

Methodology Note for Activity for Accord Healthcare Ireland Ltd reporting of Transfer of Values

1. PURPOSE

There has been growing public interest in the nature of the Pharmaceutical industry's relationships with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs). Critically, the public want to know that such relationships do not unduly influence clinical decisions; that they can trust their HCP to recommend, administer or purchase appropriate care and treatments based solely on clinical evidence, education and experience.

Accord Healthcare Ireland Ltd¹ legitimately engages HCPs and HCOs to provide valuable, independent and expert knowledge derived from their clinical and management experience. This expertise makes an important contribution to our efforts to improve the quality of patient care. It is right that Accord Healthcare Ireland Ltd compensates them for their services and this is one of the legitimate reasons why Accord Healthcare Ireland Ltd transfers value to HCPs and HCOs.

As well as services, Accord Healthcare Ireland Ltd also provides grants and donations to HCOs in response to unsolicited requests to support programmes that cover unmet needs and improve patient care.

Accord Healthcare Ireland Ltd also supports the continuing medical education of HCPs by covering the costs of their fees, travel and accommodation to attend educational events. This responsible sponsorship helps ensure that HCPs are able to provide patients with the best quality of care.

The Medicines for Europe Code of Conduct requires companies to document and publically disclose certain transfers of value made to healthcare professionals and healthcare organisations, and these include information about the payments of other transfers of value provide.

The Medicines for Europe Code of Conduct also requires member companies to publish a note summarising the method used by the company in preparing its Disclosure Report and identifying transfers of value for each category of spend relating to HCPs and HCOs ("Methodology Note"). This document represents Accord Healthcare Ireland Ltd's Methodology Note for the reporting period 1st January 2019 to 31st December 2019.

2. PRINCIPLES

Accord Healthcare Ireland Ltd is committed to making the transfers of value made to HCPs and HCOs transparent. In making them transparent all reasonable efforts will go into making sure they are accurate, valid and complete.

Accord Healthcare Ireland Ltd complies with all laws, rules and regulations. Laws in the EU protect the rights of citizens in relation to the way their personal data is processed. HCPs are covered by Data Privacy laws and this affects the way in which Accord Healthcare Ireland Ltd can publish the HCP's transfers of value. Equally, confidentiality clauses within contracts with HCOs may prohibit Accord Healthcare Ireland Ltd from disclosing the transfer of value.

Where Accord Healthcare Ireland Ltd has been unable to obtain consent from an HCP that is fully compliant with General Data Protection Regulation (GDPR), or other legal reasons prevent Accord Healthcare Ireland Ltd from disclosing individually for an HCP or HCO, their transfers of values have been added to an aggregate figure within the Disclosure Report. Please see the 'Reportable transfers of value to HCPs/ HCOs' section within this Methodology Note for more information.

3. SCOPE

This Methodology Note applies to the Disclosure Report for Accord Healthcare Ireland Ltd's transfers of value to UK HCPs and HCOs as required by Medicines for Europe Code of Conduct for the reporting period 1st January 2019 to 31st December 2019.

4. DEFINITIONS

Event

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events, including:

- Advisory board meetings
- Visits to research or manufacturing facilities
- Planning, training or investigator meetings for clinical trials and non-interventional studies (each, an "Event") organised or sponsored by or on behalf of a company.

Healthcare Professional (HCP)

Anyone that is a member of the medical, dental, pharmacy or nursing professions and any other persons in the course of their professional activities may, administer, prescribe, purchase, recommend or supply a medicine.

Healthcare Organisation (HCO)

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 entity through which an HCP (as defined above) or other relevant decision makers provide a service.

5. REPORTABLE HCPs AND HCOs

When allowed to do so, the title, first name, initial, last name, city of principal practice where registered, country of principal practice, institution, post code and email will be published alongside details of the transfer of value to an HCP. All transfers of value made to the HCP within the reporting period will be added together and within each reportable category and the total value published.

When allowed to do so, city where registered, principle address will be published alongside details of the transfer of value to an HCO. All transfers of value made to the HCO within the reporting period are to be disclosed on a per activity basis.

6. REPORTABLE TRANSFERS OF VALUE

6.1 Research and Development (R&D) transfers of value

These are activities related to the planning or conduct of studies that fall under one of the following categories:

- Conducting non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice)
- Phase I to IV clinical trials (as defined in applicable EU legislation)
- Non-interventional studies

R&D transfers of value will be disclosed in an aggregate form in line with Medicines for Europe Code of Conduct requirements.

Research activities by Accord Healthcare Ireland Ltd are not undertaken solely for the purpose of obtaining a marketing authorisation for medicinal products. Studies that are not intended for submission to regulatory authorities do not fall under the disclosure category "R&D transfers of value". These transfers will still be disclosed but in either the "Fee for service and consultancy" or "Donations and Grants to HCOs" categories as applicable.

6.3 Donations and Grants to HCOs

Donations and Grants to HCOs that support healthcare, including donations and grants to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare. These transfers of value are altruistic in nature.

6.4 Contribution to costs of Events

6.4.1 Sponsorship agreements with HCOs/ third parties appointed by HCO to manage an Event.

These are the payments that Accord Healthcare Ireland Ltd has made to third parties to organise Events (see definition). This category includes direct funding such as a sponsorship fee or the right to exhibit a stand. The transfers of value may have been to sponsor these activities:

- Rental of trade fair stands at an event;
- Advertising space (in hard copy, electronic or other format);
- Satellite symposia at a congress;
- Support for a speaker/a faculty;
- Drinks and meals provided by the event organiser, if they are part of the overall package (included in the sponsorship agreement);
- Courses provided by an organisation, but at which Accord Healthcare Ireland Ltd does not select the specific HCP presenting the course.

6.4.2 Registration Fees

Accord Healthcare Ireland Ltd supports the continuing medical education of HCPs by occasionally paying their registration fees and travel/ accommodation to attend medical/ scientific educational Events organised by third parties. Where possible these transfers of value will be disclosed individually in this sub-category (while considering Data Privacy). Where costs cannot be attributed to an individual (such as for a bus journey shared by multiple HCPs) they will not be included in the Disclosure Report.

Where Accord Healthcare Ireland Ltd has organised an Event directly, only the fees and related expenses paid to HCPs will be included in the Disclosure Report in the category 'Fee for service and consultancy'.

6.4.3 Travel and Accommodation

This sub-category will display the transfers of value for travel and accommodation attributable in relation to supporting HCPs to attend scientific or medical Events. This can include airfares, train tickets, taxis, tolls, parking fees and hotel accommodation.

Transfers of value for travel and accommodation that relate to consultancy services of an HCP at an Event will be disclosed under either the 'Related expenses agreed in the fee for service or consultancy contract...' sub-category or the 'Research and Development' category depending on the nature of the event.

6.4.4 Internal costs for internal events

Costs for internal Events such as rent for space, technical expenses or equipment hire will not be disclosed within the Disclosure Report.

6.5 Fee for service and consultancy

This category will include the fees and any related expenses covered by a consultancy agreement with an HCP. The fee will be reported under the 'Fees' sub-category and any related expenses, such as travel, accommodation or registration fees, will be reported under the 'Related expenses agreed in the fee for service or consultancy contract...'. When it is not possible to separate the fee from the related expenses, in these instances the total transfer of value will be reported in the 'Fees' sub-category.

The 'Fee for service and consultancy' category will include transfers of value relating to Market Research if the identity of the HCP is known by Accord Healthcare Ireland Ltd.

7. ACCOUNTING CONSIDERATIONS

7.1 Currency and Tax

The Disclosure Report will show transfers of value made in the currency in which payment was made. Where amount is requested is not in Euro this will be calculated on the day of approval using a currency converter tool.

The Disclosure Report will show transfers of value made with or without applicable taxes as those are the responsibility of the HCP or HCO as set out in the 'Consultancy Agreement' and Actavis is not liable for any UK taxes.

The values reported in the Disclosure Report filed by Actavis will be the gross of IE Income Tax and National Insurance.

7.2 Inclusion Criteria for Payments

A Disclosure Report covers transfers of value from the 01st January – 31st December of the year of the report. The date that Accord Healthcare Ireland Ltd's internal accounting system records the payment having been made will determine which annual Disclosure Report it is included in.

Where a project requires transfers of value to be made in several instalments, the date that the internal accounting system records the payment as having been made will determine within which Disclosure Report the transfer is contained. This may mean that a transfer of value recorded in a Disclosure Report may be a part-payment, with other payments relating to the project being reported in other annual Disclosure Reports.

7.3 Indirect Payments (Payments made to HCP/ HCO through Agency)

Accord Healthcare Ireland Ltd may contract with agencies (such as an advertising, marketing or PR agency) that go on to make transfers of value to HCPs. The end recipient (HCP/HCO) may not appear within Accord Healthcare Ireland Ltd’s accounting tool. Accord Healthcare Ireland Ltd makes the best effort to ensure that these transfers of value made on our behalf are captured and reported as if they were made directly by requesting information from our agencies.

7.4 Cross-border Transfers of Value

Transfers of value to HCPs covered by the Medicines for Ireland Code of Conduct may be made by other Accord Healthcare Ireland Ltd entities (and not from Accord Healthcare Ireland Ltd). Accord Healthcare Ireland Ltd works with the other Company entities to gather the data so that as complete a picture as possible is provided within the Disclosure Report. Accord Healthcare Ireland Ltd. will only publish the transfer of value to an HCP in the Disclosure Report for the country where the HCP has their primary practice.

7.5 Co-Promotion Partners

If Accord Healthcare Ireland Ltd has made the transfer of value and it is within our accounting tool (or notified to us by a third party such as an agency), it will be included within the Disclosure Report.

Transfers of value made by a co-promotion partner should be included in their Disclosure Report.

7.6 Elements that Exceed the Code Requirements

Prescription-Only Medicine (POM), Medical Devices & Over-the-Counter (OTC) Medicine

It is only required to report transfers of value to HCPs and HCOs that relate to POM. Accord Healthcare Ireland Ltd manufactures and markets POM, Medical Devices and OTC products. Accord Healthcare Ireland Ltd’s accounting tool does not differentiate between transfers of value to HCPs relating to these different types of product and therefore the Disclosure Report will detail all transfers irrespective of the product type they relate to.

8. REFERENCES

Medicines for Europe Code of Conduct

9. REVISION HISTORY

Revision Date	Version #	Revised By	Description of Changes
9/11/2018	01	Mary O’Meara	New version for report on 2018 data
25/05/2020	02	Margo Broderick	Amended dates to 2019.

