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# Disclosure UK: Understanding the data

## Guidance notes for analysis of the data

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## Abbreviations

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ABPI	The Association of the British Pharmaceutical Industry
CRO	Clinical Research Organisation
EFPIA	European Federation of Pharmaceutical Industries and Associations
HCO	Healthcare Organisation
HCP	Healthcare Professional
MEGS	Medical and Educational Goods and Services
ORDM	Other Relevant Decision Maker
R&D	Research and Development
ToV	Transfer of Value
VAT	Value-Added Tax



# Introduction

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These guidance notes have been prepared by RAND Europe for The Association of the British Pharmaceutical Industry (ABPI) in order to support researchers and other interested parties in their interpretation of the dataset of transfers of value (ToVs), as defined in the ABPI Code of Practice for the Pharmaceutical Industry,<sup>1</sup> from pharmaceutical companies to UK healthcare professionals (HCPs), healthcare organisations (HCOs) and Other Relevant Decision Makers (ORDMs). As such, the notes are intended to be read in conjunction with the disclosure data published on the ABPI website, along with the ABPI Code, which incorporates requirements from the European Federation of Pharmaceutical Industries and Associations (EFPIA) codes, including the EFPIA Disclosure Code.<sup>2,3</sup>

As part of the disclosure of ToVs, disclosing companies were required to provide an accompanying note summarising the methodologies they used to prepare the disclosures for the reporting period (i.e. the calendar year 2015). The following guidance notes for analysis of the data have drawn on these methodological notes (109 in total). Therefore, this document provides an overview of any variations or differences in methodology that may affect the comparability of data disclosed.

Methodological notes vary widely between companies in the scope and content of information provided. Where a company's notes do not explicitly cover an issue, the default assumption is that the methodology complied with the relevant code of practice. In identifying the key considerations laid out below, we have adopted a *de minimis* approach, which excludes a number of differences that appeared to affect less than five percent of disclosing companies. It is also important to note that while we have attempted to provide an indication of the frequency of a methodological difference by noting the proportion of disclosing companies to which it relates, this proportion does not necessarily correspond to the monetary value of the ToVs that the methodological difference affects. For example, 20 companies may disclose a particular type of ToV that is not disclosed by other companies, with a total value of £20,000 disclosed. Equally, one company may disclose a single £20,000 ToV of a type not disclosed by any other company. Thus the frequency of a methodological difference does not necessarily give an indication of its monetary impact.

The guidance notes begin with a discussion of a number of issues related to the calculation and collation of ToV data, which have relevance across the dataset. For ease of reference, the remaining sections are broadly organised according to the categories of recipient and ToV used in the disclosure. Section two

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<sup>1</sup> ABPI (2016)

<sup>2</sup> ABPI (2016)

<sup>3</sup> EFPIA (2014)

covers issues around the classification and identification of recipients, specifically HCPs, HCOs and cross-border payments. In the final section, we discuss considerations relating to specific types of ToVs, specifically Joint Working; Contribution to costs of events; Fees for services and consultancy; and Research and development (R&D). We also discuss some additional considerations relating to the scope of disclosures.

These guidance notes should be read in conjunction with the ABPI Code which details in full the requirements for disclosure which are not repeated in the guidance notes. Commentary on the differences between company methodological notes is not a judgement on adherence or otherwise to the requirements of the Code and variations in approach between companies was to be expected. Some companies may be disclosing more information than required by the Code.

Any comments or complaints relating to the ABPI Code or disclosure should be directed to [complaints@pmcpa.org.uk](mailto:complaints@pmcpa.org.uk).



# 1. Calculation and collation of transfers of value

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This section presents a number of considerations related to the calculation and collation of all types and categories of ToV discussed in the following sections, and which thus relate to the dataset as a whole.

## 1.1. Value-Added Tax and other taxes

### *Value-Added Tax (VAT)*

Where companies' approaches to reporting VAT are specified in methodological notes, there is wide variation in how it is treated in the data disclosure. Of the 90 companies (out of 109 companies in total) that specify their approach, 40 included VAT in their disclosure where they considered it applicable, thirty-three did not include VAT at all, and five included it only where it was not separable from the total ToV to be disclosed. A further 12 companies' procedures varied according to the type of payment (e.g. VAT excluded for R&D ToVs but included for other categories) or type of recipient (e.g. VAT included for ToVs to HCOs but not to HCPs or ORDMs). The ABPI Code does not require VAT to be included or excluded, and therefore no assumption can be made regarding the approach followed by the remaining 19 companies. Where one company has disclosed a particular category of ToV inclusive of VAT and another has disclosed the same category of ToV exclusive of VAT, this difference will distort any comparison of the value of ToVs made by the two companies in that category.

### *Other taxes*

Of the 23 companies that specify their policy on taxes beyond VAT (e.g. income tax and National Insurance), eight included such taxes in their disclosure where they considered this applicable. Fifteen did not consider these taxes to be within the scope of the disclosure.

## 1.2. Exchange rates

There was some variation in exchange rates used by disclosing companies for converting foreign currencies into British Pounds Sterling. Of the 70 companies that specify which exchange rates they used, the largest number (31) used the rate at the date on which the payment was made. Other companies used the average rate for the month in which payment was made (8), the average rate for the reporting period (5), the rate at the time of disclosure reporting (8), a fixed annual rate for the calendar year (7), the rate at the date when services were provided (3), the rate at the time of contracting (1), or the rate at the end of the reporting period (1). Six companies stated that the exchange rate used was dependent on the type of ToV.

### 1.3. Identifying transfer of value dates

In order to establish whether a ToV fell within the reporting period, and was therefore eligible for disclosure, some companies developed policies for identifying the ToV date. Of the 51 companies that specify their approach to dating ToVs, the vast majority (46) disclosed according to the date on which payment was made. Three disclosed according to the date on which services were performed. For indirect ToVs, one company disclosed according to the date on which payment was made to the ultimate recipient and one disclosed indirect payments according to the date on which payment was made to the third party (rather than to the ultimate recipient).

#### *Date of disclosure of ToVs for events*

Of those 51 companies, 19 disclosed ToVs related to events according to the date on which the event took place. The remainder followed the same procedure specified for ToVs not related to events.

### 1.4. Aggregation/disaggregation of transfers of value by individual activity

There was variation in the extent to which disclosing companies aggregated or disaggregated data, largely related to differing degrees of success with regard to obtaining consent to disclose from recipients and approaches to collating payment information. Of the 38 companies that specify their procedure, the vast majority (35) disclosed on a 'per activity' basis in the individually-named section of the database. Two companies disclosed all payments in aggregate (one of which had only ToVs for R&D to disclose) and one company stated that totals disclosed may include more than one event.

#### *Partial consent and partial disclosure*

In cases where HCPs and ORDMs (and HCOs where applicable) consented to the disclosure of some ToVs but refused others, the vast majority (31 of the 35 companies that specify their policy) state that they have disclosed all ToVs to those recipients in the aggregate section. However, four companies report that at least in some circumstances, partial disclosure has been allowed. This means that if the disclosure of only selected ToVs has been consented to, these ToVs are disclosed against the recipient's name and the rest are included in the aggregate figure. Of these four, one company reports it would only partially disclose ToVs where consent was given for a ToV disclosure during the reporting period, but retrospective consent was not obtained for another company. Where partial disclosure occurs, ToVs to a single recipient may appear divided across both the individually-named and aggregate sections, in which case it would not be possible to establish the full amount paid to the individual recipient.

It is not possible to ascertain whether HCPs and ORDMs agreeing to disclose payments on an individual basis have used this approach for all companies.

## 2. Classification and identification of recipients

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### 2.1. Healthcare Professionals and Other Relevant Decision Makers

According to the ABPI Code, ‘the term “health professional” 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.’<sup>4</sup> The term ORDM, according to the Code, ‘particularly includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals’.<sup>5</sup> While the majority of disclosing companies affirm adherence to these definitions (or the similar definition described in the EFPIA Code),<sup>6</sup> a small number make further specifications. Three companies specify that all registered or qualified HCPs fall within the scope of disclosure regardless of their health service status, thus explicitly including retired HCPs and academic staff who provide clinical services and support. One company specifies the inclusion of their own employee HCPs and ORDMs in their definition of HCPs and another company notes the inclusion of individuals without a clinical role who ‘write papers for different organisations’. Finally, one company takes a notably different approach, defining a HCP as: ‘Any individual or organization (private/public) who can, in their professional capacity: influence the use, purchase, ordering, prescribing or recommendation of Company products or affect tender decisions, formulary placement, award status or other preferential status of Company products.’

#### *ToVs to HCP employees of pharmaceutical companies*

There is variation among disclosing companies with regard to whether they consider ToVs (including salary and benefits) to HCP members of staff to be within the scope of the disclosure. Of the 13 companies that specify, seven consider HCP employees outside of the scope, but six include them to some degree in their disclosure. Of those six, four companies specify that they include employees whose primary occupation is that of a practising health professional, one company includes only ToVs related to the HCP’s NHS role and another discloses part-time HCP staff only, excluding those working for them full-time. Of the seven companies that exclude HCP employees, one states that they exclude those that are employed ‘directly and exclusively’ by them, and another states that the primary occupation of all the full- or part-time HCPs that they employ is not that of a practising health professional. In addition to

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<sup>4</sup> ABPI (2016), Subclause 1.4

<sup>5</sup> ABPI (2016), Subclause 1.5

<sup>6</sup> EFPIA (2014), p.11

excluding their own employees, one company also excludes HCP employees of collaboration partners, while another also excludes HCPs working for them as consultants.

#### *Classification of self-incorporated HCPs and companies owned/run by a HCP*

There is variation among companies in how they classify self-incorporated HCPs or companies owned and/or run by a HCP for the purposes of disclosure. Among the 22 companies that specify their policy, the majority (15) classify these entities as HCPs in their disclosure, while five classify them as HCOs. For another company, classification depends on the ToV type: a self-proprietor or an individual HCP's limited company would be classified as a HCP for ToVs under 'fees for services and consultancy and/or related expenses' or 'registration fees and/or travel and accommodation', but as a HCO for ToVs categorised as 'donations and grants', 'joint working' or 'sponsorship agreements'. One company states that if the personal name of the HCP is contained in the name of the legal entity, then the HCO will be considered a HCP. Finally, one company states that a ToV is attributed to the HCP where they run 'a private company or partnership, charity, etc, for the purposes of their private income', but that a contracting legal entity which is owned by a HCP is considered a HCO, and ToVs to those entities are classified accordingly.

## 2.2. Healthcare Organisations

Most definitions of HCO provided by disclosing companies are in line with the ABPI or EFPIA definitions of the term.<sup>7,8</sup> Among the 45 companies which define HCO, a small number make additional specifications. Three companies further specify that all medical societies (national or local) and all 'networks' of associations for HCPs are considered HCOs. Another company excludes from their definition 'corporate entities providing healthcare-related advice or services that employ HCPs whose primary occupation is the provision of consulting services and not that of practising HCPs'. Finally, one company excludes 'private companies such as medical education agencies, or suppliers of "temp" nurses, etc.', especially where the majority of employees are non-HCPs.

#### *HCO consent and aggregate disclosure*

Companies must ensure that they have appropriate arrangements in place to lawfully disclose information about ToVs. The UK Data Protection Act (1998) requires consent before disclosing information related to individual ToV recipients (i.e. HCPs and ORDMs). However, 13 companies report also seeking HCOs' consent to disclose ToVs. If HCO data is reported in aggregate, this implies that HCOs refused or withdrew consent. One company aggregated all ToVs (to both HCPs and HCOs) because it had not successfully obtained retrospective consent from each and every individual and organisation.

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<sup>7</sup> ABPI (2016), Subclause 1.9

<sup>8</sup> EFPIA (2014), p.11

## 2.3. Cross-border payments

Among the 59 companies that specify their policy in dealing with cross-border ToVs, most affirm that all payments are attributed to the country in which the recipient is registered or practising, if a company affiliate is present in the country. This means that if the paying company has an affiliate in the UK, their ToVs to UK-based HCPs, HCOs and ORDMs would be reported in the present disclosure. In some cases, companies specify that payments to non-UK-based recipients have also been included in the UK disclosure.

### *Disclosure of ToVs to non-UK-based recipients*

Two companies disclosed all payments to HCPs/HCOs worldwide and another included all their payments to European HCPs/HCOs and ORDMs in their UK disclosures. In addition, two companies included payments to recipients in Ireland, and another states that recipients not resident in UK, Germany, Italy or Spain, are disclosed by the entity (i.e. affiliate) that initiated the transaction. One further company states that the R&D element of their disclosure includes only ToVs paid by their UK representation, while full global spend on R&D has been disclosed by an affiliate in another European country.

### *Additional considerations related to cross-border payments*

One company notes that ToVs from the United States cannot be fully disclosed.



## 3. Types of transfers of value and scope of disclosures

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### 3.1. Joint Working

Joint working is defined by the Department of Health as arrangements where pharmaceutical companies and the NHS ‘pool skills, experience and/or resources for the joint development and implementation of patient centred projects’.<sup>9</sup>

#### *Salaries of disclosing companies’ employees on joint working projects*

Of the four companies that specify their procedure for this type of ToV, three disclosed the salaries of their employees who are practising HCPs. One company provided ToVs under a joint working agreement to employees practising as HCPs in the form of share options, but these were not disclosed.

### 3.2. Contribution to costs of events

Companies have disclosed ToVs relating to their sponsorship of the organisation and running of events, including (in most cases) payments to third party (non-HCO) organisers of events. Also covered are ToVs related to disclosing companies sponsoring HCPs or ORDMs to attend scientific or educational events, including expenses such as travel, accommodation and registration fees.

#### *Disclosure of ToVs for events in case of cancellation or non-attendance*

Of the 19 companies that specify their procedure for events that are cancelled or not attended by the intended HCP, 11 did not disclose any ToV under these circumstances. Eight disclosed ToVs regardless of cancellation or non-attendance as long as the ToV was received by the HCO or HCP.

#### *Categorisation of ToVs to HCPs sponsored to attend events*

One company disclosed sponsorship of HCPs to attend events under ‘donations and grants’, whereas all other companies that specified their procedure for this type of payment made disclosures under ‘contribution to cost of events’.

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<sup>9</sup> ABPI (2016), Clause 20

### *Disclosure of ToVs for food and drink*

Of the 31 companies that specify their policy on ToVs for food and drink as part of event sponsorship, 21 did not disclose any ToV of this type. Nine companies disclosed food and drink only where they were part of a sponsorship package or could not be separated from other expenses. One company states that some ToVs for food and drink may have been disclosed, particularly where ToVs have been provided by affiliates.

## 3.3. Fees for services and consultancy

This category covers ToVs for services and consultancy performed by HCPs, ORDMs or HCOs that do not fall under R&D. Frequently occurring types of ToV in this category include speaker fees, participation in advisory boards and provision of training. Companies have also disclosed ToVs that cover related expenses incurred in providing such services, including travel and accommodation.

### *Disclosure of ToVs related to Medical and Educational Goods and Services (MEGS)*

Of the nine companies that specify their policy in relation to MEGS, one company did not disclose training events to which the company itself invited HCPs (as long as there was no associated ToV for expenses). The rest only disclosed ToVs where the provider of MEGS was an HCO or where the ultimate recipient was identifiable as a HCP.

### *Disclosure of ToVs for 'blind' market research*

There was variation in whether companies disclosed ToVs related to 'blind' market research (where the ultimate recipient of the ToV is unknown). Of the 20 companies that specify their policy, 17 did not disclose any ToVs unless the ultimate recipient could be identified as a HCP/ORDM/HCO, while 3 disclosed the ToVs related to 'blind' market research in the aggregate.

## 3.4. Research and development (R&D)

The ABPI Code states that ToVs should be disclosed under the R&D category where they relate to the planning or conduct of non-clinical studies as defined in the OECD Principles on Good Laboratory Practice,<sup>10</sup> clinical trials as defined in Directive 2001/20/EC,<sup>11</sup> and prospective non-interventional studies that involve the collection of data from, or on behalf of, HCPs. Costs that are subsidiary to these activities can also be included.<sup>12</sup>

ToVs related to R&D not within this definition have to be disclosed on a per activity basis.

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<sup>10</sup> OECD (1997)

<sup>11</sup> European Commission (2001)

<sup>12</sup> ABPI (2016), Subclause 23.2



#### *Disclosure of expenses associated with R&D*

Of the eight companies that specify their policy in relation to expenses associated with R&D (e.g. investigator meetings, advisory boards and related travel and accommodation), three disclosed these expenses under 'Fees for service and consultancy', while five disclosed them in the R&D category.

#### *Disclosure of R&D-related ToVs involving Clinical Research Organisations (CROs)*

All 18 companies that specified their policy on this type of ToV disclosed certain types of ToV involving CROs. One disclosed all R&D-related ToVs made to or via CROs, and the remainder included only R&D-related ToVs made via CROs where the ultimate recipient was a HCO or HCP.

### 3.5. Additional considerations related to the scope of disclosures

While product-related disclosures focus primarily on ToVs concerning prescription-only medicines, there is some variation among companies with regard to the disclosure of other products. The ABPI Code applies to medicines promoted for prescribing. ToVs that are solely related to over-the-counter medicines are excluded.

#### *ToVs related to over-the-counter medicines*

Of the 22 companies that describe their policy on over-the-counter medicines, 12 did not disclose any related ToVs, while seven disclosed all ToVs related to over-the-counter-medicines. Three disclosed in full ToVs related to a combination of prescription-only medicines and over-the-counter medicines, where the value of the two types of medicine could not be disaggregated.

#### *ToVs related to medical devices*

Of the 12 companies that specify their policy on medical devices, five did not disclose any related ToVs, while five disclosed all ToVs related to medical devices. Two disclosed ToVs related to a combination of prescription-only medicines and medical devices, where the value of the two could not be disaggregated.



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