

BMJ Open Disclosure of payments by pharmaceutical companies to healthcare professionals in the UK: 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.

Strengths and limitations of this study

- Thus far, there have been no studies analysing publicly available pharmaceutical industry disclosure databases in any European country, including the UK.
- Our analysis was based on the full Disclosure UK dataset for healthcare professional (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.

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 interest¹ that may bias medical research,² treatment decisions³ and lead to wasteful public spending.⁴ In recent years, a key way of addressing these concerns⁵ — and protecting the transparency and accountability of healthcare policy and practice⁶ — 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 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 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 6 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, for example, 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 were released in June 2016, and the 2016 data were 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.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 Practice²⁶ 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 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, 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 (eg, 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 (ie, reported at individual level and aggregate) for that ToV type (see the Results section). 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 (ie, 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 1% 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 medical doctors and, among others, pharmacists, nurses and even individuals who might not be HCPs such as National Health Service managers (in ABPI documents²⁶ the latter group is referred to as ‘other relevant decision makers’, but in the database, and therefore in this study, they are counted as HCPs).

Online supplementary 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 and Accommodation’ for events, and ‘Fees’ and ‘Related expenses agreed in the fee for services and consultancy contract’, respectively (see table 1).

Each company aggregates its yearly payments at the level of individual HCP and ToV type. For example, if a

		2015				2016				ΔN	$\Delta \text{£}^*$
		N	%	£	%	N	%	£	%	%	%
Events	Registration fees	7877	14.3	3 445 579	6.8	7441	14.8	3 293 209	6.9	-5.5	-5.1
	Travel and accommodation	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	8875	16.2	6 432 985	12.6	8750	17.4	5 699 934	12.0	-1.4	-12.0
Total		54910	100	50 967 728	100	50242	100	47 548 254	100	-8.5	-7.3

*Inflation adjusted: +1.7% between 2015 and 2016.

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 and 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 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 (online supplementary 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. 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 per cent 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.

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 fee 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 (online supplementary 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 3521; 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 3409; IQR 482) and median company spending was £147 490 (min £2181; max £3 308 421; IQR £410 873), that is, 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 rates for consultancy ToV types were higher in number of ToVs (56.9% and 53.6%) than in monetary terms (47.9% and 38.4%).

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 also some large payments associated with events. For example, for travel and accommodation, the top percentile included payments equal or larger than £3729 (in 2015) and £3781.6 (in 2016).

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

		2015		2016	
		% N*	% £†	% N*	% £†
Events	Registration fees	54.6	56.0	64.4	64.1
	Travel and accommodation	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

*Consent rate for the number of ToVs.

†Consent rate for monetary value of ToVs.

Differences in HCP consent rates across companies

We found differences across companies in HCP consent rates (figure 1, online supplementary 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 the Methods section). The per cent 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, although substantial (figure 2).

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 2-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 Sweden⁷ and at least one major company.³⁰

We confirm preliminary analyses conducted on behalf of the ABPI¹⁷ showing a higher consent rate in 2016 than 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.³¹ Significantly, however, our analysis goes further than these preliminary analyses by

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	1698.9	19 836	10	395	306	1515.2	4880
	Travel and accommodation	1.5	252	465	3729	22 280	1.5	289.3	535.2	3781.6	28 160.1
Consultancy	Fees	0*	750	950	11 012.3	54 700.9	14.8	750	1100	12 857.8	81 130.2
	Expenses	1	142.7	295.1	7817.1	34 223	2	156.5	339.1	8003.1	42 942.9

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

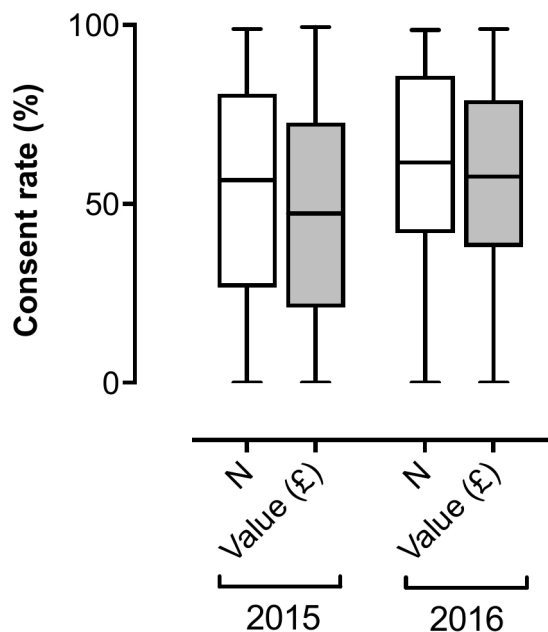


Figure 1 Box plots show author-calculated healthcare professional consent rates across companies in the 2015 (n=96) and 2016 (n=97) versions of Disclosure UK. White depicts the number of transfers of values (ToVs); grey depicts monetary value of ToVs.

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 while 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

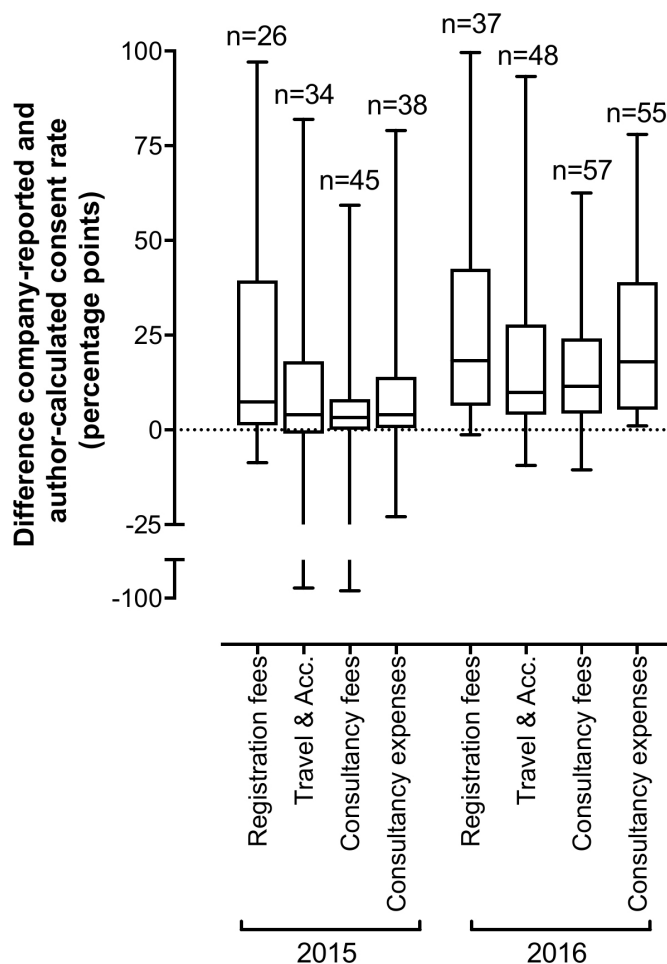


Figure 2 Box plots show the difference in percentage points between company-reported and author-calculated healthcare professional consent rates for the number of ToVs in 2015 and 2016 for each ToV type. Only discordant pairs are shown, that is, differences larger than $\pm 1.0\%$ point. The number of discordant pairs (n) in each plot are shown. Reference line indicates 0% point difference. ToV, transfers of value.

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 Sharp & Dohme reported that fewer than 2% of collaborating HCPs consented to individual-level disclosure in 2015 suggests that the PMCPA has

Table 4 Per cent 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 and accommodation	54	40/74	41	32/80
Consultancy	Fees	51	46/91	39	36/93
	Expenses	48	35/73	30	24/79

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 Research and Development (R&D) payments and it omits HCPs' ownership or investment interest—two areas highlighted as important by research on industry payments in the USA.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 (eg, prescribing) or characteristics (eg, gender or specialty), 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 that 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 per cent of all recipients for each ToV type. Intuitively, one would expect companies to summarise their HCP consent rates in total (ie, What is the company's overall consent rate?) and for each ToV type separately (ie, What is the company's consent rate, eg, for 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, although 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 are 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 2 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 drinks⁷; 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 a major company variation in consent rates or that there was a 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, that is, they do not allow for partial disclosure. However, four companies in 2015⁴⁰ and three in 2016⁴¹ 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 (eg, 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 that 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 (ie, as HCPs or healthcare organisation) self-incorporated HCPs or companies owned and/or run by a 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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