UCB Global Methodological Note

Pursuant to Chapter 5 of the EFPIA Code of Practice and Clause 24 of the ABPI Code of Practice

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 demonstrate complete integrity and honesty in our relationships with healthcare stakeholders, including patient organisations, individual patients and their caregivers, 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 (TOVs) 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 its member companies to conduct a detailed disclosure regarding the nature and scale of their interactions with healthcare stakeholders.

As an EFPIA Member Company, UCB is dedicated to comply with the disclosure of TOV 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 all TOVs made

to Patient Organisations, Patients and their caregivers, Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) during the previous calendar year.

This note describes UCB's general methodology used to prepare the disclosures in accordance with the EFPIA requirements as well as our company interpretation of the EFPIA Disclosure Code whenever this was required. Any variations or clarifications based on the requirements of the ABPI code have also been included for submission with the UK country report.

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

2.1. 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 and ABPI Code of Practice disclosure requirements.

2.1.1. Healthcare Professionals

According to the ABPI Code of Practice, a HCP is defined as any 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.
For the purpose of this document also included under the definition of HCPs are those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but are not health professionals ("Other relevant decision makers").

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 such as a hospital, clinic, foundation, medical teaching institution or learned society (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.

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.

2.1.5. Patient and caregiver

A patient is a person who is awaiting or under medical care and/or treatment; a caregiver is a person (not being an healthcare professional) who provides direct care to a patient.

It should be noted that in case a HCP or patient/patient representative invited by UCB needs the support from an accompanying caregiver, TOVs related to that caregiver, such as travel costs, are not included in the Disclosure Report.

2.2. Categories of Transfers of Value (TOVs)

Below are the categories of TOVs as defined (provided directly by UCB or through an intermediary) as defined by the EFPIA Code of Practice relating to HCP/HCO disclosure of TOV.

2.2.1. Donations and Grants

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.

When UCB marketed products are provided as in-kind donation to HCO, the value assigned is calculated using the cost ex-factory.

2.2.2. Contribution to Costs of 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 other format);
- Satellite symposium at a scientific congress;
- If part of a package, drinks or meals provided by the organisers;
- Corporate membership to an association.

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.

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.

When it is not possible to accurately allocate a TOV to a single recipient because the beneficiaries are a group of HCPs or HCOs, then the TOV will be divided equally among the number of recipients assuming that all have received an equal share of the TOV.

2.2.3. Fee for Service and Consultancy

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 TOVs 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.

2.2.4 Joint Working Contributions

This category includes the financial and in-kind TOV provided to HCOs by UCB as part of any joint working agreements to develop or implement patient centred projects. An executive summary providing more details about any such project would be made available on UCB website.

2.2.5. Research and Development

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.

Research and Development TOVs are reported 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".*

2.3 Reporting Format and Reporting Period

UCB is using the reporting template provided by the ABPI.

The Disclosure Reports will be available annually at the end of the second quarter of the year subsequent to the reporting period. For instance, the 2020 reports cover all TOVs that occurred in 2019, including the ones related to events attended or services provided in 2018.

Where the ToVs relate to multi-year contracts, only the ToVs made in the reporting year are included.

Where the ToV is a benefit in kind, the reference date is the date in which the recipient received the benefit.

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

3. UCB Specifics

3.1 Consent Management

3.1.1. Disclosure Consent

UCB is dedicated to disclose the 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. In the case of multi-year contracts that were in place before the introduction of disclosure consent, a retrospective consent has been sought.

In case consent is either not given by the Recipient or not documented sufficiently to prove the existence of consent, ToVs are disclosed on the aggregate level.

3.1.2 Individual and Aggregate Disclosure

UCB recognizes the right of an individual to decline or revoke consent to the publication of individual TOVs. 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 TOV 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.

3.2 Pre-disclosure

UCB wishes to offer to HCPs and HCOs the possibility to individually review their own Transfers of Value before disclosure and is notifying them during a pre-disclosure phase before the information is made public. During this phase, recipients are allowed to request access to their detailed information and can dispute the information UCB is intending to publish.

3.3 “Follow the Money”

3.3.1 Ultimate Beneficiary

UCB adheres to the general principle of “follow the money”: whenever possible, the ultimate beneficiary of a TOV is the one that shall be reported. The Disclosure Report includes all TOVs 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 TOVs made on behalf of UCB will be reported under the name of the ultimate beneficiary (including non-blinded market research for instance). TOVs related to market research for which the identity of the HCP/HCO are not known to UCB are not disclosed.
Payments made to a legal entity such as a HCO are reported under the name of that legal entity. UCB will not aggregate the TOVs under an overarching institution (e.g. hospital and hospital departments).
Each TOV 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 TOV occurs within or outside of that country.
TOVs to individual HCPS for an annual event via the European Medicines Group of which UCB Pharma are one of the 19 member companies are reported as 1/19th of the total value.

3.3.2. Tax and Currency

Value Added Tax (VAT) is included by default in the disclosed TOVs. The local currency is used for all disclosed amounts. Non-Euro currencies are converted to GBP as well, based on the rate at payment date for direct payments, or date of the event for indirect payments.

3.4 Public Disclosure at UCB

3.4.1. Publication

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. The Disclosure Report for UK is available here http://www.abpi.org.uk/our-work/disclosure/Pages/DocumentLibrary.aspx

3.4.2. Language

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

3.5 Other Specifics

TOVs 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.

With a view of achieving full transparency, UCB decided to include TOVs 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 Code (e.g., fees for service and consultancy).

TOVs 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.

With a view to disclosing data as accurately as possible, TOVs that seemed to be related to technical issues have been filtered out of all Reports.

Depending on contractual agreements, distributors of UCB products could be responsible for disclosing TOV independently from UCB and in accordance with their own compliance requirements.