

Methodology Note

Calendar Year: 2016

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1. Data Privacy – Consent for publication of data

As the Disclosure code is a voluntary self-obligation of the pharmaceutical industry, publication of data is dependent on the consent of healthcare professionals concerned. 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.

TESARO is requesting consent from all HCPs before declaring a Transfer of Value (ToV) to the individual concerned. If such individual consent is not granted, TESARO will only be able to publish the ToV in the aggregated section of the report; we cannot specify the name, address or other personal data of the recipient.

2. Data Privacy – Partial consent for publication of data

TESARO is seeking overall consent of an individual HCP to declare all ToVs made to them as opposed to just selected activities. However, it is possible that they choose to withdraw consent for certain selected activities. If this happens, TESARO will report all ToVs to such healthcare professionals in the aggregated section of the report. We believe that reporting only selected ToV on an individual level decreases the level of transparency by giving a distorted picture.

3. Data Privacy – Declaration of Consent

TESARO is using the following approach to obtain consent from healthcare professionals:

TESARO is requesting consent before the first relevant reporting period with the respective healthcare professional.

The healthcare professional is informed about the purpose of the ABPI Disclosure Code and the required data processing. The healthcare professional can then decide to grant consent for at least one full reporting period or to dissent to the publication of data. Partial consent is not possible.

4. Duration of Publication

Our report will be available for a period of three years. We will amend the report accordingly, if required, for specific reasons, e.g. legal, etc.

5. Cross-border interactions

ToV made by a local affiliate to a healthcare professional or organization with primary practice in a different European country will be reported by the TESARO affiliate which the HCP or HCO is based.

For those countries in which the HCP or HCO has their primary practice but there is no local TESARO affiliate, TESARO will publish the information on a central website.

The same rules apply, if a local affiliate in a non-European country grants a ToV to a healthcare professional or organization with primary practice in a European country. In other words, the ToV will be published on the central database.

6. Publication of ToV granted in a foreign currency

All ToV specified in our report will be denominated in sterling. If the original payment was not made in sterling, we will convert the amount based on the average exchange rate in the month the ToV was made.

7. VAT

The EFPIA Disclose Code allows member companies to publish gross or net figures (i.e. including or excluding VAT).

TESARO will report all ToVs as net amounts, excluding VAT.

8. Reporting Period

We will follow ToV in accordance with the following rules:

In the case of short term activities within a defined timeframe (e.g. congresses or other scientific events), the start date of the activity defines the reporting period. For long term activities, the posting date of the relevant invoice determines the reporting period. Donations are always reported in the reporting period where they are made.

In the event that an invoice for a short term activity is not received in time to include the ToV in a report, the amount will be disclosed in the following report.

In the event that our reporting methodology should change, we will ensure that all relevant ToVs are correctly reported. This means that any changes to our methodology will not result in any failure to publish details of any ToV subject to a publication requirement.

9. Sponsorship Payments made to more than one organisation

We will publish details of ToVs on an individual HCO basis in accordance with the EFPIA Disclosure Code. If an individual ToV can be allocated pro-rate to the relevant organization, then ToVs will be published under the name of the respective organization.

If such an allocation is not possible, we will assume that each organization receives an equal share and will publish this accordingly.

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

In such a case, we will disclose the individual payments based on the data when TESARO receives the respective invoices. Details spend on the contract with the consultant (e.g. what services are agreed for which time period, which amounts are foreseen for these services, etc.)

11. Recording of ToV granted to Universities and other educational establishments

University and other educational establishments or organisations are not in scope of the EFPIA Disclosure Code as per se. We will however publish details of such ToVs in the event that they are indirect ToVs to a healthcare organization, such as a university hospital, or one or more healthcare professionals. In such cases, we will publish the details of each of those ToVs under the name of the university or other educational establishment to which they were granted.

12. Indirect ToV to healthcare professionals and organisations

In the event that we become aware that ToVs granted by us to a third party have been passed on to healthcare professionals or healthcare organisations, we will publish the details of each of those ToVs under the name of the relevant healthcare professional or organisation. Our contractual arrangement with third parties includes the obligation to report the relevant data to us in the necessary level of detail. Our contract partners are also obliged to ensure that such information transfer is in line with applicable data privacy requirements.

13. Donations

In the event that the donation is clearly intended for a specific department or unit within a hospital and this department is a legal entity in its own right, we will publish details of the donation and give the name of the department. In the event that the donation is made to the

hospital as a whole, or if the department is not a legal entity we will publish under the name of the hospital or trust.

14. Sponsorships

A sponsorship under the EFPIA Disclose Code is any agreement, where TESARO grants a ToV in exchange for advertisement opportunities at an event. Under the EFPIA Disclose Code, only events organized by or on behalf of an HCO are in scope of the reporting obligations.

We will publish the entire sponsorship amount agreed in the underlying sponsorship contract unless a breakdown into disclosable versus non-disclosable items is documented.

15. Scientific and educational events – definition

We define any event (e.g. conventions, conferences, symposia, etc.) with a focus on providing medical or scientific information or serving further the medical training of healthcare professionals as scientific and educational events.

16. Scientific and educational events – registration fees

We will 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 will be published for each individual healthcare professional. Such fees can also be reported for a healthcare organisation.

17. Scientific and educational events – travel and accommodation costs

We will disclose any travel and accommodation costs for HCPs and HCOs that are not related to services or Research & Development activities in this category. This includes, for example, costs for flights, trains, taxi and hotel costs.

18. Service and consultancy fees – definition

Service and consultancy fees are due under corresponding service and consultancy agreements. We understand these to be any ToV granted in exchange for any kind of service, which is not covered by another reporting category of the EFPIA Disclosure Code. The Fees for Service and Consultancy section is divided into two separate categories, Fees (e.g. speaker fees, advisory board fees, consultancy fees) and Related Expenses (e.g. flight ticket, train tickets, taxi, hotel nights).

19. Research and Development

All payments to healthcare professionals and healthcare organisations related to research and development will be disclosed as aggregate figures pursuant to Section 3.04 of the EFPIA Disclosure Code.

20. Special Considerations for ABPI – UK Report

The United Kingdom ABPI report was populated according to the ABPI's March 2017 guidance that companies ascertain the percentage of aggregate recipients in each disclosure category by evaluating each category's aggregate number of HCPs against the total number of individuals in the report, as opposed to within each column of spend.