UCB Global Methodological Note
Pursuant to Chapter 5 of the EFPIA Code of Practice

This note describes the global position from UCB with regards to the EFPIA Code of Practice disclosure requirements. It is subject to change in each country affiliate depending on the local laws and requirements of the local industry code

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1. Context

At UCB, we focus on creating value for people living with severe diseases by delivering medicines and solutions that improve their lives.

We work with stakeholders to address the unmet needs of patients and caregivers, helping them to achieve their goals and to live the lives they want.

Patients, their representatives and their caregivers, medical professionals and organisations can offer invaluable knowledge on patients' needs, behaviour and management of diseases. Engaging with such healthcare stakeholders is therefore essential for UCB and other pharmaceutical companies to improve patient care and treatment and has long been a positive driver for advancements in innovative medicine and patient value creation.

In UCB, we believe that the interest of patients and other stakeholders in the transparency of these interactions is compelling.

We are dedicated to demonstrating complete integrity and honesty in our relationships with healthcare stakeholders, including patient organisations, healthcare professionals and organisations such as hospitals. Those interactions, initiated for proper, scientific reasons, unrelated to any purchases, prescriptions, or distribution of our products by those healthcare professionals or to their position, may be related to transfers of values, whether in kind or in cash.

Such financial relationships should occur without potential conflicts of interest and be fully independent of the clinical decisions. Patients need to know that they can trust their doctor to recommend, prescribe and administer appropriate care and treatments based solely on clinical evidence and experience. UCB recognizes its responsibility in supporting a fair and open partnership and protecting the high standards of integrity that patients, governments and other stakeholders expect. Therefore, our interactions with healthcare stakeholders are based on standards of ethics, integrity and fair market value.

There is an expectation that such interactions between corporations and society are not only conducted with integrity but are also transparent. The pharmaceutical industry believes that it is critical to respond to society's expectations and for this reason, the European Federation of Pharmaceutical Industry and Associations (EFPIA) requires to its member companies to disclose the nature and scale of their interactions with healthcare stakeholders.

As an EFPIA Member Company, UCB is dedicated to complying with the disclosure of transfer of value requirements and is ensuring that our policies continue to align with the industry standards in all the countries where we operate. On an annual basis and as from 2016, UCB is making publicly available details of transfers of value made to Patient Organisations, Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) during the previous calendar year.

This note describes UCB's general methodology used to prepare the disclosure report in accordance with the EFPIA requirements as well as our company interpretation of the above-mentioned requirements. It is subject to changes in each country affiliate depending on the local laws and requirements of the local industry code. These variations will be specified in the local methodological notes linked to country reports.

We hope that this enables public scrutiny and understanding of these relationships, and therefore contribute to the trust of stakeholders and patients in the pharmaceutical industry.

2. Scope

a. Categories of Recipients

The following categories of recipients are included in the disclosure reports published by UCB in accordance with the EFPIA Code of Practice disclosure requirements.

2.1.1. Healthcare Professionals

According to the EFPIA Code of Practice, a HCP is defined as 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 practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

2.1.2. Healthcare Organisations

A HCO is defined as any legal person/entity (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 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.

2.1.3. Patient Organisation (PO)

A PO is defined as a 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.

2.1.4. Patient Organisation Representative

A PO representative is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area.

b. Categories of Transfers of Value

Below are the categories of transfers of value as defined by the EFPIA Code of Practice relating to HCP/HCO disclosure of transfer of value.

EFPIA category	UCB activities
Donation and Grants According to the EFPIA Code of Practice Donations and Grants collectively, mean providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.	This category includes the financial or in-kind donations and grants provided to HCOs by UCB to support programs that foster increased understanding of scientific, clinical, and healthcare issues that contribute to the enhancement of patient care. This type of support is not linked to any benefit in return for UCB. Examples of programs that may be considered for such funding: • Educational workshops for healthcare providers and patients; • Development of educational tools or resources to enhance physician-patient dialogue about treatment of disease; • Innovative technology platforms that enhance management of disease and aim to improve patient lives and their care • Studentship/fellowship program; • Equipment to improve patient care or funding of a research chair at a university; • Donation of services from a third party to an external organization. UCB also supports institutions that raise awareness of the needs of those with severe diseases, to further medical and scientific knowledge, and to build strong communities in several key areas of interest in which UCB operates, such as immunology and neurology. ⚠ No donations or grants are provided to individual HCPs by UCB.
Contribution to costs and events Member Companies must comply with criteria governing the selection and support of HCPs or POs' Representatives to attend Events as provided in, or in connection with, any Applicable Code(s). No payment must be offered to compensate merely for the time spent by the HCP or PO's Representative in attending Events.	This category includes the costs associated with the sponsorship of events fostering medical and scientific knowledge. In return, UCB receives benefits such as opportunities to promote our products, our company, and/or specific disease awareness activities. Benefits covered under the terms of a sponsorship agreement can include: • Rental of booth or exhibit space at an event; • Advertisement space (paper, electronic or another format); • Satellite symposium at a scientific congress; • If part of a package, drinks or meals provided by the organisers; • Corporate membership to an association. ➢ Where allowed, individual sponsorships of HCPs to attend scientific/educational events can occur. These sponsorships are part of UCB's effort to foster continuing medical education and improving

	patient care and may cover travel, accommodation and potential congress registration fee for the HCP. ➢ In case a given HCP could not participate to the congress or meeting for any reason, and therefore could not derive any benefit from it, any costs already incurred in case of such a 'no-show' are not reported. ➢ The logistical and management fees charged by commercial agencies or travel agencies in the context of an event are not part of the disclosure.
Fee for service and consultancy 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.	UCB engages HCPs or HCOs in exchange of a monetary compensation and/or a benefit in kind for purposes such as: • Consulting or advising services (e.g. provision of scientific expertise on specific topics during an advisory board); • Speaker activities (e.g. scientific symposia or other medical/educational meetings, or similar activities at congresses); • Medical writing (e.g. editorial support for scientific publications). ➢ Service Agreements related transfers of value may include fees or honoraria, but also expenses incurred in the course of the provision of the services, such as travel and accommodation. ➢ In case of cancellation, UCB may compensate any services already incurred in the context of a contractual arrangement, such as preparation time for speaker activities and those compensations are included in UCB's reports.
Research and Development 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 536/2014); or (iii) NIS 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.	This section covers all Research and Development activities undertaken to discover and develop new therapies to treat patients suffering from severe diseases, such as but not limited to, clinical trials (UCB-conducted or independently conducted) designed to verify or study the clinical effects of one or more medicinal product(s) and identify any adverse reactions in order to ascertain its (their) safety and/or efficacy, or partnerships with both academia and leading drug discovery foundations. Affiliates that follow the reporting template as recommended by EFPIA disclose Transfers of Value relating to Research and Development in an aggregate format. ⚠ This excludes fees provided in the context of a retrospective Non-Interventional Study (NIS). Such fees and their related expenses are not considered as part of research work as defined above and will therefore be reported under the section *"Fees for Service and Consultancy"* of the Disclosure Report. Similarly, other R&D consultancy services that are not in the scope of a clinical trial agreement are reported under *"Fees for Service and Consultancy"*.

3. Patient Organisation disclosure

According to EFPIA Code of Practice, UCB will disclose as a separate report any financial and/or significant indirect/non-financial transaction with patient organisations that UCB supports or with whom UCB has engaged to provide contracted services.

The disclosure report is including a description of the nature of the support or services.

4. Form of disclosure

a. Excluded from disclosure

In the UCB Disclosure Report the following are not included:

- Transfers of Value relating to food and beverages, as well as informational and educational materials and items of medical utility, are not included in most Reports, in accordance with the EFPIA general guidance.
- In case an HCP or patient/patient representative invited by UCB needs the support from an accompanying caregiver, transfers of value related to that caregiver, such as travel costs, are not included in the Disclosure Report.
- With a view to disclosing data as accurately as possible, Transfers of Value that seemed to be related to technical issues have been filtered out of all Reports.
- Transfers of Value related to commercial agreements with an HCO (e.g. rebate, rental of advertising space) are not in scope of the disclosure requirements, except in countries where the local code specifies otherwise.
- Unless specifically required in a local law or industry code, funding of Continuing Medical Education (CME) events organized by commercial providers are not considered as part of the scope, and therefore not part of the Disclosure Report, on the condition that UCB is not involved in the organisation of the event nor in the selection of participants.
- TOVs related to individual patients are not included in the Disclosure Report.

b. Over-disclosure

In relation to working with HCPs and HCOs, since the introduction of the EFPIA Disclosure Code, EFPIA has worked to encourage Member Companies to always look to disclose and to encourage HCPs (and HCOs where relevant) to agree to individual disclosure. Member Companies will not be criticized for over-disclosure (EFPIA Code of Practice-Introduction section pg.12).

With a view of achieving full transparency, UCB decided to include transfers of value relating to all marketed products, including over-the-counter products as well as molecules or compounds in

development, whenever the purpose and nature is covered by the EFPIA Disclosure requirements (e.g., fees for service and consultancy).

c. Reporting format and Period

UCB is using the reporting template provided by the EFPIA or the local industry associations, or defined per law whenever applicable.

The Disclosure Reports will be available annually at the end of the second quarter of the year subsequent to the reporting period. The reporting period covers all transfers of values that occurred from 1st January to 31st December of the previous year, including the ones related to events attended or services provided before the reported year.

Reports will remain available online for a period of three years.

d. Platform of disclosure

The Disclosure Reports are published on the Global UCB website when there is no local UCB website, and/or for countries without a UCB affiliate in place whenever applicable. In all other instances, the respective Disclosure Reports are either published on the local UCB affiliate website, or on a national platform where required. To facilitate access to the information, links to each of the locally published Disclosure Reports are also available on the Global website.

e. Language

The language of disclosure is by default the language of the country for which it is published.

f. VAT

Value Added Tax (VAT) is included by default in the disclosed transfers of value, but local versions of the methodological note further describe tax particularities and variations. The local currency is used for all disclosed amounts. Non-local currencies are converted, based on the rate at payment date for direct payments, or date of the event for indirect payments.

5. UCB Global Specifics

a. Consent Management

UCB is dedicated to disclose the Transfers of Value (ToVs) under the names of individual recipients. At the same time, UCB is committed to complying with applicable data protection laws, which may impose certain limitations on the ability to make disclosures on an individual basis. Unless a country has a specific legislation governing the transparency of financial relationships with the pharmaceutical industry which supersedes data privacy obligations, UCB makes sure to obtain consent of individual healthcare

stakeholders prior to the actual disclosure. UCB preferred approach for consent collection is on a contract by contract basis.

UCB recognizes the right of an individual to decline or revoke consent to the publication of individual transfers of value. As a general rule, UCB has decided not to consider disclosure consent as a prerequisite for collaboration. However, UCB will not accept partial consent when the refusal or revocation only concerns a specific transfer of value or a specific time period.

When individual disclosure is declined or revoked, disclosure will happen at an aggregate level, meaning a total amount per categories as defined above for the number of anonymous recipients. Accepting revocation of consent for one or more recipients implies that Disclosure Reports are subject to change, even after publication.

b. ‘‘Follow the money’’

UCB adheres to the general principle of “follow the money”: whenever possible, the ultimate beneficiary of a transfer of value is the one that shall be reported. The Disclosure Report includes all transfers of value to any covered recipient (as defined above) regardless of whether it has been handled by UCB directly or through a third party acting on behalf of UCB (indirect payment). If the names of the individual beneficiaries as well as the benefit/actual amount are known to UCB, all the related transfers of value made on behalf of UCB will be reported under the name of the ultimate beneficiary (including non-blinded market research for instance).

Payments made to a legal entity such as an HCO are reported under the name of that legal entity. This way of reporting is subject to changes in each country affiliate depending on the local laws and requirements of the local industry code. These variations will be specified in the local methodological notes linked to country reports.

Each transfer of value is only reported once, in the recipients’ country of principal practice, taking as a reference the physical address where the individual has is home address or primary professional practice or where the HCO/PO is registered, regardless of whether the transfer of value occurs within or outside of that country.