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# Biogen: Methodological note for HCP/HCO/Patient Organizations disclosure 2025

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Biogen believes that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the advancements in patient care and the development of future research. At the same time, we acknowledge that there is a potential for conflicts of interest in the interactions between the industry and healthcare professionals. To enhance transparency and uphold to the highest standards of ethical conduct, Biogen is committed to publicly disclose interactions with Health Care Professional (HCP), Health Care Organization (HCO) and Patient Organization (PO) when associated with Transfer of Values (ToVs) in adherence with EFPIA Code of practice, established local codes and law requirements.

The purpose of Methodology Note is to inform on standards, definition, and reporting principles applied by Biogen in the execution of the transparency disclosure.

## 1 Definitions

### 1.1 Recipients

#### Recipient

Any Health Care Professional (HCP) or Health Care Organization (HCO) or Patient Organization (PO) as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

#### Healthcare Organization (HCO)

Any legal person/entity (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for Patient Organizations) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

#### Healthcare Professional (HCP)

Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe.

The definition of HCP includes: (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of Biogen whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of Biogen and (y) a wholesaler or distributor of medicinal products.

Retired HCPs: ToVs are disclosed according to the individual's status at the time the ToVs was provided. If a recipient retires during the reporting year, ToVs provided prior to the retirement are disclosed in the same way as for any active recipient, in line with applicable data protection legal basis (consent or legitimate interest). ToVs provided after retirement are disclosed only when the individual continues to meet the national definition of HCP or other relevant recipient.

Deceased HCPs: ToVs made prior to the HCP's death are disclosed according to the applicable legal basis and data protection requirements at the time of disclosure. Where local law or privacy considerations do not allow named disclosure, the ToVs will be disclosed in aggregate

Biogen is committed to maintaining up-to-date information on each HCP's status to ensure that their data and any associated Transfers of Value (ToVs) are processed and disclosed appropriately and in accordance with applicable requirements.

### **Patient Organization**

Non-for-profit legal person/entity (including the umbrella organization to which it belongs), mainly composed of patients and/or caregivers, that represent and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

### **1.2 Kind of ToVs**

#### **Financial support and/or significant indirect/non-financial support**

##### **a) To HCPs and HCOs**

Disclosure will be made on an individual basis for each clearly identifiable Recipient. The amounts reported will reflect the Transfers of Value (ToVs) attributed to that Recipient in the relevant Reporting Period and reasonably assigned to one of the defined categories below. ToVs may be presented in aggregated form on a category-by-category basis; however, itemised information must be made available (i) upon request to the Recipient and/or (ii) to the competent authorities.

##### Type of ToVs to HCO:

##### **Donations and Grants.**

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.

##### **Contribution to costs related to Events.**

Contribution to costs related to Events refers to the financial support providing or covering costs to support the attendance of an individual HCP to Event organized or created by a member company and or a Third-Party. Those costs include:

- Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event.
- Registration fee
- Travel and accommodation.

##### **Fees for Service and Consultancy.**

Transfers of Value (ToVs) arising from contracts under which a Healthcare Organisation (HCO) provides services to Biogen. These may include but are not limited to different types of consultancy, advisory, or other services not captured in other categories. The fee paid for the service performed and the related expenses reimbursed or covered in connection with the activity, as agreed in the written contract will be disclosed separately.

##### For ToVs to an HCP:

**Contribution to costs related to Events.** Refers to the financial support providing or covering costs to support the attendance of an individual HCP to the Event. Those costs include:

- Registration fees; and
- Travel and accommodation.

## **Fees for Service and Consultancy.**

Transfers of Value (ToVs) arising from contracts under which a Healthcare Professional (HCP) provides services. These may include but are not limited to different types of consultancy, advisory, or other services not captured in other categories. The fee paid for the service performed and the related expenses reimbursed or covered in connection with the activity, as agreed in the written contract will be disclosed separately.

### Aggregate Disclosure.

When a ToV attributable to one of the categories defined above cannot be disclosed on an individual basis for legal reasons Biogen will disclose the amounts on an aggregate basis. The aggregate disclosure will identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to ToVs to such Recipients.

### **b) To Patient Organizations**

Biogen discloses a list of Patient Organizations to which it has provided financial and/or indirect/non-financial support or with which it has engaged for contracted services during the reporting period.

This disclosure will include a description of the nature of the support or services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the support or the arrangement without the necessity to divulge confidential information. In addition to the name of the PO, the following elements will be included:

#### **For support:**

- The monetary value of financial support and of invoiced costs
- The non-monetary benefit that the Patient Organization receives when the non-financial support cannot be assigned to a meaningful monetary value.

**For contracted services:** the total amount paid per Patient Organization over the Reporting Period.

## **Research & Development**

Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation N° 536/2014); or (iii) 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, HCPs specifically for the study.

### **Other definitions**

#### **Events**

All professional, promotional, scientific, educational meetings, congresses, conferences, symposia, and other similar events, also related with research, organized or sponsored by or on behalf of Biogen.

#### **Third Party**

Legal person/entity or individual that represents Biogen or interacts with other Third Parties on behalf of Biogen or relating to the Biogen's Medicinal Product, such as distributors, wholesalers, consultants, contract research organizations, professional congress organizers, contracted sales forces, market research companies, advertising agencies, providers of

services related to events, public relations services, non-clinical, non-interventional studies management services

### **Sponsorship**

Support provided by a or on behalf of Biogen as a contribution to support an activity (including Events) performed, organized or created by an HCO, PO or a Third Party.

### **Travel and Accommodation**

Support for Travel and Accommodation costs to allow the attendance of an individual HCP or PO representative to an event organized or created by Biogen or Third Party.

Travel cost may include (but it is not limited to): Airfare, Both, car rental, taxi.

## **2 Disclosure's Scope**

### **2.1 Products concerned**

The scope of this Disclosure is limited to Transfers of Value connected exclusively to prescription only medicines.

### **2.2 Company concerned**

Biogen's disclosure obligations extend to subsidiaries, affiliates, and related entities to the extent expressly defined in the applicable contracts and governing legal documentation.

### **2.3 Excluded ToVs**

#### **Hospitality**

As per Art 10 of the EFPIA Code of Practice, hospitality costs are excluded from the scope of Disclosure if within the limits set in the local code.

#### **Informational and Educational Materials**

Items for HCPs information or educational materials are excluded from the scope of Disclosure provided that they are (i) "inexpensive", (ii) directly relevant to the practice of the medicine or pharmacy; and (iii) directly beneficial to the care of the patients.

#### **ToVs to Charitable Organizations**

All ToVs to non-HCO organizations and non-PO, for example charitable organizations, are excluded from the scope of Disclosure.

### **2.4 ToVs date**

The scope of this transparency disclosure covers all Transfers of Value that occurred in 2025. Payments and transfers of value are disclosed based on the date the payment or transfers of value occurred as follows:

- For direct payments (all Fees to HCPs and HCOs, Sponsorships, Grants & Donations): the transfer of value date is the date of the wire transfer to the recipient
- For indirect transfers of value: the transfer of value date is the start date of the event or the date the transfer of value took place
- For in kind support values are reported on the date the recipient received the benefit.

### **2.5 Direct ToVs**

Direct transfers of value are those made directly by Biogen for the benefit of a Recipient. In this circumstance, the ToV is disclosed under the name of the Recipient.

## **2.6 Indirect ToVs**

Indirect transfers of value are those made on behalf of Biogen for the benefit of a Recipient, or those made through a Third Party and where Biogen knows or can identify the Recipient.

- Where a Third Party providing services for R&D activities acts on behalf of Biogen to make ToVs to HCPs/HCOs, these are reported at an aggregate level under R&D (as long as their activities fall within the scope of the definition of R&D activities).
- Where Third Party manages an event, and where the HCO ultimately benefits from that ToV, these ToVs are disclosed against the HCO.
- Where Third Party mediates in ToVs for HCP/HCO who is providing services, these ToVs are disclosed against the HCP/HCO.

Any additional administration costs charged by Third Parties are not disclosed, as these are not considered ToVs to HCPs or HCOs.

## **2.7 Non-monetary ToVs**

In-kind benefits (e.g., Hours spent by employees supporting Patient Organization's activities)

## **2.8 ToVs in case of partial attendances or cancellation and refund**

In case an HCP/HCO does not receive the benefit due to no show or cancellation of the event, the associated costs are not attributed to that HCP/HCO. In case of partial attendance, only benefit received are reported.

## **2.9 Cross-border activities**

Transfers of Value made to any HCP, HCO, or Patient Organization with a principal practice, professional address, or place of incorporation within Europe are disclosed in the country in which the recipient primarily conducts its professional activities.

## **2.10 R&D**

The R&D ToVs are disclosed in aggregate due to applicable EU and national legislation's interpretation. Disclosing information about R&D has the potential to compromise confidential information and breach competition laws.

All ToV related to planning or conduct of non-clinical studies, clinical trials and non-interventional prospective studies performed by Biogen or third party on Biogen Behalf are considered R&D ToV and as such reported on an aggregate basis.

Retrospective non interventional studies are reported on individual basis under consultancy/ fee for service.

## **2.11 Voluntary disclosure**

Not applicable.

# **3 Specific considerations**

## **3.1 Country unique identifier**

Biogen will disclose the "Country Unique Identifier" for HCPs and/or HCOs where the local code has mandated the population of this data point.

### **3.2 Self-incorporated HCP**

Per guidance from local Associations in some countries, if the personal name of the HCP is contained in the name of the legal entity, namely “self-incorporated HCP”, then the HCO will be considered an HCP for consent and disclosure purposes.

### **3.3 Multi-year agreements**

Transfers of Value are reported on the applicable reporting date (either the payment date or the event date – see above), regardless of the duration of the contract.

### **3.4 Country specificities**

Not applicable.

### **3.5 Quality Checks**

Biogen conducts regular data quality checks and ongoing monitoring to ensure that the information presented in the disclosure report is as complete and accurate as possible, based on available data, and is maintained to the highest quality standards.

Through the Pre-Disclosure process, Biogen shares Transfers of Value (ToVs) with the relevant recipients, providing them with the opportunity to review the data prior to final disclosure. This ensures that any concerns or requested corrections are properly addressed, and that updates are made when necessary.

## **4 Data protection legal basis**

### **Introduction**

Under applicable data protection laws, including the General Data Protection Regulation (GDPR) and relevant national implementing legislation, the publication of personal data relating to transfers of value to HCPs must be carried out on a defined legal basis. In certain jurisdictions, national law or regulatory requirements may provide a legal basis for publication, such as: (a) compliance with a legal obligation where Biogen is obliged to make the publications on a named basis by law; or (b) the company’s legitimate interest in ensuring transparency regarding interactions with HCPs, where a national data protection authority or industry association has published an opinion that legitimate interests is an appropriate legal basis. In the absence of the legal bases mentioned in (a) and (b), Biogen relies on consent of the HCP for the disclosure of individually identifiable transfers of value.

### **4.1 Consent collection**

Where consent is the appropriate legal basis for processing of personal data, Biogen collects consent at the first point of engagement with all HCPs based on local requirements:

- If consent is given for all engagements, Biogen will disclose transfers of value to the HCP under the individual section of the applicable disclosure report.
- If Biogen does not receive consent for all engagements, Biogen will default all transfers of value to the aggregate section of the applicable Disclosure Report.  
If the consent form is not returned to Biogen, Biogen will default all transfers of value to the aggregate section of the applicable Disclosure Report.

### **Revoking of individual consent:**

- If an HCP revokes consent prior to publication of the data, Biogen will update the data and include the transfers of values for the corresponding HCP, yet without identifying them, in the aggregate section of the applicable Disclosure Report.

- If an HCP revokes consent after publication of the data, Biogen will remove personal data about transfers of value to the corresponding HCP from the Disclosure Report at the latest by the end of the month following the month in which Biogen received notice of withdrawal of consent, and will update the transfers of values for the corresponding HCP, yet without identifying them, in the aggregate section of applicable Disclosure Report.

#### **4.2 Legitimate interests or compliance with a legal obligation**

In jurisdictions where disclosure is required by national law or where the company relies on its legitimate interest in ensuring transparency regarding interactions with HCPs, Biogen may publish transfers of value on an individual basis without seeking consent. Prior to publication, Biogen informs relevant HCPs about the processing and disclosure of their personal data, including the purpose of the disclosure, the categories of data published, and their rights under applicable data protection law, through a privacy notice. Where disclosure is made on this basis, transfers of value are included in the individual section of the applicable disclosure report. HCPs retain the data subject rights granted under applicable data protection laws, including the rights of access, rectification, and, where applicable, objection to processing. If any data subject rights are raised by an HCP, this should be forwarded to the Global Privacy Office (GPO), and the GPO will assess the request and, where required, advise to update the relevant disclosure accordingly.

## **5 Form of disclosure**

### **5.1 Date of publication**

In Estonia the deadline for the EFPIA Disclosure is set as **1<sup>st</sup> June**.

### **5.2 Disclosure platform**

Biogen will publish the disclosure information for all the countries where Biogen has an Affiliated office on the: Biogen Transparency website

Biogen will also publish the disclosure information on the local Association website/central registry wherever such local country requirement exists.

Biogen will publish for all other countries in scope of EFPIA where they do not have an Affiliate on the Biogen Headquarters website located in Baar, Switzerland.

### **5.3 Disclosure language**

Disclosure shall be made in language prescribed in the national code and can be made available in English.

## **6 Disclosure financial data**

### **6.1 Currency**

All payments and transfers of value will be disclosed in local currency. If originally recorded in another currency, the amount is converted using the daily exchange rate valid on the date of the Transfer of Value.

### **6.2 VAT included or excluded**

All payments and transfers of value to be disclosed exclusive of taxes such as VAT where possible. Exceptions include when Biogen has paid a withholding tax as part of the transfer of value.

### **6.3 Calculation rules**

Not applicable.

## **7 Additional Information**

Not applicable.