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Disclosure of payments by pharmaceutical companies to healthcare professionals in the United Kingdom: analysis of the Association of the British Pharmaceutical Industry's Disclosure UK database, 2015 and 2016 cohorts

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Abstract

Objectives: To analyse the section of Disclosure UK that pertains to healthcare professionals (HCPs) in order to provide insight into the database's structure and content and suggest ways to improve its transparency.

Design and Participants: Cohort study involving drug companies and HCPs in the 2015 and 2016 versions of Disclosure UK.

Results: Companies report transfers of value (TOVs) to named HCPs or, where an HCP declines to consent, in aggregate. Only a limited number of variables describe the recipient HCP and the TOV, precluding refined analyses. In 2015, 107 companies reported 54,910 TOVs worth £50,967,728. In 2016, 109 companies reported TOVs but spending decreased by 7.3%. The spending was concentrated: the top-10 spenders reported about 50% of the total value, with consultancy-related payments comprising over 70%, and the rest being costs for events. In 2015, 55.5% (30,478) of TOVs worth £24,428,619 (47.9%) were disclosed at the individual level (i.e., to named HCPs), increasing to 64.5% (32,407) and £28,145,091 (59.2%) in 2016. We found evidence of concealment of larger-size consultancy-related payments in both years. Despite increased individual-level disclosure in 2016, the median number of TOVs disclosed by each company at the individual level was only 57.7%, with 25% of companies disclosing less than 38.6%. We found little agreement (62%-48% in 2015 and 46%-30% in 2016) between disclosure rates that we calculated based on information in the database and those provided by companies.

Conclusions

Disclosure UK represents a step towards enhanced transparency but deficiencies undercut its usefulness. Key deficiencies include: few variables describing payment recipients, a relatively low individual-level disclosure rate, variation in individual-level disclosure rates across companies and payment types, and reporting ambiguities or inconsistencies. We make recommendations on how to improve transparency, including using an easily interpretable disclosure rate statistic that allows for comparison across years, firms, and countries.

Article summary

Strengths and limitations of this study

- To the best of our knowledge, Disclosure UK has hitherto eluded in-depth analysis; indeed, we are not aware of studies analysing publically available pharmaceutical industry disclosure databases in any European country.
- Our analysis was based on the full dataset for two years.
- Our calculations of overall payment sums and individual-level disclosure rates are consistent with what was reported by the Association of the British Pharmaceutical Industry, which corroborates our methodology.
- A limitation is that we had no way of checking the accuracy of the data reported by companies.
- Our study does not consider differences in companies' approaches to interpreting and reporting of some data elements and which can invalidate direct comparison of the value of payments between companies.

Keywords: Transparency, Pharmaceutical Industry, Conflict of Interest, Disclosure, United Kingdom, Self-regulation

Introduction

Governments in many countries encourage collaborations between pharmaceutical companies and healthcare professionals (HCPs) to boost innovation and efficiency in healthcare. However, there is a recognised risk that HCPs' commercial links create conflicts of interest[1] that may bias medical research,[2] treatment decisions[3] and lead to wasteful public spending.[4] In recent years, a key way of addressing these concerns[5] – and also of protecting healthcare stakeholders' reputation for transparency and public accountability[6] – is by enhancing the transparency in the industry's financial support to HCPs[7]. The probably most recognised transparency initiative in this area is the US Government's Physician Payment "Sunshine Act", requiring pharmaceutical and medical device companies to report payments to named doctors and teaching hospitals in a public database.[5] Similarly, a few European countries have enacted transparency acts, e.g., France, Portugal and Latvia.[7] Yet most European countries have preferred relying on industry self-regulation, rather than legislative approaches, based on the European Federation of Pharmaceutical Industries and Associations' (EFPIA's) guidelines requiring companies to disclose payments or benefits in kind – also known as transfers of value (TOVs) – made to HCPs and healthcare organisations.[8]

Accordingly, following the UK's experience with pharmaceutical industry self-regulation,[9 10] the Association of the British Pharmaceutical Industry (ABPI) implemented the EFPIA guidelines in 2016 by establishing Disclosure UK, a public and yearly-updated industry payments database. In this paper, we analyse the part of Disclosure UK that pertains to HCPs. This includes payments for events registrations and travel and accommodation; and fees and expenses for consultancy and services. While the launch of the database received considerable attention and commentary,[11-14] it has so far eluded in-depth scrutiny. One key issue of concern has been that, unlike the legislative approaches obliging disclosure, the self-regulatory approach has an "opt-out" clause whereby HCPs can choose not to have their name reported due to data protection regulations. Preliminary analysis conducted on behalf of the ABPI indicated that this option allowed only 55% of TOVs made in 2015 to be linked to named HCPs,[15] increasing to 65% in 2016.[16] This preliminary analysis did not consider, however, differences in companies' ability to secure consent even though information on cross-company differences in disclosure rates might offer clues on how to enhance transparency, for example by pointing to good or bad practices. Neither did this analysis examine differences in individual-level disclosure rates across TOV types (e.g., events registration fees vs.

consultancy fees) even though information on such differences might shed light on reasons for non-disclosure.

Whether disclosure initiatives can or cannot deliver transparency also depends on the accessibility and analysability of the released data. From this perspective, a limitation in the self-regulatory approach is the lack of EFPIA provisions mandating national industry trade groups to make the data available in a downloadable, searchable and analysable format.[7] However, this limitation does not apply to the UK, where the ABPI has created the downloadable and relatively user-friendly Disclosure UK database. Yet, despite being at the frontline of pharmaceutical industry payment disclosures in Europe, the Disclosure UK initiative may not live up to the high expectations stakeholders associate with it.[17] Notably, early analyses indicate that not only do many HCPs decline individual-level disclosure,[11 12] but also that there are discrepancies across companies in how they record and report some data.[15] Thus, in conjunction with the release of the first Disclosure UK database in June 2016, the ABPI announced an estimated 70% individual-level disclosure rate for HCPs, but six months later the ABPI revised this figure to 55% after having identified differences between companies in how they recorded disclosure rates.[15] Apart from demonstrating complexities in interpreting disclosure data, this episode – including the fact the major inaccuracies in a key statistic was not identified by any outside analysts but had to be internally discovered six months later – underscores the need for in-depth, independent analyses of Disclosure UK, corresponding with the growing body of research on US data released under the provisions of the "Sunshine Act".[3 18-24]

The aim of this paper is, therefore, to carry out an assessment of Disclosure UK that goes beyond the preliminary analyses and commentary, and which can help establish a more comprehensive picture of the information in the database and suggests ways to improve its transparency. To this end, we sought to (1) describe the structure of Disclosure UK, including the kind of information and variables available as compared to the US "Sunshine Act" database; (2) calculate key statistics, e.g., number and value of payments and individual-level disclosure rates; and (3) explore the variation across companies in spending and disclosure rates, as well as possible ambiguities and inconsistencies in the way companies report this information.

For all purposes, we analysed the 2015 and 2016 database versions that were accessible in July 2017. Although our analysis is restricted to the UK our findings have implications for the interpretation of disclosure data in other countries too, especially in European countries that have adopted the self-regulatory model but where analysis is more cumbersome, if not impossible, given the limited data accessibility in the absence of centralised payment databases.[7]

Methods

Disclosure UK database

Companies report TOVs on a yearly basis in Disclosure UK. Data for 2015 was released in June 2016, and the 2016 data was released in June 2017. During the course of our study we realised that the databases were occasionally updated with some new information without notice. We decided to work with the databases downloaded in July 2017 to ensure comparability with results published on behalf of the ABPI.[15 16] From the 2015 database we excluded payments reported by Sigma-Tau because Baxalta also reported these same payments due to its acquisition of Sigma-Tau Pharma Ltd.[25] In the 2015 and 2016 databases we identified one and three payment sums registered with negative signs, respectively, that we changed to positive signs, assuming these were typos.

Structure of Disclosure UK

We used a qualitative, inductive and comparative methodology to characterise Disclosure UK. We sought to identify the key elements in the database, such as the various variables describing TOVs and HCPs, by, first, running a number of simple analyses to familiarise ourselves with the databases and, second, by comparing and contrasting key elements in Disclosure UK with the US "Sunshine Act" Open Payments database. We also reviewed, and extracted definitions from, the EFPIA Disclosure code,[8] the ABPI Code of Practice,[26] and the Disclosure Template that companies use when reporting payments.[27]

TOV numbers, monetary value and individual-level disclosure rates

Companies report TOVs to named HCPs or, where an HCP does not grant consent, in aggregate. Each TOV entry in the database can represent several payments to the same recipient for a certain TOV *type* (registration fees, consultancy fees etc.) that have been

totalled by the paying company.[27] For the payments disclosed in aggregate, companies report the number and aggregate monetary value of the TOVs by their type. We computed the total numbers of TOVs, as well as the numbers per TOV type, by, first, tallying the number of TOVs disclosed on the individual level, and then adding the number of TOVs disclosed in aggregate. We used the same strategy to compute the total monetary value of TOVs as well as value per TOV type.

Based on this information we also easily obtained the overall individual-level disclosure rate across all TOV types and the rates per TOV type (e.g., consultancy fees), both in terms of the number and the monetary value. We calculated differences between individual-level disclosure rates in terms of the number and monetary value of TOVs, in order to assess if there was a relationship between the value of TOVs and non-disclosure. Using descriptive statistics, we also calculated the distribution of the monetary value of TOVs that were disclosed on the individual level. Because this TOV data was not normally distributed we report the minimum and maximum, median, interquartile range (IQR), and the 99% percentile value.

Company-level spending and individual-level disclosure rates

We used the same strategy as described above, but on a per company basis, to compute the number and monetary value of TOVs made by each company. Based on this information, we also calculated the individual-level disclosure rate for each company in 2015 and 2016. We did this both in terms of the number and monetary value of the TOVs, and both in total and per TOV type. Ten out of 107 companies in the 2015 database did not provide information on TOVs in aggregate, and for 2016 this was of 13 out of 109. Because we cannot know if this meant these companies failed to report payments or, alternatively, they had 100% individual-level disclosure, and therefore had nothing to report in aggregate, we excluded them from this analysis. We used descriptive statistics to depict the distribution of individual-level disclosure rates across remaining 97 and 96 companies in 2015 and 2016, respectively.

Agreement between author-calculated and company-reported disclosure rates

In the database, companies should report the number of recipients disclosed in aggregate for each TOV type as per cent of all recipients for that TOV type, i.e. 1 - the individual-level disclosure rate for each TOV type. However, the ABPI has reported that although the majority of companies in the 2015 version of the database correctly understood the instructions on how

to calculate this disclosure statistic, some companies appear to have misunderstood and instead provided the number of recipients disclosed in aggregate for each TOV type as per cent of *all* recipients that received payments from the company irrespective of TOV type.[15] To gain further clarity into this issue, and to see if inconsistencies did not occur in the 2016 database, we compared the individual-level disclosure rates that we had calculated for each company (see above) with the individual-level disclosure rates directly reported by each company. Notably, because companies report disclosure rates for the number but not monetary value of TOVs we were restricted to comparing disclosure rates only for the former. Similarly, because companies report disclosure rates per TOV type, rather than across all TOV types, we compared disclosure rates on a TOV type basis.

For this analysis we excluded companies that did not submit aggregate payments reports (n=10 in 2015; n=12 in 2016). We also excluded cases in which companies had submitted aggregate payments reports but had left the cell empty in the database that were to contain the disclosure statistic for a certain TOV type (n=83 in 2015 and n=69 in 2016) since it is impossible to ascertain whether an empty cell indicates that a company simply failed to report (i.e., a missing value), or that all payments of this TOV type were disclosed at the individual-level, or that no payments were made at all of this TOV type. A few companies reported decimals rather than percentages (e.g., 0,05 instead of 5%) and we changed those to percentages. We defined any difference between author-calculated and company-reported individual-level disclosure rates greater than one percentage point as discordant in order to exclude that differences were due to rounding. We calculated the percentage of concordant pairs and used descriptive statistics to analyse disparities between the computed disclosure rates.

Patient involvement

No involvement

Results

Disclosure UK definitions and variables

Tables 1 and 2 summarise the definitions and variables in Disclosure UK relevant to HCPs. Consistent with the EFPIA standard, two higher-level TOV *categories* are used in reporting: "Contribution to costs for events" and "Fees for services and consultancy", which are each split into two lower-level TOV *types*: "Registration fees" and "Travel & Accommodation" for events, and "Fees" and "Related expenses agreed in the fee for services and consultancy contract", respectively.

Table 1. Disclosure UK definitions related to transfers of value to healthcare professionals

Element	Definition[a]
Healthcare professional	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.
Transfer of value	A direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is 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.
Contribution to costs for events	TOVs covering *registration fees* and *travel & accommodation* for all promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events, excluding costs that are clearly related to R&D.
Fees for services and consultancy	TOVs covering *fees* and *expenses* resulting from or related to contracts between companies and HCPs under which such HCPs provide services to companies, excluding costs that are clearly related to R&D.

[a] Definitions are derived from the EFPIA Disclosure code and the ABPI Code of Practice.

Table 2. Mandatory and optional variables related to transfers of value to healthcare professionals in Disclosure UK

Individual level (mandatory)	• Title of HCP • Name of HCP • Country and city of principal practice of HCP • Principal practice address of HCP • Yearly amount per HCP and TOV type

Individual level (optional)	• Speciality of HCP • Role of HCP • Total yearly amount per HCP across all TOV types
Aggregate (mandatory)	For each TOV type • the number of recipients in the aggregate disclosure • the percentage of recipients in the aggregate disclosure • the aggregate amount attributable to such recipients

Each company aggregates its yearly payments at the level of individual HCP and TOV type. A corollary to this is that many HCPs have several TOV records in the database either because they have received payments of different TOV types from the same company and/or because they have received payments from more than one company; and therefore, the number of TOV records is greater than the number of HCPs in the database.

Companies should seek to report individual-level data, including the name, title, city and principal practice address of each TOV recipient, in addition to the monetary value of the TOV (Table 2). Payments to HCPs that decline giving consent to the publication of individual-level data are reported on an aggregate basis by each company, using the four lower-level TOV types mentioned above (see also Table 3). For such aggregate reporting, each company shall specify *for each TOV type*: (1) the total amount attributable to such recipients; (2) the number of recipients in the aggregate disclosure, and (3) the number of recipients disclosed in aggregate as percent of all recipients (i.e., reported at individual level and aggregate). For example, if a company paid ten HCPs £100 each to cover their registration fees for events, but only received consent to publish individual-level data from five, the company should report in the aggregate for "Registration fees": (1) £500; (2) five recipients, and (3) 50%.

Notably, the database does not allow for calculating the number of HCPs that received payments in a particular year. This is because in the aggregate companies report information on the number of recipients per TOV type, rather than across all TOV types, and some HCPs may receive TOVs of different types from the same company, and therefore will be counted several times, and also because some HCPs may be counted several times if they have dealings with multiple companies.

Comparison with US Open Payments Database

Compared to the US "Sunshine Act" Open Payments Database, the most obvious difference is the possibility for companies in the UK, but not the US, to report payments in aggregate. Another key difference is that the UK database only includes payments by pharmaceutical companies, and is mandatory only for ABPI members, whereas reporting in the US is mandatory for all pharmaceutical companies as well as medical device manufacturers, regardless of trade group affiliation. However, the UK database includes payments to a larger spectrum of HCPs, including not only physicians but also e.g. pharmacists, nurses and even individuals who might not be HCPs such as NHS managers (in ABPI documents[26] this group is referred to as Other Relevant Decision Makers, or ORDMs, but in the database, and therefore in this study, they are counted as HCPs).

In addition, there are some important differences between UK and US databases related to the range of TOV types included and the variables describing the recipient HCP and the TOV. In this respect, the UK database is generally less informative and detailed. Regarding the range of TOV types, besides so-called General Payments that encompass the types of payments reported in Disclosure UK, the US database also includes individual-level data regarding two other payment categories: TOVs made in connection with a research agreement or research protocol (so-called Research Payments) and Physician Ownership or Investment Interest Information, including any immediate family member holding such interest.

Regarding the variables and level of detail in the Disclosure UK and the comparable US General Payments database, both contain a number of variables that provide basic information on the recipient HCP (see Table 2 for Disclosure UK), but the US database also contains a unique physician identification number that links physician records across program years and, possibly, to other databases. In addition, the US General Payments database contains a range of variables that provide further detail regarding the TOV including:

(1) Information on up to five products in relation to which the payment was made (including product codes, names, categories and therapeutic areas);
(2) The number of discrete payments being reported for each physician record, not only the total amount;
(3) The method of payment used to pay the covered recipient or to make the TOV, e.g. in-kind items or services, or cash or cash equivalent;

(4) More detail regarding TOV types including types such as "Food and Beverage", "Education", "Compensation for services other than consulting" (e.g., speaker fees), and "Honoraria";

(5) For "Travel and Lodging" payments, the destination where the covered HCP travelled.

The lack of such variables in Disclosure UK limits the types of analyses that can be made compared to the US.

Number and amount of payments in Disclosure UK

We found that, in 2015, 107 companies reported a total of 54910 TOVs for a value of £50,967,728 (Table 3). In 2016, two more companies reported TOVs but spending decreased compared to 2015 by over £3,4 million (-7.3%; inflation-adjusted) to £47,548253, and the number of TOVs decreased by 8.5%. In both years roughly 35% of the number of TOVs were consultancy fees but money-wise they corresponded to roughly 60%, reflecting the on average higher value of consultancy fee TOVs. Conversely, approximately 35% of the number of TOVs covered costs for travel and accommodation at events but they corresponded to roughly 20% of the total spending, reflecting the on average smaller size of such TOVs.

Table 3. Transfers of value to UK healthcare professionals in 2015 and 2016

		2015				2016				ΔN	Δ£[a]
		N	%	£	%	N	%	£	%	%	%
Events	**Registration fees**	7,877	14.3	3,445,579	6.8	7,441	14.8	3,293,209	6.9	-5.5	-5.1
	Travel & Accom	19,138	34,9	10,692,849	21.0	17,445	34.7	9,856,619	20.7	-8.8	-8.5
Consultancy	**Fees**	19,020	34.6	30,396,315	59,6	16,606	33.1	28,698,492	60.4	-12.7	-6.2
	Expenses	8,875	16.2	6,432,985	12.6	8,750	17.4	5,699,934	12.0	-1.4	-12.0
Total		**54,910**	**100**	**50,967,728**	**100**	**50,242**	**100**	**47,548,254**	**100**	**-8.5**	**-7.3**

[a] Inflation adjusted: +1.7% between 2015 and 2016.

In monetary value the largest decrease between 2015 and 2016 was seen for consultancy expenses (-12.0%; inflation-adjusted) but, interestingly, this was accompanied by only a minor decrease in the number of consultancy expenses TOVs (-1.4%), suggesting that the decrease in the monetary value of payments was due to fewer larger-size payments in 2016. Conversely, there was a moderate decrease in the monetary value of consultancy fee payments (-6.2%; inflation-adjusted), but this was accompanied by a greater decrease in the number of consultancy fees TOVs (-12.7%), suggesting that this decrease was associated with fewer smaller-size payments.

Variation in spending across companies

For both years a large part of the TOVs concentrated in the hands of a narrow number of companies (Appendix Table 1). In 2015, the top 10, 20 and 50 spending companies reported 48.2%, 71.8% and 93.5% of the spending, respectively. The major spender in 2015 was AstraZenca (6.9%), followed by Bayer (6.2%) and Merck-Sharp & Dohme (6.0%). The median number of TOVs reported per company was 187 (min 1; max 3,521; IQR 580.5) and median company spending in 2015 was £141,895 (min £266; max £3,535,413; IQR £444,448).

In 2016, the picture was similar: the top 10, 20 and 50 spending companies reported 49.9%, 70.8% and 92.3% of all the spending, respectively, with Bayer (7.0%), Pfizer (6.9%) and Novo Nordisk (5.3%) on the top-3 list, and with AstraZenca and Merck-Sharp & Dohme now on fourth (5.2%) and eighth (4.3%) place. The median number of TOVs reported per company in 2016 was 172 (min 2; max 3,409; IQR 482), and median company spending was £147,490 (min £2,181; max £3,308,421; IQR £410,873), i.e., comparable to 2015.

Rates of individual-level disclosure

For 2015 we established that 55.5% (30,478) of all TOVs were disclosed at the individual level, with the overall value of £24,428,619 (47.9%) (Table 4), consistent with the ABPI's estimates.[15] Regardless of TOV type, companies disclosed around 55% of the number of TOVs at the individual level, but in monies there was considerable variation in disclosure rates across TOV types. In particular, there appears to be a tendency to conceal payments for consultancies of larger size, as the disclosure rate for consultancy TOV types was clearly higher in number of TOVs (56.9% and 53.6%) than in cash amounts (47.9% and 38.4%).

Table 4. Individual-level disclosures of transfers of value in 2015 and 2016

		2015		2016	
		% N[a]	% £[b]	% N[a]	% £[b]
Events	**Registration fees**	54.6	56.0	64.4	64.1
	Travel & Accom	55.4	51.3	64.6	64.7
Consultancy	**Fees**	56.9	47.9	66.4	58.2
	Expenses	53.6	38.4	60.9	51,9
Total		**55.5**	**47.9**	**64.5**	**59.2**

[a] Individual-level disclosure rate for the number of TOVs

[b] Individual-level disclosure rate for monetary value of TOVs

In 2016, the individual-level disclosure rate had increased markedly to 64.5% (32,407) of all TOVs for a total value of £28,145,091 (59.2%). However, despite the improved disclosure rate, the practice of concealing larger-size payments for consultancies remained (66.4% and 60.9 vs. 58.2% and 51.9%) (Table 4).

Pattern of individual-level disclosure

Table 5 shows the distribution of individual-level disclosed TOVs. As expected, consultancy fees were more often larger than other TOVs types, and some of these payments were substantial: the top percentile included payments equal or larger than £11,012.3 (in 2015) and £12,857.8 (in 2016). However, and perhaps more surprisingly, there were some large payments covering events payments. For example, for travel & accommodation, the top percentile included payments equal or larger than £3,729 (in 2015) and £3,781.6 (in 2016), and the single largest disclosed payments were of £22,280 and £28,160.1, respectively.

Table 5. Distribution of transfer of value sums (£) disclosed at the individual level

		2015					2016				
		Min	Median	IQR	99%	Max	Min	Median	IQR	99%	Max
Events	Registration fees	10	394.1	292.6	1,698.9	19,836	10	395	306	1,515.2	4,880
	Travel & Accom	1,5	252	465	3,729	22,280	1.5	289.3	535.2	3,781.6	28,160.1
Consultancy	Fees	0[a]	750	950	11,012.3	54,700.9	14.8	750	1,100	12,857.8	81,130.2
	Expenses	1	142.7	295.1	7,817.1	34,223	2	156.5	339.1	8,003.1	42,942.9

a Britannia Pharmaceuticals registered this payment and it likely represents a mistake

Differences in individual-level disclosure rates across companies

There was major variation in the disclosure rates across companies (Figure 1; Appendix Table 1). In 2015, excluding the ten companies that did not submit reports regarding payments in aggregate, the median among the remaining 97 companies for TOV sums was 47.3%, with 75% of companies disclosing more than 72.8% of sums and 25% of companies disclosing less than 21.3% of sums at the individual level. This latter group included top-30 spenders like Merck Sharp & Dohme (1.2%), Allergan (12.3%), Bristol-Myers Squibb (20.8%), Napp (20.5%) and Boehringer Ingelheim (21.3%). There were fewer big companies on the other side of the spectrum: Teva (72.4%), Gilead (73.6%) and GlaxoSmithKline (95%). By 2016 individual-level disclosure rates had increased substantially (median 57.7%); still, 25% of companies included in this analysis disclosed less than 38.6% of the value of payments at the individual level, counting big spenders like Napp (10.5%), Allergan (20.8%), Novo Nordisk (31.7%), and Bayer (34%).

Ambiguity and inconsistency in company reporting of individual-level disclosure rates

We compared the individual-level disclosure rates for the number of TOVs that we calculated ourselves on the basis of information in the database, on the one hand, and the disclosure rates reported directly by companies in the database, on the other. For this analysis, we had to exclude ambiguous cases (n=83 in 2015 and n=69 in 2016) (see Methods). Defining any difference greater than one percentage point as discordant, the percent agreement between what we calculated and what companies reported for each TOV type was only 62%-48% in 2015 (Table 6). Notably, the agreement was worse in 2016: 46%-30%, i.e., after the ABPI had highlighted the problem of reporting inconsistencies. In 108 of 143 (76%) (in 2015) and 194 of 197 (98%) (in 2016) of cases of disagreement, companies reported higher rates than what we calculated. In some cases, the difference between our calculations and what companies' reported was very large (Figure 2), more consistent with the idea that some companies had misunderstood how to compute disclosure rates. In most cases, however, the difference was smaller, albeit substantial, which makes it less likely to be due to confusion about how to compute disclosure rates. In sum, our findings point to continued and possibly augmented ambiguities and inconstancies in reporting, and underline the limited transparency regarding how companies calculate disclosure rates.

Table 6. Percent agreement between author-calculated and company-reported individual-level disclosure rates

		2015		2016	
		Agreement	n/N	Agreement	n/N
Events	Registration fees	61%	40/66	46%	31/68
	Travel & Accom	54%	40/74	41%	32/80
Consultancy	Fees	51%	46/91	39%	36/93
	Expenses	48%	35/73	30%	24/79

Discussion

To the best of our knowledge, this is the first systematic analysis of the Disclosure UK database. Payments to HCPs totalling roughly £51 million and £47.5 million were reported in 2015 and 2016, respectively, concentrated in the hands of a limited number of big spenders. Consultancy-related payments comprised more than 70% of the total value, with the rest being costs for events. That the industry over the two-year period paid more than £30 million for events registration and travel and accommodation – which included some sizeable payments – is noteworthy in light of the criticism levied against industry sponsorship of

HCPs' conference and events attendance in the past,[28 29] and which has motivated the barring of such sponsorship by the industry trade group in Sweden[7] and at least one major company (i.e. GlaxoSmithKline).[30]

We confirm preliminary analyses conducted on behalf of the ABPI[16] showing an increased tendency to disclose payments at the individual level – from 48% to 59% – and this might suggest that the willingness to participate in Disclosure UK will grow as more experience accumulates. However, our analysis goes further than this by showing differences in individual-level disclosure rates across TOV types and companies. Regarding differences across TOV types, our analysis suggests a practice of concealing larger-size payments for consultancies. Regarding variation across companies, a key finding is that some big spenders, like Bayer and Novo Nordisk, tended to eschew individual-level disclosures whilst others, such as GlaxoSmithKline, disclosed almost everything at the individual level. As debates about HCP willingness to disclose payments have focused mostly on HCP behaviour and motivation[31 32] our finding of major company variation is important because it shifts the focus to company characteristics, especially policies for collecting consent from HCPs, which in turn may be associated with more general corporate cultures, as another set of likely determinants of HCP disclosure consent.

The launch of Disclosure UK was heralded as a breakthrough in pharmaceutical industry transparency.[33] Although the database does represent a step towards enhanced transparency, our study highlights deficiencies that undermine its usefulness for understanding industry connects to HCPs and associated impact on healthcare delivery. First, and consistent with EFPIA guidelines, the database only contains aggregate data on R&D payments and it omits HCPs' ownership or investment interest – two areas highlighted as important by research on industry payments in the US.[34] Second, the fact that HCPs can opt-out from individual-level disclosure, together with the fact that individual-level disclosure rates vary substantially between companies, means that, due to the risk of participation bias, it is precarious to investigate the association between receiving payments and HCP behaviour (e.g. prescribing) or characteristics (e.g. gender or speciality), as has been done extensively with US data.[3 18-24] Non-disclosure can also create bias because some HCPs may choose to disclose some types of payments but not other (e.g., events but not consultancies) or disclose their relationships with some companies but not other. A third limitation, revealed by our comparison with the US Open Payments Database, is the lack of information on a number of characteristics that

provide relevant details regarding the payment. For example, a recent study using information in the US Open Payments Database on the products connected to payments showed that firms' invested great sums to promote drugs for which more innovative, effective, safer and cheaper alternatives existed.[35] Unfortunately, this is a kind of analysis not possible to do with UK data because companies are not asked to disclose information on the products in relation to which the payment was made.

Another aspect of Disclosure UK that needs urgent improvement relates to how companies report payments in aggregate. We found that companies regularly left cells empty in the aggregate part of the database where they should inform on the individual-level disclosure rate. Companies should never leave cells empty as this creates ambiguity. Another problem concerning the present aggregate payments reporting standard – and which applies to all countries relying on the EFPIA-based self-regulatory model – is that, arguably, there are more relevant and easily interpretable data elements that companies could report other than the number of recipients disclosed in aggregate as the percent of all recipients for each TOV type. Intuitively, one would expect companies to summarise their individual-level disclosure rates in total (i.e., what is the company's overall disclosure rate?) and for each TOV type separately (i.e. what is the company's disclosure rate for, for example, consultancy fees?). Companies should provide this information both in terms of the number and value of TOVs – currently they only provide rates calculated for the number of TOVs. Should our reporting suggestions be adopted this would allow for easy comparison across years, firms and countries. Furthermore, it might offer a simple mechanism for increasing disclosure because publicising disclosure rates in a consistent and interpretable format is likely to put pressure on companies to improve their figures to avoid damage to their reputation for transparency. That the current aggregate reporting standard is unintuitive is underlined by the inconsistencies, and possible inaccuracies, in companies' reporting, and which – despite being highlighted by the ABPI – continued into the 2016 version of the database. The existence of ambiguity and inconsistency points to a broader issue of limited data quality and lack of oversight with implications for other countries too – and especially for European countries that lack a central and analysable registry for payments,[7] and that therefore rely even more on accurate and comparable reporting by companies as there is limited possibilities to independently analyse data.

Strength and limitations

The main strengths of this paper are that it is based on the full dataset for two years and that calculations are consistent with the ABPI's, which corroborates our methodology. The main limitation is that we have no way of checking the accuracy of the data. Furthermore, transparency requirements do not apply to manufacturers of generics and over-the-counter medicines and exclude some payments such as food and drinks;[7] thus, our analysis likely underestimates the true extent of payments.[36] Also, we did not take into account differences in companies' interpretation and reporting of some data elements that are detailed in the methodological note that each company provides.[37 38] Of relevance to disclosure rates is the issue of how companies deal with cases where HCPs consented to the disclosure of some TOVs but refused others. The vast majority of companies that specify a rule for this state that they disclose all TOVs to those recipients in the aggregate section, i.e., they do not allow for partial disclosure. However, four companies in 2015[37] and three in 2016[38] reported in their methodological notes that, at least in some circumstances, partial disclosure was allowed, meaning that an individual may be counted in both in the individually-named and aggregate sections, and it is unclear if this influences the disclosure rates calculated by these companies. Furthermore, some companies choose to report payments with and some without VAT and other taxes (e.g., income tax and national insurance), and some companies' procedures vary according to the type or recipient of the payment. Comparison of the value of TOVs made by two companies may also be distorted by the fact there is variation among companies with regard to whether they consider TOVs to HCP members of their own staff to be within the scope of the disclosure, and in how they classify for the purposes of disclosure (i.e., as HCPs or healthcare organisation) self-incorporated HCPs or companies owned and/or run by an HCP. Given the complexity, these methodological matters should become the subject of a separate study. Finally, we did not include payments for R&D that are reported in aggregate by companies. Future studies should investigate R&D payments, as well as the payments to healthcare organisations, and may also choose to extend the analysis to other European countries' databases where possible, for example, to explore differences in individual-level disclosures across countries on a company-per-company basis.

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Figure Legends

Figure 1. Box plots show author-calculated individual-level disclosure rates across companies in the 2015 (n=96) and 2016 (n=97) version of Disclosure UK. White depicts the number of TOVs; grey depicts monetary value of TOVs.

Figure 2. Box plots show the difference in percentage points between company-reported and author-calculated individual-level disclosure rates for the number of TOVs in 2015 and 2016 for each TOV type. Only discordant pairs are shown, i.e. differences larger than +/- 1.0 percentage point. Number of discordant pairs (n) in each plot are shown. Reference line indicates zero percentage point difference.

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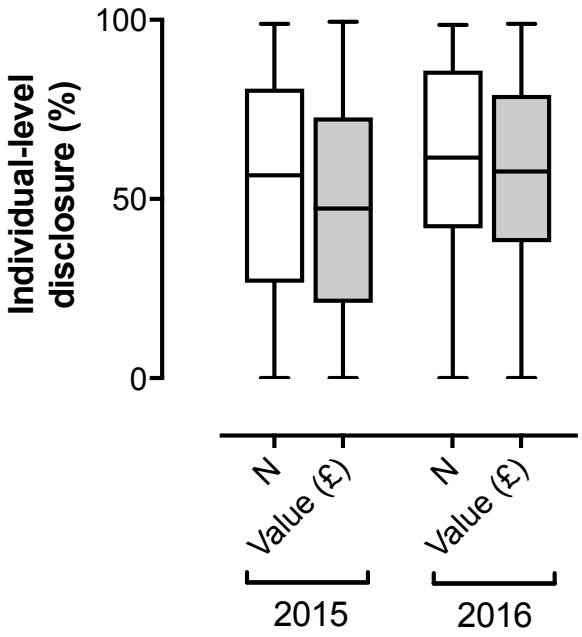

Figure 1

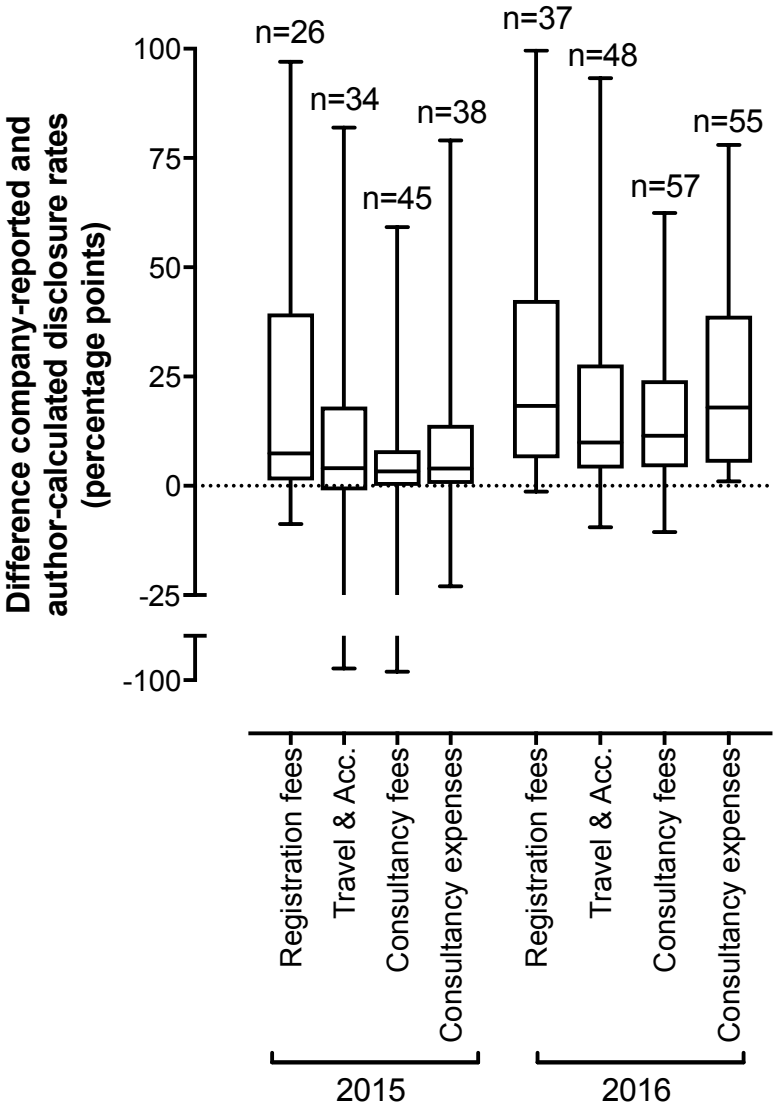

Figure 2

Appendix Table 1. Transfers of value to UK healthcare professionals: value, numbers and individual-level disclosure rates per company in 2015 and 2016

	2015 [b,c]				2016 [b,c]			
Company[a]	**£**	**Rate £**	**N**	**Rate N**	**£**	**Rate £**	**N**	**Rate N**
Bayer	3159751.53	24.9%	2817	26.3%	3308420.84	33.9%	3090	34.5%
AstraZeneca	3535413.23	66.9%	2631	88.1%	2465100.23	78.5%	2161	94,0%
Pfizer	2509453.01	51.7%	3263	62.6%	3259314.86	88.8%	3409	97.2%
Janssen-Cilag	2912280.38	68.4%	3521	85.3%	2401589.87	69.7%	2635	84.8%
Merck Sharp & Dohme	3076957.74	1.2%	2568	1.8%	2031187.84	67.8%	1753	60.1%
Novo Nordisk	2222001.79	25.9%	2099	34.2%	2517087.73	31.7%	1984	40.9%
Novartis	2211719.11	57.8%	2322	77.9%	2151112.54	85.3%	2520	93.1%
Abbvie	1564813.16	59.2%	1512	64,0%	2053533,0	65.3%	1929	66,0%
Sanofi Aventis	1466907.46	45.7%	1016	74.3%	1872099.77	60.2%	1406	85.3%
Eli Lilly	1536223,0	38.2%	1811	44.2%	1677839,0	42.5%	2193	43.6%
Astellas	1827995.2	55.4%	3019	56.6%	1215637.23	63.1%	1947	62.3%
Roche	1455735.79	54.8%	1513	52.5%	1430433.44	55.3%	1352	50.9%
Gilead	1306053.44	73.6%	1046	80.1%	1478764.99	71.8%	1295	85.9%
Bristiol-Myer Squibb	1549787,0	20.8%	1055	28.1%	851293.86	44,0%	966	30.7%
Allergan	1306149.86	12.3%	1416	10.2%	1032918.16	20.8%	1004	6.5%
GlaxoSmithKline	1456604.18	94.7%	922	96.7%	456573.77	94.7%	224	93.3%
Takeda	940687.85	39.7%	986	58.2%	728964.2	53.5%	730	57.3%
Napp	628996.24	20.5%	1083	13.1%	976205.64	10.5%	841	10.1%
Merck Serono	754664.68	39.4%	790	49.1%	826112.82	38.9%	920	41.5%
Servier	773827,0	26.4%	993	42.3%	652946,0	34.4%	769	54,0%
Boehringer Ingelheim	1048816.74	21.3%	982	17,0%	305666.53	33.1%	393	32.8%
Amgen	521029.24	70.1%	586	78,0%	746845.6	74.5%	618	81.9%
Teva	645267.2	72.7%	1004	92.7%	613419.32	89,0%	938	94.3%
Celgene	625409.08	76.4%	681	91.8%	543539.96	92.2%	616	97.4%
Biogen	591279.32	39.1%	481	36.2%	548807.95	55.7%	534	55.4%
Lundbeck	640573.65	71.4%	546	81.5%	474701.11	80.2%	288	87.2%
Shire	489890.6	40.6%	753	50.5%	609993.99	29.3%	854	41.6%
Chiesi	444695.41	47.3%	993	55,0%	458128.85	49.5%	913	68.7%
Alexion	368849.66	N/A	192	N/A	503918.85	75.7%	384	86.2%
Ferring	307893.54	97,0%	681	97.9%	407998.51	98.3%	651	98.6%
Leo Pharma	407685.31	79.8%	477	83,0%	286664.94	53.1%	375	70.4%
Ipsen	301323.9	19.2%	408	27,0%	374106.85	52.9%	530	58.5%
Actelion	313106.09	N/A	257	N/A	356376.53	N/A	303	N/A
Otsuka	408626.56	62.9%	431	61.3%	244212.9	70.5%	280	70,0%
UCB Pharma	345118.97	89.6%	482	95.9%	301511.22	74.7%	388	76.5%
Mundipharma	352716.36	31.4%	277	37.9%	270516.63	32.2%	209	30.1%
Alcon	63003.67	64.3%	107	68.2%	545034.66	4.4%	387	9.6%
Sunovion	199678.54	11.1%	359	5.0%	389470.11	20.8%	404	16.1%
Britannia Pharmaceut.	306612.79	31.4%	519	27.6%	275986.24	10.8%	296	18.2%
Genzyme	485188.61	59.7%	363	73.6%				
Almirall	278767.32	36.7%	360	33.9%	199570.03	25.8%	264	24.6%
Eisai	223359.54	1.5%	310	1.9%	245975.76	50,0%	390	47.7%
Baxter	255137.4	78.1%	745	68.3%	213814.37	85.4%	605	79.2%
Sandoz	227441.4	46.6%	336	47.9%	215214.15	66.1%	291	59.1%
Grunenthal	246726.43	71.4%	261	73.9%	190316.65	56.6%	169	63.9%
Daiichi Sankyo	220747,0	82.1%	120	73.3%	189262.35	N/A	99	N/A
Chugai Pharma	286373.49	17.4%	258	24.4%	112438.72	42.4%	208	41.3%
Stirling Anglian	294263.67	13.7%	138	15.9%	99271.44	0,0%	7	0,0%
Jazz	188260.97	N/A	234	N/A	197620.41	87.1%	215	92.6%
A. Menarini	183910.75	38.5%	290	45.9%	199534.57	47.6%	425	44.9%
Norgine	249679,0	90.4%	503	90.9%	126734,0	95.3%	310	96.8%
Vifor	177596.18	46.8%	221	50.2%	198170.14	52.8%	241	46.5%
Merz Pharma	189462.24	26.8%	321	10.6%	185739.27	82.4%	191	89.5%
Tillotts Pharma	176466.55	48.1%	251	42.2%	166281,0	40.8%	294	38.1%
Sobi	112196,0	82.9%	142	84.5%	201602,0	79.2%	195	89.7%
Bausch & Lomb	99214.94	89.6%	72	94.4%	213391.81	98,0%	38	89.5%
CSL Behring	127282.86	13.9%	208	18.8%	180149.66	17.8%	246	19.5%
Alimera	141895.08	59.2%	145	60.7%	104980.22	71.6%	120	73.3%

Baxalta	108841.04	72.9%	109	81.7%	112591.45	21.6%	104	48.1%
Santen	89402.76	40.5%	98	62.2%	117740.97	59.3%	128	65.6%
Pierre Fabre	139369.27	99.5%	187	98.9%	65778.26	N/A	96	N/A
Flynn	109136.69	97.3%	109	90.8%	81375.13	98.9%	189	98.4%
Sanofi Pasteur MSD	89631.94	99.5%	92	97.8%	99363.2	93.8%	129	90.7%
Actavis	35417.52	30.5%	115	37.4%	147490.36	25.8%	156	80.1%
Bial Pharma UK					176271.02	69.6%	172	56.4%
Besins	82198.2	58.3%	149	57,0%	85835.68	84.9%	152	78.3%
Meda	81096.74	16.2%	144	25,0%	78158.34	55.3%	115	54.8%
ALK-Abello	86092.07	87.6%	111	86.5%	72616.23	95.9%	132	93.9%
Shionogi	39219.34	28.7%	46	13,0%	110557.95	78.8%	18	50,0%
BioMarin Europe	99611,0	84.2%	79	94.9%	47256.27	82.3%	37	89.2%
Thea	57837.2	0,0%	67	0,0%	88595.53	0,0%	161	0,0%
Dermal	68976.77	87.6%	150	79.3%	72868.4	85.3%	133	73.7%
Gedeon Richter	93535.33	51.9%	154	56.5%	45916.67	37.6%	78	52.6%
Pharma Mar	43886.92	50.5%	97	48.5%	92639.69	66.2%	153	75.2%
Consilient Health	79285,0	59.3%	60	61.7%	53710,0	43.5%	73	38.4%
Fresenius-Kabi	32517.14	8.6%	65	6.2%	95531.07	71.3%	275	75.6%
Vifor F. Med. Care R.	17545.93	6,0%	12	33.3%	97196.1	52.7%	55	52.7%
Galen	70097.81	94.2%	58	98.3%	43287.14	98.3%	60	96.7%
Hospira	77501.37	0,0%	87	0,0%	24779.61	N/A	23	N/A
Biotest	54416.34	51.3%	112	77.7%	45528.94	74.9%	102	82.4%
Octapharma	42296.03	15.1%	48	52.1%	57424.94	45.9%	69	60.9%
Profile Pharma	40829.51	75,0%	22	86.4%	58360.36	58.7%	70	48.6%
ApoPharma	89730.81	2,0%	12	16.7%	8079,0	50,0%	15	20,0%
Orion Pharma	73501.22	80.5%	336	69,0%	22042.33	N/A	43	N/A
RB	33609,0	90.6%	29	82.8%	51831.91	97.5%	48	93.8%
Grifols					76806.76	34.3%	99	42.4%
Novex	44000,0	34,0%	10	30,0%	25675.7	56.5%	9	33.3%
Guerbet Laboratories	25860.99	17,0%	40	12.5%	41030.23	63.2%	37	45.9%
PTC Therapeutics	12397.2	13,0%	20	15,0%	52998.57	94.6%	58	89.7%
Intercept Pharma					62202,0	15.7%	27	48.1%
Diurnal	34223,0	N/A	1	N/A	19936,0	N/A	14	N/A
HRA Phara	50906.76	N/A	26	N/A	2181,0	N/A	2	N/A
BGP Products	52906.5	10.8%	89	19.1%				
Bracco	8497.98	39.4%	26	23.1%	39962.23	94.4%	34	82.4%
GE Healthcare					48089,0	14.3%	66	18.2%
Alliance	14547.75	72.2%	36	83.3%	29486.15	N/A	79	N/A
Syner-med	11109.38	N/A	20	N/A	30180.03	N/A	52	N/A
Aegerion	16589.98	N/A	13	N/A	13610.19	42.3%	14	85.7%
Shield TX					29447.7	97.2%	45	95.6%
Valneva					27379.38	N/A	4	N/A
Orphan Europe	25831.44	93,0%	15	73.3%				
Seqirus					24263.26	N/A	4	N/A
Bio Products	13636.52	12,0%	34	29.4%	8698.44	71.3%	20	95,0%
Martindale	14581.65	0,0%	17	0,0%	7366.37	7.5%	7	42.9%
Amdipharm Mercury	19916.43	43.9%	30	56.7%				
Amicus Therapeutics					17583.14	0,0%	16	0,0%
CEB Pharma	15431.98	83.9%	62	83.9%				
Fresenius Med. Care					15298.49	52.8%	10	60,0%
Nicovations	12331,0	0,0%	14	0,0%				
Accretio	2460,0	67,0%	8	75,0%	8906.71	66.7%	17	70.6%
Mitsubishi Tanabe	4988,0	60,0%	7	85.7%	5124.2	N/A	13	N/A
Rosemont Pharmac.	5235.17	32,0%	4	75,0%	4646.93	48.4%	5	80,0%
Cuxson Gerrard	2799.5	0,0%	9	0,0%	4369,0	0,0%	13	0,0%
Tesaro					6726.51	67.8%	8	62.5%
Augettant	1459.51	N/A	1	N/A	4153.47	N/A	5	N/A
STD Pharmaceuticals	600,0	N/A	1	N/A				
Special Products	266.2	N/A	2	N/A				
Total	**50,967728**	**47.9%**	**54910**	**55.5%**	**47,543051.1**	**59.2%**	**50241**	**64.5%**

[a] Companies are listed according to the total value of TOVs in both years
[b] Empty cells mean that company was not in database that year
[c] N/A means company did not provide information on any TOV in aggregate and therefore the disclosure rate cannot be calculated.

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Disclosure of payments by pharmaceutical companies to healthcare professionals in the United Kingdom: analysis of the Association of the British Pharmaceutical Industry's Disclosure UK database, 2015 and 2016 cohorts

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Disclosure of payments by pharmaceutical companies to healthcare professionals in the United Kingdom: analysis of the Association of the British Pharmaceutical Industry's Disclosure UK database, 2015 and 2016 cohorts

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Abstract

Objectives: To analyse the section of Disclosure UK that pertains to healthcare professionals (HCPs) in order to provide insight into the database's structure and content and suggest ways to improve its transparency.

Design and Participants: Cohort study of drug companies and HCPs in the 2015 and 2016 versions of Disclosure UK.

Results: Companies report transfers of value (TOVs) to named HCPs or, where an HCP declines to consent, in aggregate. Only a limited number of variables describe the recipient HCP and the TOV, precluding refined analyses. In 2015, 107 companies reported 54,910 TOVs worth £50,967,728. In 2016, 109 companies reported TOVs but spending decreased by 7.3%. The spending was concentrated: the top-10 spenders reported about 50% of the total value, with consultancy-related payments comprising over 70%, and the rest being costs for events. In 2015, 55.5% (30,478) of TOVs worth £24,428,619 (47.9%) were disclosed at the individual HCP level, increasing to 64.5% (32,407) and £28,145,091 (59.2%) in 2016. Despite increased individual-level disclosure in 2016, the median number of TOVs reported by each company at the individual level was only 57.7%, with 25% of companies reporting less than 38.6%. We found little agreement (62%-48% in 2015 and 46%-30% in 2016) between HCP consent rates that we calculated based on information in the database and those provided by companies.

Conclusions

Key deficiencies in Disclosure UK include: insufficient information on payments and recipients, a relatively low HCP consent rate for individual-level disclosure, differences in consent rates across companies and payment types, and reporting ambiguities or inconsistencies. We employ these findings to develop recommendations for improving transparency, including an easily interpretable consent rate statistic that allows for comparison across years, firms, and countries. If deficiencies remain unresolved, the UK should consider introducing legislation requiring mandatory disclosure to allow for adequate tracking of industry payments.

Article summary

Strengths and limitations of this study

- Thus far, there have been no studies analysing publically available pharmaceutical industry disclosure databases in any European country, including the UK.
- Our analysis was based on the full Disclosure UK dataset for HCP payments for two years.
- Our calculations of overall payment sums and HCP consent rates are consistent with what was reported by the Association of the British Pharmaceutical Industry, which corroborates our methodology.
- A limitation is that we had no way of checking the accuracy of the data reported by companies.
- Our study does not consider differences in companies' approaches to interpreting and reporting of some data elements and which can invalidate direct comparison of the value of payments between companies.

Keywords: Transparency, Pharmaceutical Industry, Conflict of Interest, Disclosure, United Kingdom, Self-regulation

Introduction

Collaboration between pharmaceutical companies and healthcare professionals (HCPs) is seen by many as vital for boosting innovation and efficiency in healthcare. However, HCPs' commercial links create the potential for conflicts of interest[1] that may bias medical research,[2] treatment decisions[3] and lead to wasteful public spending.[4] In recent years, a key way of addressing these concerns[5] – and protecting the transparency and accountability of healthcare policy and practice[6] – is by enhancing the transparency in the industry's financial support to HCPs.[7] By far the most recognised transparency initiative globally is the US Government's Physician Payment "Sunshine Act", requiring pharmaceutical and medical device companies to report payments to named doctors and teaching hospitals in a publicly accessible database.[5] A few European countries, including France, Portugal and Latvia, have enacted similar "transparency acts".[7] Nevertheless, rather than state legislation, an approach preferred in most European countries has been industry self-regulation, based on the European Federation of Pharmaceutical Industries and Associations' (EFPIA's) guidelines requiring companies to report payments or benefits in kind – also known as transfers of value (TOVs) – made to HCPs and healthcare organisations.[8]

The UK is a key case illustrating this tendency. Consistent with its established history of pharmaceutical industry self-regulation,[9 10] the Association of the British Pharmaceutical Industry (ABPI) implemented the EFPIA guidelines in 2016 by establishing Disclosure UK, a freely accessible and annually updated online industry payments database.[11] All ABPI members and any other pharmaceutical company that follows ABPI's Code of Practice for the Pharmaceutical Industry are required to report payments; in total, over one hundred companies. In this paper, we analyse the part of Disclosure UK comprising payments to HCPs, including (1) events registrations and travel and accommodation, and (2) fees and expenses for consultancy and services.

Although the launch of the database received considerable attention and commentary,[12-15] it has so far eluded in-depth research scrutiny. One key area of concern has been that, unlike the legislative approaches introducing mandatory disclosure, the self-regulatory approach has an "opt-out" clause whereby an HCP can choose not to have their name reported in line with data protection legislation.[8] Preliminary analysis conducted on behalf of the ABPI revealed that this option allowed only 55% of TOVs made in 2015 to be linked to named HCPs,[16] increasing to 65% in 2016.[17] This preliminary analysis did not consider, however, differences

in companies' ability to secure consent, even though information on cross-company differences in HCP consent rates might offer clues on how to enhance transparency, for example by pointing to effective or ineffective practices for securing consent.

In addition, early analyses indicate that not only do many HCPs decline to disclose the payments they received,[12 13] but also that there are discrepancies between companies in how they record and report some data.[16] Thus, coinciding with the release of the first Disclosure UK database in June 2016, the ABPI announced an estimated 70% HCP consent rate, but six months later this figure was revised down to 55% after the ABPI had identified differences between companies in how they recorded consent rates.[16] The fact that no outside analysis pointed to this major inaccuracy in a key disclosure statistic underscores the need for in-depth, independent analyses of Disclosure UK that would complement a rapidly growing body of research on US data released under the provisions of the "Sunshine Act".[3 18-24]

The aim of this paper is, therefore, to carry out an analysis of Disclosure UK that goes beyond the preliminary analyses and commentary to establish a more comprehensive picture of the database, and on this basis suggests ways to enhance its transparency. Specifically, we sought to (1) describe the structure of Disclosure UK, including information and variables available; (2) calculate key statistics, e.g., payment sums and HCP consent rates for individual-level disclosure; and (3) explore the variation across companies in spending and consent rates, as well as possible ambiguities and inconsistencies in the way companies report this information. For all purposes, we analysed the 2015 and 2016 database versions that were accessible in July 2017.

Methods

Disclosure UK database

Companies report TOVs on a yearly basis in Disclosure UK.[11] Data for 2015 was released in June 2016, and the 2016 data was released in June 2017. During the course of our study we realised that the databases were occasionally updated with some new information without notice. We decided to work with the databases downloaded in July 2017 to ensure comparability with results published on behalf of the ABPI.[16 17] From the 2015 database we

excluded payments reported by Sigma-Tau because Baxalta also reported these same payments due to its acquisition of Sigma-Tau Pharma Ltd.[25]

Structure of Disclosure UK

We used a qualitative, inductive methodology to characterise Disclosure UK. We sought to identify the key elements in the database, such as the variables describing TOVs and HCPs, by running a number of simple analyses to familiarise ourselves with the database. We also extracted and reviewed definitions from the EFPIA Disclosure code,[8] the ABPI Code of Practice,[26] and the Disclosure Template that companies use when reporting payments.[27]

TOV numbers, monetary value and HCP consent rates

Companies report TOVs to named HCPs or, where an HCP does not grant consent, in aggregate. Notably, any TOV entry in the database can represent several payments to the same HCPs for a certain TOV *type* (registration fees, consultancy fees etc.) that have happened during a given year and then have been totalled by the paying company.[27] For the payments disclosed in aggregate, companies report the number and aggregate monetary value of the TOVs by their type. We used the aggregate and individual-level TOV data to compute the total numbers and the monetary value of TOVs. Using descriptive statistics, we also calculated the distribution of the monetary value of TOVs that were disclosed at the individual level. Because this TOV data was not normally distributed we report the minimum and maximum, median, interquartile range (IQR), and the 99% percentile value.

We also used the aggregate and individual-level TOV data to calculate the overall HCP consent rate across all TOV types and the rates per TOV type (e.g., consultancy fees), both in terms of the number and the monetary value. We calculated differences between consent rates in terms of the number and monetary value of TOVs in order to assess if there was a relationship between the value of TOVs and HCP disclosure consent.

Company-level spending and HCP consent rates

We applied the above methodology on a per company basis to compute the number and monetary value of TOVs made by each company as well as each company's consent rates. Ten out of 107 companies in the 2015 database did not provide information on TOVs in aggregate, and for 2016 this was of 13 out of 109. Because we cannot know if this meant these companies failed to report payments or, alternatively, they had 100% HCP consent and

therefore had nothing to report in aggregate, we excluded them from this part of the analysis. We used descriptive statistics to depict the distribution of HCP consent rates across remaining 97 and 96 companies in 2015 and 2016, respectively.

Agreement between author-calculated and company-reported HCP consent rates

In the database, companies should report the number of TOV recipients disclosed in aggregate for each TOV type as per cent of all TOV recipients (i.e., reported at individual level and aggregate) for that TOV type (see Results). However, the ABPI has reported that although the majority of companies in the 2015 edition of the database correctly understood the instructions on how to calculate this consent rate statistic, some companies appear to have misunderstood the instructions and instead provided the number of recipients disclosed in aggregate for each TOV type as per cent of *all* recipients that received payments from the company irrespective of TOV type.[16] To gain further clarity on this matter, and to see whether inconsistencies occurred in the 2016 database, we compared the consent rates that we had calculated for each company (see above) with the rates directly reported by each company. Notably, because companies report consent rates for the number but not monetary value of TOVs we were restricted to comparing consent rates only for the former. Similarly, because companies report consent rates per TOV type, rather than across all TOV types, we compared consent rates on a TOV type basis.

For this analysis we excluded companies that did not submit aggregate payments reports (n=10 in 2015; n=13 in 2016). We also excluded cases in which companies had submitted aggregate payments reports but had left the cell empty in the database that were to contain the consent rate statistic for a certain TOV type (n=83 in 2015 and n=69 in 2016) since it is impossible to ascertain whether an empty cell indicates that a company simply failed to report (i.e., a missing value), or that all payments of this TOV type were disclosed at the individual level, or that no payments were made at all of this TOV type. We defined any difference between author-calculated and company-reported consent rates greater than one percentage point as discordant in order to exclude differences occurring due to rounding. We calculated the percentage of concordant pairs and used descriptive statistics to analyse disparities between the computed consent rates.

Patient involvement

No involvement

Results

Disclosure UK definitions and variables

The disclosure database includes payments to a large spectrum of HCPs, including not only medical doctors but also, among others, pharmacists, nurses, and even individuals who might not be HCPs such as NHS managers (in ABPI documents[26] the latter group is referred to as Other Relevant Decision Makers, or ORDMs, but in the database, and therefore in this study, they are counted as HCPs).

Appendix Tables 1 and 2 summarise the definitions and variables in Disclosure UK relevant to HCPs. Consistent with the EFPIA reporting standard, two higher-level TOV *categories* are used in Disclosure UK: "Contribution to costs for events" and "Fees for services and consultancy", which are each split into two lower-level TOV *types*: "Registration fees" and "Travel & Accommodation" for events, and "Fees" and "Related expenses agreed in the fee for services and consultancy contract", respectively.

Each company aggregates its yearly payments at the level of individual HCP and TOV type. For example, if a company makes two "Registration fees" payments to the same HCP the payments are registered as one "Registration fees" TOV. However, if the company makes one "Registration fees" and one "Travel & Accommodation" payment the payments are registered separately. A corollary to this is that many HCPs have several TOV records in the database either because they have received payments of different TOV types from the same company and/or because they have received payments from more than one company. An important implication is that the number of TOV records is greater than the number of HCPs in the database.

Companies are expected report individual-level data, including the name, title, city and principal practice address of each TOV recipient, in addition to the monetary value of the TOV (Appendix Table 2). Payments to HCPs who do not consent to the publication of individual-level data are reported on an aggregate basis by each company, using the four lower-level TOV types (see Table 1). For such aggregate reporting, each company shall specify in the database: (1) the total amount attributable to such recipients; (2) the number of recipients in the aggregate disclosure, and (3) the number of recipients disclosed in aggregate as percent of all recipients. For example, if a company paid ten HCPs £100 each to cover their

registration fees for events, but only received consent to publish individual-level data from five, the company should report in the aggregate for "Registration fees": (1) £500; (2) five recipients, and (3) 50%.

The database does not allow for calculating the number of HCPs that received payments in a particular year. This is because in the aggregate disclosure, companies report the number of recipients per TOV type, rather than across all TOV types. As some HCPs may receive TOVs of different types from the same company, they will be counted several times. Similarly, HCPs receiving payments from multiple companies will also be counted several times in the aggregate.

Number and value of payments in Disclosure UK

In 2015, 107 companies reported a total of 54,910 TOVs worth £50,967,728 (Table 1). In 2016, two more companies reported TOVs but spending decreased by over £3,4 million (-7.3%; inflation-adjusted), and the number of TOVs also decreased by 8.5%. In both years roughly 35% of the number of TOVs were consultancy fees but money-wise they corresponded to roughly 60%, reflecting the on average higher value of consultancy fee TOVs. Conversely, approximately 35% of the number of TOVs covered costs for travel and accommodation at events but they corresponded to roughly 20% of the total spending, reflecting the on average smaller size of such TOVs.

Table 1. Transfers of value to UK healthcare professionals in 2015 and 2016

		2015				2016				ΔN	Δ£[a]
		N	%	£	%	N	%	£	%	%	%
Events	**Registration fees**	7,877	14.3	3,445,579	6.8	7,441	14.8	3,293,209	6.9	-5.5	-5.1
	Travel & Accom	19,138	34,9	10,692,849	21.0	17,445	34.7	9,856,619	20.7	-8.8	-8.5
Consultancy	**Fees**	19,020	34.6	30,396,315	59,6	16,606	33.1	28,698,492	60.4	-12.7	-6.2
	Expenses	8,875	16.2	6,432,985	12.6	8,750	17.4	5,699,934	12.0	-1.4	-12.0
Total		**54,910**	**100**	**50,967,728**	**100**	**50,242**	**100**	**47,548,254**	**100**	**-8.5**	**-7.3**

[a] Inflation adjusted: +1.7% between 2015 and 2016.

In monetary terms, the largest decrease between 2015 and 2016 was seen with consultancy expenses (-12.0%; inflation-adjusted). This decrease was accompanied by only a minor decrease in the number of consultancy expenses TOVs (-1.4%), suggesting that the decrease in the value of payments was due to fewer larger-size payments in 2016. Conversely, there was a moderate decrease in the value of consultancy fee payments (-6.2%; inflation-adjusted),

but this was accompanied by a greater decrease in the number of consultancy fees TOVs (-12.7%), suggesting that this decrease was associated with fewer smaller-size payments.

Variation in spending across companies

For both years a small number of companies concentrated a large part of the TOVs (Appendix Table 3). In 2015 and 2016, the top-10, -20 and -50 spending companies reported 48.2% and 49.9%, 71.8% and 70.8%, and 93.5% and 92.3% of the spending, respectively. The biggest spender in 2015 was AstraZenca (6.9%; £3,535,413), followed by Bayer (6.2%, £3,159,752) and Merck-Sharp & Dohme (6.0%; £3,076,958). In 2016, Bayer (7.0%; £3,308,421), Pfizer (6.9%; £3,259,315) and Novo Nordisk (5.3%; £2,517,088) were on the top-3 list, and with AstraZenca and Merck-Sharp & Dohme now on fourth (5.2%; £2,465,100) and eighth (4.3%; £2,031,188) place. The median number of TOVs reported per company in 2015 was 187 (min 1; max 3,521; IQR 580.5) and median company spending in 2015 was £141,895 (min £266; max £3,535,413; IQR £444,448). The median number of TOVs reported per company in 2016 was 172 (min 2; max 3,409; IQR 482), and median company spending was £147,490 (min £2,181; max £3,308,421; IQR £410,873), i.e., comparable to 2015.

HCP consent rates for individual-level disclosure

For 2015 we established that 55.5% (30,478) of all TOVs worth £24,428,619 (47.9%) were disclosed at the individual level (Table 2). Regardless of TOV type, HCPs consented to disclose around 55% of the number of TOVs at the individual level, but in monies there was considerable variation in consent rates. In particular, the consent rate for consultancy TOV types was higher in number of TOVs (56.9% and 53.6%) than in monetary terms (47.9% and 38.4%).

Table 2. Healthcare professional consent rates for individual-level disclosure of transfers of value in 2015 and 2016

		2015		2016	
		% N[a]	% £[b]	% N[a]	% £[b]
Events	**Registration fees**	54.6	56.0	64.4	64.1
	Travel & Accom	55.4	51.3	64.6	64.7
Consultancy	**Fees**	56.9	47.9	66.4	58.2
	Expenses	53.6	38.4	60.9	51,9
Total		**55.5**	**47.9**	**64.5**	**59.2**

[a] Consent rate for the number of TOVs

[b] Consent disclosure rate for monetary value of TOVs

In 2016, the consent rate had increased to 64.5% (32,407) of all TOVs worth £28,145,091 (59.2%). However, despite the improved consent rate, the difference between consent rates for consultancies remained (66.4% and 60.9% for numbers of TOVs vs. 58.2% and 51.9% in monetary value).

Pattern of individual-level disclosed TOVs

Table 3 shows the distribution of individual-level disclosed TOVs. Consultancy fees were more often larger than other TOVs types, and some of these payments were substantial: the top percentile included payments equal or larger than £11,012.3 (in 2015) and £12,857.8 (in 2016). However, there were some large payments associated with events. For example, for travel & accommodation, the top percentile included payments equal or larger than £3,729 (in 2015) and £3,781.6 (in 2016).

Table 3. Distribution of transfer of value sums (£) disclosed at the individual level

		2015					2016				
		Min	Median	IQR	99%	Max	Min	Median	IQR	99%	Max
Events	**Registration fees**	10	394.1	292.6	1,698.9	19,836	10	395	306	1,515.2	4,880
	Travel & Accom	1,5	252	465	3,729	22,280	1.5	289.3	535.2	3,781.6	28,160.1
Consultancy	**Fees**	0[a]	750	950	11,012.3	54,700.9	14.8	750	1,100	12,857.8	81,130.2
	Expenses	1	142.7	295.1	7,817.1	34,223	2	156.5	339.1	8,003.1	42,942.9

a Britannia Pharmaceuticals registered this payment and it likely represents a mistake

Differences in HCP consent rates across companies

We found differences across companies in HCP consent rates (Figure 1; Appendix Table 3). In 2015, the median among companies for TOV sums was 47.3%, with 75% of companies reporting more than 72.8% and 25% of companies reporting less than 21.3% at the individual level. This latter group included top-30 spenders like Merck Sharp & Dohme (1.2%), Allergan (12.3%), Bristol-Myers Squibb (20.8%), Napp (20.5%) and Boehringer Ingelheim (21.3%). There were fewer big companies on the other side of the spectrum: Teva (72.4%), Gilead (73.6%) and GlaxoSmithKline (95%). By 2016 consent rates had increased (median 57.7%); still, 25% of companies included in this analysis reported less than 38.6% of the value of payments at the individual level, counting big spenders like Napp (10.5%), Allergan (20.8%), Novo Nordisk (31.7%), and Bayer (34%).

Agreement between author-calculated and company-reported HCP consent rates

We compared the consent rates for the number of TOVs that we calculated ourselves on the basis of information in the database, on the one hand, and the rates reported directly by companies in the database, on the other. For this analysis, we had to exclude ambiguous cases (n=83 in 2015 and n=69 in 2016) (see Methods). The percent agreement between what we calculated and what companies reported for each TOV type was only 62%-48% in 2015 (Table 4). The agreement was worse in 2016: 46%-30%. In 108 of 143 (76%) (in 2015) and 194 of 197 (98%) (in 2016) of cases of disagreement, companies reported higher consent rates than what we calculated. In some cases, the difference between our calculations and what companies' reported was very large, but in most cases the difference was smaller, albeit substantial (Figure 2).

Table 4. Percent agreement between author-calculated and company-reported healthcare professional consent rates

		2015		2016	
		Agreement	n/N	Agreement	n/N
Events	Registration fees	61%	40/66	46%	31/68
	Travel & Accom	54%	40/74	41%	32/80
Consultancy	Fees	51%	46/91	39%	36/93
	Expenses	48%	35/73	30%	24/79

Discussion

To the best of our knowledge, this is the first systematic analysis of the Disclosure UK database. Payments to HCPs totalling roughly £51 million and £47.5 million were reported in 2015 and 2016, respectively, concentrating in the hands of several big spenders. Consultancy-related payments comprised more than 70% of the total value, with the rest being costs for events. That the industry over the two-year period paid more than £30 million for events registration and travel and accommodation – which included some sizeable payments – is noteworthy in light of the criticism levied against industry sponsorship of HCPs' conference and events attendance in the past,[28 29] and which has motivated the barring of such sponsorship by the industry trade group in Sweden[7] and at least one major company.[30]

We confirm preliminary analyses conducted on behalf of the ABPI[17] showing a higher consent rate for 2016 in 2015 – from 48% to 59%. Although this increase was taken as

evidence of an increased HCP willingness to participate in Disclosure UK,[17] the ABPI recently announced a drop in HCP consent for 2017 below 2015 levels, which the trade group attributed to the new Europe-wide General Data Protection Regulation (GDPR).[31] Significantly, however, our analysis goes further than these preliminary analyses by highlighting differences in consent rates across payment categories and companies. Regarding differences across payment categories, analysis at the level payment sums showed that HCPs were less likely to consent to disclosure of consultancy payments than events payments. Furthermore, HCPs who received larger consultancy payments appeared less likely to consent to disclosure since consent rates were lower for payment sums than for the number of transfers. Regarding variation across companies, a key finding is that some big spenders, like Bayer and Novo Nordisk, reported relatively few payments at the HCP individual level whilst others, such as GlaxoSmithKline, reported almost everything at the individual level. As debates about HCP willingness to participate in Disclosure UK have focused mostly on HCP behaviour and motivation[32 33] our finding of major company variation is important because it shifts the focus to company characteristics, especially policies for collecting consent from HCPs, which in turn may be associated with more general corporate cultures, as another set of likely determinants of consent. Notably, companies that fail to live up to industry's stated commitment to Disclosure UK could be investigated and sanctioned by the Prescription Medicines Code of Practice Authority (PMCPA), the industry self-regulatory body that administers the ABPI Code of Practice.[9 10] Although a lower than average HCP consent rate does not prove company misconduct the fact that, for example, Merck Sharpe & Dohme reported that fewer than 2% of collaborating HCPs consented to individual-level disclosure in 2015 suggests that the PMCPA has reason to investigate whether some companies have eschewed disclosure.

The launch of Disclosure UK was heralded as a breakthrough in pharmaceutical industry transparency.[34] Although the database does represent a step towards enhanced transparency, our study highlights deficiencies that undermine its usefulness for understanding industry payments to HCPs and associated impact on healthcare delivery. First, and consistent with EFPIA guidelines, the database only contains aggregate data on R&D payments and it omits HCPs' ownership or investment interest – two areas highlighted as important by research on industry payments in the US.[35] Second, the fact that HCPs can opt-out from individual-level disclosure, together with the fact that consent rates vary substantially between companies, means that, due to the risk of participation bias, it is precarious to investigate the association

between receiving payments and HCP behaviour (e.g. prescribing) or characteristics (e.g. gender or speciality), as has been done extensively with US data.[3 18-24] A third limitation is the lack of information on a number of characteristics that provide relevant details regarding the payment. For example, a recent study using information in the US Open Payments Database on the products connected to payments showed that firms' invested great sums to promote drugs for which more innovative, effective, safer and cheaper alternatives existed.[36] Unfortunately, this is a kind of analysis not possible to do with UK data because companies are not asked to disclose information on the products in relation to which the payment was made.

Another aspect of Disclosure UK in need of urgent improvement relates to how companies report data on payments to non-consenting HCPs. We found that companies regularly left cells empty in the database where they should inform on the HCP consent rate. We recommend companies should never leave cells empty as this creates ambiguity. Another problem concerning the present consent rate reporting standard – and which applies to all countries relying on the EFPIA-based self-regulatory model and reporting standard – is that, arguably, there are more relevant and easily interpretable data elements that companies could report other than the number of HCP recipients disclosed in aggregate as the percent of all recipients for each TOV type. Intuitively, one would expect companies to summarise their HCP consent rates in total (i.e., what is the company's overall consent rate?) and for each TOV type separately (i.e. what is the company's consent rate for, for example, consultancy fees?). Companies should provide this information both in terms of the number and value of TOVs – currently they only provide rates calculated for the number of TOVs. Should our reporting suggestions be adopted this would allow for easy comparison across years, firms and countries. Furthermore, it might offer a simple mechanism for increasing individual-level disclosure because publicising consent rates in a consistent and interpretable format is likely to put pressure on companies to improve their figures to avoid damage to their reputation for transparency.

That the current consent rate reporting standard is unintuitive is underlined by the inconsistencies, and possible inaccuracies, in companies' reporting, and which – despite being highlighted by the ABPI – continued into the 2016 version of the database. Thus the comparison between our author-calculated and the company-reported consent rates showed that in some cases the difference was very large, more consistent with the idea that some

companies had altogether misunderstood how to compute consent rates. In most cases, however, the difference was smaller, albeit substantial, which makes it less likely to be due to confusion about how to compute consent rates. The existence of ambiguity or inconsistency points to a broader issue of limited transparency and data quality, and possibly lack of oversight, with implications for other countries too – and especially for European countries that lack a central and analysable registry for payments,[7] and that therefore rely even more on accurate and comparable reporting by companies as there is limited possibilities to independently analyse data. In the event that the ABPI is unable to swiftly resolve the various problems of limited transparency and data quality in Disclosure UK our study has revealed, we suggest – like others[37 38] – that the UK government should consider introducing legislation requiring disclosure modelled on the US Open Payments Database.

Strength and limitations

The main strengths of this paper are that it is based on the full dataset for two years and that calculations are consistent with the ABPI's, which corroborates our methodology. The main limitation is that we have no way of checking the accuracy of the data. Furthermore, transparency requirements do not apply to manufacturers of generics and over-the-counter medicines and exclude some payments such as food and drinks;[7] thus, our analysis likely underestimates the true extent of payments.[39] For analyses of company-level HCP consent rates we excluded cases that were ambiguous. However, including such cases would not change conclusions that there is major company-variation in consent rates or that there was limited agreement between author-calculated and company-reported consent rates. Also, we did not take into account differences in companies' interpretation and reporting of some data elements that are detailed in the methodological note that each company provides.[40 41] Of relevance to consent rates is the issue of how companies deal with cases where HCPs consented to the individual-level disclosure of some TOVs but refused others. The vast majority of companies that specify a rule for this state that they disclose all TOVs to those recipients in the aggregate section, i.e., they do not allow for partial disclosure. However, four companies in 2015[40] and three in 2016[41] reported in their methodological notes that, at least in some circumstances, partial disclosure was allowed, meaning that an individual may be counted in both in the individually-named and aggregate sections, and it is unclear if this influences the consent rates calculated by these companies. Furthermore, some companies choose to report payments with and some without VAT and other taxes (e.g., income tax and national insurance), and some companies' procedures vary according to the type or recipient

of the payment. Comparison of the value of TOVs made by two companies may also be distorted by the fact there is variation among companies with regard to whether they consider TOVs to HCP members of their own staff to be within the scope of the disclosure, and in how they classify for the purposes of disclosure (i.e., as HCPs or healthcare organisation) self-incorporated HCPs or companies owned and/or run by an HCP. Given the complexity, these methodological matters should become the subject of a separate study. Finally, we did not include payments for R&D that are reported in aggregate by companies. Future studies should investigate R&D payments, as well as the payments to healthcare organisations, and may also choose to extend the analysis to other European countries' databases where possible, for example, to explore differences in HCP consent rates across countries on a company-per-company basis.

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Figure Legends

Figure 1. Box plots show author-calculated healthcare professional consent rates across companies in the 2015 (n=96) and 2016 (n=97) version of Disclosure UK. White depicts the number of TOVs; grey depicts monetary value of TOVs.

Figure 2. Box plots show the difference in percentage points between company-reported and author-calculated healthcare professional consent rates for the number of TOVs in 2015 and 2016 for each TOV type. Only discordant pairs are shown, i.e. differences larger than +/- 1.0 percentage point. Number of discordant pairs (n) in each plot are shown. Reference line indicates zero percentage point difference.

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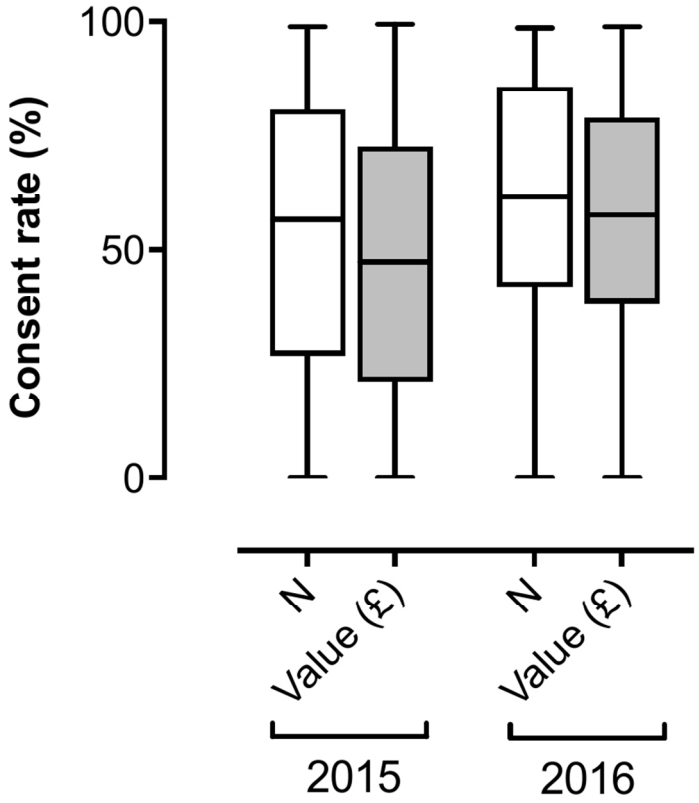
Data sharing statement: Databases are publically available on ABPI webpage.



Box plots show author-calculated healthcare professional consent rates across companies in the 2015 (n=96) and 2016 (n=97) version of Disclosure UK. White depicts the number of TOVs; grey depicts monetary value of TOVs.

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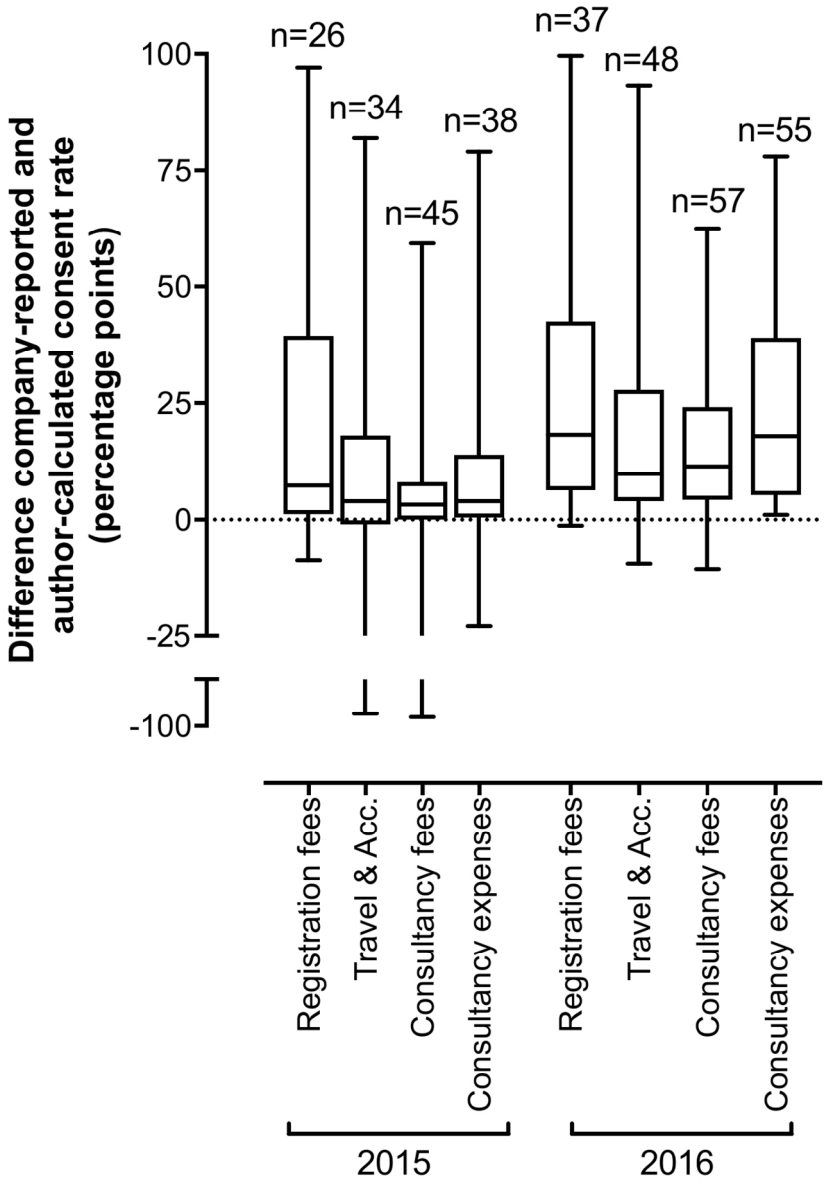

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103x148mm (300 x 300 DPI)

Appendix Table 1. Disclosure UK definitions related to transfers of value to healthcare professionals

Element	Definition[a]
Healthcare professional	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.
Transfer of value	A direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is 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.
Contribution to costs for events	TOVs covering *registration fees* and *travel & accommodation* for all promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events, excluding costs that are clearly related to R&D.
Fees for services and consultancy	TOVs covering *fees* and *expenses* resulting from or related to contracts between companies and HCPs under which such HCPs provide services to companies, excluding costs that are clearly related to R&D.

[a] Definitions are derived from the EFPIA Disclosure code and the ABPI Code of Practice.

Appendix Table 2. Mandatory and optional variables related to transfers of value to healthcare professionals in Disclosure UK

Individual level (mandatory)	• Title of HCP • Name of HCP • Country and city of principal practice of HCP • Principal practice address of HCP • Yearly amount per HCP and TOV type
Individual level (optional)	• Speciality of HCP • Role of HCP • Total yearly amount per HCP across all TOV types
Aggregate (mandatory)	For each TOV type • the number of recipients in the aggregate disclosure • the percentage of recipients in the aggregate disclosure • the aggregate amount attributable to such recipients

Appendix Table 3. Transfers of value to UK healthcare professionals: value, numbers and healthcare professional consent rates per company in 2015 and 2016

	2015 [b,c]				2016 [b,c]			
Company[a]	£	Rate £	N	Rate N	£	Rate £	N	Rate N
Bayer	3159751.53	24.9%	2817	26.3%	3308420.84	33.9%	3090	34.5%
AstraZeneca	3535413.23	66.9%	2631	88.1%	2465100.23	78.5%	2161	94,0%
Pfizer	2509453.01	51.7%	3263	62.6%	3259314.86	88.8%	3409	97.2%
Janssen-Cilag	2912280.38	68.4%	3521	85.3%	2401589.87	69.7%	2635	84.8%
Merck Sharp & Dohme	3076957.74	1.2%	2568	1.8%	2031187.84	67.8%	1753	60.1%
Novo Nordisk	2222001.79	25.9%	2099	34.2%	2517087.73	31.7%	1984	40.9%
Novartis	2211719.11	57.8%	2322	77.9%	2151112.54	85.3%	2520	93.1%
Abbvie	1564813.16	59.2%	1512	64,0%	2053533,0	65.3%	1929	66,0%
Sanofi Aventis	1466907.46	45.7%	1016	74.3%	1872099.77	60.2%	1406	85.3%
Eli Lilly	1536223,0	38.2%	1811	44.2%	1677839,0	42.5%	2193	43.6%
Astellas	1827995.2	55.4%	3019	56.6%	1215637.23	63.1%	1947	62.3%
Roche	1455735.79	54.8%	1513	52.5%	1430433.44	55.3%	1352	50.9%
Gilead	1306053.44	73.6%	1046	80.1%	1478764.99	71.8%	1295	85.9%
Bristiol-Myer Squibb	1549787,0	20.8%	1055	28.1%	851293.86	44,0%	966	30.7%
Allergan	1306149.86	12.3%	1416	10.2%	1032918.16	20.8%	1004	6.5%
GlaxoSmithKline	1456604.18	94.7%	922	96.7%	456573.77	94.7%	224	93.3%
Takeda	940687.85	39.7%	986	58.2%	728964.2	53.5%	730	57.3%
Napp	628996.24	20.5%	1083	13.1%	976205.64	10.5%	841	10.1%
Merck Serono	754664.68	39.4%	790	49.1%	826112.82	38.9%	920	41.5%
Servier	773827,0	26.4%	993	42.3%	652946,0	34.4%	769	54,0%
Boehringer Ingelheim	1048816.74	21.3%	982	17,0%	305666.53	33.1%	393	32.8%
Amgen	521029.24	70.1%	586	78,0%	746845.6	74.5%	618	81.9%
Teva	645267.2	72.7%	1004	92.7%	613419.32	89,0%	938	94.3%
Celgene	625409.08	76.4%	681	91.8%	543539.96	92.2%	616	97.4%
Biogen	591279.32	39.1%	481	36.2%	548807.95	55.7%	534	55.4%
Lundbeck	640573.65	71.4%	546	81.5%	474701.11	80.2%	288	87.2%
Shire	489890.6	40.6%	753	50.5%	609993.99	29.3%	854	41.6%
Chiesi	444695.41	47.3%	993	55,0%	458128.85	49.5%	913	68.7%
Alexion	368849.66	N/A	192	N/A	503918.85	75.7%	384	86.2%
Ferring	307893.54	97,0%	681	97.9%	407998.51	98.3%	651	98.6%
Leo Pharma	407685.31	79.8%	477	83,0%	286664.94	53.1%	375	70.4%
Ipsen	301323.9	19.2%	408	27,0%	374106.85	52.9%	530	58.5%
Actelion	313106.09	N/A	257	N/A	356376.53	N/A	303	N/A
Otsuka	408626.56	62.9%	431	61.3%	244212.9	70.5%	280	70,0%
UCB Pharma	345118.97	89.6%	482	95.9%	301511.22	74.7%	388	76.5%
Mundipharma	352716.36	31.4%	277	37.9%	270516.63	32.2%	209	30.1%
Alcon	63003.67	64.3%	107	68.2%	545034.66	4.4%	387	9.6%
Sunovion	199678.54	11.1%	359	5.0%	389470.11	20.8%	404	16.1%
Britannia Pharmaceut.	306612.79	31.4%	519	27.6%	275986.24	10.8%	296	18.2%
Genzyme	485188.61	59.7%	363	73.6%				
Almirall	278767.32	36.7%	360	33.9%	199570.03	25.8%	264	24.6%
Eisai	223359.54	1.5%	310	1.9%	245975.76	50,0%	390	47.7%
Baxter	255137.4	78.1%	745	68.3%	213814.37	85.4%	605	79.2%
Sandoz	227441.4	46.6%	336	47.9%	215214.15	66.1%	291	59.1%
Grunenthal	246726.43	71.4%	261	73.9%	190316.65	56.6%	169	63.9%
Daiichi Sankyo	220747,0	82.1%	120	73.3%	189262.35	N/A	99	N/A
Chugai Pharma	286373.49	17.4%	258	24.4%	112438.72	42.4%	208	41.3%
Stirling Anglian	294263.67	13.7%	138	15.9%	99271.44	0,0%	7	0,0%
Jazz	188260.97	N/A	234	N/A	197620.41	87.1%	215	92.6%
A. Menarini	183910.75	38.5%	290	45.9%	199534.57	47.6%	425	44.9%
Norgine	249679,0	90.4%	503	90.9%	126734,0	95.3%	310	96.8%
Vifor	177596.18	46.8%	221	50.2%	198170.14	52.8%	241	46.5%
Merz Pharma	189462.24	26.8%	321	10.6%	185739.27	82.4%	191	89.5%
Tillotts Pharma	176466.55	48.1%	251	42.2%	166281,0	40.8%	294	38.1%
Sobi	112196,0	82.9%	142	84.5%	201602,0	79.2%	195	89.7%
Bausch & Lomb	99214.94	89.6%	72	94.4%	213391.81	98,0%	38	89.5%
CSL Behring	127282.86	13.9%	208	18.8%	180149.66	17.8%	246	19.5%
Alimera	141895.08	59.2%	145	60.7%	104980.22	71.6%	120	73.3%
Baxalta	108841.04	72.9%	109	81.7%	112591.45	21.6%	104	48.1%

Santen	89402.76	40.5%	98	62.2%	117740.97	59.3%	128	65.6%
Pierre Fabre	139369.27	99.5%	187	98.9%	65778.26	N/A	96	N/A
Flynn	109136.69	97.3%	109	90.8%	81375.13	98.9%	189	98.4%
Sanofi Pasteur MSD	89631.94	99.5%	92	97.8%	99363.2	93.8%	129	90.7%
Actavis	35417.52	30.5%	115	37.4%	147490.36	25.8%	156	80.1%
Bial Pharma UK					176271.02	69.6%	172	56.4%
Besins	82198.2	58.3%	149	57,0%	85835.68	84.9%	152	78.3%
Meda	81096.74	16.2%	144	25,0%	78158.34	55.3%	115	54.8%
ALK-Abello	86092.07	87.6%	111	86.5%	72616.23	95.9%	132	93.9%
Shionogi	39219.34	28.7%	46	13,0%	110557.95	78.8%	18	50,0%
BioMarin Europe	99611,0	84.2%	79	94.9%	47256.27	82.3%	37	89.2%
Thea	57837.2	0,0%	67	0,0%	88595.53	0,0%	161	0,0%
Dermal	68976.77	87.6%	150	79.3%	72868.4	85.3%	133	73.7%
Gedeon Richter	93535.33	51.9%	154	56.5%	45916.67	37.6%	78	52.6%
Pharma Mar	43886.92	50.5%	97	48.5%	92639.69	66.2%	153	75.2%
Consilient Health	79285,0	59.3%	60	61.7%	53710,0	43.5%	73	38.4%
Fresenius-Kabi	32517.14	8.6%	65	6.2%	95531.07	71.3%	275	75.6%
Vifor F. Med. Care R.	17545.93	6,0%	12	33.3%	97196.1	52.7%	55	52.7%
Galen	70097.81	94.2%	58	98.3%	43287.14	98.3%	60	96.7%
Hospira	77501.37	0,0%	87	0,0%	24779.61	N/A	23	N/A
Biotest	54416.34	51.3%	112	77.7%	45528.94	74.9%	102	82.4%
Octapharma	42296.03	15.1%	48	52.1%	57424.94	45.9%	69	60.9%
Profile Pharma	40829.51	75,0%	22	86.4%	58360.36	58.7%	70	48.6%
ApoPharma	89730.81	2,0%	12	16.7%	8079,0	50,0%	15	20,0%
Orion Pharma	73501.22	80.5%	336	69,0%	22042.33	N/A	43	N/A
RB	33609,0	90.6%	29	82.8%	51831.91	97.5%	48	93.8%
Grifols					76806.76	34.3%	99	42.4%
Novex	44000,0	34,0%	10	30,0%	25675.7	56.5%	9	33.3%
Guerbet Laboratories	25860.99	17,0%	40	12.5%	41030.23	63.2%	37	45.9%
PTC Therapeutics	12397.2	13,0%	20	15,0%	52998.57	94.6%	58	89.7%
Intercept Pharma					62202,0	15.7%	27	48.1%
Diurnal	34223,0	N/A	1	N/A	19936,0	N/A	14	N/A
HRA Phara	50906.76	N/A	26	N/A	2181,0	N/A	2	N/A
BGP Products	52906.5	10.8%	89	19.1%				
Bracco	8497.98	39.4%	26	23.1%	39962.23	94.4%	34	82.4%
GE Healthcare					48089,0	14.3%	66	18.2%
Alliance	14547.75	72.2%	36	83.3%	29486.15	N/A	79	N/A
Syner-med	11109.38	N/A	20	N/A	30180.03	N/A	52	N/A
Aegerion	16589.98	N/A	13	N/A	13610.19	42.3%	14	85.7%
Shield TX					29447.7	97.2%	45	95.6%
Valneva					27379.38	N/A	4	N/A
Orphan Europe	25831.44	93,0%	15	73.3%				
Seqirus					24263.26	N/A	4	N/A
Bio Products	13636.52	12,0%	34	29.4%	8698.44	71.3%	20	95,0%
Martindale	14581.65	0,0%	17	0,0%	7366.37	7.5%	7	42.9%
Amdipharm Mercury	19916.43	43.9%	30	56.7%				
Amicus Therapeutics					17583.14	0,0%	16	0,0%
CEB Pharma	15431.98	83.9%	62	83.9%				
Fresenius Med. Care					15298.49	52.8%	10	60,0%
Nicovations	12331,0	0,0%	14	0,0%				
Accretio	2460,0	67,0%	8	75,0%	8906.71	66.7%	17	70.6%
Mitsubishi Tanabe	4988,0	60,0%	7	85.7%	5124.2	N/A	13	N/A
Rosemont Pharmac.	5235.17	32,0%	4	75,0%	4646.93	48.4%	5	80,0%
Cuxson Gerrard	2799.5	0,0%	9	0,0%	4369,0	0,0%	13	0,0%
Tesaro					6726.51	67.8%	8	62.5%
Augettant	1459.51	N/A	1	N/A	4153.47	N/A	5	N/A
STD Pharmaceuticals	600,0	N/A	1	N/A				
Special Products	266.2	N/A	2	N/A				
Total	**50,967728**	**47.9%**	**54910**	**55.5%**	**47,543051.1**	**59.2%**	**50241**	**64.5%**

[a] Companies are listed according to the total value of TOVs in both years

[b] Empty cells mean that company was not in database that year

[c] N/A means company did not provide information on any TOV in aggregate and therefore the consent rate cannot be calculated.