

Methodology Note

Calendar Year: 2018

Contents

1.	Data Privacy – Consent for publication of data	1
2.	Data Privacy – Partial consent for publication of data	1
3.	Data Privacy – Declaration of Consent	1
4.	Duration of Publication	1
5.	Cross-border interactions	2
6.	Publication of ToV granted in a foreign currency	2
7.	VAT	2
8.	Reporting Period	2
9.	Sponsorship Payments made to more than one healthcare organisation	2
10.	Publication of ToV relating to contractual arrangements lasting several years	3
11.	Recording of ToV granted to Universities and other educational establishments	3
12.	Indirect ToV to HCPs and healthcare organisations	3
13.	Donations	3
14.	Sponsorships	3
15.	Scientific and educational events – definition	4
16.	Scientific and educational events – registration fees	4
17.	Scientific and educational events – travel and accommodation costs	4
18.	Service and consultancy fees – definition	4
19.	Research and Development	4
20.	Special Considerations for ABPI – UK Report	5

1. Data Privacy – Consent for publication of data

As there is no law in the UK obligating healthcare professionals (HCPs) to disclose their personal data, publication of personal data is dependent on the consent of the HCP's 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 explicit consent from HCP's before declaring a Transfer of Value (ToV) against their individual names. TESARO started requesting consent in line with ABPI requirements on compliance with the General Data Protection Regulation (GDPR) from 1st of September 2018. Therefore, TESARO will publish ToV for all individuals from the 1st of January 2018 to 31st August 2018 in the aggregated section of the report. Individualized TOV will be reported for all who provided consent from 1st September 2018.

2. Data Privacy – Partial consent for publication of data

TESARO is seeking overall consent of an individual HCP to declare all ToV 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 ToV to such HCP 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 HCPs:

TESARO is requesting consent for each activity carried out with the respective HCP.

The HCP is informed about the purpose of the ABPI Disclosure Code and the required data processing requirements. The HCP can then decide to grant consent for at least one full reporting period (calendar year) or to dissent to the publication of their personal data. Partial consent is not possible.

In the case that no response is given, TESARO, will assume that consent is not given.

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 HCP or healthcare organisation with their primary practice in a different European country will be reported by the TESARO affiliate where the HCP or healthcare organisation is based.

For those countries in which the HCP or healthcare organisation 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 HCP or healthcare organisation with a 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 Disclosure Code allows member companies to publish gross or net figures (i.e. including or excluding VAT).

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

8. Reporting Period

We will report ToV in accordance with the following rules:

In the case of activities within a defined timeframe (e.g. congresses or other scientific events), the date of payment of invoice will act as the ToV date for reporting purposes. Donations are always reported in the reporting period where they are made.

In the event that our reporting methodology should change, we will ensure that all relevant ToV 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 healthcare organisation

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

If such an allocation is not possible, we will assume that each healthcare organisation 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 date when TESARO receives the respective invoices.

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 per se. We will however publish details of such ToV in the event that they are indirect ToV to a healthcare organisation, such as a university hospital, or one or more HCP. In such cases, we will publish the details of each of these ToV under the name of the university or other educational establishment to which they were granted.

12. Indirect ToV to HCPs and healthcare organisations

In the event that we become aware that ToV granted by us to a third party have been passed on to HCPs or healthcare organisations, we will publish the details of each of those ToV under the name of the relevant HCP or healthcare 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 Disclosure Code is any agreement, where TESARO grants a ToV in exchange for advertisement opportunities at an event. Under the EFPIA Disclosure Code, only

events organized by or on behalf of a healthcare organisation 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 HCPs 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 HCP in the section devoted to “registration fees”. The total amount of such fees assumed during the reporting period will be published for each individual HCP. 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 healthcare organisations 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 HCP’s 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 2019 guidance that companies ascertain the percentage of aggregate recipients in each disclosure category by evaluating each category's aggregate number of HCP's against the total number of individuals in the report, as opposed to within each column of spend.

As per requirements for 2018 ToV reporting, there are eight HCP's that have been reported under both individual & aggregate disclosure. All of these were directly attributable to the contract amendments due to GDPR changes mentioned in point 1 above.