

Gilead Patient Organisation Transparency Reporting Methodological Note

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1 Introduction

This methodological note is intended to help readers understand how **Transfers of Value (ToV)** from Gilead Sciences Inc. and its **Affiliates (Gilead)** made to **Patient Organisations** that undertake projects that ultimately provide support for those living with diseases pertaining to Gilead's therapy areas are processed and disclosed. This note covers ToV made to all Patient Organisations in **EFPIA** member countries and highlights any differences in specific countries where they may exist.

A glossary has been included at the end of this methodological note containing an alphabetical list of the main terms used within this note and their definitions. The terms in the glossary are always capitalised and appear in bold on first use within this note to aid lookup.

To enable Gilead to have assurance that all ToV to all **Reportable Recipients** will be reported in the correct format and language(s) for each country, it was decided to automate and standardise data extraction as far as possible and to use a **Reporting Engine** supplied by a **Reporting Engine Provider** to produce the reports. Gilead also uses the Reporting Engine Provider's master data to confirm Reportable Recipients, which supports Gilead's data accuracy efforts.

To help with checking and managing the data locally, Gilead has engaged a **Transparency & Monitoring Specialist (TAMS)** for each Gilead Affiliate who is responsible for ensuring completeness and accuracy of data.

2 Definition of Transfers of Value

A Transfer of Value means a **direct** or **indirect benefit** (whether money or money's worth) given to a Reportable Recipient by Gilead. ToV to Patient Organisations may arise in relation to the following broad types of activity (there may be others):

- a. Advisory Boards Patient Organisations give Gilead independent advice and contribute via their personal experiences where the knowledge cannot be obtained within Gilead. Gilead may pay an honorarium to the Patient Organisation and / or pay travelling expenses to the place where the meeting is being held.
- b. Meetings Gilead may arrange meetings focusing on disease awareness. The knowledge and expertise from Patient Organisations is often needed to help conduct these events. Gilead may pay an honorarium and / or travelling expenses to the consultants contracted via the Patient Organisation to provide a service at these disease awareness events.
- Individual support Gilead may support members of a Patient Organisation to attend a
 conference or congress which might include conference fees and / or travelling expenses paid
 via the Organisation.
- d. **Grants** and **Donations** Gilead may make grants or donations to Patient Organisations in order to support healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.
- e. Note that food and drink is not reportable under the **EFPIA Disclosure Code**.

3 Definition and Management of Cross-Border Spend

Some ToV to Reportable Recipients are made by a Gilead Affiliate, or on behalf of a Gilead Affiliate, that is not the "home country" (country of principal practice) of the Patient Organisation receiving the ToV. For example, Gilead UK might make ToV to a German Patient Organisation, or an events agency working for Gilead's European Head Office might make ToV to several Patient Organisation representatives from different countries. This is called **Cross-Border Spend**.

Any ToV made by, or on behalf of, any Gilead Affiliates to Reportable Recipients within EFPIA countries, including Cross-Border Spend, are captured as described under "How Transfers of Value are captured and recorded by Gilead".

4 Which Recipients of Transfers of Value are reported by Gilead

Gilead has flagged all Reportable Recipients as defined under the EFPIA Disclosure Code within its internal systems to aid extraction of relevant ToV. The Reportable Recipients are defined in the Glossary.

5 How Transfers of Value are captured and recorded by Gilead

5.1. Direct Spend

Gilead makes some ToV directly to Patient Organisations; these transfers are referred to as **Direct Spend.** Direct Spend typically covers items such as fees for services and associated travelling expenses.

Gilead has modified its **Enterprise Resource Planning (ERP)** system to extract all Direct Spend to any Reportable Recipient into a standardised format. These data are uploaded into an internal database where they are checked and stored temporarily before being transferred to the Reporting Engine.

5.2. Indirect Spend

ToV made to Patient Organisations by **Third Party Vendors** on behalf of Gilead are called **Indirect Spend**. Indirect Spend typically covers travel and accommodation at meetings and conferences and may also include honoraria payments.

Gilead uses a template Excel spreadsheet to enable Third Party Vendors to capture ToV to Reportable Recipients. The template Excel spreadsheet provides data in the same standardised format, which are then treated in the same way as for Direct Spend as described above.

5.3. ToV Dates

The date recorded against each ToV determines the ToV reporting period. The ToV date recorded by Gilead is the payment date except for the following instances:

- a. Air / Rail Travel: The ToV date is the date the travel ticket is issued (i.e. the date on which Gilead has committed to the travel);
- b. Travel Transfers: The ToV date is the date the transfer was provided; and
- c. Accommodation: The ToV date is the latest date on which the accommodation was provided (i.e. the last day of the hotel stay).

Some payments were made in 2020 for activities that occurred in 2019, and these are reported as ToV in the 2020 report. Equally, some payments were made, and will be reported, in 2020 that relate to activities that occur in 2021.

Some ToV made in 2020 that related to activities that were planned for 2020, which were subsequently cancelled as a result of the worldwide restrictions imposed on meetings and travel due to the COVID-19 pandemic. Some of the cancellations of these ToV did not reach Gilead's systems on time and before the generation of the disclosure report. Gilead will update its published reports when these cancellations are integrated in its Reporting Engine.

5.4. Treatment of Tax

Where the country implementation of the EFPIA Disclosure Code permits companies to choose whether to report ToV inclusive or exclusive of taxes, Gilead has chosen to report inclusive of taxes.

Three EFPIA reporting countries, Austria, Greece and Italy, have mandated that ToV are reported exclusive of taxes. Gilead has complied with that mandate.

5.5. Currency Management

Each ToV is transferred to the Reporting Engine in its original currency. The Reporting Engine has the capability to convert the ToV into any currency enabled within the system. This permits Gilead to publish the required local report in local currency, albeit some ToV may have been made in a currency other than the local currency.

The Reporting Engine Provider maintains exchange rates within the Reporting Engine using rates obtained from a well-known, reputable provider.

6 How Gilead avoids reporting duplicate transactions

Gilead has put in place several steps to ensure that ToV are reported only once. The key step is that the Gilead Affiliate that makes the ToV is responsible for capturing the ToV.

Where Gilead works with other pharmaceutical companies, each company reports the ToV relating to the activities that they organised. For jointly organised events, the companies agree in advance which ToV will be reported by each company. This mechanism avoids duplicate reporting for joint activities.

TAMS are responsible for reviewing Reportable Recipient ToV in the Reporting Engine and taking reasonable steps to identify and resolve any potential duplicates.

7 How Gilead checks the accuracy of reports

In addition to the steps above to prevent duplicate ToV, TAMS also review Reportable Recipient ToV in the Reporting Engine for accuracy and completeness. Some of the activities they undertake as part of this review may include:

- a. Sample checking ToV back to source documentation, such as signed contracts or supplier invoices; and
- b. Tracing expected ToV from planning documents through to the Reporting Engine;

Such activities as those described above give Gilead reasonable assurance that the ToV it reports are as accurate and complete as possible.

8 Publication of reports

TAMS are responsible for producing the local report required under their local EFPIA Disclosure Code implementation and publishing it appropriately. The local report is published in one of the following ways, as required locally: via the local industry association platform; on the local industry association website; on the local government website; on Gilead's Affiliate website.

Reportable Recipients may notify Gilead of any errors in reporting at any time.

In EFPIA reporting countries where Gilead has no Affiliate, but where ToV have been made to Reportable Recipients, EFPIA reporting is managed centrally by the TAMS at Gilead's European Head Office.

In EFPIA reporting countries where Gilead has no Affiliate and a local Distributor makes ToV to Reportable Recipients, Gilead is responsible for EFPIA reporting.

Gilead's document retention period is 10 years in lieu of any statutory retention period.

Any queries regarding Gilead's EFPIA reporting should be addressed to public_affairs@gilead.com

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9 Glossary

This glossary includes the technical definitions of all terms used within this methodological note, including relevant abbreviations.

Term	Meaning
Cross-Border Spend	Any payment made by one Gilead group company to a payee (Reportable Recipient) who is reportable by another Gilead Affiliate (e.g. a payment made by the UK Affiliate to a German Organisation is reportable by Gilead Germany).
Data Privacy / Data Protection	The laws relating to processing of personal data (information relating to an identifiable person), including General Data Protection Regulation (GDPR) and national legislation implementing the same.
Transparency & Monitoring Specialist (TAMS)	The Transparency & Monitoring Specialist (TAMS) is the individual in each Gilead Affiliate who is responsible for: • generating, maintaining and publishing disclosure reports • co-ordinating communications with Reportable Recipients and taking appropriate action to resolve any identified issues
Direct Spend	Direct spend means all <u>Transfers of Value</u> to a <u>Reportable Recipient</u> made directly by Gilead. In other words, all sums paid by Gilead directly to a <u>Reportable Recipient</u> . This spend is recorded in Gilead's <u>ERP</u> (finance) system. See also <u>Indirect Spend</u> .
Disclosure Code	See <u>EFPIA Disclosure Code</u> .
Donation	Philanthropic provision of funds, assets or services to a registered charity freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.
EFPIA	EFPIA or the 'European Federation of Pharmaceutical Industries and Associations' is the body that represents the pharmaceutical industry in Europe. Further information can be found here .
EFPIA Disclosure Code	EFPIA's code sets out requirements for the disclosure by the pharmaceutical industry of its financial interactions (see <u>Transfers of Value</u>). The Disclosure Code was required to be transposed into the national codes of all EFPIA member associations by 1 January 2014. The full text of the Disclosure Code and other information about transparency reporting can be found <u>here</u> .
EFPIA Report	The local report of <u>ToV</u> to <u>Reportable Recipients</u> as required by the <u>EFPIA Disclosure Code</u> .
Enterprise Resource Planning (ERP)	The system that enables <u>Gilead</u> to generate and manage purchase orders, invoices and other key business documents.
Gilead	Gilead Sciences Inc. and its Affiliates.
Gilead Affiliate	Any Gilead group company in any country, including those outside the EFPIA remit.
Grant	Provision of funds, assets or services to a qualifying independent organisation, freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.
Healthcare Organisation (HCO)	The definition given in the EFPIA Disclosure Code is: "Any legal person: .that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe; or through which one or more HCPs provide services."
Indirect Spend	Indirect spend means all <u>Transfers of Value</u> to a <u>Reportable Recipient</u> which are made by a <u>Third Party Vendor</u> on Gilead's behalf.
Patient Organisation	Patient organisations are not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers. Some Non-for-Profit Organisations (NGOs) that do not identify as 'Patient Organisations' may receive funding from Gilead to support specific projects which

	directly support the needs of patients within the scope of Gilead's therapeutic areas. Gilead considers that this funding qualifies as a reportable ToV and has therefore reported against the NGO under these circumstances. Different countries may be required to follow varying legal definitions as to what qualifies an organisation to be identified as a 'Patient Organisation', or whether it is considered an HCO. Please refer to the individual country methodological note for further clarification.
Reportable Recipient	Means any independent organisation in relation to whom Gilead is required to disclose the <u>Transfers of Value</u> that it makes.
Reportable Spend	All <u>Transfers of Value</u> made by any Gilead Affiliate, or by any third party on behalf of any Gilead Affiliate, to any <u>Reportable Recipient</u> .
Reporting Engine	The database and reporting system that holds ToV data and enables <u>Gilead</u> to produce the <u>EFPIA Reports</u> in the appropriate format and language for each <u>EFPIA</u> reporting country.
Reporting Engine Provider	The software company that owns the Reporting Engine and maintains it for Gilead.
Sponsorship	 Individual Sponsorship – financial support for Reportable Recipients to attend educational events including travel, accommodation and/or registration fees. Event Sponsorship – financial support for Third Party disease awareness educational events.
Third Party Vendors	Any agency (e.g. medical education agency, events agency, Contract Research Organisation) which makes payments to Reportable Recipients on Gilead's behalf.
Transfer of Value (ToV)	A Transfer of Value means a direct or indirect benefit (whether money or money's worth) given to a Reportable Recipient by Gilead. The EFPIA Disclosure Code defines such transfers as follows: "Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the Reportable Recipient that will benefit from the Transfer of Value."