Methodological Note
(2017 Data)

Accompanying document for the public disclosure of Transfers of Value to Healthcare Professionals, Other Relevant Decision Makers and HealthCare Organisations

Takeda UK

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Methodological Note

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.

2. Scope of the Disclosure

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

2.1. Recipient scope

2.1.1. Healthcare Professionals (HCP): Definition and scope

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 1.4:

> *"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."*

The addresses of the HCPs that are taken into account in the disclosure report are public addresses related to the HCPs' primary place of work.

2.1.2. Healthcare Organisations (HCO): Definition and scope

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 1.9:

> *"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 addresses of the HCOs that are taken into account are the public addresses of the HCOs.

2.1.3. Other Relevant Decision Makers (oRDM): Definition and scope

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. Company owned by an HCP

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

Takeda has put in place an internal process in order to ensure that transfers of value are allocated to the appropriate HCP/oRDM or HCO, and to ensure that the disclosed information is accurate and complete (e.g. name, address, unique, official ID whenever required and primary country of practice).

2.2. Medicinal scope

The report refers solely to prescription only medicine and not over the counter products

2.3. Activities scope

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 to HCO

All transfers of value regarding a donation or a grant between Takeda and an HCO are included in the scope of the disclosure. The transfers of value could be for instance:

i. Donations (monetary and non-monetary)
ii. Charitable contributions (if the organisation is classified as an HCO in the UK)
iii. Grants, as follows:
    - Medical educational grants (e.g. support of the education of HCPs): Monetary and non-monetary (i.e. in-kind; e.g. anatomical models)
    - Non-Medical educational grants (e.g. support for healthcare institutions in improving infrastructure)

2.3.2. Medical and Educational Goods and Services (MEGS)

Medical and educational goods and services are defined as those which enhance patient care, or benefit the NHS and maintain patient care. Takeda has provided MEGS to a number of HCOs.
The value of services which Takeda has transferred to HCOs as MEGS is considered an indirect transfer of value. 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.

2.3.3. Contribution to costs of event

All the transfers of value regarding a contribution to costs of an event between Takeda and an HCP/oRDM (directly, or indirectly via a third party) or an HCO are included in the scope of the disclosure. These transfers of value could be for instance:

i. A travel fee *(e.g. flight, train, taxi, car hire, tolls, mileage reimbursement, parking, visa or other official documents necessary for an HCP/oRDM to secure travel arrangements, travel health insurance, etc.)*
ii. An accommodation fee
iii. A registration fee *(Fees paid for an HCP/oRDM or an HCO, to allow HCPs/oRDMs to attend medical/educational events organised by a third party and not organized by Takeda.)*
iv. A sponsorship agreement with an HCO or a third party appointed by an HCO to manage an event, for instance Third Party Scientific Conferences, Congresses or Exhibits: *Sponsorships via Medical Societies; National Industry Organizations; Hospitals and Teaching Institutions; Scientific Organizations; Regional, National, International and Global Conferences; Local Hospitals; Medical Centres.*

2.3.4. Fees for Services and Consultancy

All the transfers of value regarding a fee for services and consultancy between Takeda and an HCP, oRDM or an HCO are included in the scope of the disclosure. These ToV concerns, for instance a meeting or event (promotional or non-promotional) where the HCP/oRDM or the HCP/oRDM working for an HCO is a speaker, a trainer, an advisor, etc., could be:

i. Fees *(e.g. fee for services such as preparation time, rehearsal time, reasonable travel time and time required for the activity, etc.)*
ii. Related expenses to consultancy *(e.g. travel cost accommodation fees, etc.)*

Note that any expenses incurred for an event which is later cancelled have been disclosed.

Examples of fees that could be covered under "*Fee for Services & Consultancy (HCPs/oRDMs and HCOs)*" in the Takeda disclosure report: s*peaker fees for speaker programmes and roundtables; ad hoc consulting/advising arrangements; faculty for speaker training programmes or training of Takeda employees or external parties; faculty for advisory board meetings; study participant for market research (only when the identity of the participant is known); medical writing; data analysis; development of educational materials; consultancy (e.g. advice relating to; clinical protocol, market access, reimbursement, health technology assessment, etc.)*

2.3.5. Research & Development

Transfers of value related to a Research and Development (R&D) activity are included in the scope of the disclosure. These transfers of value include transfers of value to HCPs or HCOs related to the planning or conduct of:

i. Non-clinical studies intended for submission to regulatory authorities (as defined in OECD Principles on Good Laboratory Practice)
ii. Clinical trials (as defined in the European Directive 2001/20/EC)
    a. Any clinical trial in humans using an unapproved medicinal product;
    b. Any clinical trial in humans using an approved medicinal product where it will be used for an unapproved indication or otherwise it will be prescribed outside the terms of its marketing authorisation, or where patients are prospectively assigned to different treatments, or where the protocol requires diagnostic or monitoring procedures which would not have been performed if the patient was not in the trial;
    c. Any other clinical trial in humans for which clinical trial approval from the regulatory authorities would be needed if the trial were to be conducted in the EU in line with EC Directive 2001/20.
iii. A prospective observational study where the patient is prescribed and treated with an approved medicinal product in accordance with the marketing authorisation and current practice and with the other requirements set out in section 15.01 of the EFPIA HCP Code.
iv. Other type of activity:
    d. Activities associated with planning the inclusion, design or timing of non-clinical studies, clinical trials and/or prospective observational studies within the context of a development plan for a medicine
    e. Activities associated with planning of particular non-clinical studies, clinical trials or prospective observational studies.
    f. Activities associated with conduct of particular non-clinical studies, clinical trials or prospective observational studies.

Examples of activities that could be covered under "*R&D transfers of value*" in the Takeda disclosure report: *Clinical trials: regional and/or global, local non-interventional studies.*

The transfers of value realized indirectly via a Clinical Research Organisation (CRO) are also included in the R&D section of the disclosure report.

Transfers of value related to R&D are reported as an aggregate total figure, with the exception of transfers of value related to retrospective non-interventional studies, which shall comply with the provisions of Article 15 of the EFPIA HCP Code, which are disclosed under the name of the individual recipient.

2.4. Transfers of value in Cross border interactions

Takeda is a global organisation and when a UK registered HCP/oRDM is engaged or sponsored by any part of the company other than the UK organisation, the associated cross border ToV will be disclosed in this report. The cross border activities are disclosed in the country of the HCP recipient's primary practice address.

3. Privacy Consent to Disclosure and Aggregate Amount

The individual disclosure of the ToV provided to an HCP/oRDM is covered by the local privacy regulation. Takeda has collected the privacy consent for each transfer of value between an HCP/oRDM and Takeda. When Takeda engages with an HCP/oRDM, a Consultancy Agreement is signed by both parties; the agreement commences on the day of signing and ends on 31st March of that year. At the same time the HCP/oRDM is asked to sign and return a consent form which requires the HCP/oRDM to provide an answer as follows: *"I consent / I do not consent to the company making a public disclosure of the fees paid to me on an individual basis"*.

If the HCP/oRDM gives their consent for each ToV, then all the related ToV are disclosed on an individual basis. If the HCP/oRDM does not give consent for at least one ToV, then all the ToV related to this individual are disclosed on an aggregate basis. For instance, if an HCP/ORDM provides a service at two meetings and gives consent for both, but has another contract with Takeda where he/she does not give his/her consent, then all the related expenses for all of these three activities are disclosed in the aggregate section of the report. An HCP/oRDM may withdraw their consent at any time, and if this happens, Takeda will record the consent withdrawal in their tracking system and disclose all ToV relating to this HCP/oRDM in the aggregate section.

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.

4. Working Assumptions

4.1. Date of Transfers of Value

The Takeda disclosure report concerns all transfers of value completed during the year 2017 (from January 1st to December 31st). The date taken into account for the transfers of value is the date of payment. The date of payment is the date that the payment was released in Takeda's internal system, conditioned by the execution of the service and Takeda's internal approval mechanisms.

4.2. Currency

Takeda UK has used GBP for the disclosure report. In the case of a ToV being made in another currency, the amount has been converted using Takeda Company Treasury exchange rates that are updated

monthly. An example of a ToV being made in a foreign currency might be where the HCP/oRDM incurred travel costs in another country where he/she has delivered the service which Takeda reimbursed.

4.3. Taxes

Takeda has ensured that each HCP/oRDM signs to confirm that all relevant taxes concerning the ToV are paid by the individual, by including the following statement in the Consultancy Agreement:
"The Consultant undertakes to the Company that he will duly pay the tax and national insurance contributions which are due from him whether in the United Kingdom or elsewhere in relation to the payments to be made to him by the Company pursuant to this agreement and further agrees to indemnify the Company in respect of all and any income tax and national insurance contributions which may be found due from the Company on any payments made to him under this agreement together with any interest, penalties or gross-up thereon?".

4.3.1. Value-Added Tax (VAT)

Each ToV disclosed includes any related VAT.

5. Dispute Resolution Management

Takeda has implemented an internal process for Dispute Resolution Management for the tracking and resolution of general questions and disagreements with the data that has been reported, and/or requests to add or remove HCP/oRDM/HCO privacy consent to disclose data.