Gilead Transparency Reporting Methodological Note

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1 Introduction

This methodological note is intended to help readers understand how the **Transfers of Value (ToVs)** from Gilead Sciences Inc. and its **Affiliates** (**Gilead**) to **Healthcare Professionals (HCPs), Healthcare Organisations (HCOs)** and Patient Organisations (collectively referred to as Reportable Recipients) within **EFPIA** countries have been collated and reported. This note covers all EFPIA 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. The glossary also contains hyperlinks to other terms defined within the glossary to aid understanding.

Gilead began its EFPIA transparency reporting project in 2013 to supplement existing country transparency reporting mechanisms in Denmark, France, Netherlands, Portugal, and UK. This was to ensure that Gilead would be ready to capture all relevant ToVs to **Reportable Recipients** prospectively throughout 2015 prior to the first EFPIA disclosure in 2016.

To enable Gilead to have assurance that all ToVs 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.

In 2021, Gilead changed the Reporting Engine and its Provider as part of an overhaul and streamlining of its transparency systems globally within Global Transparency Project. The principles and methodology described in this document continue to apply in the new system and where there is a change as a result of this transition this is explicitly stated herewith.

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

2 Definition of Transfers of Value

ToVs may arise from the following broad types of activity (there are others):

a. **Advisory Boards** - HCPs give Gilead independent advice and contribute with their expertise on particular aspects of Gilead's strategy or the use of Gilead's medicines, where the knowledge cannot be obtained within Gilead. Patient Organisations via their representatives also may give Gilead independent advice and contribute via their personal experiences where the knowledge cannot be obtained within Gilead. Gilead may pay an honorarium to each participant and / or pay their travelling expenses to the place where the meeting is being held.
b. **Meetings** - Gilead arranges meetings for HCPs on different topics such as education on a specific therapy area or other scientific events. The knowledge and expertise of HCPs are often needed to help conduct these events. Gilead may arrange meetings focusing on disease awareness. The knowledge and expertise from Patient Organisations are often needed to help

conduct these events. Gilead may pay an honorarium and/or travelling expenses to the consultants and Patient Organisation representatives participating in these events.

c. **Individual support** – Gilead may support one or more HCPs or members of Patient Organisations to attend a scientific conference or congress which might include paying the HCPs' conference fees and / or their travelling expenses.
d. **HCO Sponsorship** - Gilead may Sponsor one or more HCOs who will choose which HCPs to send to a conference. In this case, Gilead does not know which HCPs received the ToVs and will therefore report the ToVs against the relevant HCOs.
e. **Clinical trials** prior to approval - Gilead pays HCOs to participate in clinical trials which are an essential part of ensuring that medicines are effective and have an appropriate safety profile. Gilead may also pay travelling expenses for HCPs involved in clinical trials to travel to meetings with other HCPs involved in the same clinical trials. Clinical trials ToVs are reported within the aggregated figure for research and development activities within each country provided the clinical trials are not Non-Interventional Retrospective. Following the relevant EFPIA guidance, any ToVs for Non-Interventional Retrospective clinical trials are reported at individual level as fees for services and associated travelling expenses.
f. **Market research** - small ToVs might be made to HCPs in return for answering questions about Gilead products and / or a therapeutic area. Gilead only participates in "blind" market research where it does not know any individual patient data. Gilead has therefore not reported any ToVs for market research activities.
g. **Investigator Sponsored Research** – research may be undertaken by individual HCPs and / or HCOs where they would like to investigate a particular aspect of a Gilead medicine. This type of research, where supported by paying a **Grant** to the relevant HCO, is reported as a ToV under the appropriate heading.
h. **Grants** and **Donations** – Gilead may make grants or donations to HCOs or Patient Organisations to enhance patient care or for the purpose of supporting research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.
i. Note that food and drink is not reportable under the **AIFP Code of Practice**.

3 Definition and management of Cross-Border Spend

Some ToVs 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 Reportable Recipient receiving the ToVs. For example, Gilead UK might make ToVs to a German HCP, or an events agency working for Gilead's European Head Office might make ToVs to several HCPs from different countries. This is called **Cross-Border Spend**.

Any ToVs 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 AIFP Code of Practice within its internal systems to aid extraction of relevant ToVs. The Reportable Recipients are defined in the Glossary.

Where an HCP has set up a separate legal entity through which to deliver his services, Gilead discloses the transfer of value under the name of the HCP himself wherever clearly identifiable and where compliant with privacy legislation; otherwise, the transfer of value is disclosed under the name of the legal entity, being treated as an HCO.

Where Gilead has made a transfer of value to a department within an HCO, that transfer of value is disclosed under the name of the HCO, not the department.

In all EFPIA reporting countries, the local reporting template used is in the local language(s) and includes any additional fields required by particular countries such as a specific unique identifier for HCPs and / or HCOs.

Professional Congress Organisers (PCO) are not the Reportable Recipients. Transfers of Values made to PCOs are disclosed under the end recipients (HCOs or HCPs) if the end recipients and values transferred to them are identifiable based on information made available by the PCOs.

5 How Transfers of Value are captured and recorded by Gilead

5.1. Direct Spend

Gilead makes some ToVs directly to Reportable Recipients; these transfers are referred to as **Direct Spend.** Direct Spend typically covers items such as fees for services and associated travelling expenses, plus any non-monetary ToVs made to HCPs via Gilead employee out-of-pocket expenses.

Gilead has modified its **Enterprise Resource Planning (ERP)** system and employee expense reimbursement 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

ToVs made to Reportable Recipients 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 ToVs 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 departure date of the respective trip.;
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 2022 for activities that occurred in 2021, and these are reported as ToVs in the 2022 report. Equally, some payments were made, and will be reported, in 2022 that relate to activities that occurred in 2023.

5.4. Treatment of Tax

Gilead has chosen to report inclusive of taxes.

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 ToVs 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 manages Consent

Gilead has sought **Consent** from Reportable Recipients as required by local **Data Privacy** legislation for individual disclosure of their ToVs in the **AIFP Report**. Such Consent has been obtained either on an engagement-by-engagement basis, or by reporting period, based on Gilead Affiliate business processes.

Gilead does not permit “cherry-picking”: either all ToVs made to a Reportable Recipient in a reporting period are disclosed individually, or they are disclosed in aggregate.

7 How Gilead avoids reporting duplicate transactions

Gilead has put in place several steps to ensure that ToVs are reported only once. The key step is that the Gilead Affiliate which has the seat in the country of the ToV’s recipient is responsible for disclosing the ToV.

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

Transparency & Monitoring Specialists are responsible for reviewing Reportable Recipient ToVs in the Reporting Engine and taking reasonable steps to identify and resolve any potential duplicates.

As a minimum, Reportable Recipients who Consent to individual disclosure are pre-notified of the ToVs Gilead intends to disclose in their name, and therefore have the opportunity to identify any duplications or other errors.

8 How Gilead checks the accuracy of reports

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

a. Identifying inconsistencies in the AIFP Report output, such as travelling expenses associated with services with no fees for services, or travelling expenses related to Individual Support without any associated registration costs;
b. Sample checking ToVs back to source documentation, such as signed contracts or supplier invoices; and
c. Tracing expected ToVs from planning documents through to the Reporting Engine;
d. Before the disclosure publication, reportable recipients are given the opportunity to review the ToVs associated with them, and request amendment if required.

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

9 Publication of reports

Transparency & Monitoring Specialists are responsible for producing the local report required under their local AIFP Code of Practice implementation and publishing it appropriately. The local report together with this Methodological Note is published on Gilead's Czech Republic website.

Reportable Recipients may notify Gilead of any errors in reporting or withdraw their Consent at any time.

Gilead's document retention period is 10 years, unless the national regulation requires a longer time period.

Any queries regarding Gilead's AIFP reporting should be addressed to cz.transparency@gilead.com.

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10 Glossary

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

Term	Meaning
AIFP Code of Practice	The AIFP Code of Practice constitutes the collection of ethical rules agreed by AIFP members for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility. The Code applies to all types of communication and interaction (traditional and digital).
AIFP Report	The local report of ToVs to Reportable Recipients as required by the AIFP Code of Practice.
Association of Innovative Pharmaceutical Industry (AIFP)	is the representative body of the innovative pharmaceutical industry in the Czech Republic and a member of EFPIA.
Consent	Consent refers to the Reportable Recipient agreeing to Gilead's use and disclosure of that Reportable Recipient's personal data for Data Privacy purposes. To be valid, Consent must be given freely and must be informed. For Consent to be 'informed', Gilead must tell the Reportable Recipient in advance of Consent being given: (i) what personal data of that Reportable Recipient Gilead wants to collect; and (ii) how Gilead intends to use that personal data. Consent can be withdrawn by the relevant Reportable Recipient at any time by giving notice to Gilead.
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 HCP 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.
Direct Spend	Direct spend means all Transfers of Value to a Reportable Recipient made directly by Gilead. In other words, all sums paid by Gilead directly to a Reportable Recipient. This spend is recorded in Gilead's **ERP** (finance) system. See also Indirect Spend.
Donation	Philanthropic payment to a registered charity 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.
Enterprise Resource Planning (ERP)	The system that enables Gilead 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	Funding given to independent organisations, such as HCOs, 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)	Any legal person/entity: (i) 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) whose business address, place of incorporation or primary place of operation is in the Czech Republic; or (ii) through which one or more HCPs provide services.
Healthcare Professional (HCP)	Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the purpose of AIFP Code, the definition of HCP includes: (i) any official or state employee, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer medicinal products; and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes: (i) all other employees of a Member Company; and (ii) a wholesaler or distributor of medicinal products.
Indirect Spend	Indirect spend means all Transfers of Value to a Reportable Recipient which are made by a Third Party Vendor on Gilead's behalf.
Investigator Sponsored Research	Research may be undertaken by individual HCPs and / or HCOs where they would like to investigate a particular aspect of a Gilead medicine. Gilead may choose to support this research by paying a Grant to the relevant HCO.
Patient Organisation	Not-for-profit legal person/entity (including the umbrella organisation to which it belongs and including patient organizations as defined by Czech law), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in the Czech Republic
Reportable Recipient	Means any HCPs/HCOs/Patient Organisations in relation to whom Gilead is required to disclose the Transfers of Value that it makes.
Reportable Spend	All Transfers of Value made by any Gilead Affiliate, or by any third party on behalf of any Gilead Affiliate, to any Reportable Recipient.
Reporting Engine	The database and reporting system that holds ToV data and enables Gilead to produce the EFPIA Reports in the appropriate format and language for each EFPIA reporting country.
Reporting Engine Provider	The software company that owns the Reporting Engine and maintains it for Gilead.
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)	Direct or indirect benefit (whether money or money's worth) given to a Reportable Recipient by Gilead.

	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 a third party and where the Member Company knows or can identify the Recipient that will benefit from the Transfer of Value.
Transparency & Monitoring Specialist	The Transparency & Monitoring Specialist 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