



Methodological Note (2020 Data)

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

Takeda Russia

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Methodological Note

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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 Association of International Pharmaceutical Manufacturers (“AIPM”) in Russia 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 disclosure report and how the disclosed activities are defined within Takeda. Please note that although Shire Pharmaceuticals are now part of Takeda, disclosure reports will continue to be generated and published separately until the company has become one legal entity, which for Russia occurred in August 2020.

2. Scope of the Disclosure

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

2.1. Transfers of Value scope

As per the AIPM Code of Practice Clause 1.2 (for the purposes of chapter VII of this Code):

Transfers of Value – direct and indirect transfers of value, whether in cash, in kind or otherwise, made for the purposes allowed by the applicable legislation and by this Code in connection with the development and sale of prescription-only pharmaceutical products exclusively for human use. Direct transfers of value are those made directly by a pharmaceutical company for the benefit of a recipient. Indirect transfers of value are those made on behalf of a pharmaceutical company for the benefit of a recipient, or transfers of value made through an intermediate and where the pharmaceutical company knows or can identify the healthcare professional/healthcare organization that will benefit from the transfer of value.

2.2. Recipient scope

2.2.1. 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 AIPM Code of Practice Clause 1.2:

The term ‘health professional’ includes “doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists the professional activity of which is concerned with pharmaceutical products and who in the process of their professional activity have the right to prescribe, recommend, purchase, supply, or administer pharmaceutical products.”

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.

2.2.2. 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 AIPM Code of Practice Clause 1.2 (for the purposes of chapter VII of this Code):

The term 'healthcare organisation' means "any legal entity (i) that is a healthcare, medical, pharmaceutical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution (except for patient organizations) whose business address, place of incorporation or primary place of operation is in Russia or (ii) which provides services through one or more healthcare professionals."

The addresses of the HCOs that are taken into account are the public addresses of the HCOs.

2.3. Activities scope

Within Takeda, all our interactions with HCPs 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 and grants. Donations and grants to healthcare organizations that support healthcare, including donations and grants (monetary and non-monetary) to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare.

2.3.2. Contribution to costs of event

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

These transfers of value could be for instance:

- i. A travel and accommodation fees (e.g. flight, train, taxi, tolls, visa or other official documents necessary for an HCP to secure travel arrangements, travel health insurance, etc.)
- ii. A registration fee (Fees paid for an HCP or an HCO, to allow HCPs to attend medical/educational events organised by a third party and not organized by Takeda.)
- iii. A sponsorship agreements with HCO or with third parties appointed by a HCO to manage an event

2.3.3. Fees for Services and Consultancy

All the transfers of value regarding a fee for services and consultancy between Takeda and an HCP or an HCO are included in the scope of the disclosure.

Transfers of value resulting from or related to contracts between pharmaceutical companies and healthcare professionals under which such healthcare professionals provide any lawful type of services to a pharmaceutical company, 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 related expenses agreed in the fee for service or consultancy are disclosed combined in the report, including travel, accommodation and registration fees.

2.3.4. 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. Pre-clinical studies;
- ii. Clinical trials;
- iii. Post-registration observation (non-interventional) studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study, including without limitation transfers of value to healthcare organizations under clinical trial agreement, including laboratory and instrumental investigations; fees for the providing of scientific and/or pedagogic services by healthcare professional being a medical professional and services in the course of performance of clinical studies.

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

Research and development ToV in each reporting period shall be disclosed by each pharmaceutical company on an aggregate basis.

3. Privacy Consent to Disclosure and Aggregate Amount

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

If the HCP gives their consent for each ToV, then all the related ToV are disclosed on an individual basis. If the HCP 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 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 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 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 2020 (from January 1st to December 31st) and transfers of value previous periods used the payment date of contract for related expenses agreed in the fee for service or consultancy relevant to the past contracts, if such expenses have not been disclosed earlier. 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. For TOVs for activities within the reporting period and applied the event date for In Kind TOVs in 2020 year.

4.2. Currency

Takeda Russia has used RUB for the disclosure report. In the case of a ToV being made in another currency, it will be converted into RUB based on the date at which the TOV occurred and corresponding daily exchange rate.

4.3. Value-Added Tax (VAT)

For honorarium associated with services and consultancy, Takeda Russia will report the full invoice amount including withholding (personal income) tax. For In Kind costs related to Events (such as registration fees, travel and accommodation), Takeda will report the full invoice amount including 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 and HCO privacy consent to disclose data.

6. Company Acquisition Shire

In January 2019, Takeda acquired Shire. Starting August 2020, full Legal Entity Optimisation was completed in Russia. Takeda and Shire will, therefore disclose their 2020 ToVs data separately for the time period 1st of January – 6th of August 2020, and as one Takeda entity, August 2020 and forward.