “fee for service and consultancy”, we record the service fees paid for the services provided. Fees paid for travel and accommodation will be recorded under “Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract”.

8. Service and consultancy fees – reimbursement of expenses

8.1. Question

What will we do about the publication of any ToV relating to R&D activities?

8.2. 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.

9. R&D – definition

9.1. Question

Which ToV falls under "R&D"?

9.2. Our approach

In terms of the category "R&D", we will only publish those ToVs relating to "regulatory necessary" studies. These are any studies which are required in order to obtain approval for or reimbursement of 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 Section 19 EFPIA Code. We also include the 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

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.

11. R&D – basic research

11.1. Question

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

11.2. Our approach

In terms of basic research, we make a distinction between whether this relates to a specific product and whether it is intended to extend its scope of use. In such case, we will publish the total value of ToV under the category "R&D".

If there is no connection to a specific product and the research is general in nature, we will generally publish it under the category "service agreements" rather than under "R&D". In the event, however, 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 and grants to HCOs".