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## Payments to healthcare organisations reported by the medical device industry in Europe from 2017 to 2019: An observational study

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## ABSTRACT

**Objective:** Medical device industry payments to healthcare organisations (HCOs) can create conflicts of interest which can undermine patient care. One way of addressing this concern is by enhancing transparency of industry financial support to HCOs. *MedTech Europe*, a medical device trade body, operate a system of disclosure of education payments to European HCOs. This study aimed to characterise payments reported in this database and to evaluate the disclosure system.

**Methods:** An observational study of education-related payments to HCOs reported by the medical device industry in Europe was conducted. Data was manually extracted from [transparentmedtech.eu](http://transparentmedtech.eu). The primary outcome variable is the value of the payments, overall, and for each year, payment type, and country. The accessibility, availability and quality of the database was also analysed, using a proforma with 15 measures.

**Results:** Overall, 116 medical device companies reported education-related payments in 53 European and non-European countries, valuing over €425 million between 2017 and 2019, increasing in value between 2017 and 2019, from €93,798,419 to €175,414,302. Ten countries accounted for 94% of all payments and ten companies accounted for 80% of all payments. The accessibility, availability and quality of the database rated low for six measures, medium for six measures, and high for three measures.

**Conclusion:** There is a large amount of education-related payments from medical device companies to European HCOs, creating substantial potential for conflicts of interest. *MedTech Europe's* disclosure system has many shortcomings. A European-wide publicly mandated disclosure system for both the medical device and pharmaceutical industries should be introduced.

**Public interest summary:** The medical device industry pay healthcare organisations (e.g. hospitals) large amounts of money. Industry states that this money is to help pay for healthcare professionals' education. However, these payments can have a negative impact on healthcare professionals' decision-making. This study sought to examine a website run by *MedTech Europe*, a representative body for the medical device industry, which outlines details of some of these payments ([www.transparentmedtech.eu](http://www.transparentmedtech.eu)). Our analysis found that between 2017 and 2019 the medical device industry made 'education' payments valuing €425 million to healthcare organisations in Europe. We also assessed how comprehensive and user-friendly the database was and found a range of issues. For example, the database is not downloadable and some other important types of payments, such as payments for consultancy, are not included. We concluded that a mandatory database for both the medical device and pharmaceutical industry run by the European Union, would significantly improve transparency.

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## Introduction

Each year, billions of euro are paid by medical device and pharmaceutical companies to healthcare professionals (HCPs) and healthcare organisations (HCOs), ostensibly for research, consultancy and HCPs' education, among other areas [1–5]. The medical device industry accounts for a large proportion of this, with some estimating that they make up the majority of industry payments [1]. Medical devices are a vital component for health systems, used for diagnosis, treatment, and as aids to everyday activities [6]. Medical devices used in clinical practice range from tongue depressors to diagnostics to implanted surgical devices such as joint replacements with implanted medical devices likely to be subject of the greatest marketing activity given their large market share [1]. Despite this, most research has examined the patterns and possible effects of pharmaceutical industry payments to HCPs and HCOs [2–5]. These payments can create conflicts of interest [7]. Extensive evidence shows that receipt of payments from the pharmaceutical industry is associated with higher prescribing rates, higher prescribing costs, and lower prescribing quality [8–11]. Recent research suggests that similar issues may exist for medical device companies [12,13]. For example, a 2020 study showed that US physicians' choice of medical device is associated with medical device industry payments [12]. Some medical device industry payments have also been associated with legal breaches, for example, of the US Anti-Kickback Statute which prohibits paying anything of value to induce physicians to procure certain medical products, under state programs [14].

To start addressing these issues within both the pharmaceutical and medical device industries, several countries, including the US, France and more recently, Italy, have introduced legal requirements for industry to disclose payments to HCPs and HCOs [15,16]. However, the preferred approach to payment disclosure in Europe is industry self-regulation, which is based on codes-of-practice developed and implemented by national-level industry trade associations, rather than legal requirements [16]. There is a growing amount of research on industry payments to HCPs and HCOs in European countries, outlining a range of transparency limitations [16]. These include poor accessibility and limited disclosure, for example, related to the mis-labelling of recipients, incorrect inclusion of certain recipients such as patient organisations, and anonymisation of some recipients [4,5,9,16–19]. However, these studies primarily focus on the pharmaceutical industry [4,5,9,16–19]. This study is, to our knowledge, the first European and multi-country study of medical device industry payments to HCOs.

The importance of this research is highlighted by the recent implementation of the European Medical Devices Regulation, which aims to impose tighter pre-market controls on high-risk devices and enhance transparency in the medical device industry through the establishment of a comprehensive EU database, known as EUDAMED, containing information on all medical devices available within the EU [20]. The regulation's only provisions related to conflicts of interest are placing transparency requirements and some restrictions on conflicts of interest for experts informing the development and implementation of the regulation. However, when it comes to the disclosure of payments made by the medical device industry, it is *MedTech Europe*, the primary trade association for the European medical device industry, that oversees and regulates European transparency.

## Policy background

In 2023, 137 companies were members of *MedTech Europe* [21]. This represents a small proportion of medical device companies. A 2015 article [22], estimated that less than 10% of medical device companies operating in the UK were members of the Association of British Healthcare Industries, which is a member of *MedTech Europe*. Examples of *MedTech Europe* member companies include Roche, Medtronic and

Abbott [21]. Notably, several member companies have large pharmaceutical portfolios, such as Johnson and Johnson [23] and Baxter [24].

*MedTech Europe* has implemented a code-of-practice for their member companies to disclose details of 'educational grants' on a website ([www.transparentmedtech.eu](http://www.transparentmedtech.eu)) [25,26]. These educational grants are described as supporting "Healthcare Professionals' independent medical education". They also include grants for 'public awareness campaigns' as well as scholarships and fellowships [25]. *MedTech Europe* member companies are required to report education related payments to HCOs registered in member countries of the EU, the European Free Trade Area (Switzerland, Norway, Liechtenstein and Iceland), as well as the United Kingdom, Russia, and Turkey [26]. However, it should be noted that there are exceptions for four EU countries (Belgium, France, the Netherlands and Portugal), because, in those countries, the *MedTech Europe* disclosure website is superseded by local laws [26]. Also, several categories of payments are not published on [transparentmedtech.eu](http://transparentmedtech.eu), for example consultancy fees and associated expenses. These areas are published on the US Open Payments website [27] and are important because they have been found, in cases, to be associated with illegal activity [14]. Non-compliance with the *MedTech Europe* disclosure code can lead to sanctions, such as 'written reprimand' or an audit 'of the offender's relevant compliance systems' [25]. However, there is very little information about investigations or sanctions on the *MedTech Europe* website [28].

A Europe-wide database is in contrast to the approach of the European Federation of Pharmaceutical Industries and Associations (EFPIA) which allows each of its national trade group members to set up its own disclosure system [16]. While the pharmaceutical industry disclosure data must conform to certain minimum standards, in most European countries it is characterised by several limitations when compared to state-run disclosure systems [16,19,29]. These challenges have undermined independent attempts at creating a pan-European payments database drawing on industry data, with the largest project of this kind, [eurosfordocs.eu](http://eurosfordocs.eu), only covering five countries [4].

Publications on the [transparentmedtech.eu](http://transparentmedtech.eu) website began in 2018, for payments made in 2017 [30]. Only payments to HCOs are reported. According to the *MedTech Europe* definition, HCOs include hospitals, clinics, laboratories, pharmacies, research institutions, foundations, universities and professional societies, but exclude patient organisations (full definition in Appendix Box 1). For the definition of medical devices used by *MedTech Europe* see Appendix Box 2. In 2018 *MedTech Europe* introduced a rule that member companies could no longer make payments directly to HCPs for third party organised events; instead payments would be made to HCOs, acting as intermediaries, who would then disburse the payments to HCPs [22,25]. This rule was considered an effort to reduce conflicts of interest, [22] though its effectiveness and the process involved with devising the rule are unclear.

## Aim and objectives

Overall, a Europe-wide database offers a unique opportunity to understand the scale of payments made by the medical device industry to HCOs in Europe, and to inform regulation developments in this area. To achieve this, the aim of the study is to characterise payments reported in the *MedTech Europe* database from medical device companies to HCOs from 2017 to 2019 and to evaluate the system of disclosure itself.

## Methods

This is an observational study of payments to HCOs reported by the medical device industry in Europe. It includes data from 2017 to 2019 provided by medical device companies who are members of *MedTech Europe*. A protocol was registered for this study in February 2022 [31]. Details of protocol deviations are in Appendix Box 3.

**Database overview**

The *MedTech Europe* disclosure website contains data on two payments categories: (1) *support to educational events* and (2) *other educational grants*. Definitions are not provided for these categories but examples are. Educational events include ‘Support for HCP Participation at Third Party Organised Educational Events’ and other educational grants include ‘Scholarships, Fellowships and/or Grants for Public Awareness Campaigns’ as well as educational grants to support general medical education topics. Payments to HCOs are supposed to be aggregated on a year/donation-type basis – for example, all payments under ‘other educational grants’ in 2017 by one medical device company to one HCO should be included in a single entry, though this was not always adhered to.

**Data extraction and processing**

A data extraction form was developed in Microsoft Excel, capturing details of medical device company, payment year, HCO name, HCO country of registration and payment value. Data was manually extracted from [www.transparentmedtech.eu](http://www.transparentmedtech.eu), via an exhaustive search (details in Appendix Box 4) conducted in June 2021. Data extraction was conducted by two authors (AUTHOR-DETAILS). Data extraction was not conducted in duplicate.

In some instances, medical device company subsidiaries or affiliates reported separately from their parent company. For analysis, these companies were merged (Appendix Table 1). To determine the relationship between reporting companies the following information was used: (1) The contact email address provided by the reporting entity on the website and (2) the parent company’s website and where available the subsidiary/affiliate’s website.

All payments were exchanged to euro using the European Central Bank’s average annual exchange rates for the respective year [32]. The figures reported are adjusted for inflation to 2019 values using World Bank figures [33]. All totals were rounded to the nearest euro. *MedTech Europe* stipulate that all payments should be exclusive of VAT [25]. Three 2017 entries for ‘Other Educational Grants’ totalling €14,000 were removed because the recipient was ‘TEST’.

**Outcome variables**

The primary outcome variable is the value of the payments, overall, and for each year, payment type, and country. Several secondary outcomes are also included. Number of unique entries was also analysed for each year, payment type, and country. Gini coefficients are used as a measure of concentration of payments across all countries and companies. A Gini coefficient is a measure of statistical heterogeneity, often

used to calculate income or wealth inequality, that can range from 0 to 1, where 1 represents the highest possible level of concentration (e.g., one company accounting for all payments) and 0 represents the lowest possible level of concentration (e.g., all companies making the same value of payments). The Gini coefficient can provide information on the distribution of payments between companies and also whether those companies are distributing payments evenly across countries or focusing on some countries more than others. Gini coefficients are calculated for the period 2017–2019 and not for any individual year.

Additional secondary outcome variables are included for the ten countries, companies and HCOs with the highest total payment value, because they accounted for a significant proportion of the total value of payments. Gini coefficients are used across countries within each of the top 10 companies and across medical device companies within each of the top 10 countries. For each of the top 10 countries, companies and HCOs, the percentage of the total value of payments accounted for by each country, company or HCO was included. For each of the top ten countries, outcome variables also include: the total value of payments per 1,000 population, and the number of medical device companies reporting payments in that country. Population figures for payments per 1,000 population and Gini coefficient calculations were gathered for 2019 only, from Eurostat [34] and World Bank data [35]. For Gini coefficients, population figures are needed in order to understand what would have been a proportional payment value for a country. For each of the top ten companies, outcome variables also include the number of countries where payment recipients are located. For the top ten HCOs, outcome variables also include: number of companies each HCO was in receipt of payments from, the company with the greatest value of payments to each HCO, and the country the HCO is registered in.

Background information of the ten medical device companies who made the highest total value of payments is in Appendix Table 2. This includes the areas in which each company makes the greatest amount of revenue and the overall revenue of the companies.

The accessibility, availability and quality of the database is included as a secondary outcome. This was assessed using an adapted version of the proforma developed by Ozieranski and colleagues to examine the accessibility and quality of pharmaceutical industry payment data [16]. Several changes were made to the proforma to provide a more comprehensive assessment (details of changes in Appendix Box 5). The proforma contains 15 measures: nine measures of accessibility, three measures of availability and three measures of quality. The measures can be rated at one of three levels from low to high, though for seven of the measures there are only two levels, low and high (full proforma in Appendix Table 3). Other issues with the database, not covered in the proforma, were inductively assessed.

**Table 1**  
Payments broken down by payment type.

	2017	2018	2019	Total
<i>Overall spending (% of total)</i>				
Support to Educational Events	€79,439,026 (84.7%)	€124,705,816 (79.8%)	€132,400,996 (75.5%)	€336,545,838 (20.9%)
Other Educational Grants	€14,359,393 (15.3%)	€31,624,875 (20.2%)	€43,013,306 (24.5%)	€88,997,574 (79.1%)
Total	€93,798,419	€156,330,691	€175,414,302	€425,543,412
<i>Value (€) per entry, mean (SD)</i>				
Support to Educational Events	€20,639 (€705,247)	€14,908 (€549,248)	€15,635 (€541,871)	€16,272 (€578,590)
Other Educational Grants	€16,116 (28,185)	€24,067 (€87,353)	€19,288 (€148,074)	€20,067 (€115,972)
Overall	€19,789 (€635,620)	€16,152 (€511,625)	€16,397 (€486,809)	€16,942 (€523,399)
<i>Value (€) per entry, median (IQR)</i>				
Support to Educational Events	€2446 (€1024-€6464)	€2052 (€904-€5392)	€2000 (€810-€5320)	€2065 (€883-€5614)
Other Educational Grants	€5119 (€1547-€20,435)	€5472 (€1684-€22,120)	€2579 (€733-€11,000)	€3718 (€1059-€16,256)
Overall	€2636 (€1033-€8190)	€2312 (€968-€6462)	2039 (€800-€6000)	€2271 (€910-€6613)
<i>Number of unique entries (% of total)</i>				
Support to Educational Events	3849 (81.2%)	8365 (86.4%)	8468 (79.2%)	20,682 (82.3%)
Other Educational Grants	891 (18.8%)	1314 (13.6%)	2230 (20.8%)	4435 (17.7%)
Overall	4740	9679	10,698	25,117

**Table 2**

Ten countries with highest value of reported payments to healthcare organisations between 2017 and 2019.

	Country	Support to educational events	Other educational grants	Total value of payments (€)	€ per 1,000 population	% of the total value of payments accounted for by each country	Number of medical device companies reporting payments	Gini coefficient for companies within country*
1	Switzerland	€167,151,800	€10,695,414	€177,847,213	€20,820	41.8%	54	0.96
2	Spain	€62,440,087	€23,508,420	€85,948,507	€1831	20.2%	82	0.78
3	UK	€19,091,661	€18,196,265	€37,287,926	€559	8.8%	67	0.82
4	Italy	€24,475,934	€6,231,386	€30,707,319	€509	7.2%	57	0.74
5	Netherlands	€7,498,518	€14,314,364	€21,812,881	€1262	5.1%	38	0.83
6	Germany	€16,937,040	€4,359,797	€21,296,837	€257	5.0%	56	0.79
7	Austria	€6,208,914	€3,091,021	€9,299,935	€1050	2.2%	47	0.80
8	Poland	€5,085,917	€545,226	€5,631,142	€148	1.3%	36	0.75
9	Turkey	€4,035,773	€1,133,437	€5,169,210	€63	1.2%	20	0.65
10	Russia	€2,820,888	€1,574,113	€4,395,001	€30	1.0%	18	0.61

\* Gini coefficient here refers to the concentration of payments between all medical device companies who made payments to HCOs in the database in that country.

**Table 3**

Ten medical device companies with highest value of payments disclosed between 2017 and 2019.

	Company	Support to educational events	Other Educational grants	Total value of payments (€)	% of the total value of payments accounted for by each company	Number of countries where payment recipients are located	Gini coefficient for countries within companies*
1	Johnson & Johnson Medical	€172,841,987	€11,465,777	€184,307,765	43.3%	27 (26 eligible <sup>+</sup> )	0.90
2	Abbott Laboratories	€30,846,900	€13,531,092	€44,377,993	10.4%	31 (26 eligible)	0.58
3	Boston Scientific	€19,994,120	€13,520,420	€33,514,540	7.9%	26 (20 eligible)	0.52
4	Medtronic International Trading Sàrl	€18,782,013	€5,718,771	€24,500,784	5.8%	29 (26 eligible)	0.58
5	Baxter	€6,833,885	€9,234,150	€16,068,035	3.8%	23 (21 eligible)	0.82
6	Carl Zeiss Meditec Iberia	€8,000,408	€0	€8,000,408	1.9%	1 (1 eligible)	N.A.
7	Smith & Nephew Orthopaedics AG	€3,449,090	€4,341,717	€7,790,807	1.8%	31 (15 eligible)	0.25
8	Roche	€4,365,362	€3,198,804	€7,564,166	1.8%	27 (24 eligible)	0.20
9	BIOTRONIK	€4,121,587	€3,437,163	€7,558,750	1.8%	18 (14 eligible)	0.68
10	Zimmer GmbH	€1958,085	€5122,630	€7080,715	1.7%	20 (17 eligible)	0.59

\* Gini coefficient here refers to the concentration of payments between all member countries, without superseding legislation, where a specific medical device company has made payments. Calculations account for the population of each country.

<sup>+</sup> Countries where companies are required to disclose their payments on transparentmedtech.eu are considered eligible.

## Quantitative analysis

Payment values are summarised using totals, means and standard deviations, and medians and interquartile ranges. Number of unique entries is summarised using totals. For the calculation of Gini coefficients for countries overall and for the countries within each of the top 10 companies, only *MedTech Europe* member countries who do not have national laws that supersede industry body guidance were included. A sensitivity analysis for Gini coefficients was conducted using 2018–2019 data only (Appendix, Table 4). This was conducted because of the rule, introduced for 2018 and 2019 data, that member companies could not make payments directly to HCPs for third party organised events; instead payments would be made to HCOs, acting as intermediaries, who would then disburse the payments to HCPs. For analysis of HCOs, naming was inconsistent, so detailed analysis was not possible. Analysis was conducted for the top 10 HCOs only, based on their names as reported. Payments per 1000 population for eligible countries is represented on a map, using the tmap function in R which uses the Jenks optimisation method to create payment groupings, this involves minimising within-group variation and maximising between-group variation [36]. Quantitative analysis was conducted using R-4.1.1 software.

## Content analysis

For analysis of the accessibility, availability and quality of the database, data was coded by one author (JL) and cross-checked by a second (FM). During the process of data extraction, analysis and database assessment, a content analysis was conducted to document other issues with the database that had not been included in the assessment of the accessibility, availability and quality of the database. This was conducted by one author [JL] and cross-checked by a second (SM or FM).

## Results

### Payment patterns overall

In total, 116 medical device companies reported payments valuing €425,543,412 between 2017 and 2019. Increasing 87.0% between 2017 and 2019, from €93,798,419 to €175,414,302. The number of companies reporting payments in each year also increased, from 66 in 2017 to 101 in 2018 and 94 in 2019, a 42% increase between 2017 and 2019. The dominant payment category in each year was *Support to Educational Events* (between 75.5% and 84.7% annually). However, *Other*



**Table 4**  
Ten named recipients with highest value of payments received between 2017 and 2019\*.

	Healthcare organisation	Support to educational events	Other educational grants	Total value of payments (€)	Number of companies in receipt of payments from	Company with greatest value of payments to HCO	% of the total value of payments accounted for by each company	Country
1	AO Foundation**	€152,652,535	€0	€152,652,535	1	Johnson & Johnson Medical	35.9%	Switzerland
2	Sociedad Española De Enfermería Nefrológica	€43,050	€6,652,374	€6,695,424	1	Baxter	1.6%	Spain
3	European HCO and PCO	€2,883,019	€0	€2,883,019	1	B. Braun	0.7%	Germany
4	Fundacion para la Investigacion en Gastroenterologica y Hepatologia	€12,000	€2,520,905	€2,532,905	1	Boston Scientific	0.6%	Spain
5	Osteosynthesis and Trauma Care Foundation	€2,368,386	€0	€2,368,386	1	Stryker	0.6%	Switzerland
6	Nubbecas Focused Solutions For Companies	€2,087,273	€0	€2,087,273	1	Baxter	0.5%	Spain
7	CME4U GMBH	€2,021,972	€30,748	€2,052,720	6	Boston Scientific	0.5%	Germany
8	Fundacion Fidis	€1,592,536	€6,700	€1,599,236	1	Baxter	0.4%	Spain
9	Fundacion Senefro	€259,320	€1,311,787	€1,571,107	4	Baxter	0.4%	Spain
10	Avoris Retail Division S.L.	€1,419,298	€0	€1,419,298	3	Coloplast	0.3%	Spain

\*May not be a fully accurate reflection of payments due to inconsistent naming of HCOs.

\*\*AO foundation and ‘AO technology ag’ were merged.

Educational Grants showed a higher overall increase (15.3% of all payments in 2017 vs 24.5% in 2019). More details in Table 1.

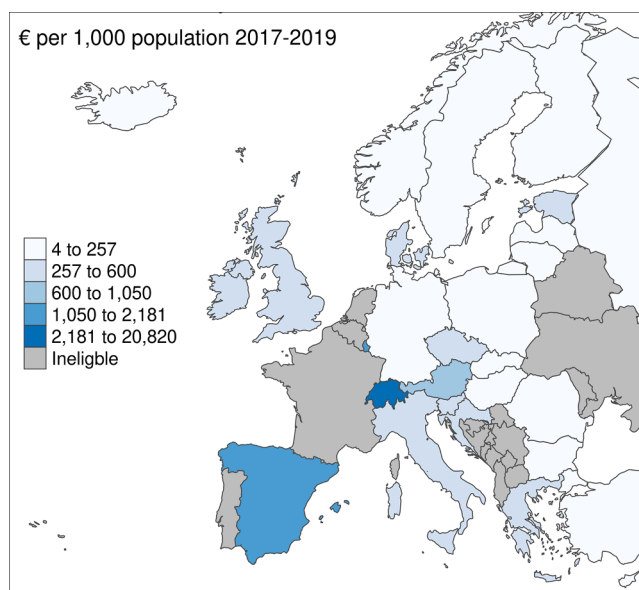
**Countries**

In total, payments were reported in 53 countries (Appendix Tables 5 & 6). Payments were reported in the four countries with superseding national legislation; €21,812,881 in the Netherlands, €120,710 in Portugal, €2,215,207 in France and €1,547,566 in Belgium (Appendix Table 5). Also, €436,275 in payments was reported in 21 countries that were not MedTech Europe members (Appendix Table 5).

Ten countries made up 93.8% of the total value of payments (Table 2). Switzerland made up 41.8% of the total value of payments, followed by Spain (20.2%). Notably, there was a very high concentration of payments in Switzerland, where across the 54 medical device companies making payments, the Gini coefficient was 0.96, compared to 0.78 for Spain (a higher Gini coefficient represents a large concentration of payments among one or a few companies and a lower coefficient represents a more evenly distributed payment pattern). The Gini coefficient for the 28 countries without superseding national legislation was 0.72. When examining euros paid per 1,000 population (Fig. 1 and Appendix Table 6), Switzerland remains the highest recipient (€20,820), followed by Luxembourg (€2,181). Croatia, Slovenia and Ireland also have high levels of euros paid per 1,000 population, all with over €400 per 1,000 population. The three countries with the lowest levels of euros paid per 1,000 population were Cyprus, Bulgaria and Romania, all with less than €25 per 1,000 population.

**Companies**

Of the 116 medical device companies who reported payments between 2017 and 2019 (Appendix Table 1), ten companies made up 80.2% of payments (Table 3). This large concentration amongst the top ten companies is reflected in the Gini coefficient for the concentration of payments across all medical device companies which was 0.89. This high degree of concentration was largely driven by one medical device company, Johnson & Johnson Medical, who accounted for 43.3% of all payments. Their largest product category is Surgery (Appendix Table 2). Examples of surgery medical devices include surgical instruments and sutures (the product examples in this section are illustrative, it was not possible to identify top selling products within companies). Johnson & Johnson Medical themselves also had a very high concentration of



**Fig. 1.** Payments (€) per 1000 population across member countries without superseding laws from 2017 to 2019.

Note: Countries where companies are not required to disclose their payments on transparentmedtech.eu are considered ineligible.

payments across countries; across the 26 member countries without superseding legislation in which the company made payments, the Gini coefficient was 0.90, largely explained by its payments in Switzerland. The Gini coefficient for Abbott Laboratories was 0.58. Another notable element of the top 10 companies is that Medtronic International Trading Sàrl only disclosed payments in 2017 and 2018.

With regard to the type of companies in the top 10, two are involved in *in-vitro* diagnostic devices and medical devices, and 7 are involved in medical devices only. A medical device is a tool or product designed to diagnose, treat, or prevent diseases, monitor health, or modify physiological processes in the human body. An *in-vitro* diagnostic device is designed for examining body specimens, like blood or tissues, to gather information about health conditions (refer to Appendix Box 2 for full definitions). In our analysis of the three product areas that generated the

greatest revenue for the top ten medical device companies, we found that the areas that appeared most frequently were cardiac rhythm management (e.g. implantable defibrillators), orthopaedics (e.g. joint replacement implants) and surgery (e.g. surgical instruments). These areas appeared in the top three revenue generating areas for three companies each. Full overviews of the top ten companies are in Appendix Table 2.

### Healthcare organisations

There were 13,916 uniquely named HCOs who received at least one payment between 2017 and 2019. However, this likely includes many cases of the same HCO being included with a different spelling or a different name. The top 10 HCOs are shown in Table 4. AO Technology in Switzerland received €152,652,535, representing 35.9% of all payments. AO Technology only received payments from Johnson and Johnson Medical, for *Support to Educational Events*. Another notable entry is 'European HCO and PCO' which received the third largest amount. However, this is likely an aggregation of several payments to different HCOs and *Professional Conference Organisers* by B. Braun (Definition of *Professional Conference Organisers* in Appendix, Box 1.) Notably, seven of the top ten recipients each received all of their payments from single companies. Also, six of the top ten companies are registered in Spain and the other four are registered in Germany or Switzerland.

### Accessibility, availability and quality of the database

Overall, using the accessibility, availability and quality proforma, the database rated low on six measures, medium on six measures, and high on three measures (full details in Appendix Table 3). The areas where the database rated high were (1) the database format was a website as opposed to individual PDFs, (2) structure; all companies follow a single template, and (3) clear tax reporting; VAT is excluded for all entries. The areas where the database rated low were (1) availability of customisable summary statistics, (2) downloadability, (3) year limits (data appears to be removed four years after disclosure), (4) breadth of recipients, (5) breadth of donors, and (6) breadth of payment areas (several areas were not included, including consulting, gifts, and charitable donations). The areas where the database rated medium were (1) database searchability, (2) use of unique identifiers, (3) methodology note availability, (4) provision of terminology definitions, (5) aggregation of payments, and (6) spectrum of disclosed characteristics.

Other issues with the database that were inductively noted included (1) itemisation of payments, contrary to guidance [25] (2) disclosure of payments to patient organisations and individual HCPs, contrary to guidance, [25] and (3) payments disclosed on the transparentmedtech.eu website but not the respective mandatory disclosure system (Full details in Appendix Box 6).

## Discussion

### Summary

Between 2017 and 2019 medical device companies in Europe disclosed €425 million in educational grants to HCOs on transparentmedtech.eu, creating a large potential for conflicts of interest. These payments were made by 116 medical device companies to HCOs registered in 53 countries. The top 10 companies accounted for 80% of payments, and Johnson and Johnson Medical accounted for 43% of payments, which were primarily to one HCO; AO Foundation in Switzerland. Seventy-nine percent of the €425 million in educational grants were for HCP participation at third party organised educational events, and the other 21% was for scholarships, fellowships, educational grants to support general medical education topics or for public awareness campaigns. The database was rated as low for six of the 15

measures of accessibility, availability and quality, indicating major shortcomings with this disclosure system.

### Results in context

Overall, the figure of €425 million likely underestimates the true extent of medical device industry payments. Pharmaceutical companies reporting payments on the self-regulatory disclosure website for the British pharmaceutical industry [37] made payments to HCOs and HCPs registered in the UK valuing €2.96 billion between 2017 and 2019, [38] compared to the €37 million reported by medical device companies to UK HCOs on transparentmedtech.eu. In the US, medical device companies pay about \$904 million annually, just to physicians [1]. There are several possible reasons for this underestimate, and they primarily relate to shortcomings with the self-regulatory disclosure system. Firstly, many companies are not members of *MedTech Europe* or the national associations within *MedTech Europe*, [22] which is likely to lead to large underestimates of payments. This is a consistent problem with systems that employ self-regulation [19]. Secondly, the large increase in payments between 2017 and 2018 is very likely a function of the rule introduced in 2018 that member companies could no longer make payments directly to HCPs for attendance at third party organised educational events. Instead payments would be made to HCOs such as hospitals or professional societies, acting as intermediaries, who would then make the payments to HCPs [25]. Therefore, the 2017 figure is likely a large underestimate of the value of educational grants provided. Thirdly, according to *MedTech Europe*, in 2019, 5% of *MedTech Europe* national associations had not banned their member companies from providing direct sponsorship of HCPs [39]. So the figures for 2018 and 2019 are also likely to be underestimates. Finally, it is not clear whether all medical device companies are reporting all relevant payments. For example, Medtronic reported no payments in 2019 despite disclosing payments of €24.5 million across 2017–2018. This may be as a result of no payments being made or alternatively no disclosure being submitted to transparentmedtech.eu. Like self-regulatory codes for the pharmaceutical industry, [19] *MedTech Europe* does not appear to require member companies to make a report if they have not made payments in a given year. Under-reporting has been documented in other self-regulatory systems [17,18].

Unlike in the legally-mandated US Open Payments database, on transparentmedtech.eu, no information is provided on the therapeutic area or device that each payment relates to. However, the examination of the top recipients, who account for 42% of all payments, provides an opportunity to understand what areas the payments relate to. AO foundation, the largest recipient, hosts educational events for surgeons, in the areas of 'trauma and disorders of the musculoskeletal system.' [40]. The fifth highest recipient, Osteosynthesis and Trauma Care Foundation, also focusses on orthopaedics [41]. Two of the top ten are nephrology HCOs. Several of the top ten HCOs appear to be Medical Education and Communication Companies, which are primarily for-profit companies who arrange continuing medical education events and programs, and are also sometimes involved with marketing campaigns related to branding, amongst other activities [42]. Nubbecas Focused Solutions For Companies, [43] and CME4U GMBH [44] are two examples of such companies within the top ten HCOs. In terms of product areas that generated the most revenue for the top ten medical device companies: cardiology, orthopaedics, and surgery appeared the most frequently. These areas are similar to four of the top five payment areas in the US for medical devices [1].

In terms of the countries HCOs are registered in, two of the top ten are based in Switzerland; AO Foundation and Osteosynthesis and Trauma Care Foundation. However, both organisations appear to hold events in multiple countries [40,41]. Given that payments registered for Switzerland are likely being used in other countries, it partly undermines the validity of the database. Six of the top ten companies are registered in Spain, and for at least three of these companies, [45–47]

their activities appear to be primarily in Spain. This information, along with the fact that Spain is one of the highest recipients of payments, implies that industry marketing activities might be especially prominent there. This is reinforced by a recent study of the pharmaceutical industry which found that Spain stood out in a seven-country comparison because of its higher payment amounts [4]. There are a few countries with relatively low payments, like Romania and Bulgaria. Some countries in Eastern Europe are likely to be commercially less attractive to medical device companies which may explain the lower payments. Romania and Bulgaria, for example, had the lowest per capita health expenditure in 2017 in the EU [48] and, like other countries in Eastern Europe, have substantially lower per capita expenditure on medical devices than Western European countries [49,50].

Also of note is the large amount of payments reported in countries with separate mandatory reporting systems. For example, €21.8 million in payments were declared in the Netherlands. This creates confusion as it is unclear whether these payments were also reported via the national mandatory disclosure systems. As noted in the content analysis, there are several cases of payments disclosed on the transparentmedtech.eu website but not the respective mandatory disclosure system. The limited disclosure on transparentmedtech.eu of payments in countries with separate mandatory reporting systems means the overall payment values for this study are likely significant underestimates both for those countries and for Europe overall.

In terms of the concentration of disclosed payments, there was a similar Gini coefficient for UK pharmaceutical companies; 0.85<sup>5</sup> compared to 0.89 for European medical device companies, demonstrating the dominance of a few companies. Also, the large concentration of payments amongst the top ten medical device companies is similar to the top ten pharmaceutical companies making payments to HCOs in the UK. In the UK, the top ten companies made up 82% of the total value of reported payments, [5] compared to 80% for medical device companies in Europe.

In terms of accessibility and quality of the database, its general low rating was similar to the rating of the few existing pharmaceutical industry disclosure databases in European countries, most of which are also not downloadable, do not use unique identifiers consistently, and do not make customisable summary statistics available [16]. The two areas that transparentmedtech.eu scored medium or high, where most pharmaceutical industry disclosure systems scored low, [16] were availability of a limited search function and clarity of tax inclusion/exclusion, respectively.

A major limitation is the narrow breadth of payments covered by the database, far more limited than most pharmaceutical industry databases, be they publicly mandated or self-regulatory [16]. It should be noted that Eucomed, a representative body for European medical device companies which is now part of *MedTech Europe*, [51] previously considered disclosing the following payments areas: (1) Consultancy fees and related expenses, (2) Charitable donations, (3) Research grants, and (4) Gifts and give-aways, [52] though some of these areas may overlap with the payment areas disclosed on transparentmedtech.eu. Also, many pharmaceutical industry disclosure websites disclose research and development payments to HCPs and HCOs, which make up a large proportion of payments (though in Europe this is usually presented as an aggregated value for each company) [29]. Nonetheless, these areas are not covered by the transparentmedtech.eu database [25]. Other major areas that are not covered by transparentmedtech.eu, but are covered by US Open Payments, are royalties and ownership of, or shares in, medical device companies [25,53]. Wider coverage of payments is very important, as several of these non-covered areas have been found, on occasion, to be used for improper payments to physicians [54]. The limited breadth of payment areas along with the other shortcomings discussed above may be the primary reason for the large differences between the payment levels found in this research, compared to those found in studies of the UK pharmaceutical industry [38] and the US medical device industry [1].

Overall, the usefulness of the database itself, and therefore also of the data in this study, is severely limited; it does not provide transparency on the true scale and nature of payments. Given the deficiencies, there does not appear to be a clear intended user or audience for the database. Like other self-regulated disclosure systems, it may instead be a means of creating an appearance of credibility and compliance in order to avoid regulation of the industry's marketing activities [55].

### Strengths and limitations

A major strength of this study is the large number of countries and companies covered. Also, this is the first Europe-wide analysis of medical device industry payments to HCOs. Another strength was the analysis of data over a three-year period. A further strength is the advancement of the assessment tool developed by Ozieranski and colleagues [16].

A limitation is the lack of analysis of HCOs. This was due to the inconsistent use of unique identifiers by medical device companies when reporting payments. Also, the inability to download the database meant that manual data extraction was conducted, which could have led to errors. Furthermore, data extraction was not crosschecked by another author, which could have led to errors. Many of the other limitations with the study are associated with the accessibility, quality and availability of the data itself, discussed above. An example of this is that the large increase in payments between 2017 and 2018, this is likely a function of the rule introduced in 2018 that member companies could no longer make payments directly to HCPs for attendance at third party organised educational events, though other factors may also have contributed.

### Implications

This research adds to the extensive literature documenting the shortcomings of self-regulated disclosure systems for industry payments to HCPs and HCOs [2,3,5,16,56]. Overall the shortcomings of this database are reflective of issues seen with self-regulation across several industries, such as pharmaceutical, [57,58] nutrition [59] and alcohol [60]. This highlights the need for a publicly mandated payment disclosure database. This could be EU-wide and cover both the medical device and pharmaceutical industry. This would address the duplication of effort that this study shows is occurring as a result of the current mix of self-regulation and legislation across European countries, with some payments being reported in multiple databases. Several groups have suggested harmonisation of minimum standards for transparency across Europe, which would include a high-quality pan-European database [16, 19]. The database could be downloadable, cover a broad range of payments to HCPs, HCOs and patient organisations, and provide information on the therapeutic area and device that each payment relates to in ways that allow integration with the planned EU database on medical devices [20]. However, to the authors' knowledge, there has been no indication of potential EU legislative reforms in this area.

The main implication of this study is the large potential for conflicts of interest in European healthcare arising from the large value of the payments (at least €425 million) being made by the medical device industry to HCOs related to education. These payments provide medical device companies with an opportunity to influence a range of HCOs such as hospitals, universities, and professional training bodies, all of which have significantly influence healthcare practice. There is extensive evidence suggesting that payments of this nature have a negative influence on pharmaceutical prescribing [9–11]. There is some evidence that these payments are associated with sub-optimal medical device procurement in the USA, [12,13] though more research is needed in this area to understand the relationship between medical device industry interaction and clinical practice across countries.

A seminal US Institute of Medicine report pointed out that: 'The disclosure of individual and institutional financial relationships is a



critical but limited first step in the process of identifying and responding to conflicts of interest.' [7]. Some academics have gone further and suggested that disclosure has had no impact, or in some cases a negative impact, by creating a moral license for the presentation of biased information [61]. To address conflicts of interest more effectively, many have called for greater restrictions in the relationship between industry and physicians/HCOs [7,62,63]. However, restrictions around certain areas such as education may create a funding gap. Alternative funding sources such as state funding, a hypothecated medical device industry tax, [57] or HCPs paying for education using their own personal income, could be considered.

## Conclusion

This study shows the large amount of payments made by the medical device industry to HCOs in Europe. While this provides a first estimate of the scale of payments, the major shortcomings with the database make it likely that the total value of payments is significantly larger. An EU mandated system of disclosure for the medical device and pharmaceutical industries could address these shortcomings, and enhance transparency in the healthcare sector's interactions with industry. However, greater transparency is just one step in addressing the potential negative effects that industry payments to HCOs can have on healthcare.

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## Ethical approval

Not required.

## Declaration of competing interest

J.L., P.O., T.F., K.L. and F.M. have no competing interests. S.M.'s partner is employed by ICON, a global Contract Research Organization whose customers include many pharmaceutical and medical device companies. A.O. has received speaking payments from Kyowa Kirin Inc. and consultancy payments from MNES Inc.

## CRedit authorship contribution statement

**James Larkin:** Conceptualization, Data curation, Formal analysis, Methodology, Writing – original draft. **Shai Mulinari:** Formal analysis, Methodology, Writing – review & editing. **Piotr Ozieranski:** Methodology, Writing – review & editing. **Kevin Lynch:** Investigation, Writing – review & editing. **Tom Fahey:** Conceptualization, Writing – review & editing. **Akihiko Ozaki:** Writing – review & editing. **Frank Moriarty:** Conceptualization, Formal analysis, Visualization, Writing – review & editing.

## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.hlpt.2024.100865](https://doi.org/10.1016/j.hlpt.2024.100865).

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