PMCPA Prescription Medicines Code of Practice Authority

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. In addition, new requirements mean that data identifying individuals who have received certain transfers of value during 2015 will be published for the first time on a publicly available central platform. Transfers of value to healthcare organisations will also be disclosed on the central platform on a per activity basis. This will start with the 2015 data which will be published by the end of June 2016. Pharmaceutical companies have been provided with details including the timetable so that the necessary timelines for the disclosure of data on the central platform are met.

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 will also be accessible via the central platform, and will give 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 methodologies applied 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, 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?
- How has consent been obtained? For example is it per activity or annual consent post activity?
- How have non-monetary transfers of value been quantified?
- When working with other pharmaceutical companies, how are disclosures handled? How are transfers of value divided amongst the parties (eg ABPI therapy groups, joint working projects etc)?

December 2015