**Disclosure of Certain Transfers of Value from Pharmaceutical**

**Companies to Health Professionals and Healthcare Organisations**

**Methodological Note - Points for Consideration**

**Introduction**

In recent years there has been growing public interest in the pharmaceutical industry’s relationships with health professionals (HCPs), other relevant decision makers (ORDMs) and healthcare organisations (HCOs). Members of the public want to be confident that such relationships are appropriate and that they can trust their health professional to provide high quality care based on clinical evidence and experience. There are already detailed requirements in the ABPI Code of Practice for the Pharmaceutical Industry setting out the basis of these relationships. Since 2012 certain transfers of value have been required to be collected and disclosed in aggregate the following year. Current requirements mean that data identifying individuals who have received certain transfers of value are published on a publicly available central platform, Disclosure UK. This was launched in June 2016 when 2015 data was published. Disclosure UK lists data for three calendar years. The 2018 data will be published in June 2019 and the 2015 data will be removed. Transfers of value to healthcare organisations are also disclosed on the Disclosure UK on a per activity basis.

By creating greater transparency around the pharmaceutical industry’s collaborations and partnerships with HCPs, ORDMs and HCOs, the ABPI Code requirements for disclosure of certain transfers of value aim to improve understanding and increase the public’s confidence in these relationships.

The ABPI Code disclosure requirements are predominantly set out in Clause 24, however information can also be found in Clauses 1, 19, 20, 21, 22 and 23.

**Methodological Note**

As part of the requirements of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, which has been transposed in the ABPI Code, each company is required, at the same time as it discloses the data, to publish a methodological note. This is accessible via Disclosure UK and gives important additional information about, and context to, the disclosed data. Clause 24.10 of the ABPI Code states:

‘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. The note, including a general summary and/or country specific considerations, must describe the recognition methodologiesapplied and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of transfers of value for the purposes of this Code.’

Companies are likely to take different approaches in developing their methodological note; some might develop a document to cover the whole of Europe whilst others might decide on a separate methodological note for each country. The length and content of a methodological note will differ from company to company; much will depend on the size of the company and the range and complexity of its relationships with HCPs, ORDMs and HCOs. It is important that it is written in such a way as to help a member of the public easily understand the data disclosed.

The form of the methodological note is for each company to determine. However for 2018 data onwards the methodological note must make clear the number of individuals who have agreed to some transfers of value being disclosed individually and some in aggregate (as set out on the disclosure template for 2018 data. In addition the following points may be helpful when preparing methodological notes.

How has the company treated:

* Tax considerations?
* VAT (included or not)?
* Currency aspects (including conversion rates)?
* Cross border payments?
* Multi-year contracts?
* Over-the-counter transfers of value? Are they/some included?
* Medical device transfers of value? Are they/some included?

Other aspects for consideration:

* Do the disclosures go beyond what is required by the Code? If so, is this made clear?
* How has the company defined ‘Donation’, ‘Grant’, ‘Sponsorship’ and has this been made clear?
* Are the appropriate arrangements in place to lawfully disclose the information and are recipients aware of the process?
* How have non-monetary transfers of value been quantified?
* Is it clear whether the disclosures cover subsidiaries, affiliates etc?
* If the company has changed name or merged etc how is this explained?. Can relevant disclosures be easily tracked?
* When working with other pharmaceutical companies, how are disclosures handled? How are transfers of value divided amongst the parties (eg joint working projects etc)?
* Are the necessary links included and active eg for joint working project executive summaries?

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