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Takeda UK Ltd: Methodological note for HCP/ORDM/HCO disclosure 2025

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

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1 Definitions

1.1 Recipients

1.1.1 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.

1.1.2 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.

1.1.3 Other Relevant Decision Makers (ORDMs):

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.

1.1.4 Retired HCPs and ORDMs:

Takeda will assess retired HCPs and ORDMs on a case-by-case basis and include disclosures in either the HCP / ORDM or Member of the Public category

1.1.5 Third Party and Professional Congress Organiser / Education Provider (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 products. Among others, these third parties can be distributors, travel agents, consultants, contract research organisations.

Professional Congress Organiser / Education Provider (PCO) is a company/individual specialized in the organisation and management of congresses, conferences, seminars, educational modules and similar events (all "Events")

1.1.6 Deceased HCPs and ORDMs:

Takeda will assess deceased HCPs and ORDMs on a case-by-case basis and include disclosures in either the named or aggregate sections of the HCP / ORDM category.

1.2 Kind of ToVs

[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 UK Company definitions.

1.2.1 Donations and grants:

- i. Donations (physical items, services, benefits in-kind, or charitable contributions)
- ii. Grants are the provision of funds to
 - a) Address an unmet educational or research need in the medical and patient community
 - b) Support improvement in patient outcomes
 - c) Promote excellence in patient care

1.2.2 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 organised 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., organisational 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.*

1.2.3 Collaborative Working

Monetary and non-monetary transfers of value incurred during collaborative working projects are disclosed in accordance with Code requirements.

A link to the relevant collaborative working executive statement is provided in the Disclosure UK portal.

1.2.4 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:

- i. *Consultancy Fees (fees for services such as preparation time, rehearsal time, travel time, and time expended on the activity)*
- ii. *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)*

- iii. Homecare providers whom Takeda contract with to provide a comprehensive managed homecare service to patients via nurse services

1.2.5 Membership / Affiliation fees

Where Takeda has paid a membership fee to an HCO, this has been disclosed under 'Contribution to costs of Events' in accordance with Note M of the ABPI Disclosure Template.

2 Disclosure's Scope

2.1 Products concerned

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

2.2 Company concerned

[Takeda UK Ltd. Please note Shire Pharmaceuticals is now part of Takeda and the disclosure report for 2025 is fully combined.

2.3 Excluded ToVs

[Subsistence is excluded.

2.4 ToVs date

The period covered by this disclosure is 01 Jan 2025 to 31 Dec 2025

2.5 Direct ToVs

Direct ToVs include payments made from Takeda to HCPs and HCOs in relation to e.g. fees for service, event sponsorship etc

2.6 Indirect ToVs

[Indirect ToVs include travel and accommodation funded directly by Takeda, payments made via third parties, non-monetary donations.

2.7 Non-monetary ToVs

[Non-monetary ToVs include donations of staff time or equipment and some patient support programs.

2.8 ToVs in case of partial attendances or cancellation and refund

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.

2.9 Cross-border activities

[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.

2.10 R&D

[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 unauthorised medicinal product
 - b) Clinical trials in humans where an unauthorised medicinal product is used in an unauthorised indication or is otherwise prescribed beyond the scope of the marketing authorisation, 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 authorisation 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 authorisation and standard practice, and the other requirements as set out in section 15.01 of the EFPIA HCP Code.
- iv. Other activities:
 - a) Activities related to the planning of the inclusion criteria, the design or the timing of nonclinical studies, clinical studies and/or prospective non-interventional studies within the framework of the drug development plan.
 - b) Activities related to the planning of certain non-clinical studies, clinical studies, or prospective non-interventional studies.
 - c) 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:"

- clinical trials: regional and/or global,
- local non-interventional trials.
- 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.

2.11 Voluntary disclosure

Not applicable

3 Specific considerations

3.1 Country unique identifier

[Onekey unique identifiers are submitted to the Disclosure UK Portal, where available]

3.2 Self-incorporated 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.

3.3 Multi-year agreements

Payments made in relation to multi-year agreements are included in the disclosure submission for the year of payment.

3.4 Country specificities

Links to relevant collaborative working executive statements are available in the Disclosure UK portal

3.5 Quality Checks

Data is validated to check the correct recipient has been identified and the values are accurate.

4 Data protection legal basis

4.1 Consent collection

Not applicable.

4.2 Legitimate interests

[The individual disclosure of transfers of value provided to an HCP/ORDM is covered by local privacy regulation.

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 01 January 2022. Therefore, 2025 data has been collected under the legal basis, legitimate interests and consent is no longer required. Individuals retain a statutory right to object to named disclosure under the legal basis, legitimate interests. All TOV recipients are obliged to sign an agreement before incurring TOV, which details the way an objection can be raised. Takeda has a process in place to manage such objections whereas the reason for the objection is weighed against Takeda's legitimate interests in making the disclosure.

5 Form of disclosure

5.1 Date of publication

[30 June 2025

5.2 Disclosure platform

[Disclosure UK – www.disclosureuk.org.uk

5.3 Disclosure language

[English

6 Disclosure financial data

6.1 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.

6.2 VAT included or excluded

[In general, Takeda excludes Tax and VAT for Monetary payments/transfers of value and includes Tax and VAT for In Kind transfers of value.

6.2.1 Sales tax

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

6.3 Calculation rules

In kind donations of employee or third party time is calculated based on an approximate hourly rate payable for the type of role supplied.

7 Additional Information

[7.1 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 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 01 January and 31 December, 2025, the transfer is included in our 2025 disclosure report.

If payment for an activity at the end of 2024 was made at the beginning of 2025, Takeda will consider this transfer, including associated expenses, if relevant, in 2025 disclosure report.

Where the ToV is a benefit in kind, values are reported on the date the recipient received the benefit.

In the case of an HCP's attendance of an event, Takeda discloses transfers of value as if they occurred on the date of the event or the final payment related to that event, even if flights and accommodation were paid in advance.]

Contacting Takeda

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