

Disclosure UK: understanding the data

Guidance notes for analysis of the 2022 data

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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 2022. 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 2021,¹ which incorporates requirements from the consolidated European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice 2019.²

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¹ ABPI (2021); <https://www.pmcpi.org.uk/>

² EFPIA (2019); <https://www.efpia.eu/relationships-code/the-efpia-code/>

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Abbreviations

ABPI	The Association of the British Pharmaceutical Industry
CCG	Clinical Commissioning Group
COVID-19	Coronavirus Disease 19
CRO	Clinical Research Organisation
EFPIA	European Federation of Pharmaceutical Industries and Associations
GDPR	General Data Protection Regulation
GP	General (Medical) Practitioner
HCO	Healthcare Organisation
HCP	Healthcare Professional
ICS	Integrated Care System
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 wider efforts to increase transparency, all pharmaceutical companies abiding by The Association of the British Pharmaceutical Industry (ABPI) Code of Practice are required to disclose Transfers of Value (ToVs) to healthcare professionals (HCOs), other relevant decision makers (ORDM) and healthcare organisations (HCOs). This disclosure requires companies to provide an accompanying note summarising the methodologies they used to prepare the disclosures for the reporting period (i.e. the calendar year 2022). The following guidance notes for analysis of the 2022 data draw on information from the 145 methodological notes submitted by these companies.³ 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 number of disclosing companies that report using it. However, this number 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.

At the end of 2021, the ABPI introduced changes to their recommended approach towards the legal basis for individual disclosure. The publication of data associated with individuals – whether HCPs or ORDMs – is regulated by the UK Data Protection Act and GDPR requirements in the UK.⁴ To date, most companies have used ‘consent’ as the lawful basis to publish information related to individuals. This means that disclosure is dependent on whether individual HCPs and ORDMs provide informed consent for the publication of ToVs that they received from pharmaceutical companies. This poses a challenge in further improving transparency through Disclosure UK as some individuals choose to exercise their rights under the GDPR and do not provide consent. To address this challenge, the ABPI has since encouraged companies

³ Note that sometimes a company will submit more than one set of data and hence more than one set of notes, for reasons such as a name change or a merger part way through the year. We count these as distinct sets of data and distinct notes.

⁴ GDPR is not applicable to HCOs.

to use ‘legitimate interests’ as the lawful basis for processing and disclosing individual data.⁵ This change was reflected in the approach of 23 companies (out of a total 145), which stated that they disclosed ToVs to individuals on the basis of legitimate interests for 2022. Further details about this can be found in Chapter 1, Section 1.4.

Occasionally, disclosing companies and their associated data are removed from the Disclosure UK database before the end of the three-year publication lifespan for disclosure information. This can be due to several reasons, such as the entity closing operations in the UK, or no longer being commercially active in the UK, or the legal entity has changed due to a merger or acquisition. In such instances, a researcher may see that the number of disclosing companies for a single data year has reduced since the initial June data publication. Chapter 1 discusses companies’ approach to the calculation and collation of ToVs, including matters concerning VAT, currency and exchange rates, identifying ToV dates, the lawful basis for disclosure, aggregation and disaggregation of ToVs, as well as cross-border payments. Chapter 2 outlines the way that methodological notes approach defining key terms such as HCPs, ORDMs and HCOs. Chapter 3 discusses the types of ToVs and the scope of disclosure, including companies’ approach to collaborative working, contributions to costs of events, contracted services, indirect ToVs, and some additional considerations related to the scope of disclosures.

These guidance notes should be read in conjunction with the ABPI Code of Practice, 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.

⁵ ABPI Press Release “ABPI champions use of ‘Legitimate Interests’ to boost transparency” 9 December 2021: <https://www.abpi.org.uk/media/news/2021/december/abpi-champions-use-of-legitimate-interests-to-boost-transparency/>

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

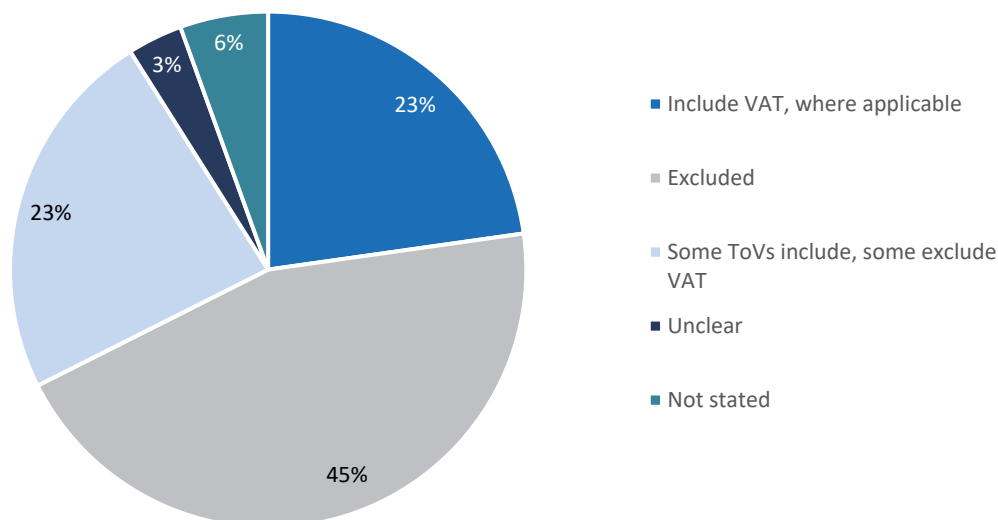
Out of 145 companies that submitted methodological notes, 137 companies submitted detail on their approach to VAT disclosure. Of these, 65 companies excluded VAT from their disclosures and reporting. Thirty-three companies included VAT in their disclosures and reporting. Thirty-four companies reported a combination of ToVs including or excluding VAT. Five companies provided unclear information about their approach to VAT:

- Two companies reported that the individuals or organisations paid were responsible for their own taxes and stated that VAT would be paid against the delivery of a valid invoice but did not clarify how they would report VAT as part of their disclosure.
- One company reported that all fees and appropriate local taxes such as VAT would be paid at the specified local rates but did not clarify how it would report VAT as part of its disclosures.
- One company reported that all clinicians were paid their respective fees together with payment of VAT at the prevailing rate but did not clarify how it would report VAT as part of its disclosures.
- One company stated that all transactions were correctly accounted for with regards to VAT and corporation tax purposes but did not clarify how it would report VAT as part of its disclosures.

Examples of VAT being treated differently in reporting by companies include different treatment of direct vs indirect ToVs, different treatment of kinds of ToV (e.g. fees for services and travel and accommodation) and cases where a company opted to exclude VAT but, in some instances, could not accurately exclude the amount of 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 2022 disclosure (n=145)



1.2. Currency and exchange rates

Currency

Most (135 out of 145) companies that submitted methodological notes specified which currency they used in the disclosure. All these 135 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 countries into GBP. Of the 126 companies that specified their approach to the exchange rates they used to convert payments made in foreign currency to GBP: 12 stated that no payments had been made in non-GBP currencies and therefore no exchange rates were required; 27 used the exchange rate prevailing at the time of payment but did not state if ‘the time’ refers to the day, month, or year; a further 20 used the exchange rate of the date of ToV; while 19 companies used the average exchange rate of the month in which the payment was made; and 20 companies used an average annual exchange rate. A further 28 companies provided other specifications for their approach to exchange rates:

- Nine companies stated that currency conversion had been conducted using approved exchange rates or processes but did not provide further details.
- Five companies stated that currency conversion had been conducted on the specific date or time of reporting.
- Two companies stated that currency conversion had been conducted on the day of approval for the ToV.
- Two companies stated that exchange rates would be provided on a case-by-case basis.

- Two companies stated that direct and indirect ToVs would be converted based on the date of ToV while cross-border ToVs would be converted using the average rate of the month in which the ToV occurred.
- One company provided the specific exchange rate used.
- One company stated that currency conversion had been conducted based on the time of activity.
- One company stated that currency conversion had been conducted based on time of entry into the accounting package.
- One company stated that all payments were reported in the currency in which they took place.
- One company stated that fees for services paid in Euros were converted on the day of payment, fees for services agreed in Euros and paid in GBP were converted at the time of contracting, and fees for services agreed in Euros and paid in Euros were converted at the time of the event.
- One company stated that direct payments were converted on the day of payment, while indirect payments were converted on the date of the event.
- One company stated that ToVs made by the company itself were converted based on the day of documenting, while ToVs by foreign affiliates were converted using average annual exchange rates.
- One company stated that currency conversions were conducted using either the average daily rate for the relevant date or the average annual exchange rate.

1.3. Identifying transfer of value dates

From the total of 145 companies who submitted methodological notes, 65 did not provide an explanation of the way the date of ToV was determined. The remaining 80 companies developed policies for identifying the ToV date to establish whether a ToV fell within the reporting period (2022) and was therefore eligible for disclosure.

Of the 80 companies that provided details of their approach to dating ToVs, 50 companies disclosed according to the date on which the ToV was made or the date of payment. Two companies disclosed according to the date on which the activity took place rather than the date of payment or the date of the ToV. The remaining 28 companies used a different methodology depending either on the activity, the nature of the ToV (direct or indirect) or a mixture of both:

- Twenty-one companies disclosed according to the date of payment for direct ToV and according to the date of event, last date of event or receipt of benefit for indirect ToV.
- One company disclosed according to the date of payment for direct ToV and the date of event for indirect ToV and sponsorship of events.
- One company disclosed according to the date of payment for direct ToV and the date the on which the therapy review took place for “therapy reviews delivered as a donation.”
- One company disclosed according to invoice date for the direct ToV and the payment date for indirect ToV.
- One company disclosed payments and reimbursements to HCPs/HCOs and congresses and event ToVs on the date of payment, travel and accommodation on the date of booking, and

reimbursements in relation to investigator meetings on the date that the ToV was submitted for payment by the organiser.

- One company disclosed “short term activities within a defined timeframe” on the start date of the activity, and “long-term activities” on the posting date of the relevant invoice.
- One company stated they would disclose either on the date on which funds were due under the contract, or the date of the relevant trip or activity, or on the date on which services were provided, but did not state in which circumstances each of these would be used.
- One company disclosed according to date of payment except for ToV to HCPs/ORDMs in a different country, which it would disclose according to the event date.

Multi-year agreements and contracts

Most companies (103; 71 percent) explicitly stated their policy on agreements spanning several years and how these were recorded for the 2022 disclosure. Of these, 85 companies (up from 79 last year) stated that they included the proportion of the ToVs relating to the given reporting period where ToVs relate to multi-year contracts. Seventeen companies stated that they did not have any multi-year agreements in place. One company stated that an instalment payment for one multi-year contract was included in the 2022 disclosure but did not provide further information.

1.4. Disclosing data based on legitimate interests

Under GDPR and the UK Data Protection Act, companies must have a lawful basis to publish personal data about individuals (HCPs or ORDMs). While the consent framework, used by the majority of companies in previous years, requires the explicit agreement of the individual HCP or ORDM before their name is included in a disclosure, a ‘legitimate interests’ basis instead allows a company to assert their transparency requirements over the data rights of the individual. This means that a company will not ask the HCP or ORDM for consent to publish their name and practice address with the value received but must still provide an opportunity for the individual to raise objections. Any objections are subject to a strict balancing test, as laid out in the GDPR, to determine whether the objection outweighs the publication of ToV data. In December 2021, the ABPI released new guidance⁶ encouraging companies to adopt legitimate interests to increase the number of named individuals included in their disclosure.

Twenty-three companies stated in their notes that they disclosed ToV information on the basis of legitimate interests, an increase from 9 companies in the 2021 methodological notes. Of the 23 companies, 19 provided further details of their specific approach to legitimate interest:

- Ten companies used the phrasing of ‘legitimate interests’ but did not provide any details of a ‘balancing test’ by which it would be determined whether the information should be removed.

⁶ ABPI Press Release “ABPI champions use of ‘Legitimate Interests’ to boost transparency” 9 December 2021: <https://www.abpi.org.uk/media/news/2021/december/abpi-champions-use-of-legitimate-interests-to-boost-transparency/>

- Six companies stated that they would disclose on the basis of legitimate interests and invited HCPs to raise objections but stated that these objections would be subject to a balancing test or process of consideration.
- Two companies stated that they would disclose on the basis of legitimate interests except where the objection raised to disclosure by an HCP ‘overrides legitimate interest in disclosure’ or where the HCP in question dies by the time of disclosure.
- One company stated that they would disclose under legitimate interests and that it was a ‘priority to maintain a balance between our legitimate interests and HCPs/ORDMs’ privacy’ but provided no further details.

Three further companies provided a time frame in 2022 within which they would move from a consent to a legitimate interests framework, while one company stated in their disclosure that they have adopted a legitimate interests approach in some markets but did not specify whether this included the UK. Finally, one company referred to using both a consent and a legitimate interests approach but did not specify which of these approaches would be used in a given situation.

1.5. Aggregation and disaggregation of transfers of value

HCPs and aggregate disclosure

A total of 130 companies provided information on their approach to disclosure. The majority of these companies (123; 95 per cent) disclosed at an individual level if they had consent from HCPs (100) or based on legitimate interests (23). 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. The remaining seven companies provided further detail about their specific approach to disclosure:

- Three companies provided a time frame within 2022 in which a move from consent to a legitimate interests framework was made.
- One company referred to using both a consent and legitimate interests approach but did not specify which of these approaches would be used in a given situation.
- One company stated that they adopted a legitimate interests approach in some markets but did not specify whether this includes the UK.
- One company stated that consent is collected as required at country-level but did not specify whether this was being applied to the UK.
- One company reported that no payments were made to individual HCPs in 2022.

As for disclosing the percentage of HCPs that are reported in the aggregate part of the disclosure, different companies interpreted the data request differently. Most companies (122) did not provide any clarification. Of the remaining 23 companies, six reported on the number of ToV recipients involved in the aggregate category, six included a percentage or proportion of all submissions reported in the aggregate, and a further 11 reported both the number of recipients and provided a percentage.

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 (42) of the 44 companies that commented on partial consent (down from 53 companies that commented last year) 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.

HCOs 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. In alignment with this, it is not possible to report HCOs in aggregate via Disclosure UK. However, 49 companies opted to clarify their consent policy regarding HCOs. Eighteen companies reported that they sought consent from HCOs for the disclosure of ToVs. Twenty-seven companies reported that they did not seek consent from HCOs. A further four companies provided further details:

- Three companies reported that they would seek consent from HCOs as required by the jurisdiction but did not comment specifically on their approach with regards to the UK.
- One company reported that it would seek consent from HCOs under “exceptional circumstances.”

There were no further details recorded about exceptions to consent and disclosure in relation to HCP and HCO disclosures and partial consent.

1.6. Cross-border payments

A total of 86 companies stated their approach to cross-border transactions. As shown in Table 1-1, 73 of these companies confirmed that 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. Six companies did not make any cross-border ToVs within the disclosure period.

Table 1-1 Methodology on cross-border ToVs in 2022 disclosure (n=145)

Methodology on cross-border ToVs	Number of companies
Disclosed in HCP/HCO primary country of practice	73
Disclosed ToVs made to overseas recipients	7
Did not make any cross-border ToVs within disclosure period	6
Not stated	59

Seven companies reported including disclosure to overseas recipients, and all provided further specifications to their cross-border ToVs. Of these seven, three disclosed ToVs made to HCPs and HCOs in Europe. One company disclosed ToVs made to HCPs and HCOs in the Republic of Ireland. Another stated that it had disclosed ToVs made to “reportable recipients within EFPIA countries.” A third company stated that

following its acquisition, it would move from disclosing ToVs to all “in-scope” recipients worldwide, to all recipients within Europe on a specific date within the disclosure period. Finally, a fourth company stated that all cross-border transfers of value would be included as part of the submission.

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.”⁷

Transfers of values to either HCPs or ORDMs are collectively reported under the category of HCPs in Disclosure UK. Seventy-two companies, out of 86 that commented on the classification of HCPs, specified compliance with the ABPI and/or EFPIA Codes’ definitions of HCPs. Fourteen other companies made further specifications. Of these 14 companies, 12 included ORDMs in their definition of HCPs. One further company included ORDMs in their definition of HCPs, together with all employees of NHS or private HCOs regardless of employment status. Finally, one company clarified that their definition of HCP did not include staff working for the company itself due to salary and bonus disclosures.

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.”⁸

A total of 65 companies defined ORDMs in their submission (an increase on 47 from the previous year). Of these 65 companies, 51 classified ORDMs in line with ABPI or EFPIA guidelines. Fourteen companies provided further detail about their approach. Of these, 12 stated that ORDMs had been disclosed under the category of HCPs, while one included ORDMs in their definition of HCPs, together with all employees of NHS or private HCOs regardless of employment status. An additional company stated that it would disclose ToV to retired ORDMs as if they were still practising.

⁷ ABPI (2021, Clause 1.9)

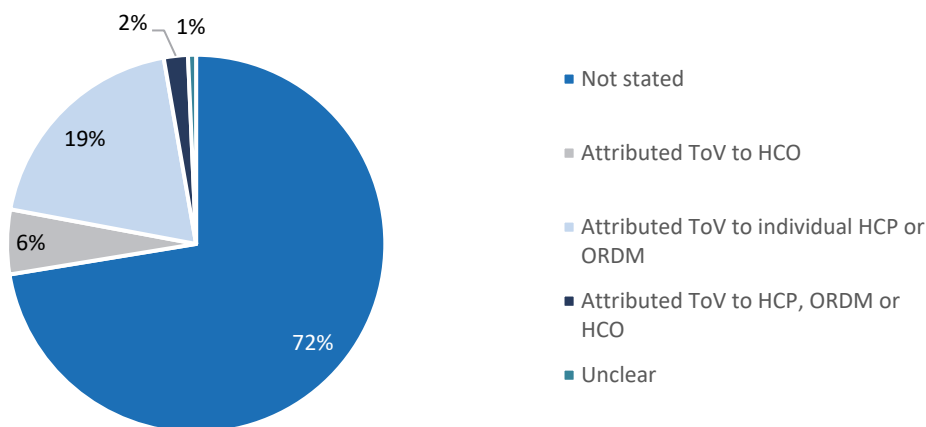
⁸ ABPI (2021, Clause 1.13)

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

Forty companies specified their policy on self-incorporated HCPs or companies owned and/or run by an HCP. Of these, 28 companies attributed the ToV to the individual HCP or ORDM (Figure 2-1). Of these 28 companies, five clarified that they would take this approach only if the HCP was sole director of the company, while another stated that ToVs would be disclosed against the HCO if consent was not given for the individual HCP in question.

Eight companies simply attributed the ToV to the HCO, often stating that the ToV was disclosed against the contracting party. Three companies attributed ToV to either the HCP, ORDM or HCO, depending on the underlying contract. Finally, one company did not provide specific details on self-incorporated HCPs but stated that they adopted a 'follow the money' policy by which ToVs would be reported under the name of the ultimate beneficiary.

Figure 2-1 Classification of self-incorporated HCPs (n=145)



2.2. Classification of Healthcare Organisations

Out of 80 companies that defined HCOs, most definitions (74; 93 per cent) were in line with the ABPI or EFPIA definitions of the term. Six companies made additional specifications, stating that in the UK HCOs would include hospitals, Clinical Commissioning Groups (CCGs), Integrated Care Systems (ICSs), GP practices and other places of work for HCPs treating patients or providing services related to the treatment of patients.

2.3. Patient organisations and members of the public

Companies are required to publish disclosures of ToVs to patient organisations and members of the public on the company's own website (ABPI Code 2021, clauses 29 and 30). While data on ToVs to patient organisations and members of the public is not integrated into Disclosure UK in the same way as data about ToVs to HCPs, ORDMs and HCOs, the information can be accessed via the Disclosure UK website via separate 'gateways'. The gateways comprise a list of hyperlinks to patient organisation and/or member of the public data published on individual company websites, enabling quick access to that information.

Sixty-two companies provided information on their procedure regarding ToVs to patient organisations (an increase on 41 the previous year). Fourteen companies stated that ToVs to patient organisations were not included in their HCP, ORDM and HCO disclosure. Thirty-three companies stated that they provide this information directly on the company's website. Eleven companies disclosed full or partial ToVs made to patient organisations in the submission. Four companies provided further specifications:

- One company stated that Patient Organisations would only be included in the disclosure report “if they are in scope for reporting as defined in the country code/law.”
- One company mentioned Patient Organisations as part of Educational Grants that it would disclose.
- One company mentioned Patient Organisations under the category of Donations but did not make clear if any ToV would be included in the disclosure.
- One company stated that it had made three Unrestricted Educational Grants and no Donations to Patient Organisations in 2022 but did not make clear if these ToVs would be included in the disclosure.

3. Types of transfers of value and scope of disclosure

The ABPI Code requires ToVs made to HCP, ORDMs and HCOs in relation to R&D activities to be disclosed as a single, aggregated value via Disclosure UK. ToVs related to non-R&D activities are published against individually named HCP, ORDMs or HCOs, where legally able. How companies have defined these ToVs is discussed in the following sections.

3.1. Research and development

A total of 65 companies commented on how they defined R&D in their methodological notes (see Figure 3-1). Of these, 57 defined R&D in line with the key components of the EFPIA and ABPI Codes, using the definition of non-clinical studies in the OECD Principles on Good Laboratory Practice⁹ 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 Code.¹⁰ Eight companies included further specifications, in addition to how ABPI and/or EFPIA define R&D:

- One company stated that they included meetings related to research activities in the R&D category.
- Another company noted that R&D includes all activities aiming at discovering and developing new therapies for severe diseases, as well as partnerships with academia and drug discovery foundations.
- One company specified that clinical trials that have a retrospective element have been disclosed as a fee for service at an individual level. They also noted that R&D does not include any biological samples and investigational compounds because they are regulated under the Clinical Trial Directive. Finally, they added that any instances where laboratory equipment was lent out to conduct a study, and which has subsequently been returned at the end of the study, have not been included as ToVs for disclosure purposes.
- One company stated that they classify research activities as those that are not undertaken solely for the purpose of obtaining a marketing authorisation for medicinal products. Similarly, they noted that studies not intended for regulatory approval do not fall under the R&D disclosure category –

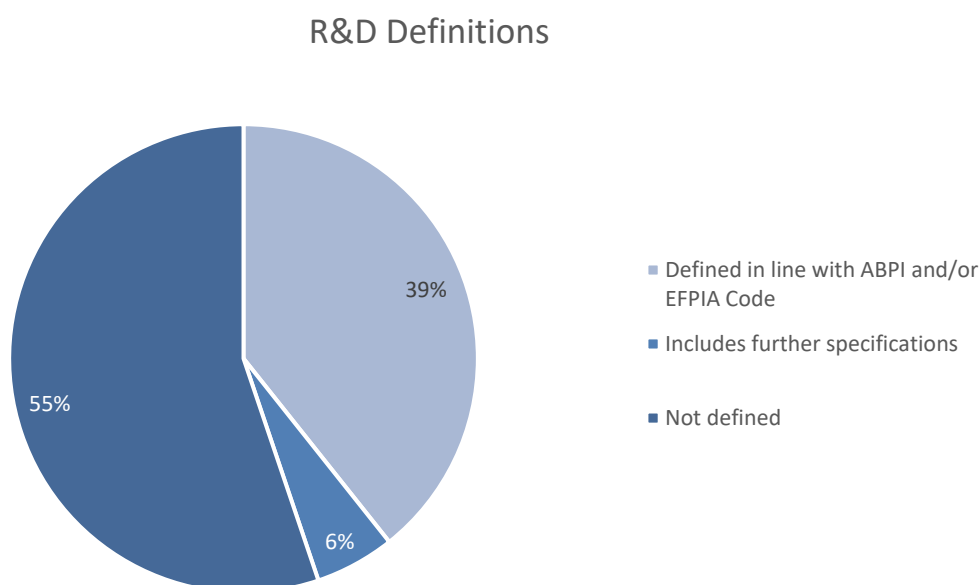
⁹ OECD (1998)

¹⁰ European Commission (2001)

instead, they are disclosed under the fee for service and consultancy or donations and grants categories.

- Another company noted that their definition of R&D includes investigator sponsored research as well as retrospective non-interventional studies.
- One company stated that R&D also included ToVs related to travel and accommodation associated with research-related events.
- One company listed that their definition of R&D included clinical trials, data monitoring committees related to studies, prospective non-interventional studies, investigator initiated research, clinical and research collaborations, investigator fees for patient visits paid to clinical trial site staff or to clinical research organisations (CROs), and costs of investigator meetings and committees.
- One company specified that ToVs related to R&D that do not fall under expenses that are defined by the EFPIA Code have been disclosed under the fees for services and consultancy category.

Figure 3-1. Reported R&D definitions (n=145)



3.2. 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 arrangements, including Joint Working, between the pharmaceutical industry and healthcare organisations are aimed at benefiting patients or the NHS or both.¹¹ Of the 145 methodological notes for the 2022 disclosure, 70 commented on the company's approach to collaborative working and/or Joint Working. Of these, 30 mention both collaborative and Joint Working, eight of which specified that collaborative working included Joint Working. 19 companies mentioned only collaborative working, while 21 mentioned only Joint Working.

3.3. 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 145 total companies reporting, 128 commented on at least some aspect of their approach to disclosing ToVs related to contributions to costs of events.

Disclosure of ToVs for internally organised events

Eighteen companies included mention of whether they include disclosure of ToVs for internally organised events. Of these, eight stated that they do not disclose ToVs related to internally organised events. Eight companies stated that they included ToVs related to internally organised events, with one of them specifying that they provide aggregated values for travel to internal events, but that other costs related to internal events, such as rent for space, technical expenses or equipment hire, are not part of the disclosure. Two responses were unclear:

- One company mentioned that they did not include logistical costs related to internal events, but that they did include information related to travel, accommodation, and speaker fees to HCPs in the relevant cost categories.
- One company stipulated that in some cases, they may reimburse HCPs/ORDMs for attendance in internal events, however, they did not specify whether this information is disclosed. At the same time, the company mentioned that for some events, a ToV was disclosed using a value for a comparable course.

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

Forty-four companies commented on how they handle disclosure in the case of cancellation, non-attendance, or partial attendance at events. Three of these stated that they included ToVs for events in case of cancellation or non-attendance in their disclosure reports, while 21 stated that they do not disclose such ToVs. Twenty companies noted that they disclosed only partial attendance at the event, meaning ToV would not be disclosed if the HCP/ORDM did not attend any part of the event or if no other benefits were received. Of these 20 companies, 12 stated that only the benefits received by the HCP/ORDM would be

¹¹ ABPI (2021, Clause 20)

reported, while six also included any expenses already incurred or reimbursed including HCP/ORDM preparation time. One company stated that the full amount would be disclosed in relation to partial attendance. Another stated that it would only disclose ToVs which were not cancellable or reimbursable.

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.¹² 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.’¹³

Sixty-one companies commented on how they handle disclosure for food and drink. Of these, seven companies noted that they included such ToVs, three of which stated that they included these under the fees for services disclosure category. Fifty-four companies stated that they do not disclose ToVs for food and drink. Of these, 22 companies noted that an exception would be made where subsistence costs are part of a sponsorship agreement or cannot be separated from other charges, such as event registration fees or hotel bills.

Disclosure of ToVs for travel and accommodation

Amongst the 145 companies’ methodological notes, 116 companies commented on whether they disclose ToVs for travel and accommodation. Of these, 112 companies included ToVs for travel and accommodation in their disclosure. Only four companies noted that they did not include ToVs for travel and accommodation, three of which explained that this was because they made no payments for travel in 2022.

Disclosure for sponsoring HCPs to attend events

A total of 116 companies commented on their approach to disclosing ToVs related to sponsorship of HCPs to attend scientific meetings and events. Of these, 111 companies (96 per cent) stated that sponsorship costs were included; three 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; one mentioned that they do not disclose this information at all; and one company commented that all ToVs are disclosed in accordance with the relevant policies in line with the ABPI Code of Practice, but was unclear about what this entailed in practice.

Disclosure for sponsoring an event

One hundred and thirteen companies made remarks 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. A total of 109 companies noted that they disclosed information on ToVs for sponsoring an event. One company stated that they did not disclose information related to sponsoring events, while two others noted that they

¹² ABPI (2021, Clause 28.1)

¹³ ABPI (2021, Clause 10.7)

did not disclose this information because they had no sponsorships in 2022. One company was unclear about whether they included information specifically related to ToVs for sponsoring events, only stipulating that they followed the ABPI Code of Practice guidance when disclosing ToVs more generally.

3.4. 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 118 companies stated that they disclose fees for contracted services. One company said that they do not disclose ToVs related to fees for contracted services, specifying that they disclose these as part of the ToVs related to conferences and exhibitions instead.

Disclosure of ToVs related to contracted services – travel and accommodation expenses

Eighty-four companies noted that they included ToVs related to travel and accommodation associated with contracted services in their disclosure. Four companies stated that they did not disclose ToVs related to travel and accommodation associated with contracted services. One of these companies stated that no payments were made for travel or accommodation in 2022, while another company specified that they disclosed such expenses as ToVs related to conferences and exhibitions instead.

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) are likely to be disclosed under either donations or collaborative working. Only nine companies stated that they included MEGS in their disclosure. Two of these companies noted that they included MEGS as part of grants and donations.

Disclosure of ToVs related to training and development other than MEGS

Twenty-six companies included mention of ToVs related to training and development other than MEGS. Six companies noted that they disclosed ToVs related to training and development other than MEGS. Twenty other companies stated that they included such ToVs but disclosed them as (see Table 3-1): part of fees associated with speaker training (n=7), contribution to costs of events (n=3), consultancy (n=4), clinical trial training (n=2), product training (n=1) and assistance with training as part of ToVs to patients, journalists and other members of the public (n=3).¹⁴

¹⁴ The total does not sum to 20 because one of the companies included mention of both consultancy fees and assistance with training as part of ToVs to patients and public.

Table 3-1. Disclosure of ToVs related to training and development other than MEGS (n=20)

Disclosure of ToVs other than MEGS	Number of companies
Speaker training	7
Costs of events	4
Consultancy	4
Training for patients, journalists and other members of the public	3
Clinical trial training	2
Product training	1

Note: The total of the second column does not sum to 20 because one of the companies included mention of both consultancy fees and assistance with training as part of ToVs to patients and public.

Disclosure of ToVs for 'blind' market research

The ABPI Code of Practice¹⁵ requires disclosure of payments in relation to market research where the identities of participants are known. Twenty companies specified that they did not disclose ToVs for 'blind' market research. Of these, five noted that they include payments related to market research only when the identities of participants are known.

ToVs related to co-promotions

Nineteen companies commented on their disclosure practices related to co-promotions. Of these, five stated that they did not include ToVs related to co-promotions in their disclosure. One of these specified that this was because there were no such expenses for their company in 2022. Thirteen companies noted that they included ToVs related to co-promotions in their disclosure. Of these, ten specified that they only included ToVs paid directly by their company, not by the company that they undertook co-promotion activities with. One company was unclear about their disclosure practices related to ToVs for co-promotions, stating that such ToVs are split between the pharmaceutical companies participating in the project.

3.5. 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'.¹⁶ Seventy-two methodological notes included comments on the approach towards indirect ToVs. Of these, 18 stated that they included such ToVs and attributed them to either an HCP, an ORDM or an HCO. Five companies noted that they attributed indirect ToVs to HCOs, while 21 stated that they attributed them to individual HCPs. Twenty-six methodological notes stated that the

¹⁵ ABPI (2021, Clause 24.5)

¹⁶ ABPI (2021, Clause 1.25)

company included indirect ToVs in the disclosure, but they either did not provide details of how this has been disclosed or the information provided was unclear. Two companies noted that they did not include indirect ToVs in their disclosure at all.

3.6. Additional considerations related to the scope of disclosures

ToVs related to over-the-counter medicines

Of the total 145 companies, 51 outlined their approach to ToVs related to over-the-counter medicines. Of these, ten stated that they included over-the-counter medicines in their disclosure. The remaining 41 companies noted that they did not disclose ToVs related to over-the-counter medicines.

ToVs related to medical devices

Forty-two companies included mention of their approach to ToVs related to medical devices. Of these, eight noted that they included ToVs related to medical devices in their disclosure. One other company stated that they included ToVs for medical devices where the device could not be split from a pharmaceutical. Thirty-three companies stated that they did not include ToVs related to medical devices in their disclosure.

Donations and grants

One-hundred and five companies (up from 76 last year) specified their approach to donations and grants. Of these 105, six stated that they did not provide any donations and grants, while 85 noted that they disclosed donations and grants under the HCO category. Nine companies stated that they included donations and grants under either the HCP or the HCO category. Another five companies were unclear in their methodological approach towards donations and grants, not specifying under which category these fall in their disclosure. Of these five, one company included additional detail stating that while they made no grants, they have made donations in the form of therapy review services.

Excluded ToVs beyond those discussed

Of the 145 companies that provided methodological notes, six noted specific types of ToVs that they were excluding from their disclosure:

- One company mentioned that additional event costs, such as the rental of equipment associated with one-off events were excluded from disclosure for internal meetings.
- Another company stated that food supplements and cosmetics were excluded from disclosure.
- One company noted that they did not disclose ToVs for any medicines provided on request to HCPs for individual patients which come under 'Compassionate Use Supply'. They also excluded ToVs to homecare providers for the provision of homecare services.
- One company clarified that they excluded ToVs for consultants that do not work in healthcare.
- Another company excluded educational materials for HCPs and patients, as well as logistical costs related to internal meetings and events.
- One company stated that they excluded samples, package deals, promotional aids, and items for patient support.

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

Association of the British Pharmaceutical Industry (ABPI). 2021. “ABPI champions use of ‘Legitimate Interests’ to boost transparency” Press release 9 December 2021: <https://www.abpi.org.uk/media/news/2021/december/abpi-champions-use-of-legitimate-interests-to-boost-transparency/> .

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