



Methodological Note - 2025

Annex to the public Transparency document on
Transfers of Value to healthcare professionals
and healthcare organisations and patient organisations

Takeda Farmacéutica España S.A.
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Content

Methodological Note 2025.....	2
1. Introduction	3
2. Scope of disclosure.....	3
2.1 Definitions	3
2.2 Scope of publication	7
2.3 Review or audit of information quality	7
3. Data disclosure.....	7
4. Working assumptions	8
4.1 Date of the transfer of value.....	8
4.2 Currency	9
4.3 Taxes	9
4.4 Calculation rules	9
5. Conflict management and resolution.....	9

1. Introduction

Patients are the primary beneficiaries of the collaboration between the pharmaceutical industry and healthcare professionals. This is a relationship that has delivered a large number of innovative medicines and has transformed the way in which many diseases affect our lives. The pharmaceutical industry and healthcare professionals collaborate on a range of medical research activities, sharing best clinical practices and exchanging information about how new medicines are adapted to patient treatment. Ensuring that this vital relationship — already well regulated in itself — is conducted with the greatest possible transparency means strengthening the foundations for future collaboration. Society's expectations regarding transparency are increasing, and nowhere more so than in the healthcare context. Takeda, as a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), is committed to ensuring that these expectations are met.

In accordance with the EFPIA guidelines, Takeda will carry out the current disclosure period for 2025 in June 2026 as a single entity.

This Methodological Note is intended for anyone wishing to gain a deeper understanding of the working assumptions used to prepare Takeda Farmacéutica España's disclosure report and of how Takeda defines the activities included in it. This Note will be published on Takeda's website in both Spanish and English; the Transfers of Value will be published in Spanish only.

2. Scope of disclosure

2.1 Definitions

A number of internal interpretations were required in order to identify precisely which items are considered reportable Transfers of Value (ToV) under the EFPIA guidelines applicable for the current year (<https://efpia.eu/media/676434/220718-efpia-code.pdf>), as well as under the guidelines set out in the Code of Good Practice of the Pharmaceutical Industry and Farmaindustria (<https://www.codigofarmaindustria.org/servlet/sarfi/codigo/codigo.html>).

Set out below is a summary of the interpretation and working assumptions we have applied during data collection, including what we understand by covered recipients and the activities and costs included.

2.1.1 Scope of the recipient

2.1.1.1 Healthcare professionals (HCPs): definition and scope

In its disclosure report, Takeda applies the definition of HCP established by the Code of Good Practice of the Pharmaceutical Industry (Farmaindustria), and the published Transfers of Value are presented accordingly. In the disclosure report, the address indicated for the included HCPs is the principal address at which they carry out their activity..

2.1.1.2 Healthcare organisations (HCOs): definition and scope

In its disclosure report, Takeda applies the definition of HCO as set out in the Code of Good Practice of the Pharmaceutical Industry (Farmaindustria), and the *Transfers of Value are published accordingly: scientific societies, hospital federations, hospital departments, healthcare training centres, clinics, dental clinics, dispensaries, institutions, faculties, universities, academies, foundations, associations of pharmacists,*

healthcare institutions, etc. In the disclosure report, the address indicated for the included HCOs is their registered office.

2.1.1.3 Patient Organisations: definition and scope

In its disclosure report, Takeda applies the definition of Patient Organisation as set out in the Code of Good Practice of the Pharmaceutical Industry (Farmaindustria), and the Transfers of Value are published accordingly.

2.1.1.4 Company owned by a Healthcare Professional

Where the company (HCO) belongs to an HCP, the Transfer of Value will be published as having been made to that professional. If it belongs to more than one, the Transfer of Value will be recorded as having been made to the HCO.

2.1.1.5 Clearly identifiable recipient

Takeda has implemented an internal process to ensure that Transfers of Value are made to the appropriate HCPs or HCOs, as well as to ensure the accuracy and completeness of the published information (e.g. name, address, CIF/NIF where required, principal country of practice). In cases where the NIF/CIF is not available at the time of publication, it will be shown as XXXXXX.

2.1.1.6 Retired or deceased healthcare professional

Takeda will also publish the Transfers of Value relating to Healthcare Professionals who, between the date of the transfer and the date of this report, have retired or passed away. Likewise, Transfers of Value relating to Healthcare Professionals who were already retired at the time the activity and the corresponding transfer took place will be published. All such publications will be managed following the same process applied to the Transfers of Value of active Healthcare Professionals.

2.1.2 Typology of Transfers of Value

The definition of activities may differ from one company to another. At Takeda, all interactions with healthcare professionals are governed by internal policies and standard operating procedures, drawn up in accordance with the Codes and guidelines of the pharmaceutical industry and in compliance with local legislation and sector requirements. Set out below is a series of definitions specific to our company, intended to facilitate the reading of the disclosure report.

2.1.2.1 Donations, grants and grants-in-aid to HCOs

Any Transfer of Value between Takeda and a Healthcare Organisation relating to a donation or grant may be reportable. Examples of such Transfers of Value may include:

- i. Financial or other types of donation
- ii. Contributions to charitable organisations (where the organisation is classified as an HCO in the country)
- iii. Grants, such as:
 - o Medical education grants (e.g. support for HCP training): these may be financial or non-financial in nature (benefits in kind, for example, anatomical models)
 - o Grants not intended for medical education (e.g. support to healthcare institutions for infrastructure improvements)

2.1.2.2 Contribution to the costs of an event, training and scientific/professional meetings

Any Transfer of Value between Takeda and an HCP (whether directly or indirectly through a third party) or an HCO intended to contribute to the costs of an event (training activities and scientific/professional meetings) may be reportable. Examples of Transfers of Value in this category may include:

- i. Travel expenses (flights, train tickets, vehicle hire, tolls, mileage, parking, visas or any other official documents that may be required to arrange an HCP's travel, travel medical insurance, etc.)
- ii. Accommodation expenses
- iii. Registration fees (amounts paid for the attendance of an HCP or an HCO at medical/training events not organised by Takeda)
- iv. Sponsorship agreements with an HCO or a third party appointed by an HCO to manage an event — for example, third-party scientific conferences, congresses: sponsorships through medical societies; national sector organisations; hospitals and training institutions; scientific organisations; global, international, national and regional conferences; local hospitals; medical centres

Where we sponsor an HCP's attendance at a third-party event and that HCP has had to cancel their participation, the report will record these cancellation costs and associated expenses, except where the cancellation is due to justified reasons.

Examples of activities that could be covered under the heading "Sponsorship agreements" in Takeda's disclosure report: stand hire, advertising space (electronic, paper, etc.), satellite symposia at scientific congresses, scientific courses offered by an HCO, opportunities to promote our products, meeting sponsorship (e.g. support for the organisation).

2.1.2.3 Fees for the provision of services and consultancy

Any transfer of value relating to service and consultancy fees between Takeda and a healthcare professional or a healthcare service provider is within the scope of disclosure. Such transfers of value include, for example, a meeting or event (promotional or non-promotional) in which the healthcare professional acts as a speaker, trainer or consultant. These include, among others::

- i. Fees (payment for services covering the time spent on preparation, preparatory meetings, travel where applicable, and the time required for the activity itself)
- ii. Indirect costs (e.g. related expenses such as transport and/or accommodation)

Examples of expenses that could be covered under the heading "Fees for the provision of services and consultancy (HCPs and HCOs)" in Takeda's disclosure report: speaker fees at conferences and round tables; preparation of ad hoc consultancy/advisory services; experts for conferences or training programmes for Takeda employees delivered by third parties; experts for Advisory Board meetings; participants in market research studies (only where they are not double-blind); medical writing; data analysis; development of educational materials; market surveys (only where they are not double-blind); consultancy (e.g. protocol advice, market access, reimbursement, health technology assessment).

2.1.2.4 Research and development

Any Transfer of Value relating to research and development (R&D) activities may be reportable. These Transfers of Value include all those made to HCPs or HCOs that relate to the planning or conduct of:

- i. Non-clinical studies for submission to regulatory authorities (as defined in the OECD Principles of Good Laboratory Practice)
- ii. Clinical trials (in accordance with European Directive 2001/20/EC):
 - a. Clinical trials in humans using non-approved medicines;
 - b. Clinical trials in humans using approved medicines where the intended use is for a non-approved indication, or which will otherwise be prescribed outside the conditions of the marketing authorisation, or in which patients are prospectively assigned to different treatments, or in which the protocol requires diagnostic or monitoring procedures that would not have been carried out had the patient not participated in the trial;
 - c. Clinical trials in humans not included in the preceding points which would require approval by the regulatory authorities if the trial were conducted in the EU, in accordance with Directive 2001/20/EC
- iii. Any prospective observational study in which an approved medicine is prescribed and administered to the patient in accordance with the marketing authorisation and current practice, as well as with the other requirements described in the relevant section of the EFPIA Code of Good Practice on the Promotion of Medicines and on Interactions between the Pharmaceutical Industry and Healthcare Professionals.
- iv. Other activities:
 - a. Activities relating to the planning of the inclusion, design or timeframe of non-clinical studies, clinical trials and/or prospective observational studies within the context of a medicine's development plan.
 - b. Activities relating to the planning of specific non-clinical studies, clinical trials or prospective observational studies.

Examples of activities that could be covered under the heading "Transfers of Value in R&D" in Takeda's disclosure report:

- Clinical trials: regional and/or global or local interventional studies.
- Clinical studies: regional and/or global or local non-interventional studies.

Transfers of Value made indirectly through Clinical Research Organisations (CROs) are also included under the R&D heading of the disclosure report.

Transfers of Value relating to R&D are included as a single aggregate figure, with the exception of transfers relating to retrospective non-interventional studies, which must comply with the provisions of Article 16 of the EFPIA Code of Good Practice on the Promotion of Medicines and on Interactions between the Pharmaceutical Industry and Healthcare Professionals, and which are included under the name of the individual recipient.

2.2 Scope of publications

2.2.1 Excluded transfers of value

This Methodological Note excludes all transfers of value made by Takeda España that are not considered reportable under the Code of Good Practice of the Pharmaceutical Industry of Farmaindustria.

2.2.2 Products

The report refers solely to medicines supplied by Takeda España. These products are prescription medicines.

2.2.3 Non-monetary transfers of value (in kind)

Takeda does not make non-monetary transfers of value.

2.2.4 Cross-border activities or collaborations: international transfers of value

International Transfers of Value are included within the disclosure report. International activities are published in the country where the recipient's principal place of activity is located.

For example, if an overseas Takeda affiliate engages a Spanish consultant HCP, Takeda will include the corresponding Transfer(s) of Value in Spain's disclosure report, in accordance with the HCP's principal place of activity

2.2.5 Transfers of value published on a voluntary basis

This report will publish only those transfers of value that are considered reportable — and whose transparency is therefore mandatory — under the Code of Good Practice of the Pharmaceutical Industry of Farmaindustria..

2.2.6 Transfers of value to patient organisations

Takeda will make public all collaborations carried out with Patient Organisations during the period from 1 January to 31 December of the current year to which it has provided financial support and/or any other type of significant support.

2.3 Review or audit of information quality

Takeda will voluntarily carry out a review, prior to the publication of this report, of the quality of the data and information relating to the transfers of value published herein.

3. Data Disclosure

The disclosure of the individual Transfers of Value of an HCP is carried out in accordance with local data protection regulations. Accordingly, the legal basis and justification for publishing the Transfers of Value — without the consent of the Healthcare Professional (HCP) being required — is the existence of a legitimate interest, in accordance with the report of the Spanish Data Protection Agency of 22 April 2016, this position remaining unchanged following the entry into force of the GDPR, which continues to provide for that legal basis in Article 6.1(f).

Takeda ensures that Healthcare Professionals are informed, before carrying out any activity or practice involving a Transfer of Value, about the processing of their personal data and, in particular, that their data and the said Transfers of Value will be published on the company's website, on an individual basis, within the first six months of the year following their occurrence.

Likewise, Takeda recognises that, as data subjects, individuals in the EU have certain rights which may still be subject to limitations and/or restrictions in this context. These rights include the right to: (i) request access to their personal data and the rectification or erasure thereof; (ii) obtain restriction of processing or object to the processing of their personal data; and (iii) the right to data portability. Data subjects may exercise these rights through a web form, by email, or as provided in the most up-to-date version of the applicable privacy notice.

Should they have any questions about the processing of their data in this context, HCPs are informed that they may contact Takeda by email at the following address: privacyoffice@takeda.com.

The company has adopted security protocols and levels to prevent the information from being indexed by search engines. The website also states that publication of the information does not provide a general authorization for those accessing the site to carry out any additional processing of the professionals' data, such as cross-referencing it with information published on the websites of other associates.

4. Working assumptions

4.1 Date of the Transfer of Value

At Takeda, each and every activity involving HCPs and HCOs is subject to a rigorous analysis of need and to an internal approval process. Once approval has been obtained, Takeda initiates the contracting process, which includes the Transfer of Value in accordance with what has been approved by Takeda under its internal procedures. The provision of the requested service is monitored, so that payment is made in accordance with the terms of the contract.

In our country, and in line with local industry requirements, we use the Event End Date as the point of recognition of the Transfer of Value.

By Event End Date we understand the date on which the activity takes place, and this is the date used for disclosure of the ToV in this report, regardless of the payment date; consequently, some payments may in fact be made at a later date.

The cut-off criterion we apply is as follows:

For transfers of value to Patient Organisations, the Payment Date will be taken as the point of recognition of the Transfer of Value.

Takeda rarely uses multi-year contracts, and for the most part these relate to R&D activities. As regards the remaining multi-year contracts relating to other activities, we have valued the services rendered during a calendar year as the criterion for inclusion in that calendar year's disclosure report.

4.2 Currency

Takeda Farmacéutica España S.A. has adopted the Euro as the currency of the disclosure report, as it is the official currency of the country as at the date of the report. Where a Transfer of Value is made in a currency other than the official one, the amount will be converted using as a reference the exchange rates applied by Takeda's Treasury Department, which are updated on a monthly basis.

For example, a Transfer of Value made in a foreign currency would be the travel expenses incurred by an HCP in a foreign country in which they were providing the service and whose transport costs we paid.

4.3 Taxes

The fees paid are subject to taxation. The amounts included in our report are gross.

4.3.1 Value Added Tax (VAT)

Expenses arising from travel and accommodation are subject to VAT. The data collected and disclosed do not include VAT.

4.4 Calculation rules

In the case of monetary transfers, the value determined as fair market value (FMV) under Takeda's internal policies will be applied.

5. Conflict management and resolution

Takeda has implemented an internal conflict management and resolution process to address any issues that may arise — for example, general questions or discrepancies in relation to the reported data and/or requests to add or withdraw the consent of HCPs/HCOs for the disclosure of data.

In order to improve the quality of the data subject to transparency, and prior to its disclosure in the transparency report, Takeda will provide an individual report to those healthcare professionals for whom an email address is available, in order to convey this information to them.

Should you have any questions or comments regarding the processing of your personal data by Takeda, this Methodological Note, the content of the disclosure report, or Takeda's Privacy Policy, please contact the Ethics & Compliance Department of Takeda Farmacéutica España at "ES_transparencia@takeda.com".