

EFPIA DISCLOSURE METHODOLOGICAL NOTE
PIERRE FABRE PHARMACEUTICALS

Transfers of Value 2019 -
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1. PREAMBLE

Across Europe, by 30 June 2016, the pharmaceutical industry has been disclosing payments made to health professionals, such as sponsorship to attend meetings, speaker fees, consultancy and advisory boards. Bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Industry is being proactive, based on its commitments to this relationship. Collaboration between industry and health professionals' benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives. Industry and health professionals collaborate in a range of activities from clinical research to sharing best clinical practice and exchanging information on how new medicines fit into the patient pathway. Society has increasingly high expectations for transparency, none more so than in healthcare. As a member of EFPIA, Pierre Fabre group wants to ensure we meet those expectations complying with EFPIA Code of Practice.

The EFPIA Code of Practice is a code of conduct that requires all EFPIA member companies and companies that are members of EFPIA member associations to disclose transfers of value to Healthcare Professionals (HCPs) and healthcare organizations (HCOs).

The first disclosures were made by 30 June 2016, for payments made in 2015. For Pierre Fabre affiliates in Europe, Russia, this information is published on a public platform, which could be on a central national platform, combining data from different companies, on each affiliate company's own website or, on the company's corporate website when affiliate doesn't have its own website.

Some details as the approach to timing, tax and currency aspects of Transfer of Value (ToV) disclosure are not defined by the EFPIA Code. Companies are free to define an appropriate methodology and are obliged to publish it as per the EFPIA Code, Chapter 5.

Pierre Fabre Pharmaceuticals, as a member of EFPIA, fulfills this requirement by publishing this document alongside 2019 transparency disclosure reports where possible. All data in the disclosure report were correct at time of publication.

2. PURPOSE

In accordance to Chapter 5 of the EFPIA Code of Practice, this document is used as required methodological note, and describes the EFPIA Code requirements, Pierre Fabre company Group, local considerations and adaptation in accordance with local applicable laws and regulations.

This Methodological note applies to PIERRE FABRE GROUP.

2.1. Abbreviations

CRM	Customer Relationship Management
Cross-border ToV	Cross-border Transfers of Value
EFPIA	European Federation of Pharmaceuticals industries and Associations
ERP	Enterprise Resource Planning Software
HCP	Healthcare professional
HCO	Healthcare Organizations
OTC	Over-The-Counter
POM	Prescription-Only-Medicine

3. SCOPE OF DISCLOSURE

3.1. Recipients

3.1.1. HCP

- EFPIA Definition

“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 Europe. For the purpose of this 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.”

- Pierre Fabre Group

Pierre Fabre Pharmaceuticals are fully aligned with HCP / HCO EFPIA scope, adjusted when necessary to accommodate country trade association definitions expected by the market.

3.1.2. HCO

- EFPIA Definition

“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 POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services”.

- Pierre Fabre Group

Pierre Fabre Pharmaceuticals are fully aligned with HCP / HCO EFPIA scope, adjusted when necessary to accommodate country trade association definitions expected by the market.

3.2. Medicinal product

- EFPIA Definition

“Medicinal Products has the meaning set forth in Article 1 of the Directive 2001/83/EC, namely: (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”.

- Pierre Fabre Group

Transfers of Value to Health-Care Professionals and Health-Care Organizations may concern Medicine-related activities:

- Prescription-Only-Medicine (POM) related activities
- Or Group of products including POM-related activities
- Or Over-the-Counter (OTC) Medicines promoted to prescriber-related activities.

3.3. Transfers of Value: Categories and definitions

3.3.1. ToVs: Definition

Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of POM exclusively for human use. Direct ToVs are those made directly by a Member Company for the benefit of a Recipient. Indirect ToVs 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 knows or can identify the Recipient that will benefit from the Transfer of Value.

3.3.2. ToVs to HCO: Donations and Grants

- EFPIA Definition

“Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 12 of the EFPIA Code). “

- Pierre Fabre Group

Donations and Grants to HCOs as defined by the EFPIA Code are published at an individual level. According to local requirements, if the HCO consent is required for publishing at an individual level, the HCO who does not wish to consent to the disclosure of its personal data, disclosure is made on an aggregate basis, without naming the HCO.

3.4. ToVs to HCO: Contribution to costs related to Events

- EFPIA Definition

“Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or Third Parties, including support to HCOs to attend Events, such as:

- Registration fees;
- Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event; and
- Travel and accommodation (to the extent governed by Article 10).”

- Pierre Fabre Group

Contribution to costs related to Events as defined by the EFPIA Code is published at an individual level. According to local requirements, if the HCO consent is required for publishing at an individual level, the HCO who does not wish to consent to the disclosure of its personal data, disclosure is made on an aggregate basis, without naming the HCO.

3.4.1. ToVs to HCO: Fees for Service and Consultancy

- EFPIA Definition

“ToVs resulting from or related to contracts between Member Companies and HCOs under which such HCOs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.”

- Pierre Fabre Group

Fees for Service and Consultancy as defined by the EFPIA Code are published at an individual level. According to local requirements, if the HCO consent is required for publishing at an individual level, the HCO who does not wish to consent to the disclosure of its personal data, disclosure is made on an aggregate basis, without naming the HCO.

3.4.2. ToVs to HCP: Contribution to costs related to Events

- EFPIA Definition

“Contribution to costs related to Events. Contribution to costs related to Events, such as:

- Registration fees; and
- Travel and accommodation (to the extent governed by Article 10).”

- Pierre Fabre Group

Contribution to costs related to Events as defined by the EFPIA Code is published at an individual level. If the HCP does not wish to consent to the disclosure of his/her personal data, disclosure is made on an aggregate basis, without naming the HCP.

3.4.3. ToVs to HCP: Fees for Service and Consultancy

- EFPIA Definition

“ToVs resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.”

- Pierre Fabre Group

Fees for Service and Consultancy as defined by the EFPIA Code are published at an individual level. If the HCP does not wish to consent to the disclosure of his/her personal data, disclosure is made on an aggregate basis, without naming the HCP.

3.4.4. Research and Development ToVs

- EFPIA Definition

“Research and Development ToV. Research and Development ToVs in each Reporting Period must be disclosed by each Member Company on an aggregate basis. Costs related to Events that are clearly related to activities covered in this section can be included in the aggregate amount under the “Research and Development Transfers of Value” category.”

Transfers of Value relating to non-interventional studies (NIS) that are not within the definition of R&D ToVs under the EFPIA Disclosure Code must be reported on an individually named basis.

For sake of clarity, activities not falling within the definition of R&D ToVs, including NIS that are not conducted to maintain a marketing authorization (in application and following definitions of the “Clinical Trials” Regulation 536/2014), will be disclosed under “consultancy/fee-for-services”.

- Pierre Fabre Group

Research and Development ToVs in each Reporting Period must be disclosed by each Member Company on an aggregate basis. Costs related to Events that are clearly related to activities covered in this section can be included in the aggregate amount under the “Research and Development Transfers of Value” category.

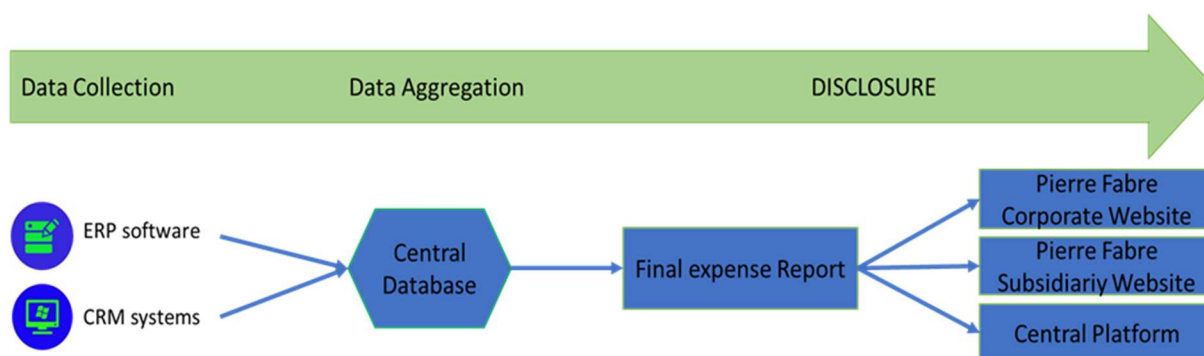
Transfers of Value relating to non-interventional studies (NIS) that are not within the definition of R&D ToVs under the EFPIA Disclosure Code are reported on an individually named basis.

Activities which don’t fall within the definition of R&D ToVs, including NIS that are not conducted to maintain a marketing authorization), are considered as “consultancy/fee-for-services”.

4. PREPARATION OF THE PUBLICATION OF TRANSFER OF VALUE

4.1. Principle

Publications are prepared by collecting all the information required for publication in accordance with the GDPR (identity of the professional, specialism, professional contact details, professional identifiers, nature and purpose of the expense and date) concerning each transfer of value from various source systems. All expenses are recorded in the Central Database. This Database enables aggregating all ToVs per recipient and producing a report on the publication of ToVs per country, per individual, or on an aggregated basis, according to the consent status recorded for each recipient.



4.2. Consent management

Consent is collected in accordance with the European Data Protection Regulation GDPR from each recipient, along with their signature on the written document covering the operation (contract or letter of agreement), or before publication upon presentation of the information to be published. Pierre Fabre Pharmaceutical commits to make its best efforts to obtain the consent to publish in individual.

Regarding consent there are 3 specific cases:

- where consent has been positively given to publish and collect data in individual, Pierre Fabre Pharmaceuticals publishes the individual recipient details,
- when HCP/HCO has given their consent to collect and publish data in aggregate, Pierre Fabre Pharmaceuticals publishes in aggregate,
- if HCP/HCO has denied their consent to collect their data, Pierre Fabre Pharmaceutical, Pierre Fabre Pharmaceutical don't publish data.

At any time, HCP/HCO can be withdrawn before or after the public disclosure.

4.3. Cross-border activities

Where a TOV is made outside of the recipient's country those TOV's are reported within the country disclosure report based on the recipient's principal practice address.

The cross-border disclosures are made on the Pierre Fabre Corporate Website or locally either on each affiliate website, or in the separate disclosure platform in accordance with local requirements.

4.4. Publication

Pierre Fabre Pharmaceuticals follow local country trade association procedures and legislation for reporting publication. When required, Pierre Fabre Pharmaceuticals will republish a disclosure report.

For countries with no external central platform: Pierre Fabre Pharmaceuticals publish the disclosure report on the country specific Pierre Fabre website in a dedicated transparency section or on Pierre Fabre corporate website in that dedicated transparency page:

<https://www.pierre-fabre.com/en/disclosure-of-payments-to-healthcare-professionals>

This methodological note will be attached to this section.

4.5. Date of Publication

Pierre Fabre Pharmaceuticals discloses before the 30th of June all relevant ToVs from previous year according to the EFPIA Code of Disclosure.

4.6. Disclosure language

Disclosure language is as determined by the country trade association.

4.7. Disclosure currency

The sums are published in euros, except for countries requiring another currency and include all taxes.

4.8. Archiving

Pierre Fabre Pharmaceutical is disclosing reports and maintaining relevant records of disclosure for a minimum of 3 years after the beginning of the publication. After this period, according to the GDPR, the reports will be removed from the publishing platforms and all data related to ToVs will be removed from the ERP software, CRM Systems and the central database.

5. **MANAGEMENT OF RECIPIENT'S REQUEST**

Request or disputes are managed both at Pierre Fabre Pharmaceutical local and global level.

A central e-mail address for requests is dedicated to HCPs/HCPs communication:

Transparency.compliance@pierre-fabre.com

Pierre Fabre Corporate commits to answer and resolve the request within 30 days of receiving notification of the dispute.

Consent to disclose can be withdrawn at any time before or after disclosure:

- If consent is withdrawn before disclosure, the consent value is changed to "No",
- when consent is withdrawn after public disclosure, the published data is set off line a revised report is uploaded that no longer shows the individual HCP ToV line but has integrated those ToVs in aggregate line.