Disclosure of Certain Transfers of Value from Clinigen Healthcare Limited to Health Professionals and Healthcare Organisations in 2020

Methodological Note

Purpose

In order to meet the European Federation of Pharmaceutical Industries and Associations (EFPIA) Transparency Code requirements as transposed locally into The Association of the British Pharmaceutical Industry (ABPI) Code of Practice in the UK, Clinigen has to collect financial data related to direct or indirect Transfers of Value (ToV) to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs). ToV is a self-regulatory initiative created by EFPIA and local country associations behind which there is no legal obligation.

Clinigen Healthcare Limited (part of the Clinigen Group) has agreed to comply with the ABPI Code of Practice and accept the jurisdiction of the Prescription Medicines Code of Practice Authority (PMCPA), which operates the Code independently of the ABPI.

Clinigen legitimately engages with HCPs and HCOs to provide valuable, independent and expert knowledge derived from their clinical and management experience. This expertise makes an important contribution to improving the quality of patient treatments.

As well as services, Clinigen also provides grants and donations to HCOs in response to unsolicited requests to support programmes that cover unmet needs and improve patient care. Clinigen supports the continuing medical education of HCPs by covering the costs of their fees, travel and accommodation to attend educational events. This sponsorship helps ensure that HCPs are able to provide patients with the highest quality of care.

Definitions

ABPI	Association of the British Pharmaceutical Industry
EFPIA	European Federation of Pharmaceutical Industries and Associations
FMV	Fair Market Value
HCOs	Healthcare Organisations - 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 other relevant decision makers provide services
HCPs	Healthcare Professionals - members of the medical, dental, 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

ORDM Other Relevant Decision Makers - 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

R&D Research and Development

ToV 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. Transfer of Value may be a) direct ToV - made directly by Clinigen for the benefit of a Recipient, or b) indirect ToV - made by a third party (such as contractors, agents, partners, affiliates (including foundations) on behalf of Clinigen for the benefit of a Recipient, where the identity of such Recipient is known or can be identified by Clinigen)

Grants and Donations

Grants and Donations are payments made to a third party without agreement or intent to receive any tangible or intangible return in exchange for such payment. A Grant to organisations or groups of HCPs or patients may be paid when it is requested to cover all or part of the cost of an event, project or program that has a scientific objective (education, health or welfare). A Grant to other organisations or groups, may be paid when it is requested to cover all or part of the cost of an event, project or program that has a cultural or charitable objective and is consistent with Clinigen ethical values.

Grants can include some research-related grants, including external sponsored studies.

Contribution to Costs of Events

This is composed of 3 categories:

- Registration fees paid by Clinigen to accommodate HCP/HCO attendance at an event
- Sponsorship agreements with HCOs or third parties appointed by an HCO to manage an event (e.g. rental of booths, advertisement space, satellite symposia at a Congress)
- Travel and accommodation provided to a HCP/HCO for an event (e.g. flights, trains, car hire, bus, tolls, parking fees, taxis and hotel accommodation). For mass group transport (e.g. a bus/coach) organised for an event, the cost is allocated to each individual HCP having benefited from the travel.

Fees for Service and Consultancy

In this category Clinigen discloses at an individual level, fees and related expenses agreed in the consultancy contract, in two separate cost types:

- Fees (e.g. Speaker's fees, Speaker training fees, medical writing fees, medical publication support fees, general consulting/advising fees, advisory board fees, market research fees)
- Related expenses (e.g. flights, train, taxis, hotel accommodation)

R&D

ToV to HCPs or HCOs related to the planning or conduct of:

- Non-clinical studies

- Clinical trials

- Non-interventional studies 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 and that are intended for submission to regulatory authorities.

Examples of R&D ToV that are disclosed in this section are clinical study agreements, consulting services agreements, speaker agreements, advisory boards, investigator meetings, ethics committee fees.

Exclusions

All direct and indirect ToV to an HCP/HCO are in the scope of this procedure, except those solely related to meals and drinks, medical samples, all ordinary course purchases and sales of medicinal products or logistical costs (e.g. hire of a facility associated with a stand-alone event).

Disclosure Consent Management

Consent collection

The collection and use of personal data are subject to data protection legislation and applies to HCPs. The purpose of the legislation is to afford rights to individuals and to assure them that information which is held about them, and from which they can be identified, may only be gathered and used if certain stipulated conditions are met. In order for Clinigen to publicly disclose a ToV from Clinigen to a HCP on an individual basis, data protection legislation requires prior consent from the HCP. Written consent is collected per activity using a standard template which includes reference to the Codes and local data protection legislation. Consent clauses are also integrated into consultancy contracts. HCPs retain the right to refuse to disclose their information and will retain their right under the law to seek correction of mistakes or deletion of their information. Signed consents should be archived and accessible for a minimum of 5 years.

Disclosure consent status

If the HCP gives their consent, ToV can be disclosed on an individual basis. If the HCP refuses to give their consent, ToV must be disclosed in an aggregated way. If there is no information regarding the disclosure consent for a ToV, data must be reported on an aggregated basis.

Disclosure consent refusal

If a HCP does not give consent for disclosure, then this should not be to their disadvantage; Clinigen should continue working with them.

Disclosure consent revocation

If a HCP revokes their consent, their data must be reported on an aggregated basis.
Consent can be revoked before or after the disclosure:

- In the case of pre-disclosure revocation: The status of the consent for the relevant expenses must be changed in the data tracker
- In the case of a post-disclosure revocation: The status of the consent for the relevant expenses must be changed in the tracker, and the Disclosure report updated

Partial disclosure consent management

Partial disclosure consent occurs when a HCP gives consent for one ToV, but refuses disclosure for another. Consistent with EFPIA position on this topic, at Clinigen, the rule is the following: If a Recipient has received a number of ToV from Clinigen within the same reporting period, and decides not to agree to disclosure of one or more of those ToV, then Clinigen discloses all the individual's ToV in its aggregate amount.

Disclosure Methodology

Disclosures should be publicly accessible in the country where the Recipient has their principal practice. By 30 June 2021, and annually thereafter, all payments made by Clinigen to UK HCPs, ORDMs and HCOs during the previous calendar year will be disclosed on a searchable and publicly accessible central database on the ABPI website known as Disclosure UK, accessed via the following web address: www.disclosureuk.org.uk.

A methodological note will be published with the Disclosure report using the general ABPI template. The information disclosed must remain in the public domain for a minimum of 3 years. Clinigen will maintain relevant records of the disclosures for a minimum of 5 years after the end of the relevant reporting period.

During 2020 Clinigen made transfers of value in respect of their pharmaceutical products in the following areas:

- Fees for service
- Travel Expenses

The following considerations have been made to accurately record transfers of value

1. VAT incurred for fees for service has been included in the total amount disclosed

2. Disclosure of work for which payment is outstanding:
   a) In situations where work was conducted in 2020 with invoices submitted in 2020, but not paid until 2021, the value is NOT included in the 2020 disclosure document.

   b) Once invoices are received and payment made they will be recorded in the year that the HCP/HCO receives payment.

3. Payments to HCPs were made in GBP and Euro at the exchange rate of 0.92 GBP to Euro for payments made in April 2020 and at a rate of 0.87 GBP to Euro for payments made in May 2020.
4. Payments to non-UK HCPs are included as part of this disclosure due to no means to disclose in their country of registration.

Dispute Management

According to data privacy regulations, HCPs have the right to access, correct or object to publication of their personal data. Any disputes or queries will be managed as follows:

Pre-disclosure

If a HCP/ORDM/HCO contacts Clinigen directly, they should be advised to login to the ABPI Disclosure system (as detailed in the ABPI pre-disclosure letter) and raise their query on the pre-disclosure database. The ABPI's database partner will generate an email containing the HCP/ORDM/HCO's contact details, details of the queried item(s) and any comments made by the HCP/ORDM/HCO. This email will be sent to the Clinigen medical information email address (mi@clinigengroup.com) within two working days of receipt of the query. Clinigen have 14 days to investigate the query and notify the ABPI of the outcome.

If required, the Disclosure UK database partner will then, within two working days, update its records, and the agreed figure will be published on the disclosure database. Disputed information will be updated in DCT if required and the ABPI Report will be updated.

Post-disclosure

The pre-disclosure database will remain accessible to HCPs/ORDMs/HCOs once the Disclosure UK database goes live. If a HCP/ORDM/HCO needs to raise a query after the database has gone live, they should be encouraged to do this on the pre-disclosure database using their individual login name and secure ID. This will ensure that each query is tracked from start to finish and to make sure that an individual's data privacy is not breached. If a HCP/ORDM/HCO is unwilling to use the pre-disclosure database they should be advised to contact the ABPI using the following email address: info@disclosureuk.org.uk. Once received, the ABPI will raise the query with the Disclosure UK database within two business days and follow the process outlined above.