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Seqirus

Guidelines for Abiding by the EFPIA Transparency Code as of the 2018 Reporting Year

Preamble

Seqirus is a new global company created in July 2015 from the combined strength and expertise of bioCSL Inc. and the influenza vaccines business formerly owned by Novartis AG. As the second largest influenza vaccine provider in the world, Seqirus is driven by the promise it shares with parent company, CSL Limited, to provide medicines that help to protect and save lives. Seqirus is a transcontinental partner in pandemic preparedness, and a major contributor to the prevention and control of influenza globally, with extensive research and production expertise.

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 organizations should be clear and transparent to the public. It is the policy of Seqirus to ensure that all of its activities comply with all applicable disclosure and marketing laws around the world.

Most of the Seqirus European affiliates belong to countries or associations that have incorporated the EFPIA code into the governing transparency code for reporting 2018 data as of 2019. These include Italy, Netherlands, Spain, United Kingdom, and 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 organizations. 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 2015, we want to document and publish details of any Transfer of Value (ToV) we may provide directly or indirectly to any healthcare professionals or organizations 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 permission from the healthcare professionals or organizations concerned in terms of publishing the information?

1.2 **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 under the General Data Protection Regulation and UK Data Protection Act for any such consent – it must be freely given, informed, unambiguous and specific. 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 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 only agrees to 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 the publication of the expenses paid in connection with attending such an event, but not to the publication of any associated consultancy fee.

2.3 **Our approach**
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

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 Seqirus transparency policy. Healthcare professionals will be requested to provide consent. However, consent is not required from healthcare organisations according to UK data privacy law. Only data will be collected that is allowed to be collected according to data privacy law, or is explicitly provided by the HCP.

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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 organization 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 organization is based, has their practice, or main office. This sort of situation includes those cases where we, as a 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.

1.3 **Our approach**
Any pecuniary ToV which is granted to healthcare professionals or organizations 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 organization 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 pounds sterling?

2.2 **Example**
A doctor based in Germany 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 pounds sterling. If the original payment was not made in pounds sterling, we will convert the amount into pounds sterling using the exchange rate applicable at the time the ToV was paid

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. We will publish the ToV paid excluding VAT for honoraria and bookings on behalf of Seqirus but the expenses paid directly by the healthcare professional will include the VAT and we will pay to them the full amount.

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

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

4.2 **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.

4.3 **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

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

5.2 **Legal background**
Same AS ABOVE

5.3 **Our approach**
Same AS ABOVE

6. Reporting period

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

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

6.3 **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

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

7.2 **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 EUR 3,500.

7.3 **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 EUR 500 would be due for the 2015 calendar year reporting period, with a fee of EUR 1,000 accruing for each of the 2016, 2017 and 2018 calendar years.

8. Sponsoring payments made to more than one organization

8.1 **Question**
What will we do in cases where we have a sponsoring agreement with several healthcare organizations?

8.2 **Our approach**
We will generally publish details ToV on an individual basis in accordance with the EFPIA Transparency Code and/or the applicable country Transparency Code. If an individual ToV can be allocated *pro rata* to the relevant organizations, these shares will be published under the name of the respective organization.
If such an allocation is not possible, we will assume that each organization receives a equal share and will publish this accordingly.

9. ToV to contract research organizations (CROs)

9.1 **Question**
What will we do in the event of ToV being granted to contract research organizations (CROs)?

9.2 **Background**
Contract / clinical research organizations are research organizations which provide clinical study planning and execution services to companies in the pharmaceutical sector in return for payment.

9.3 **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 comprised of healthcare professionals or has links to a medical institution (like a university hospital or a publicly-run organization). In such case, the CRO is considered to be an organization 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

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

10.2 **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 organization, 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

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

11.2 **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

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

12.2 **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.

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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 organizational 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. 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 – attendance fees

3.1 **Question**
What will we do about the publication of the fees we have assumed for healthcare professionals or organizations to attend external continuous professional development events?

3.2 **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.

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

5. Continuous professional development events – organization 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 organized by an events agency?

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

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 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.

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 services agreements for speakers, experts and trainers.

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

8. Service and consultancy fees – reimbursement of expenses

8.1 **Question**
What will we do about the publication of any expenses reimbursed in connection with service and consultancy fees?

8.2 **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.

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

8.4 **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 come under "R&D?"

9.2 **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.

• Clinical Trials

• Medical & Observational Studies

• Scientific Medical Education

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

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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 "monetary donations / donations in kind".