

Methodology for Compliance with the Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (“FSA”) Disclosure Code and Code on Cooperation with Patient Organizations

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Index

Annex 1: Schedule 2 of the FSA Disclosure as attachment

Annex 2: Data Privacy

Introduction

Baxter Deutschland GmbH (“Baxter”) is a member of the national Member Association of the European Association of Pharmaceutical Industries and Associations (EFPIA) in Germany (“FSA”). As a member, Baxter is obliged to comply with the FSA Code of Conduct on the Collaboration with Healthcare Professionals (“FSA Code of Conduct”), including, but not limited to, the FSA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations dated 27.11.2013 (“FSA-Kodex zur Transparenz bei der Zusammenarbeit mit den Angehörigen der Fachkreise und medizinischen Einrichtungen”, “FSA Disclosure Code”) as well as the FSA Code on Cooperation with Patient Organizations dated 13.06.2008 (“FSA-Kodex zur Zusammenarbeit mit Patientenorganisationen”). Being a company with very high compliance standards, Baxter shares the view of FSA 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”) as well as to Patient Organizations (“POs”) in line with the FSA Disclosure templates. Disclosed/published data on transfer of value to HCPs, HCOs and POs pertain to interactions in the context of pharmaceuticals (“medicinal products”, “Arzneimittel”) as well as to interactions in the context of medical devices (“Medizinprodukte”).

With respect to interactions with HCPs, HCOs and POs, 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

Healthcare Professionals (“HCPs”) as defined in the Disclosure Code

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 practicing 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 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 within the scope of the FSA Code on Cooperation with 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.

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

Patient Organizations (“POs”) as defined in the Code on Cooperation with POs

"Patient organization" are voluntary, non-profit making associations of patients and/ or their relatives, their activities focus on coping with disease, mediation information about diseases and their therapeutic options, representation of interests in the health and social policy area, the release of media to inform and support patients and/ or the provision of advisory services.

Baxter will identify the PO with the full name.

Medicinal Products

FSA only demands disclosure in relation to medicinal products (pharmaceuticals), 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 FSA Codes, 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. Therefore, the following data do not differentiate between transfers of value provided to HCPs/ HCOs/ POs in the context of pharmaceuticals in the one hand or in the context of medical devices on the other hand.



Cross-Border Payments

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

Disclosure reporting: individual vs. aggregate reporting

Where the HCP/HCO/PO 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.

In case Transfers of Value are given to HCPs or HCOs through a congress agency/ commercial congress organizer, e.g. a sponsorship to an event, Baxter will disclose these Transfers of Values as “Transfers of Value to HCOs” in the following format:

Name of (commercial) congress agency (name of scientific organizer, name of event, date, city of event).

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 (Article 3.01.1.a of the EFPIA code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals “EFPIA Disclosure Code”):

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 7 of the FSA Disclosure 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 (to the extent governed by Article 26 of the FSA Code of Conduct).
- iv. Where Event organizers are Baxter's contract partner for the Event of a medical or professional society (or association), the name of the respective society (or association) is stated in brackets.

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

- i. Registration fees; and
- ii. Travel and accommodation (to the extent governed by Article 20 of the FSA Code of Conduct)

Events as defined by Article 20 of the FSA Code of Conduct: 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") organized 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 another 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 (Article 7 (2) 2. c) of the FSA Disclosure Code).

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 (Article 7 (2) 1. b) of the FSA Disclosure Code).

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;
- Unblinded 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 Transfer of Value 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 as 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 (Article 7 (5) of the FSA Disclosure Code).

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.

Payments to Patient Organizations

Baxter will disclose the transfers of value (either cash or benefits in kind) to Patient Organizations. The subject of the ToV or the contractual achievements will be described in that way that the average readers understand the nature of the grants or agreement. However, confidential information will not be made public.

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 Germany Disclosure Code.

Disclosure Reporting

Local Law Requirements

According to applicable Data Privacy Law, HCPs who have received Transfer of value from Baxter are only listed on a named basis if they have given their written consent to publish those personal data. In the absence of data transfers of value are only published on an aggregate basis (i.e. without the personal data of the receiving HCP). For more details on data privacy please refer to Annex 2.

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

Under certain conditions HCP's are required to contribute towards costs incurred by third parties to their benefit (e.g. the cost-participation or full payment of travel or accommodation in the context of attendance of congresses or alike). In those cases, 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 German FSA Disclosure Code and PO 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.

Changes to the methodology document published 2020

No changes.



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 German Disclosure Code

Annex 2

Data Privacy

Baxter will make its best endeavors to comply with the Data Privacy laws of Germany as well as the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation; hereinafter: GDPR).

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 organizations, 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 organizational security measures.

The data Baxter will collect and process details necessary for reporting on the following:

- (i) name;
- (ii) address of the principal practice;
- (iii) unique country identifier; and
- (iv) the date, nature and amounts of the transfers of value, on an individual or aggregated basis, in accordance with the requirements of the German FSA Disclosure Code and FSA Code on cooperation with Patient Organizations.

How Baxter will process and secure this data

Data Disclosure Consent

- HCPs have the right to be informed about their personal data held by Baxter and its purposes for holding it;
- request rectification (correction of their personal data if it is inaccurate or incomplete);
- request the erasure of their personal data, unless Baxter has a legal obligation to process the personal data or another exception applies;
- request that Baxter restricts the processing of their personal data and not delete it under certain circumstances;
- request a machine-readable copy of their data from Baxter, and to have Baxter transmit that data directly to another controller, where technically feasible;
- object to the processing of their personal data for certain purposes; and



- lodge a complaint or concern with Baxter's Privacy Office at privacy@baxter.com or a supervisory authority. They can also withdraw consent to disclose payment information at any time, with the effect for the future, in most countries, or choose not to work with a company. In this regard, Baxter shall abide by local country legislation and the GDPR. The data disclosure withdrawal process is defined in the data privacy and consent form. As explicitly required in the German Disclosure Code, Baxter will collect and store consents. If Employer Consent is explicitly required that will also be collected and stored by Baxter.

Sharing data and international data transfers

Baxter is a global company and therefore uses global subcontractors as well as systems and applications. Baxter may transfer personal data to Baxter's affiliates and subcontractors located outside of the European Union and in jurisdictions which may provide a different level of privacy protection. In such case Baxter, will take measures to ensure that all recipients provide an adequate level of data protection. When transferring personal data between corporate entities, Baxter relies on various legal transfer mechanisms (e.g., standard contractual clauses or Privacy Shield certification) depending on the type of personal data needed and countries involved. Information about such third parties as well as copies of agreements which Baxter entered with them may be requested by writing to privacy@baxter.com.

For the purposes outlined above, Baxter may transfer personal data to EFPIA and its local associations. Furthermore, the data will be publicly available at www.baxter.de.

Consent Management

Baxter will only disclose personal data of HCPs as above related to Transfers of Value only if they have provided their express consent. In accordance with the German FSA Disclosure Code, where consent is not granted, Baxter shall aggregate the data.

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

If an 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

The HCPs' personal data will only be kept for as long as Baxter reasonably considers it necessary for achieving the purposes set out above, not longer than for 6 years after concluding the Agreement, or for as long as Baxter is legally required to keep it.



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 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 endeavors to ensure a process for correcting and/or removing data if on the rare occasion, it is found to be inaccurate. The data privacy and consent form contains a process on how the HCPs can inquire on their data to be disclosed.

Baxter shall ensure procedures for handling enquiries on the disclosures and for making HCOs aware of the disclosures in the data privacy and consent form.

Contact details

Any requests or inquiries pertaining to the processing of personal data at Baxter should be addressed to:

**Frau
Juliane Dietrich-Schröder
Datenschutzbeauftragte
OC Services GmbH
Innere Kanalstraße 15
50823 Köln**

**E-Mail-Adresse:
juliane.dietrich-schroeder@osborneclarke-services.com**

You can also exercise any or your rights or get additional information about your rights, or how we process your personal data, by contacting Baxter's Data Protection Office by email to: privacy@baxter.com; telephone: Ethics and Compliance Hotline at 1-844-294-5418; Mail to: Baxter International Inc., ATTN: Data Protection Officer, Global Privacy Office 1 Baxter Parkway Deerfield, IL USA 60015.