

UCB Pharma UK: Methodological Note

Pursuant to Section 3.05 of the EFPIA Disclosure Code and Clause 24 of the ABPI Code of Practice

1. Context

As the primary point of contact with patients, the medical professions and organisations can offer invaluable and expert knowledge on patients' 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 professionals, universities, and 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 a growing 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 heightened expectations and for this reason, the European Federation of Pharmaceutical Industry and Associations (EFPIA) has created the EFPIA Disclosure Code requiring its member companies for a detailed disclosure regarding the nature and scale of their interactions with healthcare professionals and organisations.

As an EFPIA Member Company, UCB is dedicated to comply with the new transparency 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 makes publicly available details of Transfers of Value made to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) during the previous calendar year.

This note describes UCB's 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, by taking this significant step, it will enable 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 Disclosure Code and ABPI Code of Practice.

2.1.1. Healthcare Professionals (HCPs)

According to the ABPI Code of Practice a HCP is defined as any member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may administer, prescribe, purchase, recommend or supply 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 (HCOs)

A HCO is defined as any legal person (i) that is a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA Patient Organisation Code) or (ii) through which one or more HCPs provide services.

It should be noted that in case a HCP invited by UCB needs the support from a non-HCP accompanying caregiver, transfers of value related to that caregiver, such as travel costs, are not included in the Disclosure Report.

2.2. Categories of Transfers of Value

Below are the categories of transfers of value (provided directly by UCB or through an intermediary) as defined by the EFPIA Disclosure Code and ABPI Code of Practice.

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.

Any benefits in-kind that have been identified have been captured where possible as an estimated monetary value and have been added to the total Transfers of Value for disclosure.

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.

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 Transfer of Value to a single recipient because the beneficiaries are a group of HCPs or HCOs, then the Transfer of Value will be divided equally among the number of recipients assuming that all have received an equal share of the Transfer of Value.

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 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.

2.2.4. Joint Working Contributions

This category includes the financial and in-kind transfers of value provided to HCOs by UCB as part of any joint working agreements to develop or implement patient centred projects.

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 Transfer of Values 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. In this report, UCB discloses Transfer of Values that occurred from 1st January 2016 to 31st December 2016.

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 at least three years.

3. UCB Specifics

3.1. Consent Management

3.1.1. Disclosure Consent

UCB is dedicated to disclose the Transfers of Value 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 professionals 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 a healthcare professional 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.

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 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). Transfer of Values 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 Transfers of Value under an overarching institution (e.g. hospital and hospital departments).

Each Transfer of Value is only reported once, in the recipients’ country of principal practice, taking as a reference the physical address where the HCP practices or where the HCO is registered, regardless of whether the Transfer of Value occurs within or outside of that country.

3.3.2. Tax and Currency

Value Added Tax (VAT) is included by default in the disclosed Transfers of Value. 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 in 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:

Transfers of Value related to commercial agreements with an HCO (e.g. rebate) 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 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 Code (e.g. fees for service and consultancy).

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.

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.

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