

## **Disclosure of Certain Transfers of Value from Colonis Pharma Limited to Health Professionals and Healthcare Organisations in 2016**

### **Methodology**

Colonis Pharma Limited (part of the Quantum Group) has agreed to comply with the ABPI Code of Practice and accept the jurisdiction of the PMCPA.

Colonis 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.

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

### **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)**

“Includes 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.”

#### **Healthcare Organisation (HCO)**

“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.”

### **Transfer of Value (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. 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 on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.”

Regarding HCP/HCO Consent, UK Data Protection Law requires Colonis Pharma Ltd to ask for consent from HCPs in order to disclose individual data. Colonis Pharma Ltd does not require HCPs to grant consent for individual disclosure in order to contract for services or for sponsorships. Colonis Pharma Ltd will disclose individual level payments when we have received consent to do so. If the HCP did not consent, then all ToV made to them are included in aggregate payment data. HCO consent is not required and therefore all ToV to HCOs are reported in full. HCPs have certain rights under the data protection laws and can withdraw their agreement for ToV data to be published under their name on the disclosure database. The UK report may be updated by Colonis Pharma Ltd to reflect changes in consent and correction of data.

‘The ABPI Code of Practice (20.2) states that HCPs and other relevant decision-making staff may be used as consultants and advisors, whether in groups or individually, for services such as:

- Speaking at and chairing meetings
- Training services
- Participation at advisory board meetings
- Participation in market research where such participation involves remuneration and/or travel. This applies when the company is aware of the identity of those participating in the market research
- Sponsorship in relation to attendance at meetings, which is registration fees and the costs of accommodation and travel.

Universities and other educational establishments or organisations are not in scope of the EFPIA Disclosure Code per se. We will however publish details of such ToVs in the event that they are indirect ToVs to a healthcare organisation, such as a university hospital, or one or more healthcare professionals. In such cases, we will publish the details of each of those ToVs under the name of the university or other educational establishment to which they were granted. As far as healthcare organisations (HCOs) are concerned, benefits in kind, fees for services, contributions towards events and joint working need to be disclosed in addition to existing requirements to disclose grants and donations. The aggregate spend on certain research and development (R&D) and payments made to patient organisations must also be disclosed.' (Source: ABPI website <http://www.abpi.org.uk/our-work/disclosure/Pages/Individualdisclosure.aspx>)

In the event that we become aware that ToVs granted by us to a third party have been passed on to healthcare professionals or healthcare organisations, we will publish the details of each of those ToVs under the name of the relevant healthcare professional or organisation. Our contractual arrangements with third parties include the obligation to report the relevant data to us in the necessary level of detail. Our contract partners are also obliged to ensure that such information transfer is in line with applicable data privacy laws.

Transfers of value effected in the reporting period are summed up (for individuals or aggregated) according to the segmentation of the disclosure template requirements. Only amounts of payments effected within the given calendar year (= reporting period) are considered with the calculation (see also note re ToV date and ToV in different calendar years). Calculation is executed with amounts of harmonized (same) currency.

During 2016 Colonis Pharma made transfers of value in respect of their medical devices and pharmaceutical products in the following areas:

- Sponsorship for meeting attendance (to cover registration fees, travel and accommodation)
- Research and development (consultancy fees)

These have been disclosed at an aggregate level in the template produced by the ABPI which is located on the Colonis website. This information will remain in the public domain for 3 years, and be retained by Colonis for 5 years after the calendar year to which it relates.

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

1. VAT:

a) VAT incurred for travel and accommodation costs has been included in the total amount disclosed

2. Currency:

a) Re-imbusement for costs incurred outside of the UK has been made in GBP using the currency conversion rate in place at the time re-imbusement made

3. Cross-border payments

a) These have been incurred

4. Disclosure of work for which payment is outstanding:

a) In situations where work was conducted in 2016 but invoices not submitted in 2016 the value is NOT included in the 2016 disclosure document. Once invoices are received and payment made they will be recorded in the year that the HCP/HCO receives payment.