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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 EPFIA and AiFD Codes 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 Türkiye.

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 Türkiye or (ii) through which one or more HCPs provide services.

Healthcare Professional (HCP)

Physicians, dentists, pharmacists, dietitians; nurses and midwives; and members of other professionals defined in supplemental Article 13 of Law No. 1219, of 11/04/1928, on the Practice of Medicine and Branches of Medicines; (Reg. Art. 4.1.f) executing their profession in Türkiye, regardless of their nationality (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/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 Türkiye.) For the purpose of the AiFD Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products. The promotion of prescription-only medicines can only be made to physicians, dentists and pharmacists. 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 Türkiye.

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:

For transfers of value made directly or indirectly by Biogen where the value per healthcare organization or institution exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage,

- i- the name of the recipient organization or institution,
- ii- tax number
- iii- the province of registration

will be reported to the Agency, along with particulars based on the examples of scope listed below:

- a) Donation
- b) Contribution to covering event-related costs
- c) Sponsorship agreement
- d) Honorarium or Consultancy Fee
- e) Any other transfers of value.

For ToVs to an HCP:

For transfers of value made directly or indirectly by Biogen to healthcare professionals, where the value exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage,

i-the name and surname of the healthcare professional,

ii-her/his TC national identification number,

iii-work address,

iv-name of the province of work address,

will be reported to the Agency, along with particulars based on the examples of scope listed below:

a) Contribution to covering event-related costs, i.e. registration fee, travel, lodging and meals.

b) Honorarium or Consultancy Fee.

c) Any other transfers of value.

b) To Patient Organizations

On annual basis, Biogen discloses on its website 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, car rental, taxi, etc.

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

Transfers of value which are considered off-scope for disclosure include the following:

- a) Free promotional samples.
- b) Promotional materials.
- c) Transfers of value not exceeding 10% of the currently applicable monthly gross minimum wage (e.g. meals or beverages).
- d) Transfers of value having the nature of a qualified investment for Research and Development (R&D).
- e) Commercial transfers of value to pharmacies, institutions, wholesalers (discounts, sales terms, etc.)

2.4 TOV in scope and calculation methodology

Biogen may transfer any values exceeding 10% of current gross monthly minimum wage to healthcare institutions and organizations, universities, to healthcare professionals and professional organizations, unions, associations and foundations with activities in the healthcare industry of which they are members; and non-governmental organizations founded to preserve and improve health, only upon the condition of abiding by the following rules:

- For any value transfer to be made within this scope, Biogen shall in accordance with the AiFD Code collect written consent (Consent Form) from the healthcare

professional, and in the institutions and organizations, of the authorized supervisor, for the acceptance of the value transfer and for the reporting of the value transfer to the Agency.

Biogen shall not make any value transfer in case the written consent from the HCP or HCO is not obtained.

Reporting Threshold: Any Transfer of Value, inclusive of VAT, whose monetary value exceeding 10% of the current monthly minimum wage shall be reported to the Agency.

Calculation Method of the Reporting Threshold: When calculating individual share of value per participant for an event, the basis will be the amount found by dividing the total expenditure incurred by the Biogen for holding the event to the number of participants

2.5 ToVs date

The following rules apply to documenting payments:

- a. For service agreement fees, donations, grants and sponsorships, the value for the calendar year in which the transfer of value was recognized will be disclosed, including agreements covering more than one year.
- b. Transfers of value for travel (e.g. flight, coach, bus tickets), accommodation (e.g. lodging costs) and registration fees related with events, e.g. congresses or meetings, will be disclosed in the calendar year in which the event occurred.
- c. In other transfers of value, payment date should be taken into account.

2.6 Non-monetary ToVs

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

2.7 ToVs in case of partial attendances or cancellation and refund

Where a healthcare professional is unable to attend an event or a part of an event for any reason, only that portion of such expenditures which was transferred to the healthcare professional will be included in the disclosure of the transfer of value. If the attendance of a participant was cancelled prior to the event for which payments were made, but the transfer of value in the name of the person could not be cancelled, the total value of such transfers must be reported to the Agency all the same, if it exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage applicable on that date.

2.8 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 Türkiye are disclosed in the country in which the recipient primarily conducts its professional activities.

2.9 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.

3 Specific considerations

3.1 Transfers of Value to an individual through a healthcare institution:

Where a contract is signed with a healthcare professional through a healthcare organization or institution which they work for, and the payments are made to the healthcare organization or institution (or to the revolving fund of the institution

- a. the transfer of value will be reported under the name of the healthcare organization or institution, stating the name of the healthcare professional concerned.
- b. Any other expenses related to the individual, such as travel, registration and accommodation, will be separately reported under the name of the healthcare professional.

3.2 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 Legitimate interests

In Türkiye where disclosure is required by AiFD Code 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 under Turkish Data Protection law. 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

Disclosures are made annually, covering the previous calendar year, and must be published by **end-June** of each year (e.g., 2025 data published by June 2026).

5.2 Disclosure platform

Biogen discloses the Transfers of Value to HCPs and HCOs to the Turkish Medicines and Medical Devices Agency (TİTCK) website, whereas the Transfers of Value related to Patient Organizations will be published on Biogen Türkiye website (<https://tr.biogen.com/>).

5.3 Disclosure language

Disclosure shall be made in Turkish 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