European Federation of Pharmaceutical Industries and Associations (EFPIA) HCP/HCO & PO Disclosure Transparency Requirements

Biogen Methodology Note
2023 Disclosure

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1. Overview of the EFPIA Requirements

European Federation of Pharmaceutical Industries and Associations (EFPIA):

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, EFPIA is the voice on the EU scene of leading pharmaceutical companies committed to researching, developing, and bringing to patient's new medicines that will improve health and the quality of life around the world.

The call for Transparency:

EFPIA believes that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe a medicine is one of the pillars of the healthcare system. EFPIA recognizes that interactions between the industry and healthcare professionals can create the potential for conflicts of interest. Consequently, professional and industry associations, including EFPIA and its member associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In order to continue to be successful, self-regulation needs to respond to the evolving demands of society. In particular, there is a growing expectation that interactions between corporations and society are not only conducted with integrity but are also transparent. Following the EU Commission initiative on Ethics & Transparency in the pharmaceutical sector, a multi-stakeholders' platform – including, among others, EFPIA – has adopted a "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector".

In line with these Guiding Principles, EFPIA believes that it is critical to the future success of the pharmaceutical industry to respond to society's heightened expectations. EFPIA has therefore decided that its previous Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the "HCP Code") and Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations (the "PO Code") should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals, healthcare and patient organisations. EFPIA hopes that, by taking this step, it can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stakeholders in the pharmaceutical industry.

Countries in Scope:

Countries with an EFPIA Member Association currently include the following 36 countries: **Austria, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom**.

2. Decisions

The purpose of this methodology note document is to provide generic & unified guidance on Biogen-specific decisions that explain the disclosure data. This document highlights the decisions that drive our collection, aggregation, and reporting process. The specific individual country information whenever appropriate is included in the Appendix.

Tax & VAT	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.
Consent	Biogen is collecting consent at the first point of first engagement with all HCPs and HCOs 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 ("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 or HCO revokes consent prior to publication of the data, Biogen will update the data and include the transfers of values for the corresponding HCP or HCO, yet without identifying them, in the aggregate section of the applicable Disclosure Report. • If an HCP or HCO revokes consent after publication of the data, Biogen will remove personal data about transfers of value to the corresponding HCP or HCO 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 or HCO, yet without identifying them, in the aggregate section of applicable Disclosure Report.
Currency	All payments and transfers of value will be disclosed in local currency. If a payment is captured in another currency, it will be converted into local country currency based on the date at which the transfer of value occurred and corresponding daily exchange rate.

Transfer of values correction	HCPs or HCOs may request correction of published transfers of values that are found to be incorrect. In these cases, Biogen will correct and re-publish these transfers of values.
Transfer of Value Dates	Biogen will disclose payments and transfers of value 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 as opposed to the date of the event • For other transfers of value (Travel & Accommodation): the transfer of value date is the start date of the event or the date the transfer of value took place
Events that are cancelled or HCP does not participate	Biogen will attribute the transfers of value that is incurred and can be reasonably associated to the HCP. In the circumstances when a flight or accommodation is booked but the event is cancelled or HCP does not attend, **no** transfer of value will be attributed to that HCP.
Disclosure of cross-border Transfers of Value	Transfers of Value to a HCP / HCO whose practice, professional address or place of incorporation is in Europe, are required to be disclosed in the country where the **recipient has its principal practice.**
Reporting of HCPs in Countries where Biogen does not have an Affiliate	Where there are transfers of value to European HCP's in countries where there is not a Biogen presence; disclosure will be made on the Headquarters website.
Language	Disclosure shall be made in language prescribed in the national code and can be made available in English.
Local Identifiers	Biogen will disclose the "Country Unique Identifier" for HCPs and/or HCOs where the local code has mandated the population of this data point
Disclosure of Recipient	Biogen will disclose the entity or the legal person to whom we transferred the value except in the circumstance when a transfer of value is made to an HCO for a registration fee or travel expenses related to attending a congress or symposia. In those situations, we will report the HCP whom we consider the beneficiary of the transfer of value.

3. Submission Requirements

Disclosure Method	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.
Disclosure Period	Each reporting period shall cover a full calendar year.
Timing of Disclosure	June 30th unless local Association sets a specific date.
Public Disclosure Retention Period	Per the guidance from EFPIA, Biogen will ensure that the information disclosed shall be required to remain in the public domain for a minimum of 3 years after such information is disclosed in accordance with the disclosure method unless, in each case: • A shorter period is required under applicable national data privacy or other laws or regulations; or • The recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked. *(Art. 22, Section 22.01.)*
Documentation & Records Retention	Per the guidance from EFPIA, Biogen will ensure that all the transfers of value required to be disclosed must be documented and retained for a minimum of 5 years after the end of the relevant reporting period, unless a shorter period is required under applicable national data privacy or other laws or regulations. (Art. 23, Section 23.04.)

4. Categories for Disclosure:

Description	Types of Transfer of Value Included to HCPs / HCOs
Donations and Grants to HCO's	Donations and Grants to HCO's that support healthcare including donations, grants and benefits in kind to institutions, organizations or associations that are comprised of HCP's and/or that provide healthcare.

Description	Types of Transfer of Value Included to HCPs / HCOs
Research & Development (Disclosed at an aggregate level)	Research and Development transfer of values to HCPs/HCOs associated with: • Non-clinical (Good Laboratory Practice (GLP) • Clinical trials in Phase I to Phase IV • Investigator sponsored studies • Non-interventional studies
Contribution to costs of Events (as per HCP Code): **1. Sponsorship agreements**	Events include all scientific professional meetings, congresses, conferences, symposia and other similar events. Sponsorships with HCOs/third party appointed by an HCO to manage an Event. Examples: • Rent of booths at an event • Advertisement space (in paper, electronic or other format) • Satellite symposia at a Congress • Sponsoring of speakers/faculty • Drinks or meals provided by the organisers (included in the "Sponsorship Agreement") • Courses provided by an HCO (where the Member Company does not select the individual HCPs participating
Contribution to cost of Events: **1. Registration Fees**	Registrations fees related to attending a Congress or Symposia.
Contribution to costs of Events: **2. Travel & Accommodation**	• Travel in relation to attending a Congress or Symposia. • Accommodation in relation to attending a Congress or Symposia. Example: • Fees for airfare, train, boat or ferry (incl. booking fees) • Car rental, car services, taxi transfers • Parking fees • Petrol • Tolls • Etc. Note: Meals that are part of a reimbursement to an HCP may be included in the Travel & Accommodation amount

Description	Types of Transfer of Value Included to HCPs / HCOs
Fee for service and consultancy: **1. Fees**	Transfers of value resulting from or related to contracts between Member Companies and institutions, organisations, associations, or HCPs under which such institutions, organisation, associations, or HCPs provide any type of services to a Member Company, or any other type of funding not covered in the previous categories. Examples: • Speaker fees • Speaker training • Medical writing • Data analysis • Development of education materials • General Consulting/Advising
Fee for service and consultancy: **2. Related expenses agreed in the fee for service or consultancy contract**	Related expenses agreed in the fee for service or consultancy contract: Example: • Fees for airfare, train, boat or ferry (incl. booking fees) • Car rental, car services, taxi transfers • Parking fees • Petrol • Tolls • Etc. Note: Meals that are part of a reimbursement to an HCP will be included in the Travel & Accommodation amount

Description	Type of Transfer of Value Included to POs
Financial support and/or significant indirect/non-financial support	Disclosure must include a total amount paid, monetary value or non-monetary benefit. Example for indirect/non-financial support: • Fees to Third Party for the benefit of PO • Hours spent by employees to support PO's activities

5. Definitions

HCO

Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational 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. 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.

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. For the avoidance of doubt, the definition of HCP per the EFPIA Code 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 or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products, and subject to local requirements.

PO (Patient Organization)

Non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents 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.

Donations and Grants

Collectively, means those donations and grants (either cash or benefits in kind) within the scope of Article 12 of the Code of Practice.

Events

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "**Event**") organised or sponsored by or on behalf of a company (*Article 10 of the Code of Practice*).

Code of Practice

The EFPIA Code constitutes the collection of ethical rules agreed by EFPIA members for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility. EFPIA Code replaces EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, which first came into effect in January 1992; EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations, which was first approved in September 2007; and EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, which was first approved in June 2013. The EFPIA Code was adopted by the EFPIA Board on 22 March 2019 and ratified by the EFPIA Statutory General Assembly on 27 June 2019.

Medicinal Products

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. (*Article 1 of Council Directive 2001/83/EC, as amended*)

Member Associations

Collectively, the national member associations or their constituent members, as the context may require, that are members of EFPIA and bound by the EFPIA Code of Practice.

Member Companies

Collectively, "corporate members" (as defined in the Code of Practice) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organisation) and any companies affiliated with corporate members or their subsidiaries if such affiliated companies have agreed to be bound by this Code of Practice.

Recipient

Any HCP or HCO or PO as applicable per local requirements, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

Research and Development Transfers of Value

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 (*Annex B EFPIA Guidance*).

1. **Non-clinical studies as defined in the OECD Principles on Good Laboratory Practice**

The OECD Principles on Good Laboratory Practice (as latest revised in 1997) define non-clinical studies as follows (Section I – 2. Definitions of Terms; section 2.3.1):

> *Non-clinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.*

For complete reference, see www.oecd.org

2. **Clinical trials (as defined in Regulation N° 536/2014)**

The Regulation EU No 536/2014 (Article 2(1)) defines clinical trials as:

> *any investigation in relation to humans intended:*
>
> *(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;*
>
> *(b) to identify any adverse reactions to one or more medicinal products; or*
>
> *(c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;*

with the objective of ascertaining the safety and/or efficacy of those medicinal products. For complete reference, see EUR-lex.europa.eu.

3. **Non-interventional studies**

The Regulation EU No 536/2014 (Article 2(4)) defines non-interventional study as:

'Non-interventional study' means a clinical study other than a clinical trial;

Transfers of Value

Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or branded prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or those made through a Third Party and where the Member Company knowns to or can identify the Recipient.

Appendix:

Sources/Reference:

Name	Document
EFPIA Code	https://www.efpia.eu/ https://www.efpia.eu/relationships-code/

Appendix 2: *(applicable for countries with local specifics)*