



# Methodological Notes – 2021

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## Accompanying document for the public disclosure concerning transfers of value to healthcare professionals and healthcare Organisations and Patient Organisations

**Takeda Pharma AG, Takeda Pharmaceuticals International AG**

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# Notes on methodology 2021

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## 1. General introduction

Collaboration between the industry and patient Organisations is beneficial to patients. This relationship has delivered numerous innovative medicines and changed the way many diseases affect our lives. Greater transparency in this important, already well-regulated relationship, should help to create a stable foundation for future collaboration. Society has ever-increasing expectations regarding transparency, especially in healthcare sector. As a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), we aim to ensure that we meet these expectations in the future.

This methodological note is intended for all those who wish to better understand the assumptions behind the creation of the patient organization disclosure report and how the disclosed activities are defined.

## 2. Scope of disclosure

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 or HCO or PO, 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, we considered the following definition of HCPs with whom we can have Transfers of Value as per Scienceindustries Pharma Cooperation Code:

*“Physicians, dentists and pharmacists who are working in a practice or hospital together with pharmacists active in retail businesses and persons who are authorized by the Swiss law on therapeutic products to prescribe, deliver, and/or administer prescription-only medicinal products for humans. This definition also includes official representatives and persons with a public-law employment contract or mandate if they perform or are authorized to perform such activities.”*

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, we considered the following definition of HCOs with whom we can have Transfers of Value as per Scienceindustries Pharma Cooperation Code:

“Legal entities under private and public law as well as companies, sole proprietorships or other entities that are not specifically regulated in legal terms who employ healthcare professionals. Under this Code, these in particular include institutions, organisations, associations or other groups of healthcare professionals who provide healthcare services or consultancy or other services in healthcare (e.g. hospitals, clinics, foundations, universities or other educational establishments, scientific societies or professional associations, community practices or networks, but not patient organisations)”

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

### **2.1.3 Patient Organisations (PO's):**

In the disclosure report, we considered the following definition of POs with whom we can have Transfers of Value as per Scienceindustries Pharma Cooperation Code:

“Not-for-profit organisations (including the organisations to which they are affiliated) based or active in Switzerland, which consist primarily of patients or their carers and which represent or support the needs of patients or their carers. This definition also includes persons who represent and/or formulate the collective concerns and interests of a patient organisation about a specific topic or a specific pathology.”

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

### **2.1.4 Companies owned by an HCP:**

If a healthcare organization consists of only one healthcare professional or other relevant decision maker, then it would be subject to the requirements in the code regarding the disclosure on the individual healthcare professional name.

### **2.1.5. Third Party and 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 covers only prescription medicines and not over-the-counter products.

## **2.3. Activities definition within the scope of disclosure**

The definitions of activities can differ from one company to the next. All our interactions with healthcare professionals are governed by internal policies and standard operating procedures which have been created in accordance with the industry codes and guidelines, local country-specific laws and principles, and local industry requirements. Below you will find our corporate definitions which should help you with the readability of the disclosure report.

### **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 or a PO are included within the scope of the disclosure. Such transfers of value include:

- i. Donations (cash and benefits in kind)
- ii. Charitable donations (if the organization is classified in the country as an HCO or PO)
- iii. Grants as follows:
  - Medical training (e.g. support in the training of HCPs):
    - monetary nature (e.g., IISR, defined as unsolicited, independent research, irrespective of whether the investigator or the organization (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 or PO representative to an Event. We consider any transfer of value made directly or indirectly through a third party to a HCO or PO as 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 and not organized by Takeda*)
- iv. A sponsorship agreement with a HCO, PO or a third party nominated by the HCO or PO 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, HCO, or PO 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 PCOs – 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 or PO (either as recipient or as beneficiary) are reported in the relevant category under the name of the HCO or PO*
- II. *in the name of benefitting HCO or PO (through include the name of Recipient PCO), if not included in direct payments to the HCO's or PO's;*
- III. *or in the name of Recipient PCO (to the benefit of include the name of benefitting HCO)*

### 2.3.3. Service and consultancy fees

Any transfer of value related to service and consultancy fees between our company and an HCP, HCO or PO 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, POs):" *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)*

#### **2.3.4. 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. Activities out of scope**

Transfers of value that:

- i. Price discounts or rebates granted on purchases of medicinal products
- ii. Cooperation projects relating to the assumption of logistics expenses
- iii. samples of medicinal products to HCPs
- iv. objects intended for HCPs, information and training materials of moderate value which are intended exclusively for the medical or pharmaceutical activity, or used for advanced, or further medical, or pharmaceutical training and which in both cases are also of benefit to patients.
- v. payment for meals (including beverages) on a reasonable and modest scale, subject to a maximum of CHF 100,00 per HCP per meal

## **2.5. Cross-border value transfer**

The EFPIA definition of cross-border payments as being a transfer of value to a HCO, HCPs or Patient Organisation that is registered outside the country where



the Takeda affiliate, who has provided the funding is based, unless local law specifies otherwise.

For example, if an HCP is engaged as a consultant by a foreign legal entity of Takeda this will generally be disclosed – consent for disclosure is needed, where applicable - the payment on the country report where the HCP's principal practice address is registered.

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

The individual disclosure of the payments provided to recipient is covered and governed by local privacy regulations.

The disclosure consent is part of each contract - based on the respective recipient decision regarding the consent of disclosure– we publish the payments as an individual or aggregate level.

The recipient should provide his/her consent to allow the publication of the received Transfer of Value (TOV) at an individual level. If, however, the recipient does not give his/her consent for at least for one contract during a business year, all payments related and made to this recipient will be disclosed as a total amount on the aggregate section of the report.

If, for instance, a recipient is contracted for five individual activities throughout the year and gives his consent to disclosure for the first four of them and refuses to provide his consent for the last one, then all the related payments will be disclosed in the aggregate section of the report.

A recipient can revoke his/its consent for a given contract. If such revocation is made before the official disclosure, then all payments for this recipient will be disclosed in the aggregate section of the report in an anonymized form.

While respecting the local privacy legislation, we made the best efforts to obtain the privacy consents necessary for the disclosure of the payments at the individual level and retains documented evidence regarding any request/receipt/denial of privacy consent.

## 4. Assumptions

### 4.1. Date of value transfer

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. In our country, we 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, the transfer is included in our 2021 disclosure report.

If payment for an activity at the end of 2020 was made at the beginning of 2021, Takeda will consider this transfer in 2021 disclosure report.

Payments made at the end of 2021 for an activity completed in early 2021 will be regarded as value transfers in 2021 for disclosure in June 2022.

### 4.2. Currency

We have decided that Swiss Francs (CHF) shall be the currency used in 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**

Any amounts paid are subject to tax. The sums stated in our report are net amounts, except for expenses such as for travel and accommodation, which are subject to sales tax - the documented and disclosed figures for such expenses include any 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/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 please get in touch with the Takeda Transparency team at [info@takeda.ch](mailto:info@takeda.ch).