Gilead Transparency Reporting Methodological Note

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Gilead Transparency Reporting Methodological Note

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 **Other Relevant Decision Makers** (collectively referred to as **Reportable Recipients**) in the UK have been collated and reported.

To enable Gilead to ensure that all ToVs to all Reportable Recipients are reported in the correct format and language(s) for each country where reporting is required, Gilead automates and standardises data extraction as far as possible, by using a database and reporting system that holds ToV data (**Reporting Engine)** to produce the reports. 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.

1 Definitions

1.1. Recipients

For the UK Gilead discloses the ToVs it makes to the following types of Reportable Recipient.

Healthcare Professionals (HCPs)

In the UK, the term **healthcare professional** includes any member of the medical, dental, pharmacy or nursing profession and any other person who in the course of their professional activities may administer prescribe, purchase or recommend or supply a medicine.

Disclosures for the UK under the heading of **healthcare professional** also include any transfers of value to **other relevant decision makers** (ORDMs), including individuals with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not healthcare professionals. (References to HCPs in this note include ORDMs).

There may be occasions on which an HCP recipient of a transfer of value ceases to practise prior to the disclosure of their ToVs, either following the decision to retire or as a result of their death. If Gilead is contacted by the next-of-kin or the employer regarding the ToVs published in relation to a deceased HCP, these ToVs will be published in aggregate as opposed to at an individual level. ToVs made to retired HCPs whilst they were still practising will be published individually unless there is no legal basis to do so, in which case they will also be published in aggregate (see section 4 for more information).

Healthcare Organisations (HCO)

In the UK, **Healthcare Organisation** means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or ORDMs provide services.

If a Healthcare Organisation consists of only one HCP or ORDM, any ToV is disclosed against the individual (see section 3.2).

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.

Transfers of values made to **professional congress organisers** (**PCO**) are disclosed against the Healthcare Organisation on whose behalf they operate. Where a PCO organises its own, independent event for healthcare professionals, Gilead will disclose any ToV Gilead makes in respect of that event under the name of the PCO within its HCO disclosures.

Patient Organisations are not considered to be HCOs. Disclosures of Gilead's ToVs to Patient Organisations are published on Gilead's website (http://www.gilead.com/en-uk/company/transparency).

In the UK, **Patient Organisation** means an organisation mainly comprised of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers.

Gilead may provide funding to or pay for services from not-for-profit organisations that support the needs of patients, for example through health-related services (such as testing) and/or advocacy. Depending on their activities, these organisations could be seen as falling within the definition of both HCO and Patient Organisation.

In these cases, Gilead will classify an organisation as either an HCO or a Patient Organisation, based on the character and primary purpose of the organisation, and apply this classification to all ToVs to that organisation. This approach makes it easier for users to locate a complete view of all Gilead payments to an organisation, on either Disclosure UK or on Gilead's website.

For example:

- A non-profit organisation whose sole purpose is to provide health-related services (such as drug treatment or other addiction services), is classified as an HCO.
- A non-profit organisation that support the needs of patients through a combination of health-related services (such as testing) and advocacy is classified as a Patient Organisation.

1.2. Kind of ToVs

Donations and Grants

Gilead provides support to HCOs for initiatives to improve healthcare, scientific research or education. This is done through the restricted provision of financial support to an HCO to be used for defined activities. For example, the funding may be used for medical and/or scientific activities aimed at supporting advances in medical education and/or public health and social care policy or community health programs and patient education (e.g., health screenings, disease awareness).

Gilead provides physical items, services or other benefits in kind to HCOs for the purpose of enhancing or maintaining patient care, or for the purpose of supporting research.

Gilead also provides financial support to not-for-profit healthcare-related organisations to be used for charitable or philanthropic purposes (e.g. humanitarian crisis response).

Collaborative Working

In the UK, Collaborative Working is a project between Gilead, the NHS and/or other organisations (including Patient Organisations) that pools skills, experience and/or resources for the joint development and implementation of projects that must either benefit patients or alternatively benefit the NHS and as a minimum maintain patient care and must also share a commitment to successful delivery.

Gilead may make direct financial or benefit-in-kind contributions to a collaborative working project. For information on the calculations used to assess non-monetary contributions, see section 6.3.

The executive summaries of collaborative working agreements can be found on Gilead's UK website - https://www.gilead.com/en-uk/responsibility/gilead-collaborations.

Event Sponsorship

Gilead provides support for educational (scientific, medical or disease awareness) events independently organised by an HCO or a PCO for the benefit of HCPs or ORDMs.

ToVs are made to either the HCO directly or to an event organiser or other third party appointed by the HCO to manage the event. In all cases, ToVs are disclosed against the HCO that ultimately benefits.

Gilead also provides funding to HCO conference organisers in the UK to support the costs of registration fees, travel and accommodation for HCPs attending national conferences organised by that HCO. Gilead has no involvement in the selection of the HCPs, and the ToV is disclosed against the HCO as sponsorship.

This category also includes funds provided to support HCO educational projects and corporate memberships of HCOs.

Event Registration, Travel and Accommodation

As part of support for continuous medical education, Gilead provides individual support to HCPs to cover registration fees, and reasonable travel and accommodation costs for HCPs to attend selected third party scientific and/or medical international conferences. The ToVs are disclosed against the HCP.

Gilead may also directly provide, or reimburse HCPs for, reasonable travel and accommodation costs to support their attendance at Gilead organised events. ToVs are disclosed against the HCP.

Costs for ground transportation (for example, bus or taxi) that are organised for group transportation and not assigned to certain HCPs are reported in aggregate, but where the identity of the HCPs is known, these are split by HCP.

Contracted Service Fees and Expenses

Gilead engages HCOs and HCPs as consultants and advisors where there is a clearly identified legitimate business need. Such contracted services include:

- Speaking at or chairing Gilead organised events
- Providing training
- Providing advice
- Development of educational materials
- Retrospective non-interventional studies

Gilead may also agree to pay for expenses directly related to the provision of contracted services, such as travel, accommodation, visa costs.

ToVs for contracted services from HCPs are disclosed against the HCP where Gilead knows the HCP's identity.

Gilead conducts market research with HCPs through professional market research agencies. A ToV might be given to HCPs in return for answering questions about therapeutic areas relevant to Gilead. This market research is generally double blinded, and Gilead does not know the identities of the HCP participants. In this situation, Gilead does not report the ToVs paid to the HCP participants.

Where Gilead contracts with and pays an HCO for an HCP's services, this ToV is disclosed against the HCO.

Research and Development (R&D)

All ToVs to HCPs or HCOs related to the planning or conduct of non-clinical studies, clinical trials and prospective non-interventional studies involving collection of patient data from HCPs, in each case performed by or on behalf of Gilead, are **Research & Development (R&D) ToVs** and are reported on an aggregate basis.

2. Disclosure's Scope

2.1. Products concerned

Disclosure of ToVs to Reportable Recipients is limited to activities related to prescription-only medicines. Gilead does not make ToVs in relation to over-the-counter medicines, medical devices or any other product categories.

2.2. Company concerned

The report for the UK includes all disclosable ToVs made to Reportable Recipients in the UK by Gilead Sciences Limited and its affiliates, including those in countries outside of the EFPIA remit, in accordance with this methodological note.

2.3. Excluded ToVs

The following ToVs are excluded from disclosures:

a. Ordinary course purchases: routine transactions for medicinal products between Gilead and an HCP or HCO.

b. Inexpensive materials and items for patient support, to be passed on to patients;

c. Inexpensive pens/pencils and notepads provided at Gilead or third-party meetings or events;

d. Informational and educational materials for healthcare professionals and patient education

e. Hospitality and logistical costs for Gilead organised meetings, including meals, drinks, room hire and personnel);

f. Medical samples; and

g. Employee fundraising: donations made as a result of independent employee fundraising activities.

ToVs to Patient Organisations are separately disclosed on Gilead's website.

2.4. ToVs date

The date recorded against each ToV determines the ToV reporting period.

Generally, the ToV date recorded by Gilead is the payment/reimbursement date and values are reported in the calendar year of the payment.

Where Gilead arranges travel or accommodation for an HCP, the ToV date for travel is the departure date and the ToV date for accommodation is the check-out date. Similarly, if Gilead arranges conference registration for an HCP, the ToV date is the first day of the conference.

Occasionally payments may be made, (and will be reported) in one year for activities that occurred in the previous year. Equally, some payments were made, and will be reported, in one year that relate to activities that occur in the following year.

Where the ToVs relate to multi-year contracts, only the ToVs made in the reporting year are included. (See section 3.3).

Where the ToV is a non-monetary benefit in kind, the values are reported in the year the recipient received the benefit.

2.5. Direct ToVs

Gilead makes some ToVs directly to Reportable Recipients, for example fees for services and reimbursement of travel expenses and registration fees. Direct ToVs also arise in the context of grants and donations and collaborative working.

2.6. Indirect ToVs

Indirect ToVs are ToVs made to Reportable Recipients by third parties (e.g. agencies) on behalf of Gilead. Indirect ToVs made to an HCP can include travel and accommodation at meetings and conferences and may also include fee for service payments.

Indirect ToVs also include payments made by Gilead to third parties appointed by an HCO to manage an event or project.

2.7. Non-monetary ToVs

Non-monetary ToVs arise in the context of donations (for example where an item is donated or Gilead provides services) and collaborative working (for example Gilead employee time spent delivering the project).

See section 6.3 for details of how Gilead calculates the value of non-monetary ToVs.

2.8. ToVs in case of partial attendances or cancellation and refund

Gilead discloses effective transfers of value.

In cases where a Reportable Recipient is providing services to Gilead and the services are only partially completed, Gilead will pay and disclose a pro-rated fee.

Where a Reportable Recipient incurs approved expenses and their attendance is cancelled, Gilead will reimburse and disclose these out-of-pocket expenses.

Where a Reportable Recipient does not receive the benefit due to a no show or a cancellation of event, the associated costs are not reported, such as the cost of cancelling a hotel booking or accommodation. In case of partial attendance, only the ToV actually received by the Reportable Recipient are reported.

In cases where a monetary ToV to a Reportable Recipient is subsequently refunded to Gilead, this will not be disclosed unless the refund occurs in a different reporting period to the original transfer of value.

2.9. Cross-border activities

Some ToVs to Reportable Recipients are made by a Gilead affiliate, or on behalf of a Gilead affiliate, that is not in the **home country** (country of principal practice) of the Reportable Recipient. 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 and reported in the home country of the Reportable Recipient.

2.10. R&D

R&D ToVs (as defined above) are reported within the aggregated figure for research and development activities within Gilead's UK disclosure report. This includes ToVs in respect of investigator meetings.

Retrospective non-interventional studies do not fall under the category of R&D activities. The ToVs related to those studies will be reported as a fee for service to relevant Reportable Recipient.

2.11. Voluntary disclosure

In the UK, Gilead discloses in accordance with the ABPI Code. Gilead's disclosures do not go beyond the scope of this Code.

3. Specific Considerations

3.1. Country unique identifier

Gilead uses a unique identifier for HCPs and/or HCOs to facilitate collection of ToVs and ensure disclosure against the correct recipient. The unique identifiers are captured and maintained in Gilead's Customer Relationship Management system which sends this data to the Reporting Engine for inclusion in the disclosure submission.

3.2. Self-incorporated HCP

Where HCPs have set up separate legal entities through which to deliver their services, Gilead discloses the ToV under the names of the HCPs themselves wherever clearly identifiable; otherwise, the ToV is disclosed under the name of the legal entity, being treated as an HCO.

3.3. Multi-year agreements

Gilead reports each individual ToV based on its specific date (see section 2.4), regardless of whether an agreement extends beyond 12 months. This means that, for reporting purposes, a multi-year agreement is treated as a series of separate, individual transactions.

3.4. Country specificities

Working with other pharmaceutical companies

If Gilead works with other pharmaceutical companies, the companies agree in advance and document which ToVs will be reported by each company. This mechanism avoids duplicate reporting for joint activities.

Collaborative Working

Gilead's collaborative working executive summaries are available at https://www.gilead.com/en-uk/responsibility/gilead-collaborations.

3.5. Quality checks

Gilead has engaged a Transparency & Monitoring Specialist for each Gilead affiliate, including the UK & Ireland affiliate. The Transparency & Monitoring Specialist is responsible for reviewing ToVs to Reportable Recipients in their country in the Reporting Engine, to help to ensure completeness and accuracy of published information.

The activities carried out prior to data submission include:

- Remediating issues flagged by the Reporting Engine, including missing mandatory fields, potential duplicates and queries over matching the unique identifier with the correct recipient;
- Identifying inconsistencies in the Reporting Engine output, such as travel expenses associated with services with no fees for services, or travel expenses related to individual support to individuals to attend conferences without any associated registration costs;

- Sample checking ToVs to be disclosed against information from Gilead's event approval system, including for indirect payments;
- Reviewing Reportable Recipient ToVs in the Reporting Engine and taking reasonable steps to identify and resolve any potential duplicates; and
- In-person checks with business teams on specific activities to ensure effective disclosures.

These quality checks give Gilead reasonable assurance that the ToVs it reports are accurate, complete and compliant with the ABPI Code. The information disclosed represents Gilead's good faith and best efforts to comply with these obligations. If a disclosure is later determined to be incomplete or incorrect, Gilead will promptly investigate and, where necessary, update the information to ensure continued accuracy and transparency.

4 Data Protection Legal Basis

Note that a data protection legal basis is required for the disclosure personal data and not information relating to organisations.

4.1 Consent collection

Gilead does not rely on consent as a legal basis for disclosure, Gilead relies on legitimate interests (see section 4.2).

4.2 Legitimate interests

Since 2020 Gilead has relied on legitimate interest as the legal basis for disclosing ToVs to HCPs. ToVs to HCPs are publicly disclosed individually on a named basis unless an explicit objection to Disclosure is received from the HCP which meets the balancing test (see below).

We inform HCPs about the intended disclosure of their personal data and how to raise objections through multiple channels, including provisions in our contracts and in the annual pre-disclosure notifications that we send to HCPs ahead of publication, setting out the specific data we intend to disclose.

When we receive an objection, we ask the individual to provide reasons. We assess on a case by case basis, using a **balancing test,** the legitimate interest in payment disclosure at an individual level against the individual's rights and freedoms, taking into account the individual's specific circumstances, including the potential impact of disclosure on the individual.

If we uphold an objection, we move the relevant ToVs to aggregate disclosure. If we do not uphold an objection, we proceed with disclosure and explain our decision to the individual. We document all objections and respond within defined timeframes.

5 Form of Disclosure

5.1 Date of publication

The due date of publication for United Kingdom of Great Britain & Northern Ireland for 2023 disclosures is 28 June 2024 in line with the ABPI Code.

5.2 Disclosure platform

Disclosure UK – www.disclosureuk.org.uk

5.3 Disclosure language

English.

6 Disclosure Financial Data

6.1 Currency

GBP.

Each ToV is transferred to the Reporting Engine in the payment or transaction currency. The Reporting Engine has the capability to convert this currency into any currency enabled within the system. This permits Gilead to publish the required local report in the local currency.

The Reporting Engine provider maintains exchange rates within the Reporting Engine using rates obtained from a well-known, reputable provider. The currency conversion takes place on the ToV date.

6.2 VAT included or excluded

Gilead reports ToVs inclusive of any applicable VAT or other similar taxes.

6.3 Calculation rules

Gilead generally calculates the disclosure amount for non-monetary ToVs as the cost to Gilead.

For example:

- where Gilead staff time is provided as a non-monetary ToV (e.g. in the context of collaborative working), the value is calculated based on an average annual cost of a full time employee to Gilead
- where an item is donated to an HCO, the value is calculated on the basis of the cost to Gilead to produce or purchase (e.g. cost of printing a book).

7 Additional Information

Any queries regarding Gilead's transparency reporting in the UK should be sent to UKITransparency@gilead.com.