Methodological Note – 2022

Accompanying document for the public disclosure concerning transfers of value to healthcare professionals, other relevant decision makers and healthcare organisations

Takeda UK Ltd

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Notes on methodology 2022

1. General introduction

Collaboration between industry and healthcare professionals benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives. Industry and healthcare professionals collaborate in a range of activities from clinical research, sharing best clinical practice and exchanging information on how new medicines fit in to the patient pathway. Bringing greater transparency to this, already well-regulated, vital relationship is about building and strengthening the basis for collaboration in the future. Society has increasingly high expectations for transparency, none more so than in healthcare. Takeda, as a member of the European Federation of Pharmaceutical Industries and Associations ("EFPIA") and the Association of the British Pharmaceutical Industry (ABPI) want to ensure we meet those expectations going forward.

This methodological note is intended for anyone who wants to better understand the working assumptions used to generate a Takeda UK disclosure report and how the disclosed activities are defined within Takeda. Please note that Shire Pharmaceuticals are now part of Takeda and the disclosure report for 2022 is fully combined.

2. Scope of disclosure

Takeda made several decisions around reportable Transfers of Value under UK Law and the EFPIA and ABPI Codes of Practice.
We have summarized below our interpretation and working assumptions along with a definition of recipients and expenses that are in scope.

2.1. Recipients within the scope of disclosure

We introduced an internal process to guarantee that transfers of value are assigned to the correct HCP, oRDM or HCO, and to ensure that the disclosed information is correct and complete (e.g., name, address, unique official ID (if necessary) country where the principal practice is located).

2.1.1. Healthcare professionals (HCPs):

In the disclosure report, Takeda has taken into account the following definition of HCPs with whom we can have Transfers of Value as per the ABPI Code of Practice Clause 1.9:

> *"The term 'health professional' includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. In relation to the annual disclosure of transfers of value (Clause 28), the term also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional."*

The published addresses considered in the disclosure report are public addresses related to the HCP's primary place of work.

2.1.2. Healthcare Organisations (HCOs):

In the disclosure report, Takeda has taken into account the following definition of HCOs with whom we can have Transfers of Value as per the ABPI Code of Practice Clause 1.8:

> *"The term '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 other relevant decision makers provide services.*

The published addresses considered in the disclosure report are the respective business addresses of the entity.

2.1.3. Other Relevant Decision Makers (oRDM):

The term *'other relevant decision makers'* particularly includes those 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 health professionals.

2.1.4. Companies owned by an HCP

If a healthcare organisation consists of only one healthcare professional or other relevant decision maker, then it would be subject to the requirements in the code regarding individual healthcare professionals. If a healthcare organisation consists of more than one healthcare professional or other relevant decision maker, then it would be subject to the requirements in the code regarding healthcare organisations.

2.1.5. Third Party and Professional Congress Organiser (PCO)

Third parties are entities or individuals that represent our company in the marketplace or interact with other third parties on behalf of our company or relating to our company's product. Among others, these thirds parties can be distributors, travel agents, consultants, contract research organisations.

PCO is a company/individual specialized in the organisation and management of congresses, conferences, seminars, and similar events (all "Events")

2.2. Medical scope

The report refers solely to prescription only medicines and not over-the-counter products.

2.3. Activities definition within the scope of disclosure

Within Takeda, all our interactions with HCPs, oRDMs and HCOs are guided by Takeda internal Policies and Standard Operating Procedures that have been developed in alignment with local country laws and regulations and local industry requirements. Please see below for Takeda Company definitions.

2.3.1. Donations and grants

We provide funds, assets or services 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. All transfers of value related to donations or grants to a HCO are included in the scope of the disclosure. Such transfers of value include:

i. Donations (cash and benefits in kind)
   Benefits in kind include the provision of Whole Blood Kit Testing, a testing service provided by Takeda for testing of rare diseases using whole blood samples; services where the value of the transfer has been calculated based on the salary of the person providing the service and a proportion of the service development costs where applicable.
ii. Grants as follows:
   - Medical training (e.g. support in the education of HCPs):
     - monetary nature (e.g., IISR, defined as unsolicited, independent research, irrespective of whether the investigator or the organisation (academic, private, or state) acts as sponsor, where Takeda provides support in the form of the study medication and/or financing)
     - non-monetary nature (e.g., benefits in kind such as anatomic models)
   - Non-medical educational training (e.g. support for healthcare institutions to improve their infrastructure)

2.3.2. Contribution to events costs

We may provide support or cover the costs of the attendance of an individual HCP to an Event. We consider any transfer of value made directly or indirectly through a third party to a HCO as within the scope of the disclosure. Such transfers of value include for example:

i. Travel expenses *(flights, rail travel, taxi, rental car, tolls, mileage, parking, visas, or other official documents required by an HCP for arranging travel, overseas health insurance, etc.)*
ii. Accommodation expenses
iii. Registration fees *(fees paid to permit HCPs to attend medical congresses/training events organized by a third party)*
iv. A sponsorship agreement with a HCO, or a third party nominated by the HCO for managing an event, such as scientific conferences, congresses, or exhibitions by third parties: *sponsorships by medical associations, national industry Organisations, hospitals, and educational establishments; scientific Organisations; regional, national, international, and global conferences; local hospitals, medical centres*.
v. Examples of activities that may be listed in the disclosure report under "Sponsorship Agreements:" *booth rental, advertising spaces (digital, paper, etc.), satellite symposia at a scientific congress, scientific courses provided by an HCP or HCO, opportunities to present our products (including non-promotional presentations), event sponsorships (e.g., organizational support)*

Contributions provided to events through a third-party company or a PCO – that would therefore be the recipient of the payments – will be considered as indirect payments and will be reported as follows:

I. *all payments to an HCO (either as recipient or as beneficiary) are reported in the relevant category under the name of the HCO*
II. *all payments to third party companies or PCOs where there is no organising HCO, or the event initiator is not a recognised legal entity are reported in the relevant category under the name of the third party company or PCO.*

2.3.3. Cancelation of an event

If an HCP had to cancel the sponsored attendance of a third-party event, this will not be included in our report. This also applies to any cancellation fees.

2.3.4. Service and consultancy fees

Any transfer of value related to service and consultancy fees between our company and an HCP or HCO are included within the scope of the disclosure. Such transfers of value include for example, a meeting or event (promotional or non-promotional) where the HCP, or the HCP working for an HCO, appears as a speaker, trainer, or consultant. These include, among others:

vi. Consultancy Fees *(fees for services such as preparation time, rehearsal time, travel time, and time expended on the activity)*
vii. Related costs *(e.g., travel expenses, accommodation)*

Examples of fees that may be included in the disclosure report under "Service and consultancy fees (HCPs, HCOs): "*speaker fees for workshops, symposia and panel discussions; ad hoc consultancy/advisory agreements; training facility for speaker training programs or for training Takeda employees or external parties; training facility for advisory board meetings; market research participants (except double-blind studies); medical writing; data analysis; development of training materials; market survey (except for double-blind studies); consulting (e.g., protocol advice, market access, reimbursement, leading-edge technology assessment)*

2.3.5. Research and development

Transfers of value related to research and development (R&D) activities are covered by the scope of the disclosure. This includes transfers of value to HCPs or HCOs for planning or conducting:

i. non-clinical studies for submission of data to regulatory authorities (as defined in the OECD Principles of Good Laboratory Practice).
ii. clinical trials (as defined in European Directive 2001/20/EC).
    a. Clinical trials in humans with an unauthorized medicinal product
    b. Clinical trials in humans where an unauthorized medicinal product is used in an unauthorized indication or is otherwise prescribed beyond the scope of the marketing authorization, or where patients are previously assigned to different treatments, or where the protocol proposes diagnostic or monitoring procedures that would not have been performed if the patient had not taken part in the trial.
    c. Other clinical trials in humans that would necessitate marketing authorization from the regulatory authorities if they were to be conducted in accordance with EU Directive 2001/20/EC.
iii. a prospective non-interventional study in which the patient is treated with an approved medicinal product in accordance with the marketing authorization and standard practice, and the other requirements as set out in section 15.01 of the EFPIA HCP Code.
iv. Other activities:
    d. Activities related to the planning of the inclusion criteria, the design or the timing of non-clinical studies, clinical studies and/or prospective non-interventional studies within the framework of the drug development plan.
    e. Activities related to the planning of certain non-clinical studies, clinical studies, or prospective non-interventional studies.
    f. Activities related to conducting certain non-clinical studies, clinical studies, or prospective non-interventional studies.

Examples of activities that may be included in the disclosure report under "R&D value transfers:"

a. clinical trials: regional and/or global,
b. local non-interventional trials.
c. value transfers made indirectly through clinical research Organisations (CROs)

Transfers of value with respect to R&D are reported as a gross sum, except for value transfers associated with retrospective non-interventional studies which must comply with the provisions of Article 15 of the EFPIA HCP Code and are listed under the name of the respective recipient.

2.4. Cross-border value transfer

Takeda is a global organisation and when a part of the company other than the UK organisation makes a transfer of value to a UK registered HCP, oRDM or HCO, it will be disclosed in this report. The cross border activities are disclosed in the country of the HCP recipient's primary practice address.

3. Consent to disclose under data protection law and gross sum

The individual disclosure of transfers of value provided to an HCP/oRDM is covered by local privacy regulation. Takeda has collected the privacy consent for each transfer of value between an HCP/oRDM and Takeda.

These are the decisions made to avoid the "cherry picking" of transactions for individual disclosure:

- If consent is given for all engagements, by an HCP/oRDM, we will disclose transfers of value to the HCP/oRDM under the individual section of the applicable Disclosure report.
- If we do not receive consent for all engagements, from an HCP/oRDM, we will default all transfers of value to the HCP/oRDM, to the aggregate section of the applicable Disclosure report.

These are the decisions made for the revoking of individual consent:

- If an HCP/oRDM revokes consent prior to publication of the data, Takeda will update the data and include the transfers of value to the HCP/oRDM, in the aggregate section of the applicable Disclosure report.
- If an HCP/oRDM revokes consent after publication of the data, Takeda will update the information retrospectively or prospectively based on local requirements at the first reasonable time.

While respecting the local privacy legislation, Takeda has made the best efforts to obtain the privacy consents necessary to disclosure of transfers of value at the individual level. Takeda retains evidence of the request/obtainment/denial of privacy consent.

Takeda UK Ltd moved from using consent as the legal basis for making disclosures in relation to TOV to using the legal basis, legitimate interests on 1st January 2022. Therefore, the majority of 2022 data has been collected under the legal basis, legitimate interests and consent is no longer required.

4. Assumptions

4.1. Date of value transfer

For monetary payments, the following assumptions are made.

After the service is provided and the contract is concluded, the payment is made and depending of the consent this amount will be disclosed in the individual or in the aggregate section of the report.

The provision of the commissioned service is monitored so that payments can be made in accordance with the terms of the contract. Takeda use the date on which the payment is made as acknowledgement of the transfer of value.
By date of payment we mean the date on which the payment is released in our internal system. This is subject to the provision of the service and compliance with the EFPIA Code and the internal approval mechanisms of Takeda Pharma AG and Takeda Pharmaceuticals International AG.

We thereby apply the following rule:

If the payment date was between January 1 and December 31 2022, the transfer is included in our 2022 disclosure report.

If payment for an activity at the end of 2021 was made at the beginning of 2022, Takeda will consider this transfer, including associated expenses, if relevant, in 2022 disclosure report.

For In Kind TOVs, the date of payment will be considered to be the most appropriate for when the recipient benefited from the TOV and Takeda is aware of all associated confirmed costs.

4.2. Currency

Takeda UK has used GBP for the disclosure report as this is the official local currency at the time of disclosure. If value is transferred in a currency other than the official local currency, the amount will be converted using the monthly updated exchange rates of the Takeda Company Treasury. Value is transferred in a foreign currency, for example, if travel expenses are incurred by an HCP abroad, where the services have been rendered, and we reimburse these expenses.

4.3. Taxes

In general, Takeda excludes Tax and VAT for Monetary payments/transfers of value and includes Tax and VAT for In Kind transfers of value (except Whole Blood Kit donations).

4.3.1. Sales tax

Expenses such as for travel and accommodation are subject to sales tax. The documented and disclosed figures generally include sales tax.

5. Conflict management

Takeda has introduced an internal conflict management process with which to handle, for example, any general questions and inconsistencies relating to the published data and/or requests for addition or removal of the consent under data protection law of an HCP/oRDM/HCO with a view to disclosure of data.

If you have any comments or questions concerning the processing of your data by Takeda, these methodological notes, the content of the disclosure, or the privacy policy of Takeda UK Ltd please get in touch with the Takeda Transparency team at transparencyUKIE@takeda.com