

Immedica Pharma UK Ltd

Methodological Notes for Disclosure 2019

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Background

Collaborative working between medical professionals and healthcare organisations has long been important for advancements in patient care and the development of innovative medicines.

Healthcare professionals and organisations should be fairly compensated for the services they provide to pharmaceutical companies. The EPFIA Disclosure Code and the Association of British Pharmaceutical Industry (ABPI) 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 Irish Pharmaceutical Healthcare Association (IPHA) Codes of Practice.

Clause 24.1 of the Association of the British Pharmaceutical Industry's Code of Practice (ABPI Code) states *"Companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe"*.

To this end, Clause 24.10 states that *"Each company providing transfers of value must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of transfer of value."*

This document sets out the methodology used by Immedica Pharma UK Ltd in the UK for recording Transfers of Value in 2019.

Definitions

Definition of an HCP:

The term 'health 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. A 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

Sponsorship – Sponsorship may include fees for service and consultancy and related expenses. Financial or non-financial support to legitimate, established organisations for medical or scientific education of external stakeholders, organising or hosting educational or scientific events

ToVs are made to either the HCO directly or to an event organiser or other third party appointed by the HCO to manage the event. In all cases, ToVs are disclosed against the HCO that ultimately benefits.

Donation and grants– A donation is defined as a payment where there is no obligation on the part of the receiver and as such is a free contribution. Such donations cannot be given to a HCP as this would be considered a potential breach of any local anti-bribery laws. Donations can only be provided to HCOs and patient organisations and in these situations there is mandatory requirement for an approved agreement that is signed by both parties on the basis that both parties will publicly disclose the donation. Grants may include contributions or sponsorships (or referred to as grants) that support initiatives in HCP Education, including education about healthcare systems and practices, medical or scientific research, or partnerships.

Non-monetary transfers of value - Such ToV would be quantified on the cost of the apparatus provided (e.g. as part of a clinical trial) or calculated on an hourly basis determined by the fair market value.

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 “Transfers of Value Tracker” (Contract Tracker or TVT), specifying (as relevant):

Name of the event, date of the event, healthcare professional’s (HCP’s) or other relevant decision maker’s (ORDM’s) name, name of the healthcare organisation (HCO), nature of support, permission for individual disclosure obtained.

How we manage transfers of value

Data Capture:

The marketing UK functional area of the business was responsible for uploading the data in the TVT.

Data Review and Validation:

Immedica Pharma UK has disclosed Transfers of Value that were made to UK HCO's, HCP's and ORDMs during the period 1 January 2019 and 31 December 2019.

Where a UK HCP or ORDM was contracted prior to 2019, but actually received their Transfer of Value in 2019, the 2019 Disclosure report includes these Transfers of Value.

The completed TVT 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 the ABPI approved spreadsheet.

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.

Submission to ABPI:

The completed Immedica Pharma UK ABPI spreadsheet is submitted to the ABPI in 2020 - <https://www.abpi.org.uk/our-ethics/disclosure-uk/>

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 Data Act and the General Data Protection Regulation (GDPR). A consent clause and consent agreement forms are included in every engagement contract. Consent is also followed up with each individual HCP via email before disclosures are published.

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. Immedica Pharma will not be engaging in any research and development at this point.

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 2019 were paid in GBP.
2. Transfers of Value were made to a HCP/ORDM directly or to a relevant organisation directly.
3. Where consent to disclose was not provided, data has been provided in aggregate format.
4. Multi-year contracts - Immedica will not engage in multi-year contracts
5. Immedica Pharma over the counter transfers of value are not applicable, hence this is not covered in this methodology
6. Immedica Pharma medical device transfers of value are not applicable, hence this is not covered in this methodology
7. Company name change – Medical Need UK Ltd changed its name to Immedica Pharma UK Ltd during 2019. The process for collection of ToV remains the same and all relevant disclosures can be easily tracked. 2019 disclosures will include both Medical Need and Immedica Pharma

Glossary of Terms

ToV – Transfer of value

EFPIA - European Federation of Pharmaceutical Industries and Associations

ABPI – Association of the British Pharmaceutical Industry

TVT – Transfer of Value Tracker (Contract Tracker)

HCP – Healthcare Professional/Health Professional

ORDM – Other Relevant Decision Maker

HCO – Healthcare Organization

FMV- Fair Market Value

References

- 2019 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations
- 2019 ABPI Code of Practice for the Pharmaceutical Industry:
 - Health professional (HCPs) are defined in Clause 1.4, other relevant decision makers (ORDMs in Clause 1.5), and healthcare organizations (HCOs) in Clause 1.9
 - Clause 24
 - Clauses 24.3 and 27.7 (whereby transfers of value to patient organizations are disclosed separately)