Methodology for Compliance with the Research-Based Pharmaceutical Industry (LIF) Disclosure Code

Date Published: 31 May 2017

Index

Introduction

Baxter Medical AB ("Baxter") is a member of the national Association of the European Association of Pharmaceutical Industries and Associations (EFPIA) in Sweden ("The Research-Based Pharmaceutical Industry (LIF)"). As a member, Baxter is obliged to comply with the Ethical Codes of Conduct, including, but not limited to, the Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations ("Disclosure Code"). Being a company with very high compliance standards, Baxter shares the view of EFPIA and its national Associations that the transparency of interactions between the pharmaceutical industry and members of the medical community is in the interest of patients and other stakeholders, and as well as the industry itself.

Baxter will disclose its transfers of value to Healthcare Professionals ("HCPs") and Healthcare Organisations ("HCOs") in line with the Research-Based Pharmaceutical Industry (LIF) Disclosure template.

With respect to interactions with HCPs and HCOs, Baxter follows the Baxter Global Policy on Interactions with the Medical Community and Government Officials ("Policy").

In accordance with this Policy, Baxter's interactions with the Medical Community and Government Officials must, always occur in an ethical manner, in compliance with local laws, regulatory requirements and industry codes.

No one at Baxter may offer or provide anything of value to a member of the Medical Community or a Government Official either directly or through others with the intent to improperly influence or reward his or her decision to prescribe, purchase, recommend or use a Baxter product, therapy or service.

The purpose of this document is to explain the implementation of Baxter's disclosure reporting, in line with Schedule 2 of the Disclosure Code. In order to protect its business, Baxter does not disclose commercially sensitive data.

General Comments

<u>Healthcare Professionals ("HCPs") as defined in the Disclosure Code</u>

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 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.

Baxter will identify the HCP as per Schedule 2, with the full name, city of principal practice, address, and country of practice.

Healthcare Organizations ("HCOs") as defined in the Disclosure Code

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 whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Baxter will identify the HCO as per Schedule 2, with the full name, city where registered, address and country of practice.

Medicinal Products

The Research-Based Pharmaceutical Industry (LIF) only demands disclosure in relation to medicinal products, and not with respect to medical devices. Baxter being a diversified healthcare company, Baxter's franchises are often a combination of medicinal products, as referenced in the Research-Based Pharmaceutical Industry (LIF) HCP Code of Conduct, and medical devices, e.g. a consulting agreement could cover a therapy that relates to both. As it is often too complex to separate medicinal products and medical devices, Baxter has decided to over-disclose such that the interactions related to medical devices are included in Baxter's disclosure as well as interactions related to medicinal products.

Cross-Border Payments

Baxter will disclose Transfers of Values in the country where the HCP or HCO, who receives the Transfers of Value, operates.

Disclosure reporting : individual vs. aggregate reporting

Where the HCP/HCO has consented to the disclosure or consent is not required, disclosure will take place on an individual basis.

If consent is required and not obtained or revoked, Baxter will disclose Transfers of Values in the aggregate.

Indirect Transfers of Value

In case Transfers of Value are given to HCPs through HCOs, e.g. a sponsorship to an event, Baxter will disclose these Transfers of Values as "Transfers of Value to HCOs".

Baxter will work to ensure that Transfers of Value will only be disclosed once, in particular where the recipient is a HCO and the beneficiary is a HCP.

Baxter will not report indirect transfers of value, e.g. through congress organizers, in cases where Baxter has no knowledge of the HCPs/HCOs chosen or has no influence on the selection of HCPs/HCOs.

Donations and Grants

Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare Code on the Promotion of prescription-only medicines to, and Interactions with Healthcare Professionals (HCP Code)).

- Programs to advance patient care
- Programs to foster medical science

Baxter will disclose all Transfers of Value provided to HCOs to support their missions, visions, goals and programming.

Events

Contribution to costs related to Events.

a) for HCOs: Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:

i. Registration fees;

ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and

iii. Travel and accommodation

b) for HCPs: Contribution to costs related to Events, such as:

i. Registration fees; and

ii. Travel and accommodation

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.

Contribution to Costs of Events to HCOs (Sponsorship Agreements)

Contribution to Costs of Events include amongst others:

- Rental of booths at an "Event";

- Advertisement space (in paper, electronic or other format);
- Satellite symposia at a congress;
- Sponsoring of speakers/faculty;
- If part of a package, drinks or meals provided by the organisers (included in the "Sponsorship Agreement");
- Courses provided by a HCO (where Baxter does not select the individual HCPs participating).

In cases where Baxter sponsors an event, organized by a vendor, and the sponsorship is for more than one HCO, Baxter will disclose the Transfers of Value as follows:

If Baxter knows, which Transfer of Value the HCOs have received, Baxter will disclose the Transfers of Value on an individual basis for each HCO.

In cases where Baxter does not know the value each HCO has received, Baxter will divide the Transfers of Value by the number of HCOs supported and report equal shares of Transfers of Value per HCO.

Contribution to Costs of Events to HCPs

In case of indirect sponsorship of HCPs through HCOs, Baxter will disclose these Transfers of Values under Sponsorship agreement with HCOs.

Registration Fees

Baxter will disclose payment of registration fees.

Fees for Services and Consulting

Fees for Service and Consultancy to HCOs: Transfers of Value resulting from or related to contracts between Member Companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations 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 Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

Fees for Service and Consultancy to HCPs: Transfers of Value 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 Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

Fees for Services and Consulting include among others:

- Speakers' fees;
- Medical writing (unless the medical writing forms an integral part of an Investigator Initiated trial, then it will be disclosed as Research);
- Data analysis;
- Development of education materials;
- General consulting / advising;
- Un blinded market research;

- Retrospective non-interventional studies.

The following Transfers of Value, under Fees for Service and Consulting, will only be disclosed in the aggregate:

- Market research, where the identity of the participants is not known to Baxter. Aggregate disclosure of ToV provided to company conducting the market research. In these cases Baxter will contractually oblige the market research company to make the disclosure in countries that require disclosure under local law.

Expenses include

- Travel: standard or first class for rail service and local transportation; economy class for air travel, with the option of upgrading up to business class for non-stop transcontinental flights longer than 6 hours.
- Accommodation: standard single room in a business class mid-scale hotel.

If a fee for service is paid to a legal entity owned by an individual HCP, Baxter will disclose the Transfer of Value under the name of the legal entity (considered a HCO).

Research and Development

Research and Development Transfers of Value in each Reporting Period shall 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 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 Directive 2001/20/EC); 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.

Baxter will disclose the Transfers of Value to HCPs or HCOs related to Research and Development in line with the Disclosure Code.

Exclusions

Baxter may make transfers of value to HCPs / HCOs if demanded by the tender requirements (in a given country). As these transfers of value will be made public in the context of the tender, Baxter will not disclose these payments under the Research-Based Pharmaceutical Industry (LIF) Disclosure Code.

Finance Related Matters

Amount

The Transfer of Value being disclosed will be equal to the cost to Baxter converted into local currency. This cost will include any taxes paid on behalf of HCPs/HCOs and any VAT not recoverable by Baxter. The amount will exclude any VAT recoverable by Baxter.

Local Currency

Amounts paid by Baxter in a foreign currency will be converted to the local currency using Baxter's monthly actual rates of currency translation. These are calculated at the beginning of each month based on market conditions.

Timing

Transfers of Value will be disclosed on the date that the payment leaves the Baxter bank account.

Payments from HCPs

For reporting purposes, the net amount will be disclosed, i.e. Baxter cost less amount contributed by the HCP.

Data Privacy

As a multi-national company Baxter is committed to comply with regional and local data privacy regulations. For more details on data privacy please refer to Annex 2.

Management of Process Methodology

Baxter shall ensure that this Process Methodology is kept up-to-date and aligned to the Research-Based Pharmaceutical Industry (LIF) Disclosure Code. As such, this Process Methodology is subject to regular internal management review. Any changes shall be reflected in the updated and published methodology document.

Questions?

In case of questions on the methodology, please contact the Baxter Ethics & Compliance helpline under https://secure.ethicspoint.com/domain/media/en/gui/28323/index.html .

Annex 1

Disclosure Schedule as per Schedule 2 of the Research-Based Pharmaceutical Industry (LIF) Disclosure Code

Annex 2

Data Privacy

Baxter will make its best endeavours to comply with the Data Privacy laws of Sweden.

Baxter's Approach And Commitment To Data Privacy

'Personal data' means any information relating to an identified or identifiable individual or entity. To achieve its main objective, the law sets out certain requirements concerning the processing of personal data by organisations, including Baxter, such as that personal data must be:

- Processed fairly and lawfully;
- Collected for specified, explicit and legitimate purposes and not further processed for incompatible purposes;
- Adequate, relevant and not excessive for the purpose for which they are collected and processed;
- Accurate and, when necessary kept up to date;
- Processed outside the EEA only when there are adequate levels of protection of the personal data, unless certain exemptions apply;
- Protected through appropriate technical and organisational security measures.

The Data Baxter Will Collect Details Necessary for Reporting on the Following:

Interaction Request

HCO, HCP, Consultant Information, History and Payment

Hospitality, Meeting, and Working Relationships Type (e.g. promotional, scientific etc.) specific information (e.g. agenda, travel, meals, lodging etc.) and costs

Consultancy

Research and Development

Market Research

Contributions

Working Relationship / Hospitality Details

Contract and or Service Agreements

Patient Organisations

How Baxter Will Process and Secure This Data

Data Disclosure Consent

HCPs have the right to refuse to disclose their information and the right to seek correction of mistakes or deletion of their information. They can also withdraw consent to disclose payment information, in most countries, or choose not to work with a company. In this regard, Baxter shall

abide by local country legislation. The data disclosure withdrawal process is defined in the HCP agreement.

As explicitly required in the Research-Based Pharmaceutical Industry (LIF) Disclosure Code, Baxter will collect and store consent. If Employer Consent is explicitly required that will also be collected and stored by Baxter.

Consent Management

Baxter will use its best endeavours to obtain the consents necessary to disclose Transfers of Value at the individual level and will use aggregate disclosure only in exceptional circumstances.

- There are countries where Baxter is required to offer the option of providing, withholding and/or revoking consent.
- There are countries where Baxter is required by national law or regulations to obtain consent of the recipient for individual disclosure in advance of the interaction being processed.
- There are countries where if consent is refused by the Recipient, it is forbidden to undertake an interaction.

In accordance with the Research-Based Pharmaceutical Industry (LIF)Disclosure Code, where consent is not granted, Baxter shall aggregate the data.

In countries, where Baxter has a legal obligation to disclose Transfers of Value Information (e.g. France, Denmark, Portugal and Slovakia) Baxter will disclose the Transfers of Value on an individual basis, irrespective of the consent given by the recipient, because the disclosure is necessary to comply with local law.

Baxter shall ensure disclosure wording is included in agreements with HCPs, if required by local law.

Baxter will use its best endeavours to renegotiate and novate any existing agreements with HCPs to make sure that all agreements contain the necessary consent provisions.

If a HCP revokes the consent to disclose under the Disclosure Code, Baxter will aggregate the data for the future but not retrospectively. Any consequences of withdrawal of consents shall be defined in the relevant Agreement.

Data Retention

Baxter will maintain the relevant records of the disclosures made under this Code for a minimum of 10 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.

Baxter recognises The Right To be Forgotten. As such, and when required, Baxter shall implement processes to ensure all relevant data is removed from its systems.

Data Validation and Dispute Resolution

A critical part of Disclosure Compliance, as well as Data Integrity laws across EMEA is to ensure that the all HCPs, HCOs and Consultants are accurately identified and validated. Baxter endeavors to ensure that the HCP information is consistently matched with the correct HCP identifiers.

As is the case with most data collection processes, occasionally incorrect or incomplete data will enter the system.

Baxter will use its best endeavours to ensure a process for correcting and/or removing data if on the rare occasion it is found to be inaccurate. The HCP/HCO/Consultant agreements contain a process on how the HCPs/HCOs/Consultant can inquire on their data to be disclosed.

Baxter shall ensure procedures for handling enquiries on the disclosures and for making HCOs/HCPs/Consultant aware of the disclosures in the agreements to be concluded with the HCP / HCO/Consultant.