

## Methodology Note for Activity Regarding Disclosure of Transfers of Values

### 1. PURPOSE

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

As well as services, Accord-UK Ltd may also provide grants and donations to HCOs in response to unsolicited requests to support programmes that cover unmet needs and improve patient care and provides sponsorships to HCOs for educational events and conferences. Accord-UK 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 ABPI (Association of the British Pharmaceutical Industry) Code of Practice 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-UK Ltd's Methodology Note for the reporting period 1<sup>st</sup> January 2019 to 31<sup>st</sup> December 2019.

Actavis UK Ltd became a subsidiary of Accord Healthcare Ltd in 2017. In previous years Actavis UK Ltd and Accord Healthcare Ltd operated as two separate companies, but from 2018 they have operated as one company so disclosure since this year incorporates data for both Actavis UK Ltd and Accord Healthcare Ltd under the name of the UK company, Accord-UK Ltd (i.e. "The Company"). Disclosure for the UK also incorporates payments made by other Accord affiliates to UK-based HCPs and HCOs.

## 2. PRINCIPLES

Accord-UK 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-UK 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-UK Ltd can publish the HCP's transfers of value. The Company must seek permission (consent) from the HCP or have other legal reasons to individually publish their transfers of value.

Accord-UK Ltd discloses individual transfers of value only where full informed consent has been obtained from the individual. Where we have been unable to obtain consent from an HCP that is fully compliant with General Data Protection Regulation (GDPR), or other legal reasons prevent Accord-UK Ltd from disclosing individually for an HCP or HCO, their transfers of values have been added to the 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 The Company's transfers of value to UK HCPs and HCOs as required by the ABPI Code of Practice for the reporting period 1<sup>st</sup> January 2019 to 31<sup>st</sup> December 2019.

## 4. DEFINITIONS

Definitions used within the Disclosure Report and Methodology Note are consistent with ABPI terminology:

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

**Transfer of Value (TOV)**

A direct or indirect transfer of value, whether in cash, in kind 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 a 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 identity of the company is known to, or can be identified by, the recipient.

## 5. REPORTABLE HCPs AND HCOs

UK HCPs engaged by The Company are provided with a disclosure consent form and information on the ABPI's Disclosure process.

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. An HCP can withdraw or withhold consent for their individual data to be disclosed at any time. Where consent is not provided, any transfers of value are disclosed as part of The Company's anonymous aggregate so as not to be able to identify them.

For an HCO, the city where the HCO is registered and the principle address will be published alongside details of the transfer of value to the 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 ABPI's requirements.

Research activities by Accord-UK 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-UK 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-UK Ltd does not select the specific HCP presenting the course.

#### **6.4.2 Registration Fees**

Accord-UK Ltd may also support the continuing medical education of HCPs by 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-UK 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-UK 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 GBP 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 Accord-UK Ltd is not liable for any UK taxes.

The values reported in the Disclosure Report filed by Accord-UK Ltd will be the gross of UK Income Tax and National Insurance.

### **7.2 Inclusion Criteria for Payments**

A Disclosure Report covers transfers of value from the 01<sup>st</sup> January – 31<sup>st</sup> December of the year of the report.

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

Accord-UK Ltd may contract with agencies (such as an advertising, marketing or PR agency) that go on to make transfers of value to HCPs. Accord-UK 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. Accord-UK Ltd's Disclosure consent forms will be passed to HCPs through agencies where transfers of value have been made.

#### **7.4 Cross-border Transfers of Value**

Transfers of value to HCPs covered by the ABPI Code of Practice may be made by other Accord affiliates (and not from Accord-UK Ltd). Accord-UK Ltd works with the other affiliates to gather the data so that as complete a picture as possible is provided within the Disclosure Report. Accord-UK Ltd will only publish the transfer of value to an HCP in the Disclosure Report if the UK is the country where the HCP has their primary practice.

#### **7.5 Co-Promotion Partners**

If Accord-UK Ltd has made the transfer of value and it is aware of the payment through our systems, 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**

The ABPI Code of Practice only requires transfers of value to HCPs and HCOs that relate to POMs. Accord-UK Ltd manufactures and markets POMs, Medical Devices and OTC products. Accord-UK Ltd 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**

ABPI (Association of the British Pharmaceutical Industry) Code of Practice for the Pharmaceutical Industry

## **9. REVISION HISTORY**

| <b>Revision Date</b> | <b>Version #</b> | <b>Revised By</b> | <b>Description of Changes</b>                    |
|----------------------|------------------|-------------------|--|
| 3/27/2019            | 01               | Laura Stewart     | New version for 2018 disclosure as Accord-UK Ltd |
| 2/19/2020            | 02               | Laura Stewart     | Updated for 2019 disclosure                      |