

Immedica Pharma UK and IE Ltd

Methodological Notes for Ireland Disclosures 2022

Contents

- Background
- Definitions
- Kind of transfers of value
- How we record Transfers of value
- How we manage Transfers of Value
- Consent collection
- Tax and VAT considerations
- Joint working
- Cross border requests
- Research and Development
- Other relevant information
- Glossary of terms
- References/Links
- Contacts

Background

Immedica Pharma are committed to working transparently with healthcare professionals and organisations. We believe they should be fairly compensated for the services they provide to pharmaceutical companies. The EPFIA Disclosure Code and the Irish Pharmaceutical Healthcare Association (IPHA) code of practice provides accuracy and transparency in disclosing the scope and value of such collaborative work.

Immedica Pharma has robust processes for engaging with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs). All engagements are planned in accordance with The ABPI and IPHA Codes of Practice.

The ABPI and IPHA Codes of Practice require Immedica Pharma to disclose specific transfers of value to HCPs and HCOs.

This requires companies to document and publicly disclose transfers of value (ToV) made directly or indirectly to HCPs and HCOs. Companies must also publish a note summarising the methodology used for disclosures which also highlights each category of ToV.

This document sets out the methodology used by Immedica Pharma UK Ltd in Ireland for recording Transfers of Value in 2022.

Definitions

Definition of an HCP:

The term 'healthcare professional' includes members of the medical, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

Disclosure will also apply to 'other relevant decision makers' (ORDMs), this includes 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 who are not health professionals.

Definition of an HCO:

The term 'healthcare organisation' means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or ORDMs provide services.

Transfer of Value (ToV)

The term 'transfer of value' means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of the recipient. An indirect transfer of value is one made by a third party on behalf of a company for the benefit of a recipient where the third party's identity is known to, or can be identified by, the company. An indirect transfer of value could also be the cost of travel or accommodation incurred by the company in order for the HCP to complete work where the HCP has been contracted by the company (e.g. attending an advisory board meeting).

Fair Market Value (FMV)

Immedica Pharma usually compensate HCPs for their time when working with the company. The payment rate is determined by a process known as Fair Market Value (FMV). This is an industry-wide standardised calculation which tells the company what a HCP would actually earn for their time in practice, based on their specific credentials and qualifications. Immedica Pharma uses this information to ensure each HCP's compensation is fair and reasonable for the amount of time necessary to provide the requested service. The fee provided by Immedica Pharma is a calculation based on preparation, disturbance (travel) and actual time costs. All arrangements and payments require internal approval. An HCP may also decide not to be paid (e.g. altruistic reasons, own hospital rules for interactions with pharmaceutical companies, etc.)

Kind of transfers of value

Contracted Services

Health professionals, other relevant decision makers or their employers on their behalf, healthcare organisations, patient organisations, individuals representing patient organisations, and members of the public, including patients and journalists, may be used as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/ scientific studies, clinical trials or training services, writing articles and/or publications, participation at advisory board meetings, and participation in market research where such participation may involve remuneration and/or hospitality.

Examples of contracted services disclosed by Immedica Pharma include the following:

Meeting Sponsorship - Immedica sponsors a scientific or professional meeting, congress, conference, symposia, or other similar event arranged by or on behalf of healthcare organisation or a patient organisation

Sponsorship for HCPs to Attend Educational Meetings - Immedica may provide support for individual HCPs or other ORDMs to attend events. Support in this context is the provision of a financial contribution, in whole or in part, whether paid directly or indirectly to individual health professionals or other relevant decision makers to attend events.

Speaker Agreements – Immedica may engage healthcare professionals to provide consultancy services in relation to a meeting such as a speaker at a symposium.

Advisory board agreements - Immedica wishes to engage an HCP or ORDM to serve as an advisor at a meeting

Donation and grants - Donations and grants are funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return. Donations and grants to individuals are prohibited.

Examples of donations and grants disclosed by Immedica Pharma include the following:

Grant Agreements - Grants are the provision of funds. Immedica is approached by independent companies to provide funding in relation to educational projects. These circumstances require that Immedica has no influence over the details of the project.

Donation Agreements- Donations provided by Immedica may include physical items, services or benefits-in-kind which may be offered or requested.

Donations to HCOs are disclosed on an excel spreadsheet on the Immedica global website. Donations to patient organisations are disclosed on the company website.

How we record transfer of value and consent

Transfers of Value data were manually captured and maintained in the form of an Excel spreadsheet (the “Disclosure and Contract Tracker” , specifying (as relevant):

Description of the event, who is responsible from Immedica, the relevant approval reference, date of the event, transfer of value recipient, name of the healthcare organisation (HCO), nature of support, status of consent for individual disclosure obtained and the amount of TOV to be disclosed. Evidence of their consent is also saved separately.

How we manage transfers of value

Data Capture:

The Medical and Marketing UK and Ireland functional area of the business were responsible for uploading the data in the Disclosure and Contract tracker.

Data Review and Validation:

Immedica Pharma has disclosed Transfers of Value that were made to UK and IE HCO’s, HCP’s and ORDMs during the period 1st January 2022 and 31st December 2022.

Where a UK or IE HCP or ORDM was contracted prior to 2022, but actually received their Transfer of Value in 2022, the 2022 Disclosure report includes these Transfers of Value.

The completed disclosure and contract tracker was subject to review and sign off by the UK’s General Manager, finally signed off by Immedica Pharma UK Medical Director and data was then entered onto a spreadsheet published on the Immedica global website.

All disclosures of transfers of value during this timeframe are disclosed individually when there is a legal basis to allow it (e.g. individual consent have been obtained), otherwise they are disclosed in aggregated form.

Consent collection

HCO consent

In United Kingdom of Great Britain & Northern Ireland HCOs are reported without the need for consent as they are legal entities.

HCP consent

All efforts have been made to achieve a high level of individual HCP payment disclosure whilst recognising the UK and IE Data Act and the General Data Protection Regulation (GDPR). A consent clause and consent agreement forms are included in every engagement contract.

Tax and VAT considerations

VAT was included where applicable to contracts.

- Fee for service – not applicable
- Out of pocket expenses – the entire expense is disclosed
- Registration fees – cost including VAT is disclosed
- Travel and accommodation – cost including VAT is disclosed
- Other transfers of value (sponsorships etc) - the cost excluding VAT is disclosed

It is the responsibility of the receiving HCP to settle local tax requirements.

Joint working

Where Immedica Pharma jointly markets a product with another pharmaceutical company, Immedica Pharma will only declare those payments made directly from Immedica Pharma. Immedica Pharma endeavours to make all of its ToV through bank accounts. These transactions are listed and kept as part of the normal business operation and used to support the ToV Disclosure preparation. ToV made by its co-marketing partners will be disclosed separately by those organisations

Cross border requests

Cross border payments are disclosed in the country that the HCP is registered to practice.

Research and Development

All payments to a HCP, HCO and patient organisations relating to research and development are disclosed as aggregate figures in accordance with local Codes of Practice. These may include, Pre-clinical research and clinical research (includes Investigator Sponsored Research (ISR)), Non-interventional Studies, Advisory Boards and consultancy services in relation to clinical research, Real world data studies and Health Outcomes research.

Other relevant information

1. Transfers of value were initially registered in the currency paid by Immedica Pharma UK. Immedica uses the annual average exchange rates from the Bank of England. All transfers of value paid in 2022 to Irish recipients were paid in EUR.
2. Transfers of Value were made to an HCP/ORDM directly or to a relevant organisation directly.
3. Multi-year contracts - Immedica will not engage in multi-year contracts
4. Immedica Pharma over the counter transfers of value are not applicable, hence this is not covered in this methodology
5. Immedica Pharma medical device transfers of value are not applicable, hence this is not covered in this methodology

Glossary of Terms

ToV – Transfer of value

EFPIA - European Federation of Pharmaceutical Industries and Associations

ABPI – Association of the British Pharmaceutical Industry

HCP – Healthcare Professional/Health Professional

IPHA - Irish Pharmaceutical Healthcare Association

ORDM – Other Relevant Decision Maker

HCO – Healthcare Organization

FMV- Fair Market Value

References

- 2021 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations
- 2021 IPHA code of practice, edition 8.5: https://2hmcryw3psofj2qo3f8w6f17-wpengine.netdna-ssl.com/wp-content/uploads/2021/03/IPHA-Code-of-Practice-for-the-Pharmaceutical-Industry-V8.5_effective-01.03.21.....pdf

Contacts

For further information, please contact:

compliance.uk@immedica.com