

CSL Behring

CSL Behring UK Ltd

Methodological Notes

Guidelines for Abiding by the ABPI Transparency Code

Disclosure Period: Calendar Year 2016

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 to the public. It is the policy of CSL Behring to ensure that all of its activities comply with all applicable state and federal disclosure 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 data. These include Austria, Belgium, Denmark, Finland, France, Greece, Italy, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom and bioCSL GmbH in Germany.

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

In order to establish transparency as intended in EFPIA Transparency Code, 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

Question

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

Legal background

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

Our approach

We require all healthcare professionals to provide their consent to us for publishing itemised details of any ToV they receive from us. This consent is sought through individual contract agreements on an activity by activity basis. Upon receipt of the signed contract, details of whether consent has or has not been granted are documented in a disclosure log. If this consent is denied, we will only publish the total aggregate value of the ToV to the name of the recipient.

2. Partial consent

Question

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

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.

Our approach

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

3. Declaration of consent

Question

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

Our approach

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

4. Duration of data publication

Question

How long do we make the information available for on our platform?

Our approach

The information disclosed will remain on our platform for at least three years from the time of disclosure in line with the ABPI Code.

II. General Questions

1. Cross-border issues

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?

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

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 (eg. Finland). Any pecuniary ToV which is granted by another affiliated company to healthcare professionals or organisations based in the United Kingdom shall be published by the United Kingdom affiliate in line with the ABPI Code.

2. Publication of ToV granted in a foreign currency

Question

What do we do when the ToV is granted in any currency other than British Pound Sterling (GBP)?

Example

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

Our approach

All ToV specified in our report will be denominated in GBP. If the original payment was not made in GBP, we will convert the amount into GBP using the exchange rate applicable at the time the ToV was paid

3. VAT Question

Will the figures we publish indicate VAT?

Legal background

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

Our approach

We will publish the ToV paid excluding VAT.

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

Question

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

Legal background

Under the EFPIA Transparency Code, ToV are only covered in connection with prescription-only medications. In practice, however, such ToV may relate to a group of products made up of a combination of prescription-only and non-prescription pharmaceuticals and other products.

Our approach

We will allocate the full amount of ToV as relating to prescription-only pharmaceuticals and will publish it in the appropriate category.

5. ToV for non-prescription pharmaceuticals

Question

What will we do if the ToV relate to a group of products which includes non-prescription pharmaceuticals?

Legal background

Same as above

Our approach

Same as above

6. Reporting period

Question

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

Example

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

Our approach

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

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

Question

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

Example

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

Our approach

In such case, we would calculate the *pro rata* amount relating to the relevant reporting period and would publish this accordingly. In the example given above, a fee of GBP 500 would be due for the 2015 calendar year reporting period, with a fee of GBP 1,000 accruing for each of the 2016, 2017 and 2018 calendar years.

8. Sponsoring payments made to more than one organisation

Question

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

Our approach

We will generally publish details ToV on an individual basis in accordance with the EFPIA Transparency Code and the ABPI 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.

9. ToV to contract research organisations (CROs) Question

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

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.

Our approach

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

- the CRO is comprised of healthcare professionals or has links to a medical institution (like a university hospital or a publicly-run organisation). In such case, the CRO is considered to be an organisation and details of any ToV granted to it will be published by us individually in accordance with the general regulations.
- the CRO is used to indirectly grant ToV to healthcare professionals ("pass-through costs"). In such case, we will publish the individual details of each of these ToV, indicating the relevant healthcare professional in each case.

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

Question

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

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 organization falls into the HCO category according to a country law or the respective Country Transparency Code that is more specific than the EFPIA 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.

11. Indirect payment of ToV to healthcare professionals

Question

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

Our approach

In the event that we become aware that ToV granted by us to a third party have been passed on to healthcare professionals, or those persons have benefitted from such, we will generally publish the details of each of those ToV under the name of the relevant healthcare professional, if possible. Our contractual arrangements with third parties include provisions that third parties will provide us with all transfer of Value information, subject to applicable transparency codices and that third parties will also be committed to obtain in cooperation with us the required consent declarations of the respective Health Care Professionals for the disclosure and to inform Health Care Organizations about the disclosure in written form.

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.

12. Transport costs for joint transportation

Question

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

Legal background

It is not necessary under the EFPIA Transparency Code or ABPI 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.

III. Questions on the Data Forms

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

Question

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

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.

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) - company unique identifier is that of the contractual recipient.

2. Sponsorships

Question

Which ToV will we publish relating to sponsoring agreements?

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.

Our approach

We will disclose sponsoring fees and travel and accommodations as required by each country law or affiliate.

3. Continuous professional development events – definition

Question

What do we understand by continuous professional development events?

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.

4. Continuous professional development events – attendance fees

Question

What will we do about the publication of the fees we have assumed for healthcare professionals or

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organisations to attend external continuous professional development events?

Our approach

We will generally publish the payment of attendance fees as a ToV to the relevant healthcare professionals in the section devoted to "fees". The total amount of such fees assumed during the reporting period will be published for each individual healthcare professional.

5. Continuous professional development events – travel and accommodation costs

Question

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

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 unless required by national law (eg. France and limited Portugal).

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

Question

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

Our approach

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

7. Continuous professional development events – costs for internal events

Question

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

Our approach

In the event that we charge an attendance 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

Question

Which TOV do we record as service and consultancy fees?

Legal background

Service and consultancy fees are due under corresponding service and consultancy agreements. We understand these to be services agreements for speakers, experts and trainers.

Our approach

Under the category service and consultancy fees, we record the service fees and any travel and accommodation as required.

9. Service and consultancy fees – reimbursement of expenses

Question

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

consultancy fees?

Legal background

In terms of ToV falling under the category "service and consultancy fees", the data record template provides for any expenses reimbursed being published in addition to and separately from the fee itself. These expenses may include travel and accommodation costs. If, for example in the case of the joint transportation of a number of healthcare professionals, these costs are very insignificant and the effort required to record them separately is disproportionate to their value, only the total amount of the costs will be published.

10. R&D activities

Question

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

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.

R&D – definition

Question

Which ToV come under "R&D"?

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 Section 19 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.

R&D – "non-clinical health and environmental safety tests" Question

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

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.

R&D – basic research

Question

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

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 "monetary donations / benefits in kind".