

Disclosure UK: understanding the data

Guidance notes for analysis of the 2021 data

Brandi Leach and Avery Adams

RAND Europe

RR-A2087-2

16 June 2022

Prepared for the Association of the British Pharmaceutical Industry



Preface

These guidance notes have been prepared by RAND Europe for The Association of the British Pharmaceutical Industry (ABPI) to support researchers and other interested parties in their interpretation of the ‘Disclosure UK’ dataset of transfers of value (ToVs) from pharmaceutical companies to UK healthcare professionals (HCPs), healthcare organisations (HCOs) and Other Relevant Decision Makers (ORDMs) during 2021. The notes are intended to be read in conjunction with the disclosure data published on the ABPI website, along with the ABPI Code of Practice for the Pharmaceutical Industry,¹ which incorporates requirements from the consolidated European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice.²

For more information about the project or this report, please contact:

Dr Brandi Leach
Senior Analyst, RAND Europe
Westbrook Centre, Milton Road
Cambridge CB4 1YG
United Kingdom
Tel. +44 (1223) 353 329
bleach@randeurope.org

¹ ABPI (2021)

² EFPIA (2019)

Table of contents

Preface	iii
Abbreviations	vi
Introduction	1
1. Calculation and collation of transfers of value.....	3
1.1. Value-Added Tax	3
1.2. Currency and exchange rates	4
1.3. Identifying transfer of value dates.....	5
1.4. Disclosing data based on legitimate interests	6
1.5. Aggregation and disaggregation of transfers of value.....	6
1.6. Cross-border payments.....	8
2. Classification and identification of recipients.....	10
2.1. Healthcare Professionals and Other Relevant Decision Makers	10
2.2. Classification of Healthcare Organisations	11
2.3. Patient organisations	12
3. Types of transfers of value and scope of disclosure	13
3.1. Collaborative working.....	13
3.2. Contributions to costs of events	14
3.3. Contracted Services.....	17
3.4. Indirect ToVs.....	18
3.5. Additional considerations related to the scope of disclosures.....	19
References	21

Abbreviations

ABPI	The Association of the British Pharmaceutical Industry
CCG	Clinical Commissioning Group
COVID-19	Coronavirus disease 19
EFPIA	European Federation of Pharmaceutical Industries and Associations
GDPR	General Data Protection Regulation
GP	General (Medical) Practitioner
HCO	Healthcare Organisation
HCP	Healthcare Professional
MEGS	Medical and Educational Goods and Services
ORDM	Other Relevant Decision Maker
OTC	Over-the-counter (medicine)
R&D	Research and Development
ToV	Transfer of Value
VAT	Value-Added Tax

Introduction

As part of the disclosure of Transfers of Value (ToVs), disclosing companies are required to provide an accompanying note summarising the methodologies they used to prepare the disclosures for the reporting period (i.e. the calendar year 2021). The following guidance notes for analysis of the 2021 data draw on information from the 139 methodological notes submitted by these companies. The guidance notes aim to provide an overview of variations in methodology that may affect the comparability of the data across companies.

Methodological notes vary widely between companies in the scope and content of information provided. We provide an indication of how frequently a methodological approach is used by noting the proportion of disclosing companies that report using it. However, this proportion does not necessarily correspond to the monetary value of the ToVs that the difference in methodological approaches 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, how frequently a methodological approach is used does not have a direct relationship to any monetary value.

The ABPI Code of Practice was updated in 2021,³ which included updating certain terminology in the disclosure categories displayed on Disclosure UK⁴ for 2021 data onwards. The terminology updates are to ensure that pharmaceutical companies attribute the correct values to each of the categories. During the 2021 update of the ABPI Code of Practice, the category ‘Joint Working’ was incorporated into a new broader category, ‘Collaborative Working’ (which includes Joint Working), introduced in July 2021. This could mean that higher values are reported under Collaborative Working from 2021 data onwards compared to previous years, as it is a broader type of working than the previous Joint Working framework for activities as defined by the Department of Health and Social Care and previous versions of the ABPI Code. The changed category headings are defined in Table 0-1 below.

³ ABPI (2021)

⁴ Disclosure UK is a searchable database of transfers of value made by the pharmaceutical industry to healthcare professionals and organisations in the UK. <https://www.disclosureuk.org.uk>

Table 0-1 Changes to ABPI Code of Practice transfer of value categories for 2021 data onwards

Previous wording for 2019 and 2020 data	New wording for 2021 data onwards
Joint Working	Collaborative Working
Donations, Grants, Benefits	Donations, Grants
Service Fees	Contracted Services - Fees
Service Expenses	Contracted Services - Expenses

The guidance notes on the following pages begin with a discussion of the 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. Chapter two covers issues around the classification and identification of recipients, specifically Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) and other highlighted recipients such as Other Relevant Decision Makers (ORDMs), HCPs employed through a limited company, and patient organisations. In the final chapter, we discuss considerations relating to specific types of ToVs including:

- Collaborative working;
- Contribution to costs of events; and
- Contracted services.

In the final chapter we also discuss indirect ToVs (i.e. via an intermediary) and some additional considerations relating to the scope of disclosures, in particular those relating to donations and grants, and the impact of the COVID-19 pandemic on 2021 data.

These guidance notes should be read in conjunction with the ABPI Code of Practice (ABPI 2021), which details in full the requirements for disclosure, and which are consequently not repeated in these guidance notes. Commentary on the differences between company methodological notes is not a judgement on adherence to the requirements of the ABPI Code of Practice, as variations in approach between companies are to be expected. Some companies may be disclosing more information than required by the Code.

Any comments or complaints relating to the ABPI Code of Practice or disclosure should be directed to complaints@pmcpa.org.uk.

1. Calculation and collation of transfers of value

This section presents considerations relating to the calculation and collation of all types and categories of ToV which are discussed in subsequent sections, thereby relating to the analysed dataset as a whole.

1.1. Value-Added Tax

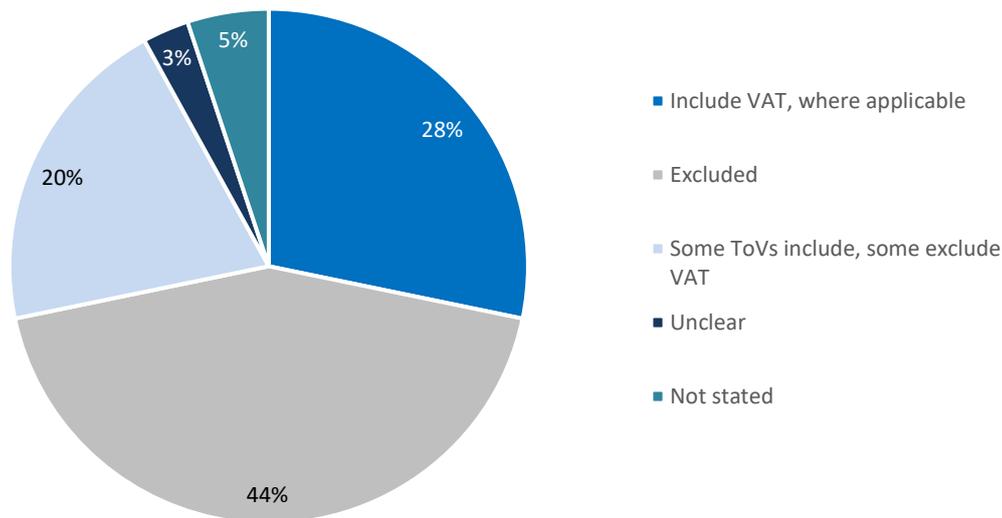
Out of 139 companies that submitted methodological notes, 132 companies provided detail on their approach to VAT disclosure. Of these, 61 companies excluded VAT from their disclosures and reporting. Thirty-nine companies included VAT in their disclosures and reporting. Twenty-eight companies reported a combination of ToVs including or excluding VAT. Four companies provided unclear information about their approach to VAT:

- One company reported that ToV would be recorded with or without applicable taxes, as these are the responsibility of individual HCPs and HCOs as set out in its consultancy agreements.
- One company reported that ToV would be reported at the amount paid.
- One company reported that all fees and appropriate local taxes such as VAT would be paid at specified local rates but did not clarify how it would report VAT as part of its disclosures.
- One company reported that all transactions had been correctly accounted for with regards to VAT and corporation tax but did not clarify how it would report VAT as part of its disclosures.

Examples of VAT being treated differently in reporting by these companies include different treatment of direct vs indirect ToVs, within border or cross-border ToVs, or cases where a company opted to exclude VAT but in some instances were unable to accurately exclude the amount from VAT.

Figure 1-1 below depicts the approach to the treatment of VAT for all companies submitting methodological notes.

Figure 1-1 Treatment of VAT in 2021 disclosure (n=139)



1.2. Currency and exchange rates

Currency

Most (132 out of 139) companies that submitted methodological notes specified which currency they used in the disclosure. All 132 companies stated either that they disclosed their ToVs in British Pounds Sterling (GBP) or that they disclosed in the local currency in which the disclosure report was submitted, which is British Pounds Sterling (GBP).

Exchange rates

There was variation in the approach to specifying exchange rates used by disclosing companies for converting foreign currencies into GBP. Of the 115 companies that specified their approach to the exchange rates they used to convert payments made in foreign currency to GBP, 30 used the exchange rate prevailing at the time of payment, but they did not state if ‘the time’ refers to the day, month or year. A further 22 used the exchange rate of the date of ToV, while 13 companies used an average exchange rate for the month in which the payment was made, and 17 companies used an average exchange rate for the year. A further 33 companies provided other specifications for their approach to exchange rates:

- Seven companies stated that exchanges had been conducted using an “internal” currency exchange, meaning a methodology decided internally by the company but not explained in further detail.
- Five companies stated that no payments had been made in non-GBP currencies and therefore no exchange rates were required.
- Four companies stated that they used a methodology to convert payments to GBP but did not provide further details.
- Four companies provided specific values for the rates of exchange between GBP and other currencies they had used.

- Three companies stated that the exchange rate had been calculated at the time of generation of the report.
- Two companies stated that the exchange had been conducted based on monthly average exchange rates for cross-border ToV and date of payment for all other transactions.
- One company provided a single date from which the daily exchange rate was used for all conversions.
- One company stated that exchange had been conducted based on invoice date.
- One company stated that exchange had been conducted based on the first day of the month of payment.
- One company stated that exchange had been conducted based on the last day of the month of payment.
- One company stated that exchange had been conducted based either on the date of ToV or had used the annual average exchange rate, without stating which was used in specific cases.
- One company stated that research and development related ToV had been calculated using an annual exchange rate, while all other ToV had been calculated using a monthly average exchange rate.
- One company used the exchange rate on the date of payment for fees for service, the exchange rate at the time of contracting for fees agreed in Euros but paid in GBP, and the exchange rate at the time of the event for fees for service agreed in Euros and paid in Euros.
- One company used the exchange rate on the date of payment for financial payments, and the exchange rate on the date of interaction for other ToV.

1.3. Identifying transfer of value dates

From the total of 139 companies who submitted methodological notes, 68 did not provide an explanation of the way the date of ToV was determined (up from 49 in the previous year). The remaining 71 companies developed policies for identifying the ToV date to establish whether a ToV fell within the reporting period (2021) and was therefore eligible for disclosure.

Of the 71 companies that provided details of their approach to dating ToVs, 34 companies disclosed according to the date on which the ToV was made or the date of payment. Three companies state that the date of invoice was used. For another 16 companies, the dates used vary depending on the activity associated with the ToV. A further 11 companies used different dates depending on the nature of the ToV (indirect vs direct), while 2 companies used different dates depending on the recipient of the ToV. The remaining 5 companies used different methodology:

- Two companies were unclear about the methodology used other than specifying that internal processes were used.
- One company specified the use of payment date but stated that ToVs made were reported within six months from the end of a given calendar year.
- One company used the date of internal approval for the activity associated with the ToV.
- One company used the date of the activity associated with the ToV.

Multi-year agreements and contracts

Most companies (96; 69 percent) explicitly stated their policy on agreements spanning several years and how these were recorded for the 2021 disclosure. Of these, 79 companies (up from 59 last year) stated that they included the proportion of the ToVs relating to the given reporting period where ToVs relate to multi-year contracts. Fifteen companies stated that they did not have any multi-year agreements in place. The remaining two companies adopted different approaches to multi-year projects and agreements. One reported the contracted full amount using the date of last payment, while the other used the date when funds are due for Joint Working or Medical and Educational Goods and Services (MEGS) and the date of principle meeting for contracted services.

1.4. Disclosing data based on legitimate interests

Nine companies stated that they disclosed ToV information on the basis of ‘legitimate interests,’⁵ an increase from 7 companies in the 2020 disclosure. One additional company stated that they would disclose ToV based either on legal duty, legitimate interests, or consent of HCPs but did not specify which of these would be used in each situation. One further company made no mention of legitimate interests and stated that they did not seek consent and that all ToVs were disclosed in aggregate.

1.5. Aggregation and disaggregation of transfers of value

HCP consent and aggregate disclosure

A total of 127 companies provided information on their approach to disclosure. The large majority of these 127 companies (122; 96 per cent) disclosed at an individual level, if they had consent from HCPs (113) or based on legitimate interests (9). If consent was not obtained from an HCP/ORDM to disclose the ToVs received against their name, or if consent was obtained but subsequently withdrawn, then the ToVs made to that HCP/ORDM were disclosed anonymously in the aggregate figure. Of the remaining 5 companies, one did not seek consent and so aggregated all values, and 4 companies were unclear about their specific approach to consent:

- One stated that ToVs were disclosed based either on legal duty, legitimate interests, or consent but did not specify which approach was used.
- One company said that legal permission was obtained prior to disclosing personal data related to individual ToVs but did not specify the legal basis for disclosure.
- Two companies said that HCPs agreed to disclosure by signing their contracts with the company but did not specify the legal basis for disclosure.

As for disclosing the percentage of HCPs that are reported in the aggregate part of the disclosure, different companies interpreted the data request differently (Table 1-1). Most companies (119) did not provide any clarification, an increase from the previous year (88). Of the remaining 20 companies, 6 reported on the

⁵ Information Commissioners Office (2022)

number of ToV recipients involved in the aggregate category, 4 included a percentage or proportion of all submissions reported in the aggregate, and a further 7 reported both the number of recipients and provided a percentage. Of the remaining three companies who provided details about aggregate reporting, two had no refusals for consent from HCPs and therefore did not provide any aggregate figure. The other made no payments to HCPs during the disclosure period and therefore similarly did not provide an aggregate figure.

Table 1-1 Methodology accompanying aggregated ToVs in 2021 disclosure

Methodology on aggregated ToVs	Number of companies
Number of recipients and percentage	7
Number of ToV recipients reported in the aggregate	6
Percentage of all submissions reported in the aggregate	4
Other	3
Not stated	119

Partial consent and partial disclosure

Concerning the possibility that HCPs and ORDMs might consent to be named for the disclosure of some ToVs but refuse consent for other ToVs from the same company, the majority (47) of the 53 companies that commented on partial consent stated that they do not allow for partial consent and have disclosed all ToVs to those recipients in the aggregate section. Two companies stated that they allow partial consent. Four companies provided further details, with three of these not clarifying their policy on partial consent but instead stating that there had been no partial disclosures made by HCPs or ORDMs. One company did not clarify its policy explicitly but stated that it had disclosed individual transfers of value only “where full informed consent has been obtained from the individual.”

HCO consent and aggregate disclosure

In the UK, companies are not required to gather consent from HCOs, nor use another legal basis under the Data Protection Act, to disclose their ToVs. However, a small number (36) of companies opted to clarify their consent policy regarding HCOs in addition to HCPs. Fifteen companies reported that they sought consent from HCOs for the disclosure of ToVs. Twenty-one companies provided further information around HCO consent:

- Nine companies either stated that they had not obtained consent or referred to HCO consent not being a legal requirement in the UK.
- Four companies grouped HCOs and HCPs together in their discussion of consent and did not provide further details.
- Five companies stated that they obtained HCO consent where required by law.
- One company stated that consent had been assumed for all NHS HCOs, “consistent with the NHS policy of openness and transparency.”
- One company stated that ToVs to HCOs had been reported without consent, as per the ABPI guidelines.

- One company stated that HCOs were informed in contracts that the company would disclose all ToVs made to them.

Other exceptions to consent and disclosure

Eight companies provided further details about exceptions to consent and disclosure which were not recorded above in relation to HCP and HCO disclosures and partial consent. Each of these included one or more of the following caveats:

- HCPs that are employees of the reporting pharmaceutical company are not included in the disclosure data, as their primary occupation is not providing health care (5 companies);
- Where an HCP is retired or non-practising, the ToV is disclosed in the aggregate (one company);
- Where an HCP is retired or non-practising, the ToV is excluded (2 companies); and
- In the case of public tendering in which ToVs are demanded by the tender requirements, the data were not disclosed under the ABPI Code of Practice on the grounds that the data are already made public in the context of the tender (one company).

1.6. Cross-border payments

A total of 81 companies stated their approach to cross-border transactions. As shown in Table 1-2, 53 of these companies confirmed that reported cross-border payments are attributed to the country in which the recipient is registered or practising, and/or exclude payments to non-UK entities. This means that these companies only report ToVs to UK-based HCPs, HCOs and ORDMs in the present disclosure. Nine companies did not make any cross-border payments within the disclosure period. Eighteen companies reported disclosure to overseas recipients; and 13 of these 18 provided further specifications to their cross-border ToVs. Of these thirteen, ten companies reported that ToVs made from overseas affiliated to UK HCPs and HCOs are disclosed. One company stated that payments to healthcare organisations in Northern Ireland and the Republic of Ireland has been disclosed. Another stated that it had disclosed ToVs made to “reportable recipients within EFPIA companies.” A third company made it clear that cross-border payments were included in their disclosure but did not provide any further details, while a fourth stated that it discloses payments to HCPs in countries where it has a “commercial presence.” For all other European countries, this company would disclose the payments to European HCPs “through the UK database due to the limited number of transactions.”

Table 1-2 Methodology on cross-border ToVs in 2021 disclosure

Methodology on cross-border ToVs	Number of companies
Disclosed in HCP/HCO primary country of practice	53
Disclosed ToVs made to overseas recipients	19
Did not make any cross-border payment within disclosure period	9
Not stated	58

2. Classification and identification of recipients

2.1. Healthcare Professionals and Other Relevant Decision Makers

Classification of HCPs

According to the ABPI Code of Practice:

“The term ‘healthcare 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.”⁶

Sixty-nine companies, out of 79 that commented on the classification of HCPs, specified compliance with the ABPI and/or EFPIA Codes’ definitions of HCPs. Ten other companies made further specifications, namely:

- Three companies clarified that individuals who would otherwise be classified as HCPs, but who are employed or provided with a salary by the company making the disclosure, are not included in the disclosure, and therefore are excluded from the definition of HCPs.
- Three companies stated that they regarded employees of the NHS or other Health Care Providers as HCPs, including retired HCPs and academic staff.
- Two companies specified that they included ORDMs in their definition of HCPs.
- One company noted that ToVs would be disclosed for retired HCPs in the same manner as for those still in practice.
- One company specified the professions which it considered to fall under the category of HCP: physicians, medical doctors, pharmacists, midwives, and nurses.

Classification of ORDMs

According to the ABPI Code of Practice, the term ORDM “includes someone 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 is not a health professional.”⁷ A total of 47 companies defined ORDMs in their submission (an increase on 35 from disclosures of the previous year). Of these 47 companies, 46 classified ORDMs in line with ABPI or EFPIA guidelines. One company provided a

⁶ ABPI (2021, Clause 1.9)

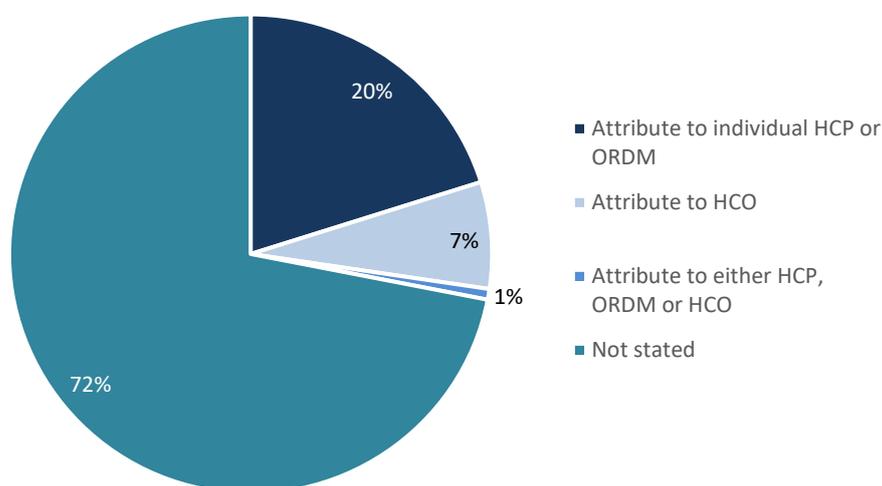
⁷ ABPI (2021, Clause 1.13)

definition which was in line with the ABPI Code of Practice but stated that ORDMs had been disclosed under the category of HCPs.

Classification of self-incorporated HCPs and companies owned/run by an HCP

Thirty-nine companies specified their policy on self-incorporated HCPs or companies owned and/or run by an HCP (see section ‘Disclosure of ToVs to HCOs when the ultimate beneficiary is an HCP’ on page 20 for more info). Of these, 28 companies attributed the ToV to the individual HCP or ORDM (Figure 2-1); however, three of these 28 companies noted that if the HCP had not given consent for individual disclosure then the ToV would be disclosed under the name of the self-incorporated HCO. Ten companies simply attributed the ToV to the HCO, often stating that the ToV was disclosed against the contracting party. One company attributed ToVs to either the HCP, ORDM or HCO, depending on the underlying contract.

Figure 2-1 Classification of self-incorporated HCPs (n=139)



2.2. Classification of Healthcare Organisations

Out of 75 companies that defined HCOs, most definitions (71; 95%) were in line with the ABPI or EFPIA definitions of the term. Four companies either deviate from that definition or make additional specifications, as follows:

- Two companies stated that their definitions were in line with the ABPI but that in the UK, HCOs would include hospitals, Clinical Commissioning Groups (CCGs), GP practices and other places of work for HCPs treating patients or providing services related to the treatment of patients.
- One company provided further details of specific healthcare organisations, including hospitals, healthcare institutions or clinics, group medical practices, relevant service providers, the medical departments of universities, foundations and charities involved in the medical domain, medical and learned societies, medical education companies and associations of healthcare professionals.

- One company stated that while laboratories are not considered HCOs, if the laboratory test is part of an activity within the scope of the code (e.g. Research & Development), then the related ToV would be included under the HCO category.

2.3. Patient organisations

Forty-one companies specified their procedure regarding ToVs to patient organisations (an increase on the previous year's 24). Eight companies stated that ToVs to patient organisations were not included in their disclosure. Twenty-two companies stated that they provide this information directly on the company's website. Seven companies disclosed full or partial ToVs made to patient organisations in their submission. Two companies provided a definition for patient organisations but did not clarify whether they made ToVs to patient organisations, and how these ToVs would be disclosed. Two companies stated explicitly that they made no ToVs to patient organisations and that hence these would not be included in the disclosure.

3. Types of transfers of value and scope of disclosure

3.1. Collaborative working

The ABPI Code of Practice was amended in 2021, which required updating certain terminology in the ToV disclosure categories displayed on Disclosure UK for 2021 data onwards. The terminology updates are to ensure pharmaceutical companies attribute the correct values to each of the ToV categories.

During this update of the ABPI Code of Practice, Joint Working was incorporated into a new broader category, collaborative working, introduced in July 2021. This change could mean that higher values are reported under collaborative working from 2021 data onwards as it is a broader type of working than the previous Joint Working framework for activities as defined by the Department of Health and Social Care and previous versions of the ABPI Code of Practice. To fully understand the disclosure data, the 2021 ABPI Code of Practice should be consulted.

Collaborative working

Collaborative working arrangements between the pharmaceutical industry and healthcare organisations are aimed at benefiting patients or the NHS or both.⁸ As noted above, this category includes Joint Working arrangements. A total of 54 companies commented on their collaborative working arrangements; although, 28 of these companies referred only to ‘Joint Working’ and not to ‘collaborative working’. It is unclear from the notes whether this is because companies did not update their definition of the category to encompass the broader collaborative working category, or if they are reporting on only Joint Working activities.

As shown in Table 3-1, 32 companies reported that they included ToVs related to collaborative working or Joint Working in their disclosure, while 22 companies stated that they did not engage in collaborative working or Joint Working.

⁸ ABPI (2021, Clause 20)

Table 3-1 Approach to disclosure for companies mentioning collaborative working or Joint Working

Approach to disclosure	Only mention Joint Working	Only mention collaborative working	Mention both collaborative working and Joint Working	Total
Included in their disclosure	14	4	14	32
Not involved in collaborative working or Joint Working	14	6	2	22
Total	28	10	16	54

3.2. Contributions to costs of events

This category refers to events organised or sponsored by pharmaceutical companies, including internal events and payments to third party, non-HCO, event organisers. It includes associated costs such as sponsorships, event registration fees and costs related to travel, accommodation, and subsistence. Of the 139 total companies reporting, 115 commented on their approach to disclosing ToVs related to contributions to costs of events.

Disclosure of ToVs for internally organised events

Twelve companies commented on their approach to disclosing ToVs related to internally organised events. Of these, 6 companies reported that they disclose ToVs related to internally organised events. Three companies report that they did not disclose ToVs related to internally organised events, with one of these companies noting that there were anyway no relevant ToVs to disclose. A further 3 companies have unclear comments regarding disclosure for internally organised events:

- One company noted that they will only disclose fees paid to individual HCPs providing services as speakers at internally organised events, but it is unclear if these ToVs are reported under the current category or under the ‘Contracted Services – Fees’ category.
- One company noted that if they pay travel and accommodation costs for people attending internal events, then those costs will be disclosed ‘in the category provided for this purpose’. It is not clear if these ToVs are reported under ‘contributions to costs of events’ or under the ‘ToVs for travel and accommodation’ category.
- One company noted that they do not disclose logistical costs or hire fees related to internal events, but do not note if there are other costs that are disclosed.

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

Thirty-nine companies commented on how they handle disclosure in the case of cancellation, non-attendance, or partial attendance at events. Of these, 23 companies said that they did not report ToVs related to cancelled events/non-attendance. Twelve companies said that partial attendance and non-

recoverable fees from cancelled events were reported. Four companies stated that they disclosed ToVs related to cancelled events.

Disclosure of ToVs for food and drink

The ABPI Code of Practice states that if a company contributes towards the overall cost of subsistence when providing sponsorship to an event then this cost must be disclosed.⁹ However, there is no requirement to disclose subsistence provided along with support to individual HCPs or ORDMs. Under the Code, ‘the costs of any subsistence (food and drink) provided must not exceed £75 per person, excluding VAT and gratuities.’¹⁰

Forty-five companies commented on their approach to disclosing subsistence related to events and meetings (see Table 3-2). Of these, 8 companies stated that they included ToVs related to subsistence to individual HCPs in their disclosure. Twenty-five companies stated that they did not disclose costs related to subsistence provided to individuals, although 7 of these 25 companies noted that ToVs related to subsistence are necessarily included when they are inseparable from other costs, such as when breakfast is included in the cost of a hotel room.

Companies also described their approach to disclosing subsistence costs associated with the sponsorship of events, such as catering costs. Twenty-five companies stated that they included these costs in their disclosure.

Five companies had unclear approaches to disclosure:

- One company had an unclear approach to disclosure for subsistence to individuals, stating they had included costs related to ‘transport, registration fees, accommodation, and other forms of hospitality’, but it is unclear whether subsistence costs are included in this definition.
- Two companies had unclear approaches to disclosing sponsorship, with language suggesting that subsistence costs were outside the scope of disclosure.
- One company stated that they did not include ToVs related to ‘meals and drinks’, but is unclear if this refers to subsistence for individual HCPs, subsistence related to sponsorship agreements, or both.
- One company noted that they do not disclose subsistence ‘except in some countries in which meals are required to be included in the disclosure’. It is unclear if they included meals in their UK disclosure and if this applied to disclosure for individual subsistence or subsistence related to sponsorship of events.

⁹ ABPI (2021, Clause 28.1)

¹⁰ ABPI (2021, Clause 10.7)

Table 3-2 Approach to disclosure of ToVs for food and drink

	Included	Not Included	Not Stated	Unclear
ToVs related to food and drink for individual HCPs	8	25	103	3
ToVs related to food and drink provided as part of sponsorship agreements	25	-	110	4

Note: Two of the 'unclear' approaches apply to both disclosure for individual HCPs and sponsorship agreements, for a total of 5 companies with unclear approaches.

Disclosure of ToVs for travel and accommodation

A total of 101 companies noted their approach to the disclosure of ToVs for travel and accommodation related to meetings and events, with 97 of these companies (96%) stating that these costs were included in their disclosure. Four companies stated that they did not have any ToVs related to travel and accommodation for scientific meetings and so they were not included in the disclosure. No companies stated that they did not disclose ToVs related to travel and accommodation.

Disclosure for sponsoring HCPs to attend events

Across the 139 companies' notes, 103 companies commented on their approach to disclosing ToVs related to sponsorship of healthcare professionals to attend scientific meetings and events. Of these, 99 companies (96%) stated that sponsorship costs were included, 3 companies noted that they did not have any costs associated with this category because they did not sponsor any healthcare professionals to attend meetings or events, and one company commented that they disclosed sponsorship costs, but it was unclear whether this referred to sponsorship of healthcare professionals to attend meetings or sponsorship of events (the next category).

Disclosure for sponsoring an event

Companies also commented on their approach to disclosure of costs related to sponsorship of events. These are typically related to agreements with HCOs, or third-party event organisers working on behalf of HCOs, for pharmaceutical companies to sponsor a scientific meeting or event. One hundred and six companies commented on this disclosure category, with 104 (98%) of them stating that ToVs related to sponsorship costs were included in their disclosures. Two of the companies commenting on this category had unclear disclosure statements related to this category, with one of them stating that they disclosed sponsorship costs, but not being clear about whether this referred to sponsorship of healthcare professionals to attend meetings or sponsorship of events.

Several companies offered further specifications about what was included in their sponsorship disclosures. These typically described the various direct and indirect costs associated with sponsorship (e.g. catering, logistics, advertising space, support for speakers, rental of exhibition stands, educational courses). However, two companies noted that their sponsorship contracts may contain a provision requiring HCOs to invite a number of HCPs selected by the sponsoring pharmaceutical company. In these cases, the ToVs related to those specific HCPs would be disclosed against the individual HCPs and not the HCO.

3.3. Contracted Services

Disclosure of ToVs related to contracted services – fees

This category covers ToVs for services and consultancy performed by HCPs, ORDMs or HCOs that do not fall under R&D. The majority of ToVs that fall within this category relate to speaker fees, speaker training, development of educational materials, advisory boards, and travel and accommodation fees. A total of 105 companies stated that they disclose fees for contracted services. No company said that they do not disclose ToVs related to fees for contracted services.

Disclosure of ToVs related to contracted services – expenses

Of the 105 companies commenting on contracted services, 75 stated their approach to disclosing ToVs related to associated expenses, with most of these (68 companies) stating that travel and accommodation costs were included in their disclosure. Four companies noted that they did not have any costs associated with travel and accommodation for contracted services, and for a further two companies their policies were unclear. One company said that they did not include expenses such as “meals and drinks, travel and accommodation” related to contracted services in their disclosure.

Disclosure of ToVs related to medical and educational goods and services (MEGS)

Under the 2021 ABPI Code of Practice, medical and educational goods and services (MEGS) which were previously disclosed under Clause 19 of the 2019 Code have been reclassified.¹¹ Under the 2021 Code, MEGs are now likely to be disclosed under either donations or collaborative working. Companies with ongoing MEGs from 1 July 2021 may still disclose these activities as MEGs without reclassification until 31 December 2021.

Ten companies commented on ToVs related to MEGs. Of these, seven companies stated that they included MEGs in their disclosure, with one company explicitly citing the 2021 guidance allowing continued disclosure of ongoing MEGs activities without reclassification through to 31 December 2021. The remaining three companies that commented on MEGs noted that any ToVs related to MEGs were disclosed under ‘Donations and Grants’, in accordance with the updated 2021 ABPI Code of Practice.

Disclosure of ToVs for ‘blind’ market research

The ABPI Code of Practice¹² requires disclosure of payments in relation to market research where the identities of participants are known. Forty-one companies commented on their disclosure practices related to market research. Of these, 8 companies stated that they did not include ToVs related to market research, with 3 of them specifically noting that this was because they did not participate in market research where the identities of the participants were known to them. Thirty-three companies mentioned that they include ToVs related to market research in their disclosure in some form:

- Twenty-seven companies stated that they include ToVs for market research when the identities of participants are known.

¹¹ ABPI (2021, Clause 20)

¹² ABPI (2021, Clause 24.5)

- Five companies stated that they include ToVs for market research without giving further specification.
- One company noted that they include ToVs for market research, but only as an aggregate value.

ToVs related to co-promotions

A total of 12 companies mentioned their approach to disclosure of ToVs related to co-promotion activities. Eleven companies stated that they included co-promotion activities and one company noted that they had no co-promotion ToVs to disclose. Seven companies that include co-promotion in their disclosure made further specifications, most commonly noting that only payments made through their company's bank accounts or accounting systems would be disclosed. One company further specified that they only include co-promotion where they are the contracting party.

Research and development

A total of 68 companies commented on R&D in their methodological notes. One of these noted that they had no R&D activity to disclose during 2021. One company's approach to disclosure was unclear. Of the remaining 66 companies, 46 provided a definition of R&D that included the key components of the EFPIA and ABPI Codes, using the definition of non-clinical studies in the OECD Principles on Good Laboratory Practice¹³ and the definition of clinical trials and prospective non-interventional studies, as defined in Directive 2001/20/EC and Section 15.01 of the Good Clinical Practice Code¹⁴. The remaining 20 companies provided their own definitions, which frequently contained key elements of the EFPIA and ABPI Codes but also listed additional activities or further specifications that would be disclosed. Common activities that companies included in their definitions of R&D included:

- Investigator-sponsored studies, including drugs supplied to HCOs for use in investigator-sponsored studies.
- Costs associated with regulatory approvals.
- Data monitoring committees.
- Direct and indirect payments to clinical research organisations related to clinical trials.
- Advisory boards.

One company also noted that they do not include ToVs to companies that arrange patient travel and accommodation in their R&D disclosure.

3.4. Indirect ToVs

The ABPI Code defines an indirect ToV as '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'.¹⁵ The methodological notes submitted by companies describe indirect ToVs as those made to third party companies where the ultimate beneficiary is an HCP or HCO whom the company

¹³ OECD (1998)

¹⁴ European Commission (2001)

¹⁵ ABPI (2021, Clause 1.25)

can identify; however, some companies further specify their approach to disclosing ToVs made to HCOs where the ultimate beneficiary is an HCP whom the company can identify. Companies' approaches to disclosure for these two situations are detailed below.

Disclosure of ToVs to third parties when the ultimate beneficiary is an HCP or HCO

Seventy-four companies commented on their methodology for disclosing indirect ToVs to HCPs and HCOs. Of these, 49 companies stated that they attribute the ToVs to the HCP or HCO that benefited from the transfer, where possible. For 22 of the companies who mentioned indirect ToVs, their methodology of disclosure was not clear. A further 3 companies noted that they did not make any indirect ToVs and as such did not include them in their disclosure.

Disclosure of ToVs to HCOs when the ultimate beneficiary is an HCP

Thirty-five companies commented specifically on their approach to disclosing payments to HCOs when the ultimate beneficiary was an HCP whom the company could identify. Of these, 15 companies stated that they attribute the ToVs to the HCO, with companies frequently noting that they report the contracting party. Seventeen companies stated that they attribute ToVs to the HCP. Three companies had unclear policies regarding disclosure of ToVs to HCOs when the ultimate beneficiary was an HCP whom the company could identify. These companies noted that the ToV would only be disclosed once, on either recipient level (HCO or HCP), but did not specify a methodology for determining the recipient level.

3.5. Additional considerations related to the scope of disclosures

ToVs related to over-the-counter medicines

The ABPI Code of Practice applies to medicines for prescribing and does not apply to over-the-counter (OTC) medicines.¹⁶ However, 40 companies commented on their approach to disclosing OTC medicines. Thirty-two companies stated that they did not include OTC medicines in their disclosures, with 14 of these companies noting that they did not have any ToVs related to OTC medicines to disclose. Of the 8 companies that stated that they disclosed ToVs related to OTC medicines, one noted that they do so only where there was overlap with medical products that are otherwise reportable.

ToVs related to medical devices

The ABPI Code of Practice covers medicines for prescribing and not medical devices. Nevertheless, 34 companies described their approach to disclosing ToVs related to medical devices. Twenty-five companies stated that they did not disclose ToVs related to medical devices, with 12 of these companies noting that they had no ToVs related to medical devices to disclose. Nine companies stated that they included medical devices in their disclosures, with two companies stating that they only did so where there was overlap with medical products that are otherwise reportable.

¹⁶ ABPI (2021, clause 1.1)

Donations and grants

A total of 76 companies commented on their approach to reporting donations and grants:

- Most of these companies (57; 75%) stated that such ToVs were included in their disclosure under the HCO category.
- Two companies stated that, when making donations or grants to HCOs to support HCPs attending medical or scientific meetings, if the individual HCP could be identified then the ToV would be disclosed against the individual HCP. Otherwise the donation or grant would be disclosed against the HCO.
- Five companies did not provide donations and grants within the reporting period.
- Two companies had unclear methodology related to donations and grants.
- Ten companies provided definitions of ‘donations and grants’, but gave no information on their approach to disclosure.

Excluded ToVs beyond those discussed

A total of 13 companies mentioned types of ToVs that were excluded from their disclosure, beyond those discussed so far. These companies provided a mix of exclusions which covered, for example, ToVs related to ‘hospitality costs’, ‘logistical costs’, ‘donations to charitable and patient organisations’, ‘informational and educational materials’, ‘medical samples’, and ‘donations to HCOs that are funded by employee contributions’.

Impact of COVID-19 on 2021 disclosure

Eight companies noted that the COVID-19 pandemic affected their disclosure (this is down from 13 companies in 2020). Companies noted that the pandemic had led to delayed or cancelled events; reduced travel due to virtual conferences; and reduced (or no) engagement with HCPs. The practical implications for the companies’ disclosures were reported to be delayed or refunded payments related to events that were postponed or cancelled, and fewer ToVs to disclose overall.

References

Association of the British Pharmaceutical Industry (ABPI). 2021. Code of Practice for the Pharmaceutical Industry: 2021. Prescription Medicines Code of Practice Authority. As of 19 May 2022:

https://www.abpi.org.uk/media/hmadhqit/240621-abpi-code-of-practice_final.pdf

European Commission. 2001. Directive 2001/20/EC of the European Parliament and of the Council. As of 04 June 2021: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf

European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice. 2019. European Federation of Pharmaceutical Industries and Associations, 27 June 2019. As of 04 June 2021: <https://www.efpia.eu/media/602690/310521-efpia-code.pdf>

Information Commissioner's Office (ICO). 2019. Guide to the General Data Protection Regulation (GDPR). As of 04 June 2021: <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/>

Information Commissioner's Office (ICO). 2022. Legitimate interests. Information Commissioner's Office. As of 07 June 2022: <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/legitimate-interests/>

Organisation for Economic Co-operation and Development (OECD). 1998. OECD Principles on Good Laboratory Practice. Organisation for Economic Co-operation and Development. As of 04 June 2021: https://ntp.niehs.nih.gov/iccvam/suppdocs/feddocs/oecd/oecd_glpcm.pdf