

Methodology for the Disclosure in accordance with the Pharma-Cooperation Code of the Swiss association “scienceindustries”

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Introduction

Baxter AG (“Baxter”) is a member of the Business Association Chemistry Pharma Life Sciences in Switzerland (“scienceindustries”). Scienceindustries is not a direct member of the national Association of the European Association of Pharmaceutical Industries and Associations (EFPIA), but is nevertheless complying with EFPIA standards. Therefore, Baxter is obliged to comply with the Codes of Conduct, including, but not limited to the Pharma-Cooperation Code updated May 14, 2020. 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”) as well as to Patient Organisations (“POs”) in line with the Pharma-Cooperation-Code 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 1 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 practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

Baxter will identify HCPs 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 (except for patient organisations within the scope of the PO Code) 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 HCOs with the full name, city where registered, address and country of practice.

Patient Organizations (“POs”) as defined in the Code of Conduct, Article 10

"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 POs with the full name.

Medicinal Products

Scienceindustries 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 Pharma-Cooperation-Code, 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, 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, disclosure will take place on an individual basis.

If consent is 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 (Article 3.01.1.a of the 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 (as defined in 13.14 of the Pharma-Cooperation-Code (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 (defined in 34.3 of the Pharma-Cooperation-Code):

- i. Registration fees and
- ii. Travel and accommodation

Events as defined in 13.16 of the Pharma-Cooperation-Code 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 as defined in 13.15 of the Pharma-Cooperation-Code 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).

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.

<u>Fees for Services and Consulting</u>
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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 3.01.1.c of the 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 3.01.2.b of the 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 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 (Article 3.04).

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.

Support to Patient Organisations

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 Pharma-Cooperation-Code.

Disclosure Reporting

Local Law Requirements

Refer to Data Privacy Requirements – 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.

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 Pharma-Cooperation-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 in accordance with the Pharma-Cooperation-Code

Annex 2

Data Privacy

Baxter will make its best endeavors to comply with the Data Privacy laws of Switzerland.

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 organizational security measures.

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

- (i) name;
- (ii) address;
- (iii) unique country identifier (if available); 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 Pharma-Cooperation-Code.

How Baxter Will Process and Secure This Data

Data Disclosure Consent

- HCPs, HCOs and POs 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. The data disclosure withdrawal process is defined in the HCP/HCO/PO agreement.

As explicitly required in the Pharma-Cooperation-Code, Baxter will collect and store consent. 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.ch.

Consent Management

Baxter will disclose personal data of HCPs, HCOs and POs as above related to Transfers of Value only if they have provided their express consent. In accordance with the Pharma-Cooperation-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, HCOs and POs to make sure that all agreements contain the necessary consent provisions.

If a HCP, HCO or PO 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', HCOs' and POs' 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 2 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 all HCPs, HCOs and POs, are accurately identified and validated. Baxter endeavors to ensure that the HCP, HCO and PO information is consistently matched with the correct HCP, HCO and PO 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 HCP, HCO and PO agreements contain a process on how they can inquire on their data to be disclosed.

Contact details

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