WHITE PAPER

PORZIO LifeSciences

A Milestone Moment (or a Dead Jellyfish) for the Global Transparency Movement

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2016: A Milestone Moment (or a Dead Jellyfish) for the Global Transparency Movement

Introduction

2016 is a pivotal year in the global transparency movement. It is both the first year of reporting under EFPIA's Disclosure Code[1] and marks the first round of individual-level reporting in Australia.[2] Since 2013, when EFPIA[3] first adopted the Disclosure Code to demonstrate the appropriateness of industry's financial relationships with healthcare professionals ("HCPs"), as well as to forestall the adoption of new transparency laws, there has been rampant speculation about what the reports would reveal and what the reaction would be. The preliminary results are now in; they signal continuing tumult in the realm of life sciences transparency.

In this year's White Paper, we will examine not only the build-up to this spring's first round of EFPIA disclosures, but also the initial responses to the reported data. In so doing, we will review the debate between supporters and critics of EFPIA's approach. As reflected by the title of this year's Paper, industry advocates believe that the first round of disclosures represents a milestone in industry transparency, while critics are deeply skeptical, with one going so far as to characterize the voluntary industry initiative as a charade that "has all the thrust of a dead jellyfish."

But the significant developments in the global transparency landscape over the past year were not confined to the innovative pharmaceutical industry's self-reporting system in Europe. Rather, the transparency movement spread to places as far-ranging as Canada and Saudi Arabia, and to the generic and biosimilar pharmaceutical industry. In Canada, a group of pharmaceutical

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1 EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS ("EFPIA"), CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS (Consol. version 2014).

2 MEDICINES AUSTRALIA, CODE OF CONDUCT (18th ed. 2015).

3 EFPIA is comprised of thirty-three national member associations and forty-two full and affiliate corporate members.

companies announced that they plan to begin voluntarily reporting aggregate data in 2017. In Saudi Arabia, the government is evaluating whether to adopt disclosure requirements for the pharmaceutical industry. As to the European generic and biosimilar pharmaceutical industry, its representative group, Medicines for Europe, formally adopted transparency reporting requirements that are similar to EFPIA and call for data collection to begin in 2017 with first reports due in 2018. Meanwhile, the European medical device industry has chosen a different path, declining to impose reporting requirements on its members, though there is industry-code based reporting for medical device companies in a few European countries.

There has also been continued legislative activity in several European countries, including changes to the reporting requirements in France. Not to be overlooked in all of these developments is the fact that in the United States, where the transparency movement began,[4] another round of annual reporting took place and, for the first time, the federal government used Sunshine Act data in a criminal prosecution of a pharmaceutical company's former employees. We will begin our review there.

United States

The US Sunshine Act requires "applicable manufacturers," namely pharmaceutical companies and medical device companies that satisfy specific statutory requirements, to report to the Centers for Medicare & Medicaid Services ("CMS"), which is part of the federal government's Department of Health & Human Services ("HHS"), any direct or indirect payments or other transfers of value ("TOV") to a "covered recipient" or any payment provided to a third party on behalf of a covered recipient during a calendar year. "Covered recipients" are defined as physicians and teaching hospitals. There are three reports that companies might have to file: 1) a General Payments Report, which includes payments and transfers of value given to a

[4] US Patient Protection and Affordable Care Act, 42 U.S.C. § 1320a-7h (2012) (the "Sunshine Act").

covered recipient; 2) a Research Payments Report, which includes all payments and transfers of value made in connection with an activity that meets the definition of research and that is subject to a written agreement or research protocol; and 3) a Physicians Ownership and Investment Interest Report, which covers any ownership or investment interests held by a physician or immediate family member in an applicable manufacturer.

Under the US Sunshine Act and its implementing regulations, applicable manufacturers reported five months of 2013 data in 2014, and they reported their first full year of data in 2015 with respect to 2014 payments and transfers of value. In 2016, applicable manufacturers submitted their second round of full year reports to cover 2015 data. In a press release that analyzed the 2015 data, CMS announced that applicable manufacturers reported $7.52 billion in payments and ownership and investment interests, which was up slightly from the $7.49 billion reported for 2014.[5] In terms of the number of records, there were 11.90 million for 2015, which was also up slightly from the 11.86 million reported for 2014.[6]

The amounts disclosed by reporting category also were very similar from 2014 to 2015. For General Payments, the amount for 2015 was $2.60 billion, which was slightly down from 2014's $2.64 billion. There was an increase in the amount reported for Research Payments for 2015, which was $3.89 billion, compared to 2014's $3.79 billion. Lastly, the amount reported for Ownership and Investment Interests remained relatively flat, as there was $1.03 billion reported for 2015, compared to $1.06 billion for 2014. In discussing this data, CMS stressed that "[t]he Open Payments program does not distinguish between payments that are beneficial and those

[5] Press Release, Centers for Medicare & Medicaid Services, *CMS' Open Payments Program Posts 2015 Financial Data* (June 30, 2016), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases.html.

[6] *Id*.

that may indicate conflicts of interest; however, the identification of these shifts [in year to year amounts] may be of significance to researchers and other interested stakeholders."[7]

CMS also provided data about the highest paid physician types, per average total payment per physician. For 2014, the top five were: 1) Orthopaedic Surgery ($34,596.88); 2) Neurological Surgery ($26,0049.65); 3) Clinical Pharmacology ($17,014.10); 4) Neuromusculoskeletal Medicine ($10,048.29); and 5) Nuclear Medicine ($8,037.13). Four of the five physician types remained at the top for 2015 data, but Radiology replaced Clinical Pharmacology, and Nuclear Medicine jumped from the fifth spot to the top spot. For 2015 data, the top five highest paid physician types were: 1) Nuclear Medicine ($51,279.00); 2) Neurological Surgery ($26,104.33); 3) Orthopaedic Surgery ($26,080.31); 4) Radiology ($19,573.79); and 5) Neuromusculoskeletal Medicine ($15,299.15). CMS also identified the top ten reporting entities. Novartis Pharmaceuticals Corporation was in the top spot for 2015, replacing Genentech, Inc. Seven of the top ten reporting entities remained from 2014's list. The new companies for 2015 were Amgen Inc., Ellipse Technologies, Inc., and Merck Sharp & Dohme Corporation, as those companies replaced SPINEFRONTIER, INC., Sanofi US Service Inc., and Eli Lilly and Company.[8]

Furthermore, CMS produced a chart that demonstrated the percentage change of total dollar value reported by nature of payment from 2014 to 2015. The three natures that saw the biggest increase from 2014 to 2015 were: 1) Charitable Contribution; 2) Faculty for a Non-Accredited Education Program; and 3) Royalty or License. The three natures that saw the biggest decrease were: 1) Honoraria; 2) Gift; and 3) Education.[9]

In commenting on this data, Andy Slavitt, the Acting CMS Administrator, stated:

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7 *Id.*
8 *Id.*
9 *Id.*

> Open Payments is a trusted consumer resource that provides consumers and other interested stakeholders with data about the financial relationships between physicians and health care industry manufacturers. This transparency, along with our other transparency programs, helps further our mission of achieving a high-quality health care system that ensures better care, access to coverage and improved health at a lower cost.[10]

Similarly, Dr. Shantanu Agrawal, CMS Deputy Administrator and Director of the Agency's Center for Program Integrity, observed that "transparency is empowering physicians to be purposeful about their financial relationships with companies, and there is a notable shift towards charitable contributions and away from other interactions such as honoraria and gifts."[11]

CMS is continuing to work on enhancing and improving the Open Payments program. In that regard, on July 7, 2016, CMS placed the CY 2017 Medicare Physician Fee Schedule Proposed Rule with comment period on display at the Federal Register.[12] Among other things, the Proposed Rule includes a section on the Open Payments program in which CMS indicates that it may undertake future rulemaking and seeks comments regarding the following:

- Is the nature of payments categories inclusive enough to facilitate reporting of all payments or transfers of value to covered physicians and teaching hospitals;
- Feedback on how many years applicable manufacturers and GPOs should remain obligated to monitor and report on past reporting program years;
- Feedback on how many years of Open Payments data is relevant to determine how many years to continue to publish and refresh annually;
- Feedback on the requirement that manufacturers and GPOs register each year regardless of whether the entity will be reporting any payments or transfers of value and whether to require manufacturers and GPOs to identify reasons they are not reporting payments;

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10 *Id.*

11 *Id.*

12 Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments, 81 Fed. Reg. 46, 395 (July 15, 2016).

- Comments on a requirement that manufacturers and GPOs pre-vet payment information with covered recipients and physician owners or investors before reporting to the Open Payments system, specifically feedback on pre-vetting based on threshold values or random samplings of covered recipients;
- Feedback on the current definition of a covered recipient teaching hospital and requesting alternative feasible definitions;
- To help teaching hospitals in verifying payments and to avoid payment disputes, feedback on adding a new non-public data element to assist in reviewing and affirming payment records;
- Feedback on the benefit of reporting data to CMS early or ongoing throughout the year in an effort to increase data validity and minimize disputes;
- Feedback on changing reporting requirements to ensure that the industry can properly represent changes due to mergers, acquisitions, and other structural corporate changes;
- Feedback on operationally feasible definitions regarding ownership or investment interests, specifically regarding the terms "value or interest" and "dollar amount invested";
- Ideas on how to define physician owned distributors and what portion of the reported data should be shared on the website;
- Ways to streamline or make the reporting process more efficient; and
- An estimate of the time and cost burden associated with reporting to comply with the Paperwork Reduction Act.[13]

[13] *Id.*

The deadline for comments to the Proposed Rule is September 6, 2016.[14]

Since 2013, life sciences companies primarily have been focused on collecting the appropriate data and ensuring that they report it correctly to CMS. An ever present unknown has been whether the government would impose penalties for violations of the Act. Thus far, there have not been any sanctions imposed for any violations. In April 2016, CMS touched on this topic in its "Annual Report to Congress on the Open Payments Program," stating:

> For the 2013 Program Year, CMS implemented strategies to bolster compliance in the Open Payments Program using targeted outreach and education activities toward applicable manufacturers and [group purchasing organizations ("GPOs")] (and more specifically PODs) that were potentially subject to requirements in 42 CFR 403 Subpart I.
>
> To that end, CMS identified applicable manufacturers, GPOs, and PODs based on various characteristics and attempted to connect directly with those entities and encourage reporting. These outreach activities educated entities about the Open Payments program in an effort to promote compliance with program requirements. Absent a national POD database or other system of record, special effort was taken to identify and educate PODs that were potentially non-compliant with Open Payments reporting requirements. Entities were mailed an initial notification, directing them to register and report in the Open Payments system prior to the submission deadline. Entities that took no action were sent a second notification. All CMS notices were sent via certified mail, return receipt requested. Responses to these notices were reviewed, documented, and tracked.
>
> As a result of CMS' outreach efforts, no civil monetary penalties were issued for 2013 program non-compliance. Using different environmental scanning methods, CMS has identified potential entity types, which due to their complex business models, require further investigation and research before civil monetary penalties can be imposed. Compliance activities will continue for subsequent program years. CMS continues to refine its methodology to identify potentially non-compliant applicable manufacturers and GPOs that may be subject to civil monetary penalties for failing to report in accordance with the requirements found [in the US Sunshine Act and regulations].[15]

But CMS is not the only federal agency focused on compliance with the US Sunshine Act. For example, the HHS's Office of Inspector General ("OIG"), which is responsible for

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14 *Id*.

15 CMS ANNUAL REPORT TO CONGRESS ON THE OPEN PAYMENTS PROGRAM (APRIL 2016).

protecting the integrity of HHS programs and operations, issued a report in April 2016 titled, "Fiscal Year Work Plan Mid-Year Update 2016."[16] In that report, the OIG discussed its role with respect to the US Sunshine Act, as it stated:

> We will determine the number and nature of financial interests that were reported to CMS under the Open Payments Program. We will also determine how much Medicare paid for drugs and medical supplies ordered by physicians who had financial relationships with manufacturer and group purchasing organizations (GPOs) reported in the Open Payments system. Further, we will determine the extent to which data in the open payments [sic] system is missing or inaccurate and the extent to which CMS oversees manufactures' and GPOs' compliance with data reporting requirements and whether the required data for physician and teaching hospital payments are valid. … The Open Payments Program provides public transparency about provider-industry relationships; it is important that the information be complete and accurate to serve the needs of consumers making educated decisions about their health care choices.[17]

Perhaps the greatest concern for life sciences companies is that prosecutors will use data from the Open Payments program to assist in criminal or civil actions brought by the government. That happened for the first time recently, as the United States Attorney's Office for the Southern District of New York announced on June 9, 2016, that two former pharmaceutical company employees had been arrested for participating in a kickback scheme.[18]

Among other things, the defendants were charged with violating the Anti-Kickback Statute relating to their scheme to compensate HCPs with thousands of dollars for participation in sham educational programs to induce those doctors to prescribe their company's product.[19] In the Sealed Complaints that charged the two former employees with various violations of federal law, a Special Agent with the Federal Bureau of Investigation stated that he had reviewed the publicly available data from CMS concerning payments made to specific physicians by the

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16 OIG, WORK PLAN MID-YEAR UPDATE FOR FISCAL YEAR 2016.

17 *Id*.

18 Press Release, U.S. Attorney's Office S.D.N.Y., *Former Pharmaceutical Company Employees Arrested For Participating In Fentanyl Kickback Scheme* (June 9, 2016), https://www.justice.gov/usao-sdny/pr/former-pharmaceutical-company-employees-arrested-participating-fentanyl-kickback-scheme.

19 *Id*.

former employees' company. From that review, the Special Agent determined that the company had "highly compensated" certain physicians for participation in speaker programs. Further, the Special Agent also reviewed Medicare Part I billing records to ascertain that the physicians who had been revealed to be "highly compensated" according to the Open Payments program were some of the top prescribers of the company's product, which helped to build the government's case against the former employees.[20]

Although this is the first time that Open Payments data has been used by the government in a prosecution, it is highly unlikely to be the last time. The trove of information and data available in the Open Payments program can be utilized by government prosecutors in a number of ways. For example, prosecutors can use the data to build bribery cases like they did in the Southern District of New York, or they can examine the data to determine if it corroborates a whistleblower's allegations, or they can ascertain whether the data supports a pre-existing investigation into other types of company misconduct, to name just a few.

It is important to emphasize that the US Sunshine Act does not prohibit States from requiring that manufacturers disclose information that is not covered by the federal law. However, if a State's law requires a manufacturer to disclose or report the same information that must be reported under the US Sunshine Act, that portion of the State's law is preempted. Therefore, life sciences companies must comply not only with federal reporting requirements, but any applicable State reporting requirements that survive a preemption analysis.

Several states, including Minnesota, Vermont, the District of Columbia, West Virginia, and Massachusetts, have such reporting requirements. Rather than examine those well-

[20] Sealed Complaint, *United States v. Jonathan Roper*, No. 16 MAG 3628 (S.D.N.Y. June 8, 2016); Sealed Complaint, *United States v. Fernando Serrano*, No. 16 MAG 3629 (S.D.N.Y. June 8, 2016).

established reporting requirements that are covered in our prior White Papers,[21] we will highlight a few of the more important recent State-level developments. In March 2016, the District of Columbia amended its gift reporting requirements so that its categories of Nature of Payment, Form of Payment, and Primary Purpose now align with Open Payments' reporting requirements.[22] In 2014, Connecticut enacted legislation requiring applicable manufacturers that provide payments or other transfers of value to Advanced Practice Registered Nurses ("APRNs") to submit quarterly reports to the Connecticut Commissioner of Consumer Protection. In an effort to clarify this reporting requirement, on January 21, 2015, the Connecticut Senate introduced Senate Bill 257, now Public Act 15-4 ("PA 15-4"), which was signed by the Governor on May 11, 2015. As passed, PA 15-4 amends the reporting requirement, as a whole, and the Nursing Practice Act. Specifically, PA 15-4 requires applicable manufacturers to submit their reports annually, with the first report due no later than July 1, 2017. Previously, the law required that reports be submitted quarterly, with the first report due no later than July 1, 2015. PA 15-4 also clarifies that applicable manufacturers are only required to report payments made to APRNs engaged in independent practice; the previous law did not distinguish between independent APRNs and those practicing in collaboration with a physician. Further, PA 15-4 requires the Commissioner of Public Health to publish annually on the Department of Public Health's website a list of APRNs who are authorized to engage in independent practice. Applicable manufacturers must refer to this list when determining whether they must report information on payments or other transfers of value made to an APRN.[23]

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[21] D. JEFFREY CAMPBELL, ESQ. & BRIAN P. SHARKEY, ESQ., DO START BELIEVIN': THE LIFE SCIENCES INDUSTRY'S JOURNEY TO GLOBAL TRANSPARENCY 4–9 (2014); CAMPBELL & SHARKEY, THE TREND TOWARDS GLOBAL TRANSPARENCY: A CHALLENGING NEW WORLD FOR THE LIFE SCIENCES INDUSTRY 9–12 (2012).

[22] DC.GOV, *Prescription Drug Marketing Costs – Access Rx*, http://doh.dc.gov/service/prescription-drug-marketing-costs-access-rx (last visited August 2, 2016).

[23] 2015 Conn. Acts 15-4 (Reg. Sess.).

Lastly, it is important to highlight that the life sciences industry must be cognizant of not only the existing reporting laws in the United Sates, but also the efforts of several states to require companies to provide information about their marketing and sales costs. Colorado, New Jersey, Washington, Minnesota, Tennessee, Louisiana, Rhode Island, and New York have introduced legislation that would require certain manufacturers to report marketing and advertising costs associated with the promotion of their drugs.[24] While none of these States have enacted such laws yet, it is imperative that the industry monitor the bills to see whether they gain momentum. The adoption of such laws would only increase the significant reporting burdens that companies already face.

European Self-Regulation

In each of our annual White Papers over the past several years, we focused on EFPIA's progressive stance and motivations regarding code-based reporting. Those motivations were not only to provide a consistent, uniform approach to transparency reporting for the pharmaceutical industry across Europe, but also to prove to European governments that transparency laws were not necessary because industry had self-regulated and shed appropriate light on its financial relationships with HCPs. We have previously speculated about how effective EFPIA's self-disclosure system would be, in terms of whether a significant portion of the market would report and whether HCPs would provide consent to individual-level disclosure. That is, because EFPIA's Disclosure Code is a voluntary form of self-regulation, and because of the data privacy protections afforded to European Union ("EU") citizens under the governing EU Directive and

[24] H.B. 16-1102, 7th Gen. Assemb., 2nd Sess. (Colo. 2016); Assemb. B. 762, 2016 Leg. 217th (N.J. 2016); H.B. 961, 2016 H. Reg. Sess. (La. 2016); S.B. 6471, 64th Leg. Reg. Sess. (Wash. 2016); S.B. 2947, 89th Leg. 70th Day (Minn. 2016); H.B. 2206, 109th Gen. Assemb. Reg. Sess. (Tenn. 2016); H.B. 7839, 2016 Gen. Assemb. Reg. Sess. (R.I. 2016); Assem. B. 10026, 2016 Gen. Assemb. Reg Sess. (N.Y. 2016).

national laws,[25] companies must, as a general matter, obtain the consent of a recipient in order to publicly disclose the individual information called for in the Disclosure Code.[26] We also wondered how governments would react to the data that was reported and whether it would satisfy them or lead them to pass more transparency laws.

Now, for the first time, we have actual data to discuss, as well as reactions to that data. Although it is too soon to draw definitive conclusions about the long-term success and viability of the Disclosure Code, it is clear that the biggest issue that the pharmaceutical industry must confront is the consent issue, as most of the reaction from stakeholders, critics, and the press focused on the HCPs who did not consent to individual-level disclosure.

Before we examine the data that was reported and the response to it, it is helpful to first review the key provisions of the Disclosure Code. After we complete that review, we will discuss some efforts EFPIA made to publicize its reporting system in advance of the publication

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[25] There have also been recent developments with respect to the governing law in Europe for data protection. Since 2012, the EU had been working to reform its data privacy rules, as it has had, and still has, a data protection directive, Directive 95/46/EC, in place, which is implemented in the Member States through national legislation. The Data Protection Directive provides a number of privacy rights to data subjects, while at the same time also imposing a number of obligations and responsibilities on data controllers. As to the reform, the EU worked toward the adoption of a Regulation in place of the existing Directive. This is a significant difference because a Regulation is similar to a national law and it is applicable in all EU countries, thereby brining a greater level of uniformity and consistency across all Member States with respect to data privacy. On April 14, 2016, the EU Parliament adopted the data privacy Regulation, and on May 4, 2016, the official text of the Regulation was published in the EU Official Journal. Although the Regulation entered into force on May 24, 2016, it will apply from May 25, 2018.

Another privacy-related development concerned the transfer of data from the EU to the US. The Safe Harbor Program was a voluntary, self-certifying program administered by the US Department of Commerce that enabled US companies to obtain personal data from the EU. On October 6, 2015, the EU's highest court declared the Safe Harbor Program invalid. On February 2, 2016, US and EU officials announced an agreement on a new framework for transatlantic data flows to replace the Safe Harbor Program. The name of the replacement program is "EU-US Privacy Shield." After several months of uncertainty over the fate of the Privacy Shield during which key EU stakeholders and groups expressed doubt about the viability of the program, on July 8, 2016, the EU member states voted in favor of the program, though four countries (Austria, Bulgaria, Croatia, and Slovenia) abstained. On July 12, 2016, the European Commission formally adopted the Privacy Shield. The US Department of Commerce will be responsible for the operation of the Privacy Shield.

[26] On the issue of consent, the Disclosure Code includes a footnote that states: "When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, companies are encouraged to include provisions relating to the Recipients' consent to disclose Transfers of Value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure."

of the data, and then we will focus on the reporting experience in various countries across Europe.

Under the Disclosure Code, EFPIA member companies were required to publicly disclose, for the first time in 2016, their 2015 transfers of value to HCPs and healthcare organisations ("HCOs"). The Disclosure Code excludes the following transfers of value from disclosure: 1) transfers that are solely related to over-the-counter medicines; 2) transfers that are not explicitly identified in the Code, including, for example, items of medical utility, meals/drinks,[27] and medical samples; or 3) transfers that are part of ordinary course purchases and sales of medicinal products by and between a member company and a HCP or HCO.

Disclosures must be made on an annual basis, with each reporting period covering a full calendar year. Companies are required to make their disclosure within six months following the end of the preceding reporting period, and the disclosed information must remain in the public domain for three years, unless a shorter time is required under local law or a recipient revokes previously-granted consent relating to a specific disclosure. Companies are required to document all transfers of value that must be disclosed and maintain such records for at least five years, unless a shorter period is required under local law.

EFPIA and its member associations also adopted a standard reporting template. With respect to the platform of disclosure, the Disclosure Code provides two options: 1) on the reporting company's website; or 2) on a central platform, which could be developed by the national member association. As to the language of the disclosure report, the disclosures

[27] Unlike the legislation in the United States and France, EFPIA does not require companies to report on meals. Rather, Section 10.05 of the EFPIA HCP Code prohibits member companies from providing any meals to HCPs unless the value of the meal does not exceed the monetary threshold set by each national member association in its local code.

themselves must be made in the local language, though companies are encouraged to also make the disclosures in English if that is not the local language.

Companies must report, on the individual level, their transfers of value provided to HCPs and HCOs in the following categories: 1) donations and grants (for HCOs only); 2) contributions to costs related to events (including registration fees; travel and accommodation, to the extent permissible; and sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an event); and 3) fees for service and consultancy. Unlike in the United States, companies do not have to report the details of every single transaction that they have with a HCP or HCO; instead, they are permitted to aggregate all their transfers of value to a HCP or HCO on a category-by-category basis, so long as they are able to provide itemized disclosure upon the request of the recipient or the relevant authorities.

Although it is EFPIA's goal to have as much individual-level reporting as possible, if companies are unable to obtain consent from a HCP to report at the individual level, the Disclosure Code requires that the amounts attributable to such transfers of value be reported on an aggregate basis. That aggregate disclosure must identify, for each reported category, the number of recipients covered by the disclosure (on both an absolute basis and as a percentage of all recipients) and the aggregate amount attributable to all such transfers of value. A second category of aggregate reporting is transfers of value for research and development ("R&D"). Specifically, companies are required to report all of their transfers for R&D in a calendar year, which includes costs related to events that are clearly related to R&D activities, as a single aggregate number.

The Disclosure Code addresses cross-border transfers of value by providing that "[d]isclosures shall be made pursuant to the national code of the country where the Recipient has its physical address."

Another important aspect of the Disclosure Code is its requirement that companies make their "methodology" public. That is, the Disclosure Code provides that all companies must prepare and make public the methodology that they utilized in preparing their disclosure reports:

> Each Member Company shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category[.] The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

The Disclosure Code envisioned that EFPIA's national member associations would transpose the Code's provisions into their own national codes in full, except when the provisions were inconsistent with national laws or regulations. When there were such inconsistencies, EFPIA acknowledged that it would permit deviations from the provisions of the Disclosure Code, but only to the degree needed to comply with the controlling national legislation. For the most part, EFPIA's national member associations faithfully and fully transposed the Disclosure Code's requirements into their national codes, but there were a few variations on some issues.[28]

Over the past year, as EFPIA member companies were grappling with gathering their data and preparing their disclosure reports, EFPIA itself was engaged in a promotional campaign to educate industry, HCPs, and other stakeholders about the Disclosure Code and generate support for it. EFPIA regularly tweeted out information concerning its transparency initiative, which often featured the hashtag, #pharmadisclosure.[29] EFPIA also posted numerous transparency-related items on its blog, http://pharmaviews.eu/. Among the articles authored by EFPIA employees were:

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[28] We will not delve into those variations in this White Paper because we have extensively addressed them in our prior White Papers. *See* D. JEFFREY CAMPBELL, ESQ. & BRIAN P. SHARKEY, ESQ., READY OR NOT, FULL SPEED AHEAD FOR THE GLOBAL TRANSPARENCY MOVEMENT 13-27 (2015); CAMPBELL & SHARKEY, DO START BELIEVIN': THE LIFE SCIENCES INDUSTRY'S JOURNEY TO GLOBAL TRANSPARENCY 39-53 (2014).

[29] @EFPIA, Twitter, https://twitter.com/efpia.

- Andy Powrie-Smith, EFPIA's Communications Director, who wrote, "Securing the basis for collaboration in the future," http://pharmaviews.eu/securing-the-basis-for-collaboration-in-the-future/;
- Julie Bonhomme, EFPIA's Deputy Director Legal Affairs & Compliance, who wrote, "The EFPIA Disclosure Code: What needs to be disclosed?," http://pharmaviews.eu/the-efpia-disclosure-code-what-needs-to-be-disclosed/;
- Richard Bergstrom, EFPIA's Director General, who wrote, "Securing the basis for collaboration," http://pharmaviews.eu/securing-the-basis-for-collaboration/.

Other posts were authored by members of EFPIA's national member associations, including:

- Karen Borrer of the United Kingdom EFPIA member, who wrote, "Learning the lessons of aggregate disclosure: the UK perspective," http://pharmaviews.eu/learning-the-lessons-of-aggregate-disclosure-the-uk-perspective-guest-blog/;
- Paul Wouters of the Dutch EFPIA member, who wrote, "The Dutch experience: it starts with good relations and mutual trust," http://pharmaviews.eu/the-dutch-experience-it-starts-with-good-relations-and-mutual-trust-guest-blog/.

Lastly, employees of EFPIA member companies contributed posts, including:

- Tim McGuire of Eli Lilly, who wrote, "Working Hard Toward Better Transparency," http://pharmaviews.eu/working-hard-toward-better-transparency/.
- Andrew Hotchkiss of El Lilly, who wrote, "Transparency is Key When Collaborating With Healthcare Professionals," http://pharmaviews.eu/transparency-is-key-when-collaborating-with-healthcare-professionals-guest-blog/.

In addition to its blog, EFPIA also posted information and materials on its website. For example, it has a section titled, "Responsible Transparency," that features videos, updates, and

other materials.[30] Further, on a separate page of its website EFPIA posted the following documents: "About the EFPIA Disclosure Code"; "The EFPIA Disclosure Code: Your Questions Answered"; "Working Together for Patients: Role of Consultancy"; "Working together for patients: Grants and Donations"; "Working Together for Patients: Advisory Boards"; and "Understanding the working relationship between the pharmaceutical industry and healthcare professionals."[31] Furthermore, if you attended an industry conference in the past year that discussed topics like Compliance or Transparency, you were likely to find an EFPIA employee there presenting on the Disclosure Code and its benefits.

Lastly, as the deadline for the first round of disclosures drew closer in June 2016, EFPIA released its 2015 Annual Report, which included a few references to the Disclosure Code and the group's commitment to transparency, including the following statement from EFPIA's Director General, Richard Bergstrom:

> Meaningful partnerships mean finding new, open and transparent ways of working together. During 2015, EFPIA member companies have been collecting data on collaborations with health professionals and healthcare organisations, which will be disclosed publicly in June 2016. It will be the first time ever that these transfers of value have been made public across Europe, and the industry is committed to working with all stakeholders in healthcare to underscore the importance of these relationships and to ensure that the benefits of greater transparency are understood.[32]

Finally, on June 20, 2016, EFPIA issued a press release titled, "Pharmaceutical companies drive transparency and underline industry involvement in European Healthcare." In the press release, EFPIA noted that over the next ten days its members would be disclosing details of their collaboration with HCPs and HCOs across Europe. Mr. Bergstrom stated:

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30 *Responsible Transparency*, EFPIA, http://transparency.efpia.eu (last visited August 1, 2016).

31 *Publications*, EFPIA, http://www.efpia.eu/library/publications (last visited August 1, 2016).

32 EFPIA, ANNUAL REPORT 2015 (2015), *available at* http://www.efpia.eu/documents/220/61/EFPIA-Annual-Report-for-2015.

> Increasing transparency through the individual disclosure of transfers of value is good for everyone, including healthcare professionals because it builds understanding of this important collaboration. When pharmaceutical companies research, develop and introduce new medicines [into] clinical practice, it requires input from many stakeholders such as health professionals and healthcare organisations. The introduction of the EFPIA Disclosure Code helps to increase understanding of these important relationships.[33]

Since the June 30 disclosure deadline, EFPIA has not issued any press releases or updated its blog specifically about the reporting experience. However, Mr. Powrie-Smith, EFPIA's Communications Director, was quoted in an article from *Bioworld* titled, "Transparency is the goal as Europe goes live on payment disclosure."[34] That article addresses the reporting experience across Europe, as well as Mr. Powrie-Smith's thoughts about it.

For example, Mr. Powrie-Smith discussed the fact that companies needed to obtain consent from HCPs to publish their information at the individual level, which led to different consent rates across countries. Commenting on some of those variations, Mr. Powrie-Smith stated, "'[t]here are differences in culture, differences in privacy law – Germany for instance has very strong laws – there are different socio-economic conditions in different countries, so inevitably there will be variation[.]'" With respect to the support that the Disclosure Code enjoyed from various stakeholders, he stressed that, "'[t]o my knowledge there is no health professional organization . . . saying this is not a good thing to do[.]'" Discussing how to improve consent rates and maintain industry relationships with HCPs, Mr. Powrie-Smith explained that "'[t]he aim is not to shame; the aim is to make sure we do whatever we can to make the relationship as transparent as possible, to get consent and get the information in the public domain in a way the public can access it[.]'" Lastly, with respect to the notion that

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[33] Press Release, EFPIA, *Pharmaceutical companies drive transparency and underline industry investment in European Healthcare* (June 20, 2016), http://www.efpia.eu/mediaroom/344/43/Pharmaceutical-companies-drive-transparency-and-underline-industry-investment-in-European-Healthcare.

[34] Nuala Moran, *Transparency is the goal as Europe goes live on payment disclosure*, BIOWORLD.COM, http://www.bioworld.com/content/transparency-goal-europe-goes-live-payment-disclosure-0.

consent rates were not sufficiently high and that there should be more data reported, he pointed out that "'[w]e've gone from a standing start, where there was zero data in the public domain, to a leap in what is publicly available about these relationships. That is the starting point. We have to work with health care professionals and others to ensure there is understanding of why[.]'"[35]

While EFPIA was actively publicizing the Disclosure Code at the European level, its national member associations were engaged in similar efforts at the local level.

United Kingdom

We will start our trip around the EFPIA national member associations with the United Kingdom. We chose to start with the United Kingdom for several reasons, including: 1) the local EFPIA member, the Association of the British Pharmaceutical Industry ("ABPI"), actively publicized the transparency initiative in advance of the first reports; 2) the ABPI developed a central database for the reports; 3) there was a significant amount of press coverage of the first round of disclosures, including a series of articles and infographics that ran in *The BMJ*; and 4) much of the press coverage and reaction in the United Kingdom hit upon many of the same concerns and issues that were reflected throughout Europe.

In terms of educational efforts, the ABPI devoted a portion of its website to the transparency initiative, featuring videos, guidance information, press materials, and helpful website links.[36] In terms of guidance information, the Prescription Medicines Code of Practice Authority ("PMCPA"), which is responsible for operating the ABPI Code, issued a document providing advice on what companies should include in their methodological notes.[37] The ABPI

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35 *Id*.

36 *Disclosure*, ABPI, http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx (last visited August 6, 2015).

37 PMCPA, DISCLOSURE OF CERTAIN TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTH PROFESSIONALS AND HEALTHCARE ORGANISATIONS METHODOLOGICAL NOTE – POINTS FOR CONSIDERATION (2015), *available at* http://www.pmcpa.org.uk/media/Documents/Methodological%20Notes%20Final%20Dec%202015.pdf.

also actively promoted its disclosure initiative by posting blogs and issuing press releases explaining the initiative and promoting awareness of it among various stakeholders.

The ABPI created a central database on its website, titled Disclosure UK.[38] Reporting companies were required to submit their reports to the database by March 31, 2016. Those reports, and the methodological notes of the companies, were then made publicly available on the website on June 30, 2016. That database also includes a 19-page document titled, "Disclosure UK: Understanding the data Guidance notes for analysis of the data."[39] The introduction to the document explains its purpose:

> These guidance notes have been prepared by RAND Europe for The Association of the British Pharmaceutical Industry (ABPI) in order to support researchers and other interested parties in their interpretation of the dataset of transfers of value (ToVs), as defined in the ABPI Code of Practice for the Pharmaceutical Industry, from pharmaceutical companies to UK healthcare professionals (HCPs), healthcare organisations (HCOs) and Other Relevant Decision Makers (ORDMs). As such, the notes are intended to be read in conjunction with the disclosure data published on the ABPI website, along with the ABPI Code, which incorporates requirements from the European Federation of Pharmaceutical Industries and Associations (EFPIA) codes, including the EFPIA Disclosure Code.
>
> As part of the disclosure of ToVs, disclosing companies were required to provide an accompanying note summarising the methodologies they used to prepare the disclosures for the reporting period (i.e. the calendar year 2015). The following guidance notes for analysis of the data have drawn on these methodological notes (109 in total). Therefore, this document provides an overview of any variations or differences in methodology that may affect the comparability of data disclosed.
>
> Methodological notes vary widely between companies in the scope and content of information provided.[40]

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[38] *Disclosure UK*, ABPI, http://www.abpi.org.uk/our-work/disclosure/Pages/DocumentLibrary.aspx. (last visited August 6, 2015).

[39] ABPI, DISCLOSURE UK: UNDERSTANDING THE DATA GUIDANCE NOTES FOR ANALYSIS OF THE DATA (2016), *available at* http://www.abpi.org.uk/our-work/disclosure/SiteAssets/Pages/DocumentLibrary/Disclosure%20UK%20Guidance%20notes%20for%20analysis%20of%20the%20data.pdf.

[40] *Id*.

According to a press release issued by the ABPI,[41] 109 pharmaceutical companies reported TOV data (54 ABPI member companies and 55 non-member companies). The data reveals that in 2015, those companies spent a total of £340.3m working with HCPS and HCOs, of which £229.3m (67%) was for R&D work. The remaining £111m (33%) is broken down as follows:

- Fees for service and consultancy and related expenses: £46m (13% of the total amount);
- Registration fees and accommodation: £14.8m (4.3% of the total amount);
- Joint working: £3.3m (1% of the total amount);
- Contribution to cost of events: £31.4m (9.2% of the total amount); and
- Donations and grants: £30.3m (8.9% of the total amount).

The ABPI noted that companies spent an estimated average of £1,550 per HCP and £9,506 per HCO. The average amount of TOV reported by companies was £3.1m, with 84% of companies reporting TOV of less than £5m. Companies that reported more than £5m in TOV spent, on average, 71% on R&D.[42]

As to consent rates, the ABPI stated in its press release that "an estimated 70% of individual healthcare professionals are giving their consent for this information to be disclosed on a named basis." In terms of how the ABPI arrived at that figure, it explained:

> The calculation for the estimated 70% of individual healthcare professionals giving their consent for information to be disclosed on a named basis was based on the average level of disclosure per company for each activity group. This calculation was made using the data available from 105 of the 109 companies. Companies who paid more individuals were given a higher average weighting compared to companies who paid fewer individuals. We have not taken partial

[41] Press Release, ABPI, *Pharmaceutical industry spends £340.3m on working in partnership with leading UK health experts and organisations to improve patient care* (June 30, 2016), http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/Pharmaceutical-industry-spends-%C2%A3340.3m-on-working-in-partnership.aspx.

[42] *Id*.

disclosure into account in these calculations as the number of companies who have declared making these in their methodological notes is extremely low.[43]

The press release also included the following statement from the Chief Executive of the ABPI:

> **This is a milestone moment for transparency** in our industry and for the vital partnerships we have with health professionals and organisations across the UK. These partnerships matter and help our industry bring the right medicine to the right patient at the right time so we can improve quality of life and, in many cases, save lives. Getting advice from doctors, nurses and health professionals across the NHS helps us do this – we can't do it alone. We believe it's right we pay for that expertise and insight, as this is work which health professionals undertake often in addition to their day job in the NHS.
>
> We're committed to transparency – we believe it's right that the public has the opportunity to see some of the detail behind how we work with doctors, nurses, pharmacists and organisations to ensure life-enhancing medicines are developed for the patients who need them. Today, is an important step in sharing as much as of that information as we can.[44]
>
> (emphasis added)

Once the ABPI's database went live, there was an initial wave of articles in the British press about the data, including in outlets like the *Daily Mail*, the *Financial Times*, and *The Telegraph*.[45] Nearly all the articles included the data information and percentages that the ABPI

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[43] *Id.*

[44] *Id.*

[45] *See e.g., 30% of health professionals refuse to be named on drug firm payments database*, BELFAST TELEGRAPH (June 30, 2016), http://www.belfasttelegraph.co.uk/news/uk/30-of-health-professionals-refuse-to-be-named-on-drug-firm-payments-database-34847262.html; Sophie Borland, *What are they hiding? A THIRD of health workers including top doctors refuse to admit if they've been given lavish perks or payments by drug firms*, DAILY MAIL (last updated July 1, 2016, 12:03 a.m ET), *available at* http://www.dailymail.co.uk/wires/pa/article-3668633/30-health-professionals-refuse-named-drug-firm-payments-database.html; *ABPI publishes industry payments to health professionals and organizations*, THE PHARMALETTER.COM (June 30, 2016), http://www.thepharmaletter.com/article/abpi-publishes-industry-payments-to-health-professionals-and-organizations; Clive Cookson, *Database Shines light on pharma payments to UK doctors*, FINANCIAL TIMES LIMITED (June 30, 2016), *available at* https://www.ft.com/content/b3e42806-3ec7-11e6-8716-a4a71e8140b0; Edward Malnick, *Individual NHS doctors receiving £100,000 per year from drugs firms*, THE TELEGRAPH (June 30, 2016), http://www.telegraph.co.uk/news/2016/06/30/individual-nhs-doctors-receiving-100000-per-year-from-drugs-firm/; Selina McKee, *Pharma spent £340m on healthcare partnerships in 2015*, PHARMATIMES ONLINE (July 1, 2016), http://www.pharmatimes.com/news/pharma_spent_340m_on_healthcarepartnerships_in_2015__1053435; Anjali Shukla, *UK healthcare professionals received £340.3 million in benefits from pharma industry in 2015 discloses ABPI*, PHARMAFILE.COM (July 1, 2016), http://www.pharmafile.com/news/505408/uk-healthcare-professionals-secured-3403-million-worth-benefits-2015-pharma-industry-dis; Dominic Tyer, *UK pharma HCP*

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publicized.[46] A few articles had a negative slant in portraying the amount of the TOV, as well as the non-consenting HCPs. For example, one *Daily Mail* article is titled, "What are they hiding? A THIRD of health workers including top doctors refuse to admit if they've been given lavish perks or payments by drug firms."[47] While those articles cast a negative light on the non-consenting HCPs, the implicit premise of them is also that lavish and inappropriate gifts are being provided to HCPs by industry. Other articles focused on the companies that reported the most and the HCP who received the most TOV.[48]

After that initial reaction, the next wave of articles in the British press focused on two key themes: 1) the consent rate, including the fact that HCPs consenting to individual-level disclosure received less TOV than the HCPs who did not consent; and 2) the government's reaction to the data.[49] As to the first topic, several articles pointed out that although the consent

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payment database goes live, PMLIVE.COM, (July 1, 2016), http://www.pmlive.com/pharma_news/uk_pharma_publishes_hcp payments_as_disclosure database_goes_live_1053585; Ingrid Torjesen, *Database of pharmaceutical industry payments to doctors goes live*, ONMEDICA.COM (July 1, 2016), http://www.onmedica.com/newsArticle.aspx?id=0468e29f-0f19-409b-ac8e-95ad68946e1d.

[46] *Id*.

[47] Sophie Borland, *What are they hiding? A THIRD of health workers including top doctors refuse to admit if they've been given lavish perks or payments by drug firms*, DAILY MAIL (last updated July 1, 2016, 12:03 a.m. ET), http://www.dailymail.co.uk/wires/pa/article-3668633/30-health-professionals-refuse-named-drug-firm-payments-database.html.

[48] *See e.g.*, Ingrid Torjesen, *Database of pharmaceutical industry payments to doctors goes live*, ONMEDICA.COM (July 1, 2016), http://www.onmedica.com/newsArticle.aspx?id=0468e29f-0f19-409b-ac8e-95ad68946e1d; Edward Malnick, *Individual NHS doctors receiving £100,000 per year from drugs firms*, THE TELEGRAPH (June 30, 2016), http://www.telegraph.co.uk/news/2016/06/30/individual-nhs-doctors-receiving-100000-per-year-from-drugs-firm/; Anjali Shukla, *UK healthcare professionals received £340.3 million in benefits from pharma industry in 2015 discloses ABPI*, PHARMAFILE.COM (July 1, 2016), http://www.pharmafile.com/news/505408/uk-healthcare-professionals-secured-3403-million-worth-benefits-2015-pharma-industry-dis.

[49] *See e.g.*, Edward Malnick, *Drugs firms should refuse to pay doctors who won't declare earnings, says NHS*, THE TELEGRAPH (July 1, 2016), http://www.telegraph.co.uk/news/2016/07/01/drugs-firms-should-refuse-to-pay-doctors-who-wont-declare-earnin/; Mengsha Li, *Pharma Payments to UK doctors*, FINANCIAL BUZZ, http://www.financialbuzz.com/database-first-time-discloses-pharma-payments-to-uk-doctors-493010; Richard Staines, *Call for mandatory disclosure of pharma payments to NHS*, PHARMAPHORUM (July 4, 2016), http://pharmaphorum.com/news/nhs-calls-for-mandatory-pharma-fees-database/; Richard Staines, *Database shines light on industry payments to clinicians*, PHARMAPHORUM (July 1, 2016), http://pharmaphorum.com/news/database-

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rate was 70% for individual-level disclosure, the 30% of HCPs who did not consent received approximately 52% of the total TOV that was reported. On that point, the ABPI's Chief Executive acknowledged that "[t]he data suggests those people who have been paid the most have chosen not to disclose. We are disappointed about that. These people should be proud of the work that they did as they are probably some of our leading clinicians."[50]

Second, in response to the publication of the TOV data by the ABPI, NHS England[51] took the position that drug companies should no longer work with HCPs who refuse to consent to individual-level disclosure. NHS England issued the following statement through a spokesman: "The ABPI publication is an important step forward in terms of transparency, but it is not yet the complete solution. Voluntary disclosure does not go far enough, and all companies should follow industry leaders in refusing to fund individuals who decline to be transparent about their payments."[52] The ABPI's Executive Director of Research responded to NHS England's position by issuing the following statement:

> We will continue to promote transparency around payments made to health professionals and welcome the work of others, like NHS England, to achieve this. We all need to work together to support health professionals so that they are confident about talking about the valuable work they do with pharmaceutical companies, but we must also respect their rights under UK law.[53]

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shines-light-industry-payments-clinicians/; Rebecca Trager, *Unpicking doctor payments*, CHEMISTRYWORLD (July 4, 2016), http://www.rsc.org/chemistryworld/2016/07/unpicking-doctor-payments.

[50] Richard Staines, *Database shines light on industry payments to clinicians*, PHARMAPHORUM (July 1, 2016), http://pharmaphorum.com/news/database-shines-light-industry-payments-clinicians/.

[51] NHS England is an independent organization established by the Parliament that is responsible for the stewardship of the National Health Service. Specifically, it is responsible for setting the priorities and direction of the NHS and investing to continually improve health outcomes for individuals, communities and society as a whole. NHS England manages around £100 billion of the overall NHS budget and ensures that organizations are spending the allocated funds effectively. https://www.england.nhs.uk/about/.

[52] Edward Malnick, *Drugs firms should refuse to pay doctors who won't declare earnings, says NHS*, THE TELEGRAPH (July 1, 2016), http://www.telegraph.co.uk/news/2016/07/01/drugs-firms-should-refuse-to-pay-doctors-who-wont-declare-earnin/.

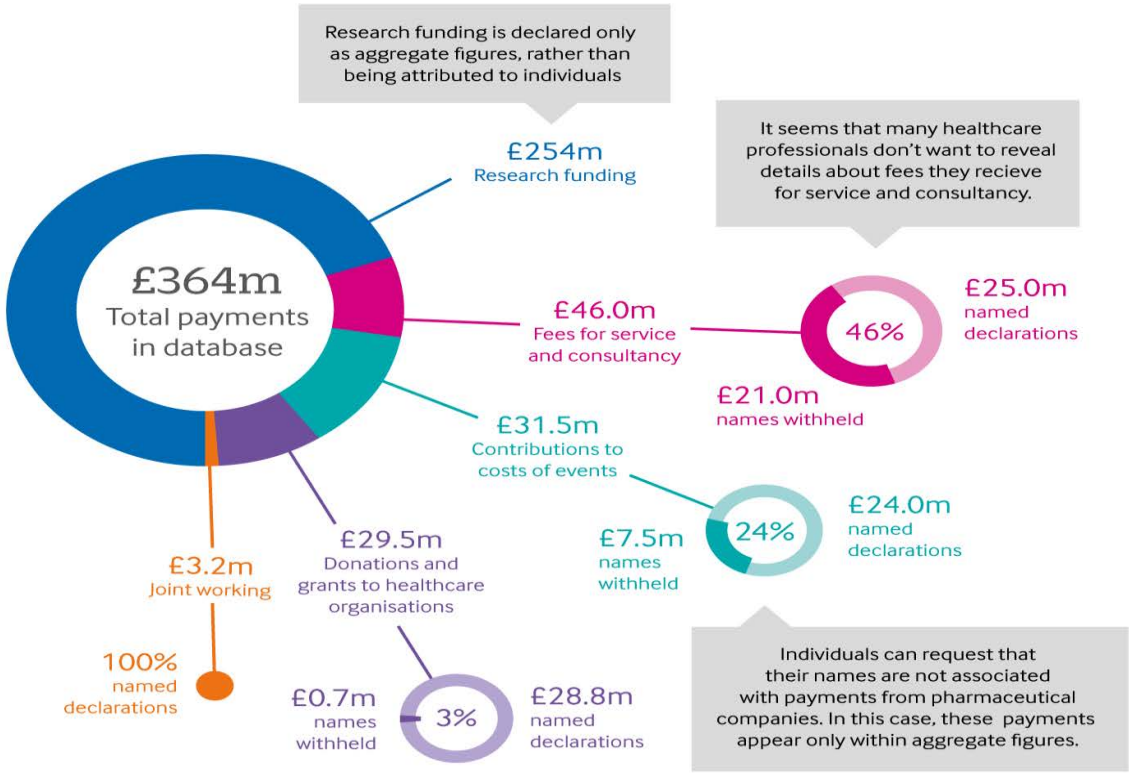
[53] *Id*.

Against this backdrop, in July 2016 *The BMJ* (formerly known as the British Medical Journal) published a series of articles and charts about the ABPI's Disclosure UK database and the TOV data that was reported by participating companies.[54] A concise summary of *The BMJ's* overall view is its statement that UK Disclosure is "a useful step towards greater transparency and public accountability, but it serves mainly to show just how far we have to go."[55] As part of its series, *The BMJ* created several visual charts. One chart[56] showed how much money was reported and who received it. The largest amount was for R&D, and the next highest category was fees for service and consultancy:

[54] *Disclosure UK*, http://www.bmj.com/content/disclosure-uk (last visited August 8, 2016); Nigel Hawkes, *Doctors getting biggest payments from drug companies don't declare them on new website* (July 1, 2016), http://www.bmj.com/content/354/bmj.i3679; Margret McCartney, *Optional disclosure of payments is pointless* (July 1, 2016), http://www.bmj.com/content/354/bmj.i3692; Duncan Jarvies, *Disclosing drug companies payments should be compulsory, say top earners* (July 4, 2016), http://www.bmj.com/content/354/bmj.i3716; Kate Adlington and Fiona Godlee, *Disclosure UK: transparency should no longer be an optional extra* (July 6, 2016), http://www.bmj.com/content/354/bmj.i3730; Zosia Kmietowicz, *Disclosure UK website gives "illusion of transparency," says Goldacre* (July 6, 2016), http://www.bmj.com/content/354/bmj.i3760.

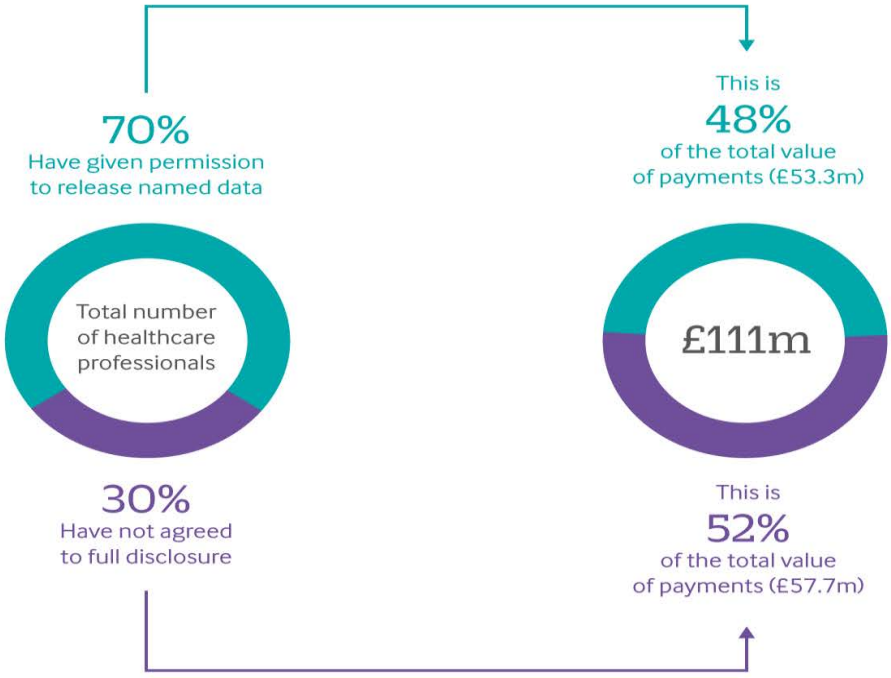
[55] *Id*.

[56] *Disclosure UK*, http://www.bmj.com/content/disclosure-uk (last visited August 8, 2016).



Another chart showed that for companies that reported over £1m, the consent rate from HCPs for individual-level reporting ranged from 97% down to 31%.[57] In addition, another graphic[58] demonstrated that although 70% of HCPs consented to individual-level disclosure, the 30% that did not consent received 52% of the overall HCP payments:

57 *Id.*
58 *Id.*



As part of its examination of UK Disclosure, *The BMJ* published an editorial by its Editor in Chief and Clinical Editor that opined that the ABPI's database is the first step to greater transparency. The editorial is titled, "Disclosure UK: transparency should no longer be an optional extra."[59] After pointing out that the average payment value to HCPs was £1,500 and the highest was £98,000, the authors argued that there were several limitations to UK Disclosure. First, due to privacy laws, HCPs had to voluntarily agree to disclosure, such that "if a doctor isn't listed this could mean either no payments were received or the doctor declined to be identified." While acknowledging the 70% of HCPs who consented, the authors were concerned that the 30% who refused to consent received 52% of the overall payments to HCPs. Second, the authors pointed out that the project only covered pharmaceutical companies and not medical device companies. Third, the authors noted that the data "are hard to interpret." In that regard, the

[59] Kate Adlington and Fiona Godlee, *Disclosure UK: transparency should no longer be an optional extra* (July 6, 2016), http://www.bmj.com/content/354/bmj.i3730.

authors found the reporting categories to be unhelpful and too general, especially with respect to R&D being reported in the aggregate. Fourth, the authors declared that "the database is far from user friendly."[60]

While hoping that the data will improve over time and that more doctors will disclose, the authors acknowledged that the UK was behind countries like the United States and the Netherlands with respect to transparency. Looking forward, they opined that "[t]here is currently little political appetite for US-style legislation, with bigger issues likely to distract parliament for some time. But there are encouraging signs of growing commitment within the profession." After chronicling those signs, including the involvement of NHS England in developing rules to govern conflicts of interest, the authors concluded their piece by declaring:

> Transparency is no longer an optional extra. It is necessary for fair, effective, and accountable healthcare. The ABPI's Disclosure UK is a welcome first step, but the public should demand and professionals should provide better. Patients deserve a comprehensive, searchable and eventually mandatory public facing database of doctors' declarations of interests, and the GMC[61] is best placed to deliver it.[62]

A second opinion piece was authored by columnist and general practitioner Margaret McCartney, titled "Optional disclosure of payments is pointless."[63] Dr. McCartney illuminated her negative perception of the ABPI's initiative by beginning her piece as follows:

> Naked, luscious transparency! Hurrah! The Association of the British Pharmaceutical Industry (ABPI) is about to reveal, ladies and gentlemen, the pounds and pence that the industry has paid to healthcare professionals, along with their names. The obfuscatory kit of amalgamated payments and anonymity is coming off. But this is all being done with the recipients' consent, **so the entire**

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60 *Id*.

61 The General Medical Council is an independent organization that helps protect patients and improve medical education and practice across the UK. It maintains the official register of doctors in the UK, determines which doctors are qualified to work in the UK, and oversees medical education and training. http://www.gmc-uk.org/about/role.asp.

62 Kate Adlington and Fiona Godlee, *Disclosure UK: transparency should no longer be an optional extra* (July 6, 2016), http://www.bmj.com/content/354/bmj.i3730.

63 Margret McCartney, *Optional disclosure of payments is pointless* (July 1, 2016), http://www.bmj.com/content/354/bmj.i3692.

> **charade has all the thrust of a dead jellyfish.** Doctors can opt out, meaning that a key opinion leader can earn hundreds of thousands of pounds while influencing patients, colleagues, formularies, and policies – and we won't know. Owing, we are told, to data protection issues (ie, consent is required for sharing), transparency is not compulsory. Worse, revealing a little may entice us to assume that we've seen a lot, including all of the important bits, when we have not.[64]
>
> (emphasis added)

The BMJ also published multiple articles about Disclosure UK. One article is titled, "Doctors getting biggest payments from drug companies don't declare them on new website."[65] This article provides an analysis of the data reported in the ABPI's database, whereby the author determined that

> [h]ealth professionals who are paid the most by UK drug companies for providing time and advice are the least likely to have voluntarily declared the payments …. The data show that 70% of healthcare professionals in receipt of payments from companies required to register details on a website hosted by the Association of the British Pharmaceutical Industry (ABPI) agreed to have the data disclosed. But the 30% who didn't agree to disclosure received 52% of the payments registered. However, *The BMJ* has been unable so far to determine how many healthcare professionals are included in the website and how many are doctors.[66]

After examining other aspects of the TOV data, the article includes quotes from the Chief Executive of the ABPI, who again characterized the release of the data as a "milestone moment," as well as quotes from the President of the Academy of Medical Sciences and the President of the Royal College of Physicians, who both voiced support for transparency but also expressed concerns about the program. Specifically, the ABPI's Chief Executive stated:

> We're committed to transparency. We believe it's right that the public has the opportunity to see some of the detail behind how we work with doctors, nurses, pharmacists, and organisations to ensure that life enhancing medicines are developed for the patients who need them. Today is an important step in sharing as much as of that information as we can.[67]

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64 *Id*.

65 Nigel Hawkes, *Doctors getting biggest payments from drug companies don't declare them on new website* (July 1, 2016), http://www.bmj.com/content/354/bmj.i3679.

66 *Id*.

67 *Id*.

From the HCP perspective, the President of the Academy of Medical Sciences commented:

> Successful partnerships between industry, academia, and the healthcare sector can speed up the rate of scientific discovery and innovation, and they are key to accelerating the translation of research into benefits for society[.] However, many people are concerned about how these partnerships might compromise the integrity of research. That is why it is of the utmost importance that the nature of these collaborations and their impact on research are communicated to the public in a clear and transparent way. Disclosure UK is a welcome step towards creating the level of transparency and accountability that the public need to assess the trustworthiness of these partnerships.[68]

And the President of the Royal College of Physicians declared:

> The register shows the extensive contribution pharmaceutical companies make, working with health professionals and organisations on activities related to the research and development of new medicines. However, the register allows healthcare professionals to opt out of disclosure and does not support healthcare professionals who wish to declare that they have not received any funding from pharma. These issues must be addressed by the ABPI and the pharmaceutical companies in the coming year to enable the public to have confidence in the register as a true picture of the relationship between pharma and healthcare professionals.[69]

Another article, featuring Dr. Ben Goldacre,[70] is titled, "Disclosure UK website gives 'illusion of transparency,' says Goldacre."[71] This article included a lengthy statement from Dr. Goldacre about the transparency initiative:

> Doctors have an obligation to be open with their patients and colleagues[.] … A financial conflict of interest does not necessarily mean somebody is biased, and there are good reasons to work with the industry, but it does introduce risks. That's why clearly declaring your conflicts matters, so we can all judge for ourselves. There is a pattern of people avoiding responsibility in this area, which is puzzling. The ABPI … says that doctors can decide if they want their payments disclosed. NHS England says companies should refuse to work with doctors who won't disclose. They should both show some leadership. GSK have said that they

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68 *Id*.

69 *Id*.

70 Ben Goldacre is academic lead at the Evidence Based Medicine DataLab at the University of Oxford and is an author, broadcaster, campaigner, medical doctor, and academic. http://www.badscience.net/about-dr-ben-goldacre/.

71 Ingrid Torjesen, *GMC says it can't force doctors to disclose payments from drug companies* (July 7, 2016), http://www.bmj.com/content/354/bmj.i3806.

> will only work with doctors who disclosed their payments, and they've now said they're stopping many classes of payment, such as fees for lectures. Other companies could do the same. And NHS England, along with the GMC, could simply tell doctors they must disclose. That is important, because pharma payments are not the only payments that matter. Doctors in clinical commissioning groups, for example, often commission health services from private companies they themselves own. Instead of chaos, and multiple partial disclosures spread around the web, all these payments and financial interests should be in one place. The GMC and the government could, and should, require all doctors to post all health related financial interests to a central register. Short of that, we have only the illusion of transparency.[72]

In addition to Dr. Goldacre's statement, the article also identified a host of "problems" with Disclosure UK, including:

- Only 48% of the specific payments have been linked to individuals or institutions.
- Undisclosed payments are published as an aggregate, rather than being listed but anonymised.
- The aggregate figures for undisclosed payments combine payments to individuals and those to institutions, although those to institutions are an order of magnitude larger. Organisations opting to hide payments they've received from a drug company, such as universities, seems to be included in the dataset.
- The way data are shared is unhelpful. For example, it is impossible to calculate, whether by company or from the total, the average size of each hidden payment to a doctor.
- There is no indication of what drug or disease area the undisclosed payments relate to.
- There are technical problems with the spreadsheets. The numbers on individual payments didn't seem to add up correctly and didn't tally with the summary numbers on payments and withheld payments.
- The documentation is incomplete, even on simple matters such as what some of the fields in the spreadsheet mean.
- The ABPI did not reply to questions about the data. That's bad practice for anyone sharing any dataset.
- The data are shared under a non-standard license that is unclear but that might forbid reasonable reuse.[73]

A third article published by *The BMJ* was titled, "Disclosing drug company payments should be compulsory, say top earners."[74] The article featured statements from a number of the highest paid HCPs identified in the ABPI's database, in which they universally defended their

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72 *Id.*

73 *Id.*

74 Duncan Jarvies, *Disclosing drug companies payments should be compulsory, say top earners* (July 4, 2016), http://www.bmj.com/content/354/bmj.i3716.

relationships with industry, asserted that they have nothing to hide (perhaps unlike the HCPs who did not consent), and supported additional steps toward more transparency.

A fourth article published by *The BMJ* was titled, "GMC says it can't force doctors to disclose payments from drug companies." This article focused on the fact that the UK General Medical Council ("GMC") lacks the legal power to force HCPs to agree to disclose payments they receive from pharmaceutical companies. While the article claimed that the 70% consent rate had caused some to call for mandatory reporting like in the United States, a spokesperson for the GMC stated:

> We very much hope that every doctor with a connection to the pharmaceutical industry will take part in the ABPI's new database, and we will be watching to see how it develops. But we do not have the legal power to make participation in the ABPI's database, or any similar scheme, mandatory[.] … Pharmaceutical companies, on the other hand, do have the option to decide not to work with any doctor who refuses to consent to disclosure[.] … In order to make it mandatory there would need to be legislative change[.] … The future does lie in greater transparency, but whatever information is made available must be proportionate, relevant, and useful. We will be gauging opinions during our consultation and will be in a position to take a firmer view later in the year [.][75]

Austria

The Austrian industry group, Pharmig, issued a press release on June 22, 2016, in which it projected that its members would reveal approximately €100 million of 2015 TOV spend, with more than 50% of that on R&D.[76] Further, at a joint press conference, members of Pharmig and HCP representatives discussed the importance of the transparency initiative and the need for industry to collaborate with HCPs. Although its press release did not indicate what the consent rate would be for individual-level disclosure, Pharmig acknowledged that not all HCPs

[75] Ingrid Torjesen, *GMC says it can't force doctors to disclose payments from drug companies* (July 7, 2016), http://www.bmj.com/content/354/bmj.i3806.

[76] Press Release, Pharmig, *Ärztekammer und Pharmaindustrie: ein klares "Ja" zu mehr Transparenz* (June 22, 2016), http://www.pharmig.at/DE/Presse/Pressemitteilungen/Pressemitteilungen%202016/Pressemitteilungen+2016.aspx.

consented and that its goal was to improve next year. In that regard, one HCP representative explained that although individual-level disclosure is the goal, it would take time and a "cultural change" to improve the consent rate because it is not customary to publicly discuss income.[77]

With respect to press coverage of the Austrian reporting experience, one article featured the head of Pharmig proclaiming his pride that more than half of the reported spend was for R&D and that 100 companies, representing 95% of the market share, had reported. However, in other coverage there was some skepticism expressed about the industry's commitment to transparency because of the ability of HCPs to block individual-level disclosure by refusing to consent. Moreover, there was some criticism of the effort it took to review all company reports because they were posted on company websites as opposed to a central database.[78]

Finally, the Austrian chapter of Transparency International ("TI") issued a press release welcoming the TOV disclosures as a step in the fight against corruption in the healthcare sector, which it opined is particularly vulnerable to corruption.[79] However, the Austrian TI chapter noted that it did not believe that pharmaceutical companies had taken an approach whereby they would refuse to work with HCPs that did not consent, a position that it supported. Accordingly, the Austrian TI chapter cautioned that it would closely study the data and potentially push for legislation if it determined the information revealed by the reports of Pharmig's members was inadequate from a transparency perspective.[80]

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77 *Id*.

78 *Pharmafirmem geben 100 Millionen Euro für Forschung und Ärtze aus*, WIRTSCHAFTS BLATT (June 22, 2016), http://wirtschaftsblatt.at/home/nachrichten/oesterreich/5032274/Pharmafirmen-geben-100-Millionen-Euro-fur-Forschung-Fortbildung.

79 Press Release, Transparency International, *Austrian Chapter begrüßt die Offenlegung von Zahlungen der Pharmaindustrie an Ärzte* (June 22, 2016), https://www.ti-austria.at/2016/06/22/transparency-international-austrian-chapter-begruesst-die-offenlegung-von-zahlungen-der-pharmaindustrie-an-aerzte/.

80 *Id*.

Belgium

Like the ABPI, the Belgian member of EFPIA, pharma.be, worked for some time on the development of an on-line central platform where its members would submit their reports that would then be made publicly available. That platform, www.betransparent.be, went live in 2015. pharma.be developed the central platform in conjunction with, among others, beMedTech, which represents the medical device industry in Belgium. As discussed *infra*, the members of beMedTech will report their transfers of value for the first time in 2017 for 2016 data. In addition to containing the TOV reports of the members of pharma.be, the central platform has informational materials, FAQs, videos, and other resources about the Belgian transparency initiative, including "Testimonials" from various stakeholders, like Catherine Rutten, the CEO of pharma.be, who declared: "Exchanges between healthcare professionals and industry representatives are in the interest of patients. The publication of these data via betransparent.be, with respect for privacy, reflects the sector's willingness to act transparently."[81]

On June 22, 2016, the data on www.betransparent.be became publicly available. According to a press release issued by pharma.be,[82] 80 companies reported their 2015 data and spent a total of €138.5 million, broken down as follows:

- 65%/€89.5 million on R&D;
- 13%/€17.3 million for grants/donations;
- 17%/€24.2 million for conference sponsorships; and
- 5%/€7.5 million for consultancy services.[83]

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81 BETRANSPARENT, www.betransparent.be (last visited August 8, 2016).

82 Press Release, pharma.be, *Belgische Innovatieve Farmabedrijven Nemen Het Voorttouw In Transparantie* (June 22, 2016), http://www.pharma.be/nl/news/persberichten/150-belgische-innovatieve-farmabedrijven-nemen-het-voortouw-in-transparantie.html.

83 *Id*.

pharma.be emphasized that 23 different HCP associations supported the transparency initiative and that over 3,000 HCPs gave consent for individual-level disclosure. The CEO of pharma.be also stressed that "[m]utual contacts between health care providers and representatives of the industry [are] done in the interests of patients. The publication of this information, respecting the right [to] privacy, [proves that industry acts] in full transparency. 78 percent of the investments are linked to research and supporting scientific activities."[84] There was some press coverage that reported generally about the transparency initiative, but there were also some critical views expressed about it. For example, one article criticized the initiative for not providing enough information about industry-HCP interactions, and also examined data reported by specific companies and identified some HCPs by name.[85]

Finland

In Finland, the local EFPIA member, Pharma Industry Finland ("PIF"), worked with relevant stakeholders to publicize the transparency initiative prior to its May reporting deadline. Specifically, the Finnish Medical Association supported the disclosure program, and the Pharmacists' Association in Finland recommended that its members give consent for individual-level reporting.[86] Further, PIF released a video featuring a member of the Finnish Medical Society and two PIF representatives discussing the transparency initiative.[87]

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84 *Id*.

85 Laurence Dardenne, *L'industrie pharma veut jouet la transparence*, LALIBRE.BE (June 22, 2016), http://www.lalibre.be/actu/sciences-sante/l-industrie-pharma-veut-jouer-la-transparence-576a872135708dcfedb4c8f7.

86 Press Release, Pharma Industry Finland, *The pharmaceutical companies used 27 million euro on cooperation with healthcare professionals* (May 31, 2016), http://www.pif.fi/en/announcements/pharmaceutical-companies-used-27-million-euro-cooperation-healthcare-professionals.

87 Pharma Industry Finland, Transparency Initiative Video, *available at* https://vimeo.com/121233799 (last visited August 8, 2016).

As to the data revealed by the first round of reporting, PIF announced that its members paid approximately €27 million to HCPs and other stakeholders in 2015.[88] The average interaction was €1,000, and the largest payments were for education and expert services, which comprised approximately €8.5 million of the overall reported amount. In addition to highlighting those figures, PIF attempted to place them in context by explaining the importance of collaboration between industry and HCPs in the healthcare field.[89] Although it does not have a central database of TOV reports, PIF does have a page on its website with links to the reports of its member companies.[90] Lastly, it is important to note that PIF adopted a revised Code of Ethics in 2016, but no changes were made to the TOV provisions of the Code.[91]

Germany

The German member of EFPIA created a website devoted to the transparency initiative, which features videos, resources, and, following the reporting deadline, links to the disclosure reports of its member companies.[92] On June 20, 2016, the German industry group issued a press release in which it announced that it anticipated that its 54 member companies would report a total of approximately €575 million for 2015 TOV, broken down as follows:

1) €366 million for R&D;

2) €119 million for consulting/lecture fees/training; and

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88 Press Release, Pharma Industry Finland, *The pharmaceutical companies used 27 million euro on cooperation with healthcare professionals* (May 31, 2016), http://www.pif.fi/en/announcements/pharmaceutical-companies-used-27-million-euro-cooperation-healthcare-professionals.

89 *Id*.

90 *Linkit*, PIF, http://www.pif.fi/laakkeet/markkinointi/laakeyritysten-ja-terveydenhuollon-ammattilaisten-yhteistyo/linkit (last visited August 2, 2016).

91 PHARMA INDUSTRY FINLAND, PHARMA INDUSTRY FINLAND CODE OF ETHICS (2016).

92 Freiwillige Selbstkontrolle für die Arzneimittelindustrie ("FSA"), http://www.pharma-transparenz.de/ (last visited August 2, 2016).

3) €90 million for sponsorship of events and training.[93]

The press release also included a number of quotes from the industry group's representatives about the importance of this initiative. Later in June, the group issued another press release in which it emphasized that a majority of the anticipated TOV data was for R&D and stressed the importance of such work to Germany and its citizens.[94]

In terms of stakeholder reaction, the German Medical Association welcomed the transparency initiative, but also seemed to embrace the idea of a US Sunshine Act-type law. In that regard, the President of the German Medical Association suggested that the German Disclosure Code is a good first step, but he supported additional steps like US-style legislation or the adoption of a common position by the pharmaceutical industry to not work with HCPs who refuse consent.[95] Others, like a spokesperson from a left-leaning political party and a patient group, were critical of the initiative and essentially deemed it to be sham transparency.[96] The local press chronicled the amount of TOV spend, but also highlighted that only 33% of HCPs agreed to individual-level disclosure. Representatives of the German industry group responded to the criticism of that consent rate by explaining that the first year of reporting was just the beginning of a longer journey to achieve greater transparency.[97]

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[93] Press Release, Freiwillige Selbstkontrolle für die Arzneimittelindustrie, *Forschende Pharma-Unternehmen setzen Transparenzkodex um* (June 20, 2016), http://www.pharma-transparenz.de/fileadmin/Downloads/Pdfs/Pressemitteilungen/PM_Transparenzkodex_endgueltig.pdf.

[94] Press Release, Freiwillige Selbstkontrolle für die Arzneimittelindustrie, *Transparenzkodex zeigt Forschungsstärke*, (June 23, 2016), http://www.pharma-transparenz.de/fileadmin/Downloads/Pdf_s/Pressemitteilungen/2016-06-23_VFA_Pressemitteilung_pm-015-2016__2_.pdf.

[95] Hinnerk Feldwisch-Drentruk, *Montgomery will korrupte Kollegen aufdecken*, DAZ.ONLINE (June 21, 2016), https://www.deutsche-apotheker-zeitung.de/news/artikel/2016/06/21/montgomery-fordert-pflicht-zu-transparenz.

[96] Kirsten Sucker-Sket, *Pharmafirmen zahlten Ärzten und Kliniken 575 Millionen Euro* (June 20, 2016), https://www.deutsche-apotheker-zeitung.de/news/artikel/2016/06/20/fsa-vfa-transparenzinitiative-575-millionen-euro-fur-aerzte/chapter:1.

[97] *Id*.

Ireland

Like many other national industry groups, in the build-up to the reporting deadline the Irish Pharmaceutical Healthcare Association ("IPHA") worked with the healthcare community to promote awareness of the transparency requirements and to emphasize the importance of HCPs consenting to the success of the initiative. And like some of its counterparts, the IPHA set up a separate website, https://www.transferofvalue.ie/, for the submission of its member companies' reports and methodology notes and their eventual public release. After that data was made publicly available, the IPHA announced that its members reported €27.2 million of TOV spend. Of that amount, €9.7 million was for R&D; €10.7 million went to HCOs; and €6.8 million went to HCPs.[98] As to the data, the CEO of the IPHA commented:

> Interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. They have delivered numerous innovative medicines and changed the way many diseases impact on our lives. This new level of transparency is designed to assure the public that they can trust their HCPs to recommend treatment or administer appropriate care based solely on clinical evidence. Along with the research based pharmaceutical industry across Europe, Ireland, as represented by IPHA, has today entered this new era of transparency. The commencement of disclosure, which will from now on be an annual event, is a clear demonstration [that] the pharmaceutical industry is committed to working with healthcare professionals and organisations to drive innovation that benefits patients.[99]

In the wake of the public release of the data, however, there were press articles that questioned the payments and the consent rate from HCPs. For example, one article, titled, "Pharma association defends payments of €27m to doctors," pointed out that pharmaceutical companies reported spending €27m in Ireland in 2015, with some HCPs receiving as much as

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[98] Press Release, IPHA, *Pharmaceutical companies commence open disclosure of payments to Healthcare Organisations and Professionals* (June 30, 2016), http://www.ipha.ie/news/latest-news.aspx?article=609f595e-c3c0-4849-b2bf-9a824e69f418.

[99] *Id*.

€12,000, but that only 55% of HCPs consented to individual-level disclosure.[100] The Chief Executive of the IPHA discussed those figures, explaining that much of the spend was for educating and training HCPs. He also commented that "I don't believe, and I don't think any reasonable member of the public believes, that doctors or nurses or dentists are compromised in their care for their patients by amounts of money of that order[.] … I don't believe that doctors are influenced in their prescribing choices by these transfers of value … it wouldn't be ethical for a doctor to do that."[101] Another article, titled, "55% of HCPs agree to release of pharma company payments," highlighted that consent rate and then examined payments made by various companies to specific HCPs and HCOs.[102]

Italy

Unlike its Irish counterpart, Farmindustria, the Italian EFPIA member, did not establish a central website for its member companies' reports. However, like its Irish counterpart, Farmindustria actively promoted awareness of its transparency project prior to the disclosure deadline. For example, Farmindustria conducted a press conference featuring its President, HCP representatives, and the Italian Minister of Health. There was a significant amount of press coverage of this event, and nearly all of the articles described the transparency initiative and that approximately 200 companies would be reporting. The articles also featured Farmindustria's prediction that HCPs would consent to individual-level disclosure at an approximately 70% rate.

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100 *Pharma association defends payments of €27m to doctors*, RTE NEWS (July 11, 2016), http://www.rte.ie/news/2016/0710/801525-pharma-payments-practice/.

101 *Id.*

102 Niamh Mullen and Dara Gantly, *55% of HCPs agree to release of pharma company payments*, IRISH MEDICAL TIMES (July 13, 2016), http://www.imt.ie/news/latest-news/2016/07/55-of-hcps-agree-to-release-of-pharma-company-payments.html.

Furthermore, at the press conference the Italian Minister of Health welcomed the transparency initiative and gave a positive statement of support for it.[103]

Following the publication of the TOV data, a number of articles in Italian periodicals addressed the transparency initiative. Most of the articles highlighted that the consent rate for individual-level disclosure was 70%, with some companies having even higher rates. The

[103] Margherita de Bac, *Sanità, online l'elenco dei medici pagati dalle case farmaceutiche*, CORRIERE DELLA SERA (June 17, 2016), http://roma.corriere.it/notizie/cronaca/16_giugno_16/sanita-online-l-elenco-medici-pagati-case-farmaceutiche-131fb5ae-33f3-11e6-b8e9-6b78a4af30ec.shtml; Andrea Barcariol, *Sanitá trasparente, ecco il Disclosure Code. Lorenzin: "Vera arma contro opacitá,"* INTELLIGONEWS.IT (June 16, 2016), http://www.intelligonews.it/articoli/16-giugno-2016/43855/disclosure-code-trasparenza-on-line-compensi-finanziamenti; Sarina Biraghi, *Se la trasparenza diventa «un'arma»*, IL TEMPO (June 22, 2016), http://www.iltempo.it/rubriche/salute/2016/06/22/se-la-trasparenza-diventa-un-arma-1.1551641; *Codice di trasparenza: i medici pronti a dichiarare compensi da case farmaceutiche*, METROPOLIS (June 16, 2016), http://www.metropolisweb.it/news/codice-di-trasparenza-i-medici-pronti-a-dichiarare-compensi-da-case-farmaceutiche/13378.html; Ruggiero Corcella, *Medici, ospedali e case farmaceutiche Online i dati sui finanziamenti*, CORRIERE DELLA SERA (last updated June 21, 2016 at 9:53 a.m. ET), http://www.corriere.it/salute/16_giugno_16/medici-big-pharma-online-dati-sponsorizzazioni-470227f0-33ce-11e6-b8e9-6b78a4af30ec.shtml?refresh_ce-cp; Valeria Covato, *Sanità, cosa svelerà sui medici il codice trasparenza di Farmindustria*, FORMICHE (June 17, 2016), http://formiche.net/2016/06/17/sanita-cosa-svelera-sui-medici-il-codice-trasparenza-di-farmindustria/; *Disclosure Code, online i compensi delle imprese ai medici*, VIRGILIO (June 17, 2016), http://quifinanza.it/soldi/disclosure-code-online-i-compensi-delle-imprese-ai-medici/71200/; Sara Frison, *Sanità: sul web la lista medici pagati dalle case farmaceutiche*, CNO WEB TV (June 18, 2016), http://www.cno-webtv.it/sanita-sul-web-la-lista-medici-pagati-dalle-case-farmaceutiche/; Barbara Gobbi, *On line i compensi delle imprese ai medici: Farmindustria e Fnomceo battezano il Disclosure Code*, Sanitá24 (June 16, 2016), http://www.sanita24.ilsole24ore.com/art/imprese-e-mercato/2016-06-16/compensi-medici-on-line-30-giugno-130851.php?uuid=ADBMbId&refresh_ce=1; *Lorenzin tiene a battesimo il Disclosure Code di Farmindustria: "La trasparenza è la nostra arma,"* QUOTIDIANOSANITÁ.IT (June 16, 2016), http://www.quotidianosanita.it/scienza-e-farmaci/articolo.php?articolo_id=40747; *Medici-aziende farmaceutiche, scatta l'ora della trasparenza*, RIF day (June 20, 2016), http://www.rifday.it/2016/06/20/medici-aziende-farmaceutiche-scatta-lora-della-trasparenza/; *Online l'elenco dei medici che ricevono soldi dalle case farmaceutiche*, DIRETTANEWS.IT (June 21, 2016), http://www.direttanews.it/2016/06/21/online-lelenco-dei-medici-ricevono-soldi-dalle-case-farmaceutiche/; Stefania Del Principe, *Chi sono i medici che hanno preso compensi dalle case farmaceutiche? Online l'elenco*, DIARIO DEL WEB (June 17, 2016), http://salute.diariodelweb.it/salute/articolo/?nid=20160617_384430; Corrado De Rossi Re, *Disclosure Code. La trasparenza come regola Etica...ma attenzione al "cronista curioso,"* DAILY HEALTH INDUSTRY (June 16, 2016), http://www.dailyhealthindustry.it/disclusure-code-la-trasparenza-come-regola-eticama-attenzione-al-cronista-curioso-ID1772.html; *Sanità, dal 30 giugno prossimo entra in vigore il codice trasparenza: online compensi medici da case farmaceutiche*, NEWS 24 WEB (June 18, 2016), http://www.news24web.it/373652016/sanita-dal-30-giugno-prossimo-entra-in-vigore-il-codice-trasparenza-online-compensi-medici-da-case-farmaceutiche/; *Sanità, online l'elenco dei medici pagati dalle case farmaceutiche: "Basta pregiudizi,"* TODAY.IT (June 17, 2016), http://www.today.it/cronaca/medici-pagati-case-farmaceutiche-elenco-online.html; *Trasparenza, 70% dei medici favorevole a pubblicare i compensi ricevuti da Big Pharma*, ABOUT PHARMA ONLINE (June 16, 2016), http://www.aboutpharma.com/blog/2016/06/16/trasparenza-70-dei-medici-favorevole-pubblicare-compensi-ricevuti-big-pharma/.

articles also tended to concentrate on the data revealed by specific companies, not only in terms of total TOV reported, but also with respect to the consent rates for specific companies.[104]

The Italian government also examined the TOV disclosures, as the Italian Senate's Industry, Trade, Tourism Committee and Hygiene and Health Committee conducted an informal hearing on Farmindustria's transparency initiative.[105] At the hearing, the President of Farmindustria stated that, although the group is at the beginning of a path to make information public, it was pleased that the average consent rate among HCPs for individual-level disclosure was 70%. He also pointed out that some companies were in the 80%-90% consent range, and in some instances even 100%. The President emphasized that the disclosure reports took an enormous effort, in terms of time and money, on the part of member companies and other stakeholders and that Farmindustria had consulted with governmental stakeholders about the disclosure project throughout the process. The Chairman of the Hygiene and Health Committee expressed support for the initiative as an important tool, but encouraged industry to make the data easier to access and to further embrace transparency.[106]

The Netherlands

In our prior White Papers, we chronicled the differences between the Dutch reporting system and EFPIA's Disclosure Code.[107] For example, the member companies of the Dutch

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[104] *Codice trasparenza Farmindustria-medici, Scaccabarozzi: "Adesioni già tra 80 e 100%*," SANITÀ24 (July 4, 2016), http://www.sanita24.ilsole24ore.com/art/lavoro-e-professione/2016-07-04/codice-trasparenza-farmindustria-medici-scaccabarozzi-adesioni-gia-80-e-100percento-180140.php?uuid=AD3Laxn; Marco Landucci, *Disclosure Code: il 70% delle aziende ha già pubblicato i dati*, DAILY HEALTH INDUSTRY (July 1, 2016), http://www.dailyhealthindustry.it/disclosure-code-il-70-delle-aziende-ha-gia-pubblicato-i-dati-ID2038.html; *Per Gsk trasparenza totale nei rapporti tra medici e azienda*, L'ARENA (July 2, 2016), http://www.larena.it/home/economia/per-gsk-trasparenza-totale-nei-rapportitra-medici-e-azienda-1.4976134.

[105] SENATO DELLA REPUBLICA, https://www.senato.it/home (last visited August 8, 2016).

[106] *Farmindustria, su codice trasparenza adesioni dei medici fino al 90%*, ABOUT PHARMA ONLINE (July 5, 2016), http://www.aboutpharma.com/blog/2016/07/05/farmindustria-codice-trasparenza-adesioni-dei-medici-al-90/.

[107] *See* D. JEFFREY CAMPBELL, ESQ. & BRIAN P. SHARKEY, ESQ., READY OR NOT, FULL SPEED AHEAD FOR THE GLOBAL TRANSPARENCY MOVEMENT 25–27 (2015); CAMPBELL & SHARKEY, DO START BELIEVIN': THE LIFE SCIENCES INDUSTRY'S JOURNEY TO GLOBAL TRANSPARENCY 45–50 (2014); CAMPBELL &. SHARKEY, THE ONGOING GLOBAL TRANSFORMATION IN LIFE SCIENCES TRANSPARENCY 12–14 (2013); CAMPBELL & SHARKEY, THE TREND

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pharmaceutical industry group first reported in 2013 on 2012 data via a central register. Moreover, while there are similarities in what must be reported under the Netherlands and EFPIA schemes, there are also key differences. Significantly, in the Netherlands there is a €500 threshold for reporting and companies need not obtain HCP consent. In April 2016, the Dutch register announced that over €51 million was reported for 2015 data, reflecting 14,000 relationships with covered recipients.[108] Significantly, the 2015 data included, for the first time, payments made to patient organizations, as well as TOV data from specific types of medical device companies, which we further discuss *infra*.

Norway

The EFPIA member in Norway, The Association of the Pharmaceutical Industry in Norway – LMI ("LMI"), sought to engage stakeholders in its transparency efforts by releasing in advance of the first reporting deadline informational brochures and videos about the reporting requirements.[109] After the deadline, LMI created a page on its website with links to the TOV reports of its members.[110] As to the data revealed by the reports, LMI did not release any specific numbers or data, but several local articles discussed those subjects. For example, a medical publication featured an article authored by GlaxoSmithKline's ("GSK") Head of Department for Public Affairs and Health Economics. In addition to discussing the transparency

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TOWARDS GLOBAL TRANSPARENCY: A CHALLENGING NEW WORLD FOR THE LIFE SCIENCES INDUSTRY 32–34 (2012).

[108] *Transparantieregister Zorg 2015*, STICHTING TRANSPARANTIEREGISTERZORG (Apr. 25, 2016), *http*://www.transparantieregister.nl/nl-NL/Nieuwsberichten/2016/Transparantieregister-Zorg-2015.

[109] *Offentliggjøring av verdioverføringer*, LMI (Dec. 16, 2014), http://www.lmi.no/fokus/offentliggjoering-av-verdioverfoeringer.

[110] *Offentliggjøring av verdioverføringer*, LMI (June 30, 2016) http://www.lmi.no/aktuelt-fra-lmi/2016/06/offentliggjoering-av-verdioverfoeringer.

initiative generally, the author discussed the specific amounts that GSK spent on HCPs, the majority of which was for clinical research.[111]

Other Norwegian press articles further fleshed out details of the reported TOV.[112] According to the articles, LMI member companies paid approximately 140-146 million Kronor for 2015, of which 87 million was for R&D, and approximately 66% of HCPs consented to disclosure. In addition, some articles focused on the largest companies in Norway by sales and the data that they reported, as well as whether they planned to only work with HCPs who consented to individual-level disclosure in the future. Others focused on the Norwegian medical associations and whether they would take a stronger stand in support of consenting to individual-level reporting for next year's reports. The articles also included quotes from the CEO of LMI, who was pleased with the first round of disclosures and expressed hope that more HCPs would consent in the future. As to the consent rate, several stakeholders suggested that it was a bit low because it was a new experience and that, from a cultural perspective, publicly discussing wages was historically a taboo topic.[113] Lastly, one article examined the data reported by companies in Norway and found that of the one hundred highest paid HCPs, only nineteen were women.[114]

Poland

In Poland, the consent rate was far lower than in Norway and many other countries, as only 22% of Polish HCPs consented to individual-level disclosure. This low consent rate

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111 Line Storesund Rondan, *Åpenhet om samarbeid mellom leger og legemiddelindustri*, DAGENS MEDISIN (June 30, 2016), http://www.dagensmedisin.no/artikler/2016/06/30/apenhet-mellom-samarbeid-om-leger-og-legemiddelindustri/.

112 Målfrid Bordvik and Øyvind Bosnes Engen, *Se hvem som fikk honorarer i fjor*, DAGENS MEDISIN (August 11, 2016), http://www.dagensmedisin.no/artikler/2016/08/11/sok-i-listen-over-utbetalinger/; Målfrid Bordvik, *Dette skal ikke være mystisk* (July 6, 2016), http://www.dagensmedisin.no/artikler/2016/07/11/-det-skal-ikke-vare-mystisk/; Målfrid Bordvik and Øyvind Bosnes Engen, *En av tre leger nektet offentliggjøring*, DAGENS MEDISIN (July 6, 2016), http://www.dagensmedisin.no/artikler/2016/07/06/en-av-tre-leger-nektet-offentliggjoring-av-honorar/; Øyvind Bosnes Engen and Målfrid Bordvik, *Industrien utbetalte 140 millioner*, DAGENS MEDISIN (July 5, 2016), http://www.dagensmedisin.no/artikler/2016/07/05/sa-mye-utbetalte-industrien/.

113 *Id*.

114 Målfrid Bordvik, *Naturlig at dette er offentlig*, DAGENS MEDISIN (Aug. 11, 2016), http://www.dagensmedisin.no/artikler/2016/08/11/-naturlig-at-dette-er-offentlig/.

resulted despite the efforts of the Polish EFPIA member, Infarma, to publicize the transparency initiative and build support for it among the HCP community. Among other things, Infarma created a website devoted to transparency, provided FAQs and other information and materials about the disclosure requirements, and conducted events explaining its initiative and touting its benefits.[115]

On July 1, 2016, Infarma held a press conference to discuss the TOV reports of its member companies. According to an accompanying press release, member companies reported approximately 623 million zloty[116] in overall spend, of which more than half was for R&D.[117] Approximately 128 million zloty was reported for HCO TOV and approximately 107 million zloty for TOV to HCPs. With respect to the types of benefits provided to HCPs, about 66 million zloty was for events and 41 million zloty for services. For HCOs, member companies reported spending approximately 18 million zloty for services, 58 million zloty for events, and 52 million zloty for grants and donations. Lastly, the average amount reported was approximately 32,000 zloty per HCO and 2,700 zloty per HCP.[118]

As to press coverage, most of the Polish press articles acknowledged that the consent rate was low, but they also tended to include explanatory and contextual statements from representatives of Infarma. As with other countries, some of the articles discussed the TOV data of the larger companies while others concentrated on the details of some HCP payments and the concerns that HCPs had about consenting to individual-level disclosure. Meanwhile, some

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115 KODEKS PRZEJRZYSTOŚCI, INFARMA, http://www.kodeksprzejrzystosci.pl/ (last visited August 3, 2016).

116 As of July 1, 2016, 1 Zloty equaled approximately 0.23 Euro. *Currency Converter*, OANDA https://www.oanda.com/currency/converter/ (last visited August 11, 2016).

117 Press Release, Infarma, *Code Transparency – transparent cooperation for the benefit of patients and the development of medicine* (July 1, 2016), http://www.infarma.pl/biuro-prasowe/aktualnosci-i-wydarzenia/kodeks-przejrzysto%C5%9Bci-transparentna-wspolpraca-dla-dobra-pacjentow-i-rozwoju-medycyny/.

118 *Id.*

coverage stressed that although the average reported fee was 2,700 zloty per HCP, the average fee for non-consenting HCPs was higher,[119] similar to the experience in the United Kingdom.

Russia

The Association of International Pharmaceutical Manufacturers ("AIPM") represents the pharmaceutical industry in Russia. During 2016, AIPM issued guidance about its disclosure requirements and created a page on its website devoted to the transparency initiative. On July 4, 2016, AIPM issued a press release that described the TOV initiative and its benefits, but it did not include any figures or numbers concerning the amount of TOV reported or consent rates.[120] The press release did, however, include a quote about the importance of transparency from Mr. Bergstrom of EFPIA, along with the following quote from the Executive Director of the Russian group:

> Due to the investments of the international industry in the Russian healthcare, inter alia, as part of cooperation with the medical community during R&D programs, professional development of doctors and other social projects, modern and highly effective medicines become available for the population of our country, even in the context of the current level of healthcare system financing. Moreover, an open and honest cooperation between the pharmaceutical industry and physicians is one of the crucial conditions for the progress in medicine, as well as an additional guarantee that the patient receives the required medical care. We hope that the initiative to improve transparency will be widely supported not

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[119] *Firmy ujawniają korzyści przekazywane lekarzom*, RYNEKAPTEK.PL (June 30, 2016), http://www.rynekaptek.pl/marketing-i-zarzadzanie/firmy-ujawniaja-korzysci-przekazywane-lekarzom,14717.html; *Ile firmy farmaceutyczne płacą lekarzom?*, GAZETA Z BIAŁEGOSTOKU (July 4, 2016), https://www.asib.pl/ludzie-i-zycie/firmy-farmaceutyczne-placa-lekarzom; Klara Klinger and Patrycja Otto, *Dwa tysiące od producenta leków*, GAZETAPRAWNA.PL (July 4, 2016), http://serwisy.gazetaprawna.pl/zdrowie/artykuly/957135,dwa-tysiace-od-producenta-lekow.html; *Lekarze dostają milliony złotych od firm farmaceutycznych*, Polska Newsweek (July 5, 2016), http://www.newsweek.pl/polska/lekarze-dostaja-miliony-od-firm-farmaceutycznych-szkolenia-etyka,artykuly,388530,1.html; *Podsumowanie pierwszego roku obowiązywania Kodeksu Przejrzystości*, FARMACJA.PL (July 1, 2016), https://farmacja.pl/aktualnosci/podsumowanie-pierwszego-roku-obowiazywania-kodeksu-przejrzystosci#; Judyta Watoła, *Lekarze nie chcą ujawniać, co dostają od firm farmaceutycznych*, WYBORCZA.PL (July 5, 2016), http://wyborcza.pl/1,75398,20350764,lekarze-nie-chca-ujawniac-co-dostaja-od-firm-farmaceutycznych.html?disableRedirects=true; Jolanta Gromadzka-Anzelewicz, *Koncerny ujawniają, ile i za co płacą lekarzom*, DZIENNIK BAŁTYCKI (June 29, 2016), http://www.polskatimes.pl/fakty/kraj/a/koncerny-ujawniaja-ile-i-za-co-placa-lekarzom,10346516/.

[120] Press Release, AIPM, *Международная фармацевтическая индустрия осуществила раскрытие информации о платежах в пользу специалистов и организаций здравоохранения* (July 4, 2016), http://www.aipm.org/news/2016/07/04/news_223.html.

only by the medical community, but also by other stakeholders, in particular by regulatory authorities and all the manufacturers[.][121]

With respect to press coverage of the Russian TOV initiative, local articles tended to generally discuss the reporting requirements, and some of the articles noted that not all of AIPM's member companies reported. According to one article, reporting companies spent 12 billion rubles,[122] of which more than 5 billion was for R&D. Similar to the press coverage in many other countries, the articles also discussed the companies that reported the largest TOV amounts.[123]

Spain

The Spanish reporting experience is significant not only in terms of their pre-disclosure efforts and the TOV data revealed by their member companies, but also because the Spanish EFPIA member, Farmaindustria, is making a major revision to its Code of Practice with respect to consent and individual-level reporting for HCPs. Before addressing that revision, it is first helpful to review the build-up to the first round of disclosures and the actual data from those reports. Prior to the reporting deadline, Farmaindustria hosted a number of media availabilities and PR sessions, which led to positive press coverage before the disclosure deadline.[124] A few

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121 *Id*.

122 As of July 1, 2016, 1 Ruble equaled 0.01 Euro. *Currency Converter*, OANDA https://www.oanda.com/currency/converter/ (last visited August 11, 2016).

123 *Pharmaceutical Industry Discloses Payments,* MOSKOVCKIE ANMEKU (July 5, 2016), http://mosapteki.ru/material/farmindustriya-osushhestvila-raskrytie-informacii-o-platezhax-7175; Елена Калиновская, *Novartis - крупнейший плательщик в пользу врачей и медорганизаций*, ФАОМАЦЕВТИЧЕСКИЙ ВЕСТНИК (July 5, 2016), http://www.pharmvestnik.ru/publs/lenta/v-rossii/novartis-samyj-krupnyj-plateljschik-v-poljzu-vrachej-i-medorganizatsij.html#.V3vefLsrIw; Анна Пореченская, *Далеко не все международные фармкомпании отчитались о своих тратах в России*, АМИ (July 5, 2016), http://riaami.ru/read/smi-daleko-ne-vse-mezhdunarodnye-farmkompanii-otchitalis-o-svoih-tratah-v-rossii.

124 *En Los Medios,* Farmaindustria, http://www.farmaindustria.es/web/en-los-medios/; Nuria Ramírez De Castro, *Farmaindustria multará a los laboratorios que no hagan públicos los pagos a médicos y organizaciones*, ABC (June 14, 2016), http://www.abc.es/sociedad/abci-farmaindustria-multara-laboratorios-no-hagan-publicos-pagos-medicos-y-organizaciones-201606142247_noticia.html; *Las farmacéuticas publicarán sus pagos a médicos y organizaciones sanitarias*, EL PERIÓDICO (June 14, 2016), http://www.elperiodico.com/es/noticias/sociedad/farmaceuticas-pagos-medicos-organizaciones-sanitarias-5205037; Alfonso Simón Ruiz, *Farmaindustria expulsará a los laboratorios que oculten pagos a médicos*, CINCO DÍAS (June ...Continued

key themes emerged from those articles and Farmaindustria's efforts to reach out to the public about its transparency initiative: 1) Farmaindustria emphasized that there can and will be sanctions for Code violations, the severity of which will depend on the nature of the violation; 2) the methodology note was an important document for companies to explain their TOV decisions; and 3) the pharmaceutical industry was taking the lead on transparency and making their interactions with HCPs open to the public, thereby inspiring the public's faith and confidence in such interactions.

After the reporting deadline passed, Farmaindustria issued a press release about the TOV reports of its members,[125] stating that members had reported TOV of: approximately €190 million for R&D; €119 million for HCPs to attend events; €66 million in support of scientific events through HCOs; fees/expenses to HCPs and HCOs in the amount of €88 million; and donations to HCOs in the amount of €33 million. Farmaindustria stressed the significant amount of money that industry invested in R&D and the importance of such work, and also emphasized that industry was committed to improving patient care, as evidenced not just by its R&D investments but also by the amount it spent on scientific and clinical education at events. In its press release, Farmaindustria also explained why industry spends money on other activities and attempted to place the amount spent in the larger context of how industry-HCP collaboration benefits society.[126] In addition to the press release, Farmaindustria created a page on its website

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14, 2016), http://cincodias.com/cincodias/2016/06/14/empresas/1465905983_923756.html; Laura Tardón, *Las farmacéuticas ponen en marcha una iniciativa de transparencia*, EL MUNDO (June 15, 2016), http://www.elmundo.es/salud/2016/06/15/576017f5ca47416b608b45e7.html; Alberto Vigario, Los laboratorios que oculten los pagos a médicos serán expulsados del sector, ELECONOMISTA.ES (June 15, 2016), http://www.eleconomista.es/sanidad/noticias/7637328/06/16/Los-laboratorios-que-oculten-los-pagos-a-medicos-seran-expulsados-del-sector.html#.

[125] Press Release, Farmaindustria, *I + D y actividades científico-profesionales, bases de las relaciones entre industria farmacéutica y organizaciones y profesionales sanitarios* (July 1, 2016), http://www.farmaindustria.es/web/prensa/notas-de-prensa/2016/07/01/4956/.

[126] *Id*.

devoted to transparency, at which it extols the virtues of transparency and provides materials and information about the transparency initiative.[127]

There were several local press articles about the TOV of Spanish companies.[128] Most of the coverage was largely objective and included the information provided by Farmaindustria's analysis of the data. Some articles focused on the larger companies and the TOV data that they reported, while others noted that the TOV data reported represented 3.75% of the sales of the reporting companies.

However, perhaps the biggest development for the Spanish reporting experience, and one that could have a broad impact across all of the EFPIA countries, concerns Farmaindustria's May 2016 announcement that it had approved changes to its Code of Practice that seemingly require individual level reporting for all TOV, except for R&D, beginning with 2018 reports covering 2017 data.[129] In making its announcement, Farmaindustria stated that it will amend its Code of Practice so that it will provide that member companies will inform HCPs that TOV made from

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[127] *Transparencia*, FARMAINDUSTRIA, http://www.farmaindustria.es/transparencia/ (last visited August 8, 2016).

[128] *Difunden en España las sumas millonarias que pagan los laboratorios farmacéuticos a médicos*, MIRADA PROFESIONAL.COM (July 1, 2016), http://miradaprofesional.com/ampliarpagina.php?id=1764&npag=3*; Editorial: El valor de la transparencia*, EL GLOBAL.NET (July 1, 2016), http://www.elglobal.net/noticias-medicamento/2016-07-01/editorial-opinion/el-valor-de-la-transparencia/pagina-opinion.aspx?idart=989831; *El código de Farmaindustria y la presión de los laboratorios*, REDACCIÓN MÉDICA (July 3, 2016), http://www.redaccionmedica.com/opinion/el-codigo-de-farmaindustria-y-la-presion-de-los-laboratorios-4389; *Farmaindustria reviews R&D and scientific-professionals activities*, THE PHARMA LETTER (July 4, 2016), http://www.thepharmaletter.com/article/farmaindustria-reviews-r-d-and-scientific-professional-activities; *I + D actividades científico-profesionales, bases de las relaciones entre industria farmacéutica y organizaciones y profesionales sanitarios*, DISCAPNET (July 5, 2016), http://www.discapnet.es/Castellano/actualidad/Noticias_Actualidad/id-activ-cientif-prof-relac-ind-farmac-org-profesionales-sanitarios.aspx; *La industria transfiere el 3,75% de sus ventas a profesionales y entidades*, DIARIOFARMA (July 1, 2016), http://www.diariofarma.com/2016/07/01/la-industria-transfiere-el-375-de-sus-ventas-a-profesionales-y-entidades?id=26950; *Los pagos de la industria a sanitarios y organizaciones suman 496 millones*, REDACCIÓN MÉDICA (July 1, 2016), http://www.redaccionmedica.com/secciones/industria/los-pagos-de-la-industria-a-sanitarios-y-organizaciones-suman-496-millones-6962.

[129] Press Release, Farmaindustria, *Farmaindustria refuerza su compromiso con la transparencia aprobando la publicación individualizada de las transferencias de valor a profesionales sanitarios* (May 26, 2016), http://www.farmaindustria.es/web/prensa/notas-de-prensa/2016/05/26/farmaindustria-refuerza-su-compromiso-con-la-transparencia-aprobando-la-publicacion-individualizada-de-las-transferencias-de-valor-a-profesionales-sanitarios/.

January 1, 2017 (to be disclosed in 2018) will be disclosed at the individual level. In doing so, Farmaindustria is moving away from the EFPIA "HCP consent to individual disclosure and if not aggregate" approach.

The evolution of the Spanish approach is based on a decision released by the Spanish Data Protection Agency ("SDPA") that found that the legitimacy of disclosure on an individual basis is supported by the current EU and Spanish data protection framework, such that it will only be necessary for companies to inform HCPs that the payments they receive will be disclosed at the individual level rather than asking HCPs to consent, so long as reporting companies take certain steps concerning protection of the privacy of HCPs. As to the SDPA's opinion, Farmaindustria observed that "[t]he report from the Spanish Data Protection Agency has therefore changed the paradigm, and makes it easier for the sector to undertake the necessary changes to fulfill the maximum aspiration of this initiative: the individualization of all data."[130] Accordingly, Farmaindustria declared that its new approach is "a pioneering step without precedents," and that the amendment to the Code further demonstrated that industry was committed to increasing transparency and improving its disclosure initiative.[131]

It will be interesting to see if other national industry groups follow the Spanish group's pioneering step and request authorization from the governing data protection authorities to no longer seek consent from HCPs for individual-level disclosure. It certainly seems that doing so would be an excellent way for national industry groups to demonstrate to their governments that they are strongly committed to the disclosure initiative and are seeking ways to be even more transparent.

130 *Id.*
131 *Id.*

Sweden

The Swedish EFPIA member, Läkemedelsindustriföreningen ("LIF"), created a web portal that includes all of its member companies' reports.[132] According to initial information released by LIF,[133] it estimated that its members reported TOV in the amount of approximately 750 million Kronor[134] for 2015, with the "overwhelming majority" being compensation for clinical research. In discussing those figures, LIF stressed the importance of collaboration and transparency and emphasized the important role that R&D plays, especially as companies are confronting a number of health challenges in Europe, including a growing number of elderly patients and a changing disease panorama. Subsequently, LIF clarified that its members reported TOV in the amount of approximately 800 million Kronor, of which 625 million was for R&D.[135]

Switzerland

In Switzerland, the local EFPIA member, scienceindustries, worked with HCPs, HCOs, and representative organizations of the medical profession to explain the benefits of transparency, raise awareness among stakeholders, and garner their support for disclosure at the individual level. Prior to the disclosures of its members, scienceindustries issued a press release discussing the transparency initiative and noting that the companies that would be reporting represented approximately 80% of the market.[136] After the reports were issued, scienceindustries

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132 *Disclosure*, LIF, http://www.lif.se/etik/samarbetsdatabaser/?type=Disclosure (last visited August 8, 2016).

133 Press Release, LIF, *Webbportal för rapportering av ersättningar till hälso- och sjukvården igång* (May 31, 2016), http://www.life-time.se/vardkvalitet/webbportal-for-rapportering-av-ersattningar-till-halso--och-sjukvarden-igang/.

134 As of July 1, 2016, 1 Kronor equaled 0.11 Euro. *Currency Converter*, OANDA https://www.oanda.com/currency/converter/ (last visited August 11, 2016).

135 Press Release, LIF, *Forskande läkemedelsföretag satsar 800 milj i samarbeten med vården* (July 1, 2016), http://www.lif.se/nyheter/forskande-lakemedelsforetag-satsar-800-milj-i-samarbeten-med-varden/.

136 Press Release, scienceindustries, *Bewährte Zusammenarbeit zwischen Pharmaunternehmen und Gesundheitsversorgern wird transparenter* (June 16, 2016), https://www.scienceindustries.ch/medien/archiv/_detail-343/46737%252Fbewaehrte-zusammenarbeit-zwischen-pharmaunternehmen-und-gesundheitsversorgern-wird-transparenter.

confirmed that over 50 companies, representing approximately 80% of the market, had reported.[137]

However, the local press expressed skepticism about the disclosure reports even before they became public, specifically over the ability of HCPs to block individual-level disclosure and the potential difficulties associated with searching for the reports of member companies on their websites rather than at a central registry.[138] Similarly, the post-reporting coverage was somewhat negative. For example, *Le Temps* had an article[139] that focused on the limited transparency that was provided by the TOV reports of the companies reporting in Switzerland. The article took the position that those interested in truly understanding the financial relationship between industry and HCPs would be disappointed because the data is often "hidden" on company websites, and also because even when there is individual-level disclosure the reports do not provide any details about the nature and extent of the relationship between a company and the HCP. The article also criticized the recipients who did not consent to individual-level disclosure.[140] Another article contrasted the reported data in Switzerland with that from Germany and Austria.[141] Unlike the latter two countries, where a significant percentage of the overall reported spend was for R&D, according to the article only one-third of the Swiss TOV

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137 TRANSPARENCY INITIATIVE: DATA ON COLLABORATION BETWEEN PHARMA COMPANIES AND HEALTHCARE PROVIDERS PUBLISHED FOR THE FIRST TIME (Scienceindustries, Zürich, Switzerland) (2016).

138 Felix Straumann, *Halbherzige Transparenz bei den Pharmageldern für Ärzte*, BASLER ZEITUNG (June 24, 2016), http://bazonline.ch/wetter/allgemeinelage/halbherzige-transparenz/story/23394136; *Pharmafirmen geben 100 Millionen Euro für Forschung, Fortbildung und Ärzte aus*, WIRTSCHAFTS BLATT (June 22, 2016), http://wirtschaftsblatt.at/home/nachrichten/oesterreich/5032274/Pharmafirmen-geben-100-Millionen-Euro-fur-Forschung-Fortbildung.

139 Willy Boder, *Transparence limitée entre pharmas et médecins*, LE TEMPS (June 29, 2016), https://www.letemps.ch/economie/2016/06/29/transparence-limitee-entre-pharmas-medecins.

140 *Id.*

141 *125 Millionen Euro für Schweizer Ärzte und Organisationen*, DAZ.ONLINE (July 8, 2016), https://www.deutsche-apotheker-zeitung.de/news/artikel/2016/07/08/125-millionen-euro-fur-schweizer-arzte-und-organisationen.

was for R&D. This article also stated that companies reported spending a greater amount on HCOs than HCPs.[142]

Lastly, an article that appeared on the website of Porträt Schweizer Radio und Fernsehen examined the data disclosed by the 55 companies that reported in Switzerland.[143] According to the article, the total amount reported was approximately 140 million Swiss francs, and the consent rate was 72%. 17 of the 55 reporting companies did not include any payments in the aggregate (other than R&D) and only reported at the individual level. The average amount paid to HCPs was 1,350 francs, with the largest payment of 73,643 francs and the smallest being 12 francs. The average payment to HCOs was 14,515 francs.[144]

Cyprus

Many of the other EFPIA national member associations had similar experiences to those outlined above. For example, in Cyprus the local industry group: 1) conducted a working breakfast with journalists about the transparency initiative; 2) highlighted the support of the Cyprus Medical Association for the initiative; and 3) created a page on its website where it provides links to the TOV reports of its members.[145]

Estonia

In Estonia, the industry group issued a press release that touted the first round of disclosures of its members, but it did not include specific data elements or amounts of TOV reported.[146] However, the press release included several supportive statements from stakeholders

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142 *Id.*

143 S. Brüggemann, A. Bünter, P. Düblin, T. Grossenbacher & J. Schmidli, F. Schwander, *So viel pumpt die Pharma in die Gesundheitsbranche*, SRF (Aug. 4, 2016), http://www.srf.ch/news/schweiz/so-viel-pumpt-die-pharma-in-die-gesundheitsbranche.

144 *Id.*

145 *Disclosure – Responsible Transparency*, KEFEA http://kefea.org.cy/responsible-transparency/disclosure/ (last visited August 11, 2016).

146 ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS IN ESTONIA, http://rtl.ee/en/ (last visited Aug. 8 2016).

about the importance of collaboration between industry and HCPs and the benefits and value of transparency.

Czech Republic

Meanwhile, in the Czech Republic the local EFPIA member developed a central database for the reports of its member companies.[147] That database can be searched by HCP, HCO, or pharmaceutical company. The Czech industry group also provides on its website a host of resources and materials about its transparency initiative, which it emphasizes is supported by both the public and the local chapter of Transparency International.[148]

Hungary

In Hungary, the local EFPIA member created a website specifically focused on the transparency initiative.[149] However, the local press coverage of the initiative largely focused on the low consent rate from HCPs for individual-level disclosure.[150]

Slovenia

On June 7, 2016, the Slovenian EFPIA member hosted a breakfast for media representatives that featured speakers from industry, patients, and doctors' groups focusing on the positive impact of the pharmaceutical industry and how and why industry works with HCPs. Along those lines, the President of the Slovenian group acknowledged that this cooperation is often the subject of speculation and misinterpretations, so it was important to demonstrate the value and appropriateness of industry's work with HCPs. Similarly, a representative of the

147 Transparentní spolupráce, AIFP, http://www.aifp.cz/cs/eticke-jednani/transparentni-spoluprace/#/ (last visited August 5, 2016).

148 Farmaceutické společnosti investují do vzdělávání lékařů, AIFP, http://www.aifp.cz/cs/aktuality/informace-pro-media/farmaceuticke-spolecnosti-investuji-do-vzdelavani-lekaru/ (last visited August 5, 2016).

149 *Transzparencia-etika*, AIPM, http://igy.hu/hu/transzparencia-etika (last visited August 5, 2016).

150 Haiman Éva, *TITKOLJÁK A TÁMOGATÁSOKAT AZ ORVOSOK*, MAGYAR IDŐK (July 3, 2016), http://magyaridok.hu/belfold/titkoljak-tamogatasokat-az-orvosok-800029/; *Ilyen a gyógyszeripari transzparencia*, WEBORVOS (July 1, 2016), http://www.weborvos.hu/lapszemle/ilyen_a_gyogyszeripari_transzparencia/232321/; *Titkolják a támogatásokat az orvosok*, WEBORVOS (July 4, 2016), http://www.weborvos.hu/lapszemle/titkoljak a_tamogatasokat_az_orvosok/232372/.

Medical Chamber of Slovenia highlighted the significant role that the pharmaceutical industry plays in educating HCPs and stressed the importance of ensuring that such relationships are transparent.[151] The Slovenian industry group also issued a press release to announce that the local chapter of Transparency International supported its initiative.[152]

When the TOV reports were made public, local press articles estimated that the total amount of spend reported was somewhere in the range of €5 to €10 million and that the consent rate was 36%. Some of the articles were skeptical about the purposes of the payments and suggested that pharmaceutical companies make TOV to HCPs with the expectation that they will receive something in return. Other articles focused on some of the larger reporting companies, and some criticized the way in which companies reported the data.[153]

Ukraine, Lithuania, Latvia, Croatia, Slovakia

Several other EFPIA national member associations have pages on their websites where the reports of their member companies or links thereto can be found. These include the groups in the Ukraine,[154] Lithuania,[155] Latvia,[156] and Slovakia.[157] The Lithuanian EFPIA member,

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151 Press Release, Mednarodni forum znanstvenoraziskovalnih farmacevtskih družb, *Vpliv sodelovanja zdravstvenih delavcev s farmacevtsko industrijo na stroko, posameznika in družbo* (June 9, 2016), http://www.firdpc.com/sl/Dogodki_in_novice/8._infozajtrk_za_medije/.

152 Press Release, Transparency International Slovenia, *OBJAVE FINANČNIH TRANSAKCIJ FARMACEVTSKIH DRUŽB KORAK V PRAVO SMER* (June 30, 2016), http://www.transparency.si/8-novice/259-objave-financnih-transakcij-farmacevtskih-druzb-korak-v-pravo-smer.

153 Sergeja Hadner, *Kam gredo donacije farmacevtskih družb?*, ZURNAL24.SI (July 14, 2016), http://www.zurnal24.si/kam-gredo-donacije-farmacevtskih-druzb-clanek-274238; Andreja Rednak, *Razkrivamo milijonska plačila farmacije zdravniškim društvom - kdo je dobil največ*, FINANCE.SI (July 5, 2016), http://www.finance.si/8846947/Razkrivamo-milijonska-placila-farmacije-zdravniskim-drustvom-kdo-je-dobil-najvec?metered=yes&sid=469775816; Andreja Rednak, *Več korupcije, bolj zdravniki skrivajo plačila farmacevtov? Pri nas dve tretjini skrivačev*, FINANCE.SI (July 18, 2016), http://www.finance.si/8847369/Vec-korupcije-bolj-zdravniki-skrivajo-placila-farmacevtov-Pri-nas-dve-tretjini-skrivacev?metered=yes&sid=469775816; *Slovenski liječnici dobili 5 mil. eura od farmaceutskih tvrtki*, POSLOVNI DNEVNIK (July 6, 2016), http://www.poslovni.hr/svijet-i-regija/slovenski-lijecnici-dobili-5-mil-eura-od-farmaceutskih-tvrtki-315104.

154 *Disclosures*, *APRaD*, http://aprad.org.ua/category/rozkrittya-informatsiy/ (last visited August 5, 2016).

155 Ifpa and VGA, http://www.vaistukodeksas.lt/sps-spo-informacijos-atskleidimo-kodeksas/atskleidimo-kodekso-ataskaitos/ (last visited August 5, 2016).

156 *Atklātības kodekss*, Starptautisko inovativo farmaceitisko firmu asociacija ("SiffA"), http://www.siffa.lv/section/show/212 (last visited August 5, 2016).

Innovative Pharmaceutical Industry Association ("IFPA"), issued a press release in which it stated that approximately 40 companies had reported under its disclosure requirements.[158] The total amount of TOV reported was €9.5 million, with the largest amount, approximately €4 million, spent on R&D. IFPA also highlighted that its members had a 70% consent rate for individual-level reporting. The attendant press coverage discussed those figures, as well as supportive statements from the Lithuanian Health Minister, who welcomed the transparency initiative but also suggested that legislation in this area might be appropriate in the future.[159]

The Latvian EFPIA member issued a press release praising the first round of disclosures from its members.[160] Although the press release did not identify total amounts reported or the consent rate, it did note that the vast majority of HCPs consented to individual-level disclosure. However, some local press coverage pointed out that the consent requirement for HCPs inherently limited the universe of HCPs who would be reported on and that companies took different approaches to a host of reporting issues.[161] According to press reports, the consent rate

…Continued

[157] *Zverejnovanie EFPIA DC*, Asociácia Inovatívneho Farmaceutického Priemyslu ("AIFP"), http://www.aifp.sk/sk/etika-transparentna-spolupraca-zverejnovanie-efpia-dc/ (last visited August 5, 2016).

[158] Press Release, IFPA *Farmacijos pramonė atskleidė investicijas į sveikatos priežiūrą*, http://ifpa.lt/naujienos/farmacijos-pramone-atskleide-investicijas-i-sveikatos-prieziura/.

[159] *Farmacijos pramonė atskleidė investicijas į sveikatos priežiūrą*, SKRASTAS.LT (July 5, 2016), http://bmsdbjm.m.skrastas.lt/?data=2016-07-05&rub=1065924810&id=1467649661; *Farmacijos pramonė atskleidė investicijas į sveikatos priežiūrą*, VERSLO ZINIOS (July 4, 2016), http://vz.lt/verslo-aplinka/2016/07/04/farmacijos-pramone-atskleide-investicijas-i-sveikatos-prieziura; *Farmacijos pramonė atskleidė investicijas į sveikatos priežiūrą*, LSVEIKATA.LT (July 4, 2016), http://lsveikata.lt/budinti-vaistine/farmacijos-pramone-atskleide-investicijas-i-sveikatos-prieziura-5182; *Farmacijos pramonė atskleis investicijas į sveikatos priežiūrą*, SKRASTAS.LT (June 28, 2016), http://skrastas.lt/?data=2016-06-28&rub=1065924810&id=1466688601; *Farmacijos pramonė atskleis investicijas į sveikatos priežiūrą*, RESPUBLIKA (June 23, 2016), http://www.respublika.lt/lt/naujienos/lietuva/verslas/farmacijos_pramone_atskleis_investicijas_i_sveikatos_prieziura/.

[160] Press Release, SIFFA, *Solis uz vēl lielāku atklātību zāļu ražotāju sadarbībā ar veselības aprūpes organizācijām un profesionāļiem* (June 30, 2016), http://www.siffa.lv/resource/show/6010.

[161] *See e.g.*, *Ārstu atbalstam – simti tūkstošu farmācijas naudas, pirmo reizi atklāj uzņēmumi*, LA.LV (July 14, 2016), http://www.la.lv/arstu-atbalstam-simti-tukstosu-farmacijas-naudas/.

in Croatia was 11% and companies reported approximately €14 million of TOV.[162] Finally, the Slovakian industry announced that the total amount reported by its members was €26.4 million with the largest share, €17.5 million, spent on R&D.[163]

Luxembourg & Iceland

Although the pharmaceutical industry groups in Luxembourg and Iceland are not members of EFPIA, both groups adopted the provisions of the EFPIA Disclosure Code and undertook similar efforts as local EFPIA members to publicize the transparency initiative. Further, both groups have pages on their websites containing the reports of their member companies.[164] Moreover, the Icelandic group, Frumtok, issued a press release in which it announced that 16 companies published reports.[165] The total amount of reported spend was 139 million Icelandic krona,[166] of which 96 million was for R&D.

MedTech Europe

While EFPIA and the European innovative pharmaceutical industry took an aggressive, proactive approach to transparency, the European medical device industry chose a different path. MedTech Europe represents the medical device industry in Europe. In fact, it is an alliance of associations. Founded in October 2012, MedTech Europe has two members: European Diagnostic Manufacturer Association ("EDMA"), which represents the European in vitro

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[162] Andreja Rednak, *Farmacevtska industrija lani v Sloveniji »donirala« več kot 10 milijonov evrov*, Fianance.si (July 18, 2016), http://www.finance.si/8847369/Vec-korupcije-bolj-zdravniki-skrivajo-placila-farmacevtov-Pri-nas-dve-tretjini-skrivacev?cctest&metered=yes&sid=469775816.

[163] Press Release, Asociácia Inovatívneho Farmaceutického Priemyslu ("AIFP"), *INOVATÍVNE FARMACEUTICKÉ FIRMY PODPORUJÚ VÝSKUM AJ VZDELÁVANIE* (June 20, 2016), http://www.aifp.sk/sk/novinky-tlacove-spravy/9/inovativne-farmaceuticke-firmy-podporuju-vyskum-aj-vzdelavanie/.

[164] *Transparence*, APL, http://www.apl-pharma.lu/transparence.htm (last visited August 8, 2016); *Birtingu Upplýsinga*, Frumtok, http://www.frumtok.is/sidareglur/dc (last visited August 8, 2016).

[165] Press Release, Frumtök, *LYFJAFYRIRTÆKI BIRTA UPPLÝSINGAR UM SAMSKIPTI SÍN VIÐ EINSTAKLINGA OG STOFNANIR Í HEILBRIGÐISGEIRANUM* (June 29, 2016), http://www.frumtok.is/frettir-og-greinar/lesa-meira/lyfjafyrirtaeki-birta-upplysingar-um-samskipti-sin-vid-einstaklinga-og-stofnanir-i-heilbrigdisgeiranum.

[166] As of July 1, 2016, 1 Icelandic Krona equaled 0.01 Euro. *Currency Converter*, OANDA https://www.oanda.com/currency/converter/ (last visited August 11, 2016).

diagnostic industry, and Eucomed, which represents the medical device industry in Europe. The mission of MedTech Europe is "to make innovative medical technology available to more people, while helping healthcare systems move towards a sustainable path."[167]

On December 2, 2015, MedTech Europe approved a new Code of Ethical Business Practices and issued a guidance document on the Code.[168] Part 2 of the Code, The Dispute Resolution Principles, entered into force on January 1, 2016. The remainder of the Code, namely, the Introduction, Part 1, and Part 3, enter into force on January 1, 2017.

Most significantly, the Code does not impose EFPIA-like transparency reporting requirements. Instead, the Code prohibits, as of January 1, 2018, member companies from providing financial or in kind support directly to individual HCPs to cover costs of their attendance at third party organized educational events (except for third party organized procedure training meetings or pursuant to a consulting agreement with a HCP speaker engaged by the company to speak at a satellite symposium).[169]

Although it has chosen to not impose reporting requirements, the MedTech Europe Code does express support for transparency as a general principle. Further, the Code also includes specific transparency sections in certain of its Chapters. For example, the Chapter on Events has a "Transparency" section that provides:

> Member Companies must ensure full compliance with national laws with regard to the disclosure or approval requirements associated with such financial support and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, as a minimum, by requiring Employer Notification (as defined in the Glossary) is made prior to the Event.[170]

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167 *About us*, MEDTECH EUROPE, http://www.medtecheurope.org/about-us (last visited August 5, 2016).

168 MEDTECH EUROPE, GUIDANCE DOCUMENT: QUESTIONS AND ANSWERS (Q&AS) ON THE MEDTECH EUROPE CODE OF ETHICAL BUSINESS PRACTICES (2015).

169 MEDTECH EUROPE, CODE OF ETHICAL BUSINESS PRACTICE (2015).

170 *Id*.

Similarly, in the Chapter focused on Consultant Arrangements, the "Disclosure and Transparency" section provides:

> Member Companies shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with the use by Member Companies of Healthcare Professionals as consultants. All required consents and approval shall be obtained, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable. Where no such national requirements apply, Member Companies shall nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement.[171]

The Guidance Document[172] explains that if there is a national requirement that addresses notification, companies simply must comply with that requirement and are not required to submit an additional notification under the Code. Moreover, the Guidance Document clarifies that, unless required by national law or regulation, when companies provide notification to an employer, companies are not required to provide details of the financial amounts involved in the interaction with the HCP. Finally, the Code suggests that Educational Grants should be publicly disclosed but does not provide any details about such a disclosure.

On its website, MedTech Europe has one section devoted to "Transparency" and another to "Transparent and Ethical Relationships." In the "Transparency" section, MedTech Europe explains that

> [u]nder the new MedTech Europe Code of Ethical Business Practice, as of 1st January 2018, member companies are no longer permitted to pay registration fees, travel and/or hospitality expenses directly to individual Healthcare Professional for their participation at third-party organised educational events.
>
> Medical education will be supported through the provision of educational grants to Healthcare Organisations or other types of funding in compliance with the rules set out in the new Code. To increase transparency of the funds allocated to

171 *Id.*

172 MEDTECH EUROPE, GUIDANCE DOCUMENT: QUESTIONS AND ANSWERS (Q&AS) ON THE MEDTECH EUROPE CODE OF ETHICAL BUSINESS PRACTICES (2015).

> medical education, member companies will document and disclose all payments related to educational grants made to a Healthcare Organisation based or registered in Europe, without limitation of value. In accordance with the Disclosure Guidelines, grants will be publicly disclosed (as from 2017) on an annual basis, on the Ethical MedTech website.[173]

In the "Transparent and Ethical Relationships" section of its website, MedTech Europe observes that

> HCPs play a key role in research and development, and are a source of innovation and creativity during the development of medical technologies.
>
> HCPs are also prime users of technologies and play an instrumental role in the successful adoption of innovative medical technologies throughout Europe and beyond. Medtech companies are required to provide HCPs with appropriate instruction, education, training, service and technical support to ensure delivery of modern, safe and effective medical technology and care to patients.
>
> This collaboration provides great opportunities for the development of life-saving technologies. It also puts great responsibility on all stakeholders to ensure that all partnerships are ethical and professional at all times, and beyond criticism to maintain the trust of regulatory, and – most important of all – patients. MedTech Europe is committed to promote legitimate and ethical business practices, encouraging responsible and ethical interactions with HCPs and HCOs.[174]

Although medical device companies do not face the same European-wide, industry code-based transparency reporting obligation as do their pharmaceutical counterparts under the EFPIA Disclosure Code, there are a few countries in which the local industry groups have chosen to adopt reporting requirements. For example, in the Netherlands, certain members of the Dutch Foundation for Medical Technology Companies ("GMH") have an obligation to report the same type of information as their pharmaceutical counterparts.[175] Those certain members of GMH were required – for the first time – to report their 2015 data in 2016 to the Dutch Healthcare Transparency Register.

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[173] *Transparency*, MEDTECH EUROPE, http://www.medtecheurope.org/industry-themes/topic/99 (last visited August 5, 2016).

[174] *Transparent and Ethical Relationships*, MEDTECH EUROPE, http://www.medtecheurope.org/industry-themes/topic/92 (last visited August 5, 2016).

[175] GMH, CODE OF CONDUCT MEDICAL DEVICES (2015).

In terms of which GMH member companies had the reporting obligation, interactions are only reportable under GMH's Code of Conduct if they occur between:

1) Doctors entered in the Dutch Register under the category "cardiology" or "orthopaedics" (including any collaboration involving these doctors, or, in the event that the interactions take place via the institutions at which these doctors are employed or participating) and
2) Companies, to the extent that the devices they supply can be classified as "implants." Specifically, an "implant" is defined as: "a medical device designed to be implanted, fully or partially, in the human body by an operative or medical method or in a natural opening by a medical intervention and intended to remain in the body following the procedure." The devices concerned are ICDs, pacemakers, stents, and hip and knee prostheses.[176]

The GMH is currently evaluating the first reporting experience of its members that occurred earlier this year and will determine whether the scope of the reporting obligation should be extended to more member companies in the future.

In its most recent code, beMedTech, the medical device industry group in Belgium, adopted the same transparency reporting requirements that apply to the members of the Belgian pharmaceutical industry group. The only difference is that while the pharmaceutical industry reported for the first time in 2016 on 2015 data, members of beMedTech will be reporting for the first time in 2017 on 2016 data.[177] Members of beMedTech will use the same reporting template as members of pharma.be and will submit their reports to the same central disclosure platform, www.betransparent.be.

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176 *Id.*

177 *About the transparency register*, BETRANSPARENT.BE, https://www.betransparent.be/en/about-the-transparency-register/ (last visited August 5, 2016).

There is another important point to make about the transparency movement in Belgium. Like the members of beMedTech, the members of FeBeGen, the Belgian industry group for generic drugs and biosimilar companies, will also be reporting, for the first time, their 2016 TOV in 2017 via www.betransparent.be.

Medicines for Europe

In that regard, FeBeGen is further along the path to transparency than the Europe generic medicines group, which is following a journey similar to EFPIA. Medicines for Europe, formerly known as the European Generic Medicines Association, is the official trade association for the European generic, biosimilar, and value-added pharmaceutical industries. In December 2015, it amended its Code of Conduct on Interactions with the Healthcare Community to include disclosure requirements for transfers of value to HCPs, HCOs, and Patient Organisations.[178] Under this Code, data collection begins in 2017, with first reports being due in 2018.

The disclosure requirements define a transfer of value as anything of value that is transferred by a member company (directly or indirectly via a third party acting at the member company's direction) to a recipient, including monetary payments or in-kind benefits, such as meals, travel, hospitality, gifts, etc. It is significant to note that meals are included in this definition. The inclusion of meals differs from the EFPIA Disclosure Code, though there are instances, outlined below, in which meals are excluded from a specific reporting obligation.

The Code requires member companies to disclose, on an individual basis, the following types of transfers of value:

1) Transfers of Value to Patient Organisations:

- Support – financial and in-kind support;

[178] MEDICINES FOR EUROPE, CODE OF CONDUCT (2015).

- Fee for services – contracted services per Patient Organisation, including a description of the nature of the transfer of value (e.g., educational summer camp; disease awareness world day; development of information brochures for an awareness campaign) and the amount provided.

2) Transfers of Value to HCPs:

- Fees for service and consultancy – aggregated honoraria (excluding expenses for meals and drinks, travel and accommodation) paid to a HCP for the provision of services, such as serving on an advisory board, speaking at a company-organised educational event, participating in a focus group, etc. Fees paid in connection with R&D activities or market research are excluded from disclosure.
- Meetings, educational support and site visits: Companies have two options for how to report such transfers of value:
  - **Option 1** - Total number (but not actual monetary value) of events for which a HCP has received support (which may include registration fees, travel, and/or hotel costs). Support is to be disclosed per HCP in the following categories:
    - Sponsorship for attending a third party organised congress where the company pays for registration fees, travel or accommodation. (Companies are required to indicate whether each event is local/domestic, within Europe or outside Europe).
    - Site visits.
    - Company organised meetings for which a HCP received company funded hotel accommodation and/or airplane travel.
  - **Option 2** – Aggregate total amount of support provided to HCPs per individual conference or meeting as follows:

- Sponsorship for attending a third party organised congress: name of congress; aggregated amount spent for the congress, including the number of HCPs financially supported to attend.
- Site visits: aggregated amount spent, including the number of HCPs financially supported to attend.
- Company organised meeting: aggregated amount spent, including the number of HCPs financially supported to attend.

3) Transfers of Value to HCOs:

- Fees for service and consultancy – aggregated honoraria (excluding expenses such as meals drinks, travel and accommodation) paid to a HCO in exchange for the provision of services, such as serving on an advisory board, speaking at a company-organised educational event, participating in a focus group, etc. Fees paid in connection with R&D activities or market research are excluded from disclosure.
- Grants and donations: aggregated monetary amounts and a brief description of the nature of the grant or donation (e.g., research grant, equipment donation, product donation, etc.).[179]

As with the EFPIA Disclosure Code, the Medicines for Europe Code requires companies to publish a methodology note summarizing the methodology they used in preparing their disclosures that addresses, among other things, multi-year contracts, VAT, currency, and other issues relating to the timing and amount of transfers of value. As to currency, the Code recommends that companies disclose in Euros if possible.[180]

179 *Id.*
180 *Id.*

Because this is an industry code-based reporting system, Medicines for Europe had to address consent and data privacy issues and did so by requiring companies to "respect the applicable data privacy laws and regulations." Thus, companies should seek the necessary consent from HCPs to publish their individual information. If a HCP refuses to consent, companies are to publish his or her information on an anonymous basis, and if there are multiple HCPs that refuse to consent, then the relevant transfers of value data can be aggregated and the company should note the total number of HCPs included in the aggregation.[181]

As to the platform of disclosure, the Code requires companies to disclose their transfers of value "in a way in which the public can easily access such information. This means via the relevant company's website, and/or on a central platform (such as one provided by the relevant government, regulatory or professional authority board, or a Medicines for Europe national association)." The Code offers companies an option concerning the governing code for reporting certain transfers of value. In that regard, the Code provides that the disclosures shall be made pursuant to the local code where the member company or affiliate holding the contractual relationship with the recipient is located, or where the physical address of the recipient is located. This provision is different than EFPIA, which focuses on the location of the recipient. However, if the company decides to report in the country where the recipient is located and it does not have an affiliate in that country, then the company shall disclose such transfers of value at the European regional level.[182]

Companies are required to ensure that their transfers of value are "accessible online for a reasonable period of time." The Code also provides that companies do not have to report if they

181 *Id.*
182 *Id.*

are already subject to the EFPIA Disclosure Code or local laws so long as they are "as robust as the Medicines for Europe's [reporting requirements], including public availability of reports."[183]

With respect to implementation of these deadlines, companies are required to begin data collection in January 2017, with first reports due between January 2018 and June 30, 2018. Disclosures will be made on an annual basis, and each reporting period will cover a full calendar year. Lastly, Medicines for Europe has not yet provided a template or report format, but in its "Code of Conduct Q&A: Questions and Answers (version 2)," it states that it "will develop a recommended disclosure table that may be used by [our] members when publishing transfers of value to the healthcare community."[184]

European Legislation

Europe's significant transparency developments in the area of codes and self-regulation have been accompanied by an ongoing evolution of legislative-based reporting requirements. In our prior White Papers, we detailed the legislative-based reporting requirements in France, Slovakia, Portugal, Denmark, Greece, and Romania, and we will not repeat those here. Rather, we will focus on developments that have occurred since the publication of our last White Paper.

As usual, some of the biggest legislative developments involved the French Sunshine Act.[185] In February 2015, the French Supreme Administrative Court (*Conseil d'Etat*) expanded the scope of reporting. Prior to that decision, pursuant to the French Sunshine Act and its implementing decrees, the amount of consulting fees paid to HCPs did not have to be reported;

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183 *Id*.

184 MEDICINES FOR EUROPE, CODE OF CONDUCT Q&A (VERSION2), *available at* http://www.medicinesforeurope.com/wp-content/uploads/2016/02/Medicines-for-Europe_Code-of-Conduct-QA-V2.pdf.

185 Loi 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé [Law 2011-2012 on strengthening the drug safety and health products], JOURNAL OFFICIEL DE LA REPUBLIQUE FRANCAISE [J.O.][OFFICIAL GAZETTE OF FRANCE], Dec. 30, 2011, p. 22667.

instead, only the existence of such an agreement did. In its ruling, the *Conseil d'Etat* determined that not reporting fees paid to consultants was inconsistent with the French Sunshine Act.

The French Parliament enacted legislation responsive to the Court's ruling in January 2016.[186] The legislation touched on a range of health-related topics, from class action lawsuits to expanded health access for the poor, to the prohibition of hiring ultra-thin models for fashion shows. Most importantly for our purposes, the law changed the transparency reporting requirements that have been in place for several years and that apply to both pharmaceutical companies and medical device companies. Specifically, under the legislation: 1) the amounts of agreements will have to be reported, above a threshold set by decree; and 2) other details about agreements (precise object, date, direct beneficiary, and end beneficiary) are to be reported.

Shortly after the French Parliament adopted the law, opposition legislators challenged it, including its transparency provisions, before the French Conseil Constitutionnel, which is France's highest Court for constitutional and legislative matters. Ultimately, the French Conseil Constitutionnel upheld the transparency related provisions of the law. Thus, at the time of the release of this White Paper, the life sciences industry is awaiting the publication of a final decree that sets out the details of the implementation of the new law's reporting provisions.

Another relevant development involved the Cour des comptes ("Cour"), which is the French governmental agency in charge of auditing the use of public funds in France. It has four key responsibilities: 1) it judges the accounts of public accountants by verifying the accuracy of income and expenditures; 2) it audits the management and proper use of public funds, thereby ensuring the compliance, economy, efficiency, and effectiveness of the management of such funds; 3) it evaluates public policy; and 4) it audits the financial statements of the State to ensure

[186] Loi 2016-41 du 26 janvier 2016 de modernisation de notre système de santé [Law 2016-41 to modernize our healthcare system], JOURNAL OFFICIEL DE LA REPUBLIQUE FRANCAISE [J.O.][OFFICIAL GAZETTE OF FRANCE], Jan. 27, 2016, No. 0022.

that the accounts of public administration are true and fair. In March 2016, the Cour issued a 98-page report titled, "La prévention des conflits d'intérêts en matière d'expertise sanitaire," in which the Cour examines, among other things, the French Sunshine Act. The Cour performed this evaluation at the request of the French Senate's Social Affairs Committee.[187]

Although acknowledging the ambitious scope of the French Sunshine Act, the Cour identified a number of major flaws, including some relating to the Sunshine provisions. Those flaws include penalties without real significance and restrictive and varying interpretations by companies of what must be reported. In addition, the Cour criticized the fact that the Sunshine provisions did not originally require the amounts of agreements to be reported, although that has changed with the aforementioned passage of a law that will require such amounts to be reported.[188]

As in France, there were legislative developments in Slovakia, where the National Council of the Slovak Republic amended the law that requires pharmaceutical companies to report certain types of financial support of HCPs.[189] Among other things, the amended law requires pharmaceutical companies to provide the Slovakian National Health Information Center with an electronic report detailing their expenditures on advertising, marketing, and monetary and in kind contributions for the previous calendar half year; the pharmaceutical company must provide the notification no later than January 31 and July 31 of the respective calendar year. The first reports under the amended law were due on July 31, 2016.[190]

In that regard, it is important to note that in our earlier EFPIA analysis, we discussed the Slovakian industry group and the fact that its member companies reported under its

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187 CE, Feb. 24, 2015, 1ère / 6ème SSR.

188 *Id.*

189 Law no. 393/2015, amending and supplementing Law no. 362/2011 Coll. On Medicines and Medical Devices (Svk.), *available at* http://www.nczisk.sk/Documents/zverejnovanie_zakon_lieky/zakon_393_2015.pdf.

190 *Id.*

implementation of the EFPIA Disclosure Code. In effect, there presently is "double reporting" in Slovakia, as well as a few other countries, under both a local law and industry Code. (This is not the case for France, Denmark, and Portugal, where EFPIA has granted its local members a waiver from having to transpose the EFPIA Disclosure Code's reporting requirements into their local codes due to the existence of local laws.) However, EFPIA has indicated that it is considering granting a similar waiver to its members in Slovakia, Romania, and Turkey.

Turkey is a particularly interesting case because in 2015 the Turkish Pharmaceutical and Medical Device Agency ("TMMDA") issued a new Regulation on the Promotional Activities of Pharmaceutical Products for Human Use.[191] Among other things, that Regulation includes disclosure requirements that differ from EFPIA reporting. Specifically, transfers of value by marketing authorization holders, whether in cash or in kind, must be disclosed to the TMMDA if: 1) they are provided to HCPs, healthcare institutions and organizations, universities, unions, associations, or foundations active in the healthcare field; and 2) their monetary value exceeds 10% of the applicable gross monthly minimum wage. The disclosure for a calendar year's reportable transfers of value must be submitted within the first six months of the subsequent calendar year. Significantly, the disclosure must be made only to the TMMDA; there is no provision in the Regulation for public disclosure of this information. The new Regulation entered into force on January 1, 2016, and companies must submit their first reports in 2017 for 2016 data. In addition, the Regulation provides that companies cannot make transfers of value to covered recipients unless the recipients provide written consent that they accept the transfer with knowledge that appropriate notification of the transfer will be submitted to the government.[192]

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[191] Turkish Agency of Medicines and Medical Devices, 29405 Official Gazette, Regulation on Promotional Activities of Human Medicinal Products, July 3, 2015.

[192] *Id.*

Leading up to the June 30, 2016, reporting deadline under the EFPIA Disclosure Code, as implemented by EFPIA's Turkish member, the Association of Research-Based Pharmaceutical Companies ("AIFD"), there was some concern about the impact of the Turkish Regulation on whether AIFD companies should publish TOV reports pursuant to the AIFD Code. Ultimately, EFPIA and AIFD determined that AIFD members should not do so, and issued the following statement on the topic:

> Healthcare professionals (HCPs) and healthcare organisations (HCOs) with whom pharmaceutical companies work provide valuable, independent and expert knowledge derived from their clinical and management experience. As owners of scientific knowledge and experts in medicinal products, pharmaceutical companies can be a unique resource to the healthcare systems and providers, which will ultimately benefit the patients.
>
> Throughout the medicines['] life cycle pharmaceutical companies work with scientists and healthcare professionals. These collaborations are essential in addressing patient needs. Industry and healthcare professionals collaborate in a range of activities from clinical research to sharing best clinical practice and exchanging information on how new medicines fit into the patient pathway.
>
> EFPIA and its member associations have adopted codes and guidelines to ensure that the interactions of their member companies with healthcare professionals and organisations meet the high standards of integrity and transparency. Building greater transparency to the relationships between pharma companies and HCPs/HCOs aims to building understanding of the collaboration and recognition of its value to patient care.
>
> AIFD, EFPIA's member association in Turkey[,] has incorporated the EFPIA [Disclosure] Code provisions into their national code. In the meanwhile, the Turkish competent authorities have adopted new Regulation requiring that pharma companies submit intended transfers of value [prior to] acceptance of the sponsorship by the healthcare professionals. Agreement on the transfer of value will then be communicated to the [Turkish government].
>
> [The Turkish government] has indicated its preference for a single reporting point, and has therefore asked that companies disclose transfers of values within the frame of the Regulation, only to the Agency.
>
> The EFPIA Board has therefore agreed to provisionally suspend full implementation of the EFPIA Disclosure Code in Turkey, whilst asking its Member Companies to communicate the transfers of value provided during 2015 to healthcare professionals and organisations in Turkey to the [Turkish government], as appropriate.

> EFPIA and AIFD will continue dialogue with [the Turkish government] on further implementation and development of the Turkish Regulation with a view to reaching a level of transparency similar that what has now become general practice around Europe. Interactions between industry, HCPs and HCOs are vital to ensure we can continue to develop medicines that advance healthcare and continue to improve the lives of patients across Europe.[193]

It will be interesting to see how the situation in Turkey is resolved, as well as whether EFPIA will grant additional waivers to other countries where there are existing laws in place, or potentially in countries that may adopt new laws over the coming year. Although there has not, for the most part,[194] been significant discussion about the adoption of Sunshine laws in other European countries, the absence of such discussion does not mean that a government, perhaps dissatisfied with the local data and consent rates reported by the national EFPIA group, will not eventually decide to enact a local Sunshine law.

As always, that possibility, or perhaps more specifically the possibility that several European governments may enact Sunshine laws, poses a threat to the continued viability of the EFPIA disclosure initiative. The first round of EFPIA disclosures were not greeted with widespread calls for legislation, but, as outlined above, there were some concerns expressed across Europe about EFPIA reporting. Therefore, it will be imperative for the pharmaceutical industry to continue working to ensure that the EFPIA disclosure initiative is given sufficient

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[193] Turkey, GLAXOSMITHKLEIN, http://www.gsk.com/en-gb/healthcare-professionals/disclosure-of-payments-made-to-hcps/europe/turkey/ (last visited August 6, 2016).

[194] In Scotland, as chronicled in our prior White Papers, a Scottish physician, Peter Gordon, submitted Public Petition No. PE01493, titled, "A Sunshine Act for Scotland." Dr. Gordon urged the Scottish government to create a Sunshine Act that would include a searchable record of all payments to healthcare workers from industry. The Scottish Public Petitions Committee took evidence and conducted several hearings on the petition over the past several years. Further, the Scottish government responded to the petition and studied the issue. On March 8, 2016, the Committee closed the petition "on the basis that the Scottish Government has committed to review the need for updated guidance on what the petition calls for and is consulting on the issue to gather views on what format it should take." On March 22, the Scottish Cabinet Secretary for Health, Wellbeing and Sport submitted a letter to the Convener of the Public Petitions Committee that enclosed a report prepared by the Scottish Health Council concerning its review of whether a Sunshine Act should be adopted. Most significantly, in the letter, the Secretary stated: "In terms of next steps, the Scottish Government will discuss the contents of this report with the appropriate regulators and scope out options of how mandatory publication of payments to healthcare professionals from industry could be delivered. As part of this work we will ensure that options are proportionate and respectful of NHS resources."

time to improve and provide further transparency, both in terms of the number of companies reporting as well as the number of HCPs that are identified at the individual level.

The Pacific Rim

As in prior years, there has been transparency activity in the Pacific Rim, primarily in Japan and Australia. In Japan, the industry groups for the pharmaceutical industry, the medical device industry, and the generics medicines industry have transparency reporting requirements for their members, all of which are largely similar.[195] Members of those groups have continued to comply with those requirements.

Meanwhile, at the end of August 2016, members of the Australian industry group, Medicines Australia, will issue individual-level HCP disclosure reports for the first time. In our prior White Papers[196] we extensively detailed the requirements of those reports. Rather than do so again, we will simply highlight that the Medicines Australia Code of Conduct requires members to prepare two types of reports: 1) HCP reports; and 2) sponsorship of third party educational event reports. Both reports are on the same reporting schedule, whereby reports are due twice a year: August 31, to cover data from November 1-April 30; and February 28, to cover the May 1-October 31 time period. The first reports under this schedule are due on August 31, 2016. Member companies are required to post HCP reports on their websites, while Medicines Australia evaluates the feasibility of creating a central database. In contrast,

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[195] *Guideline for the Relation between Corporate Activities and Medical Institutions*, Japan Pharmaceutical Manufacturers Association ("JPMA") (last updated February 2015); *Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations*, Japan Federation of Medical Devices Associations ("JFMDA"); *企業活動と医療機関等の関係の 透明性ガイドラインについて*, Japan Generic Medicines Association.

[196] D. JEFFREY CAMPBELL, ESQ. & BRIAN P. SHARKEY, ESQ., READY OR NOT, FULL SPEED AHEAD FOR THE GLOBAL TRANSPARENCY MOVEMENT 36–44 (2015), CAMPBELL & SHARKEY, DO START BELIEVIN': THE LIFE SCIENCES INDUSTRY'S JOURNEY TO GLOBAL TRANSPARENCY 55–63 (2014); CAMPBELL &. SHARKEY, THE ONGOING GLOBAL TRANSFORMATION IN LIFE SCIENCES TRANSPARENCY 19–23 (2013); CAMPBELL & SHARKEY, THE TREND TOWARDS GLOBAL TRANSPARENCY: A CHALLENGING NEW WORLD FOR THE LIFE SCIENCES INDUSTRY 36–39 (2012).

companies will submit their third party education event sponsorship reports directly to Medicines Australia, which will then post them on its website.

As noted, the substance of Australia's reporting requirements, which are a mixture of requirements similar to the United States, France, and EFPIA, as well as some that are unique to Australia, are detailed in our prior White Papers, but it is important to emphasize that for HCP reports, the first year of reporting follows the EFPIA model, whereby companies must obtain consent from HCPs to report at the individual level. If a HCP refuses to consent, then the company must report that spend in the aggregate. After the first year of reporting, companies will no longer have to obtain consent. Rather, they will simply inform the HCP that the relationship will be reported, an approach that was approved by the relevant Australian governmental authorities. If a HCP does not wish for his or her personal details to be published, presumably the burden then shifts to the HCP to not engage in the relationship.

As with EFPIA and its national member associations, Medicines Australia has been promoting awareness of its transparency reporting requirements in the build-up to the first round of reports. For example, in its Annual Report 2014-15, Medicines Australia reasoned that with its transparency reporting requirements, "the innovative Australian medicines industry is putting patients first by demonstrating the value of industry partnerships and taking the lead to boost transparency. The new Code builds on 55 years of successful, responsible, ethical industry self-regulation."[197] Moreover, in that Report, Medicines Australia described its strategy to publicize the transparency initiative:

> Having achieved the Code's authorisation, Medicines Australia has initiated a broad healthcare professional communications campaign. The campaign reinforces that a strong working relationship and ongoing knowledge exchange between the companies that make medicines and healthcare professionals are critical to better patient outcomes. Our communications through a range of media

[197] MEDICINES AUSTRALIA, CODE OF CONDUCT ANNUAL REPORT 2014-2015 15 (2015).

> seek to ensure that all relevant Australian healthcare professionals are aware of the new Code and the transparency requirements for Member companies and are confident that the transparency requirements will be implemented professionally and in accordance with Australia's privacy laws.[198]

Canada

Our tour of the global transparency landscape will conclude where it began: North America. Unlike the United States, there is no Sunshine law in Canada. And unlike EFPIA, the Canadian pharmaceutical industry group, Innovative Medicines Canada, does not include reporting requirements in its Code of Ethical Practices. However, on March 28, 2016, the headline of an article from the Canadian newspaper *National Post* declared, "Canadian drug companies agree to divulge how much they pay doctors, health groups."[199] The article described how ten pharmaceutical companies decided to voluntarily publish statistics on their overall payments to HCPs in Canada. According to the article, the categories to be disclosed cover three areas: 1) consulting, speaking, and other fees for service; 2) financial support for physicians to travel to international functions; and 3) grants provided to some healthcare organizations. Significantly, the information to be published is at the aggregate level and will not identify individual physicians.[200]

The article stated that the ten companies that agreed to this voluntary, aggregate disclosure are: Abbvie, Amgen, Bristol-Myers Squibb, Gilead, GSK, Eli Lilly, Merck, Novartis, Purdue, and Roche. Further, the article noted that the disclosure program has been endorsed by Innovative Medicines Canada. Lastly, the article observed that that the Canadian federal health minister was not available for a comment about this topic.

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198 *Id.*

199 Tom Blackwell, *Canadian drug companies agree to divulge how much they pay doctors, health groups*, NATIONAL POST (March 28, 2016), http://news.nationalpost.com/news/canada/canadian-drug-companies-agree-to-divulge-how-much-they-pay-doctors-health-groups.

200 *Id.*

Meanwhile, on March 30, 2016, the Canadian newspaper *The Toronto Star* published an editorial titled, "Ottawa should make drug companies reveal payments to doctors."[201] After recounting the voluntary program discussed above, the editorial opined that the effort is insufficient. Specifically, the editorial argued that "[a]ny step aimed at shining a light on the relationship between doctors and pharmaceutical companies is welcome. But this one doesn't go nearly far enough. That's because the companies plan to publish statistics on their *overall* payments to health professionals, not what they give to each individual physician."[202] Rather than an industry-led, voluntary disclosure program, the editorial endorsed legislation, as it declared: "What's needed [] is federal legislation requiring all pharmaceutical companies to divulge how much they give individual doctors. That's what they are already required to do in the United States under a 2010 law called the Physician Payments Sunshine Act."[203]

Similarly, Matthew Herder, an associate professor at the Health Law Institute and David Juurlink, an Eaton Scholar and professor of medicine and health policy at the University of Toronto, authored an editorial in *The Star* titled, "Let the sun shine on doctors' ties to pharma."[204] After describing the aforementioned voluntary Sunshine initiative, the authors criticized it, "because participating companies will report only aggregate amounts given to medical education, rather than how much money made its way to which doctors and why. It gives the illusion of transparency, while cloaking the money pocketed by individual physicians."[205] Instead, the authors argued for a federal Sunshine law, as they contended that

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201 *Ottawa should make drug companies reveal payments to doctors*, THESTAR.COM (March 30, 2016), https://www.thestar.com/opinion/editorials/2016/03/30/ottawa-should-make-drug-companies-reveal-payments-to-doctors-editorial.html.

202 *Id.*

203 *Id.*

204 Matthew Herder and David Juurlink, *Let the sun shine on doctors' ties to pharma*, THESTAR.COM (May 9, 2016), https://www.thestar.com/opinion/commentary/2016/05/09/let-the-sun-shine-on-doctors-ties-to-pharma.html.

205 *Id.*

> Sunshine can only result if Canada's Food and Drugs Act is amended to require individual drug manufacturers to disclose financial dealings with individual physicians. It's time the Canadian medical profession and its provincial licensing bodies publicly supported reform of this sort. Otherwise, drug companies and their agents will continue to have undue influence on what doctors prescribe.[206]

The topic of pharmaceutical transparency was also discussed during an episode of the CBC Radio program, *The Current* with Anna Maria Tremonti.[207] The episode featured discussions with a HCP, a reporter, Mr. Herder, and Russell Williams, the President of Innovative Medicines Canada. After discussing the aforementioned voluntary program, whereby the participating companies will report at the aggregate level on their websites, Mr. Williams answered a question about why Canada did not have a Sunshine law like the United States:

> [I]t's a different system. My understanding in our-- And there's been problems in other jurisdictions to try to get consent. Our privacy and consent laws would probably have to be duplicated in each of the provinces and territories. So we thought this would be the right way to start. Now, will there be progress in this area when we see what we can learn together as a society in 2017? We're open to continually improving and monitoring this. We think this is-- Society is moving towards this movement of disclosure. We think this is a helpful offering to help show the value of these relationships between our industry and health care professionals.[208]

When asked if the industry was trying to block regulatory change by having companies report in the aggregate, Mr. Williams explained:

> I think this is an offering to Canadian society in which we can bring light to the important relationship that we have with health care professionals. We already have a code of ethical practices which is very robust and many of the things that I heard earlier are just completely banned and we have rules to deal with it. But we do have a legitimate relationship with these health care professionals and we think this offering and this voluntary measure that we'll learn together from will be helpful in advancing this kind of dialogue in the future. So this is something that we are proud of and the relationship as proud of physicians and other health care professionals are very appreciative of this relationship. This is hopefully the first step of bringing some light to it.[209]

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206 *Id.*
207 Transcript, Anna Maria Tremonti, CBC, The Current, aired April 8, 2016.
208 *Id.*
209 *Id.*

It will be fascinating to watch the progress of the transparency experience in Canada. It would be surprising if the aggregate reports of ten companies is sufficient to satisfy those interested in more transparency. Rather, those aggregate reports will most likely be the first step on the way to more disclosure. The more important question is not whether there will be more transparency, because there almost undoubtedly will be, but instead whether additional reporting requirements will take the form of legislation like in the United States and France, or self-regulation like in Australia, Japan, and the EFPIA countries.

Conclusion

To return to the question posed in our title, will 2016 be considered a milestone moment in global transparency or will key stakeholders, like regulators, consider EFPIA's transparency efforts to be "a charade with the thrust of a dead jellyfish?" The success, or lack thereof, of the EFPIA reporting experience will have a direct impact on other industries, as well as other regions. If European governments determine that they need to pass their own transparency laws, the medical device and generic medicines industries will likely be included in wide sweeping regulation. Conversely, if the EFPIA transparency initiative is considered a success, then Medicines for Europe will presumably continue on its EFPIA-like path, and MedTech Europe might reconsider pursuing a similar approach. Moreover, if EFPIA is considered successful, then other life sciences industry groups throughout the world may decide to adopt similar reporting requirements for their members as a way to achieve a beneficial self-regulatory system that will prevent governmental intervention.

It is difficult to predict when a government might choose to intervene. For example, the Drug Sector of the Saudi Food and Drug Authority recently introduced a payments disclosure initiative for the pharmaceutical industry. Specifically, it prepared a draft disclosure system that would require pharmaceutical companies to report various TOV made to HCPs and healthcare

institutions. The draft is somewhat similar to the EFPIA Disclosure Code in terms of the type of information to be reported, the report format, and the reporting timeframe.[210]

Further, controversies or scandals can be the impetus for a government to act. As we detailed in earlier White Papers, the French Sunshine Act was at least a partial by-product of a public health scandal that led to broad legislative reform of the healthcare laws. Thus, any "scandal," real or perceived, could create motivation for a government to act. It is clear that government officials and other stakeholders are already paying attention to the transparency of the relationships between life sciences companies and HCPs. However, it is hard to anticipate what might transform passive scrutiny into active reform.

One such potential influencer is a June 2016 Transparency International ("TI") report titled, "Corruption in the Pharmaceutical Sector: Diagnosing the challenges."[211] The TI report deals with a host of issues concerning corruption risks in the pharmaceutical industry, but, of relevance to this Paper, parts of the report deal with Sunshine and transparency matters. In the executive summary portion of the report, TI declares that the pharmaceutical sector is "particularly prone to corruption" and that such corruption endangers positive health outcomes. TI identifies four overarching challenges that it claims facilitate corruption in the pharmaceutical sector:

1) a lack of objective data and understanding of corruption, which is inhibited by environmental context, the complexity of the issues in the pharmaceutical sector, and policymakers not viewing corruption as a problem;

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[210] PHARMACEUTICAL COMPANY PAYMENTS DISCLOSURE INITIATIVE (VERSION 1.0 DRAFT), SFDA [SAUDI FOOD AND DRUG AUTHORITY] (June 6, 2016).

[211] Jillian Clare Kohler, Martha Gabriela Martinez, Michael Petkov and James Sale, *Corruption in the Pharmaceutical Sector: Diagnosing the challenges*, Transparency International (June 2016), http://www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/.

2) a weak legislative and regulatory framework, which is due to poor investment, a lack of oversight, and national regulatory frameworks that are frequently decentralized and overly reliant on self-regulation;

3) the potential for undue influence from companies, which is the result of a high degree of industry autonomy over key decision points and unparalleled resources; and

4) a lack of leadership committed to anti-corruption efforts.

As to solutions, TI identifies and examines three key action areas it claims would mitigate corruption vulnerabilities in the pharmaceutical sector: 1) establishing leadership committed to addressing corruption; 2) adopting technology throughout the value chain; and 3) ensuring accountability through increased monitoring, enforcement, and sanctions.[212]

In the section of the report devoted to Marketing, TI recounts what it perceives to be various corruption risks posed by marketing activities, and then turns to some of the Sunshine measures that have already been implemented.[213] In a section titled "Transparency and accountable industry-HCP relationships," TI states:

> Measures to decrease marketing corruption vulnerabilities focus on regulating and monitoring the relationship between the pharmaceutical industry and HCPs. Codes of conduct can be established at the national and international levels that call for the mandatory disclosure of conflicts of interest, such as honorariums and funding connections with requirements for the quantity and quality of data disclosure. Robust monitoring mechanisms to ensure that such codes are implemented properly, along with the enforcement of sanctions, are key to tackling corruption vulnerabilities in marketing practices.
>
> Recent measures to increase the disclosure of payment transfers between doctors and pharmaceutical company show change is possible. In 2014 the Physician Payment Sunshine Act was passed in the USA, which requires companies to disclose in an online database the payments they have made to doctors over US$10, as well as aggregate payments of more than US$100 to a single doctor. Like any other measure this legislation requires continued monitoring and enforcement; doctors have complained that pharmaceutical companies have

212 *Id.*
213 *Id.*

> submitted incorrect information on the database. In Europe the European Federation of Pharmaceutical Industries and Associations (EFPIA) has implemented a code similar to the Sunshine Act, with data disclosure beginning in June 2016, while in the UK a "Sunshine rule" will require NHS hospitals and doctor groups to keep registers of gifts and hospitality given to staff from pharmaceutical companies.
>
> In each case the impacts are yet to be sufficiently analysed, so it is unclear if disclosure is a necessary and sufficient condition for change. Instead it may be more effective to ensure that conflicts of interest are avoided completely.[214]

EFPIA responded to TI's report by welcoming attention to good governance in the health sector, but criticizing the report for failing to mention a number of industry-led initiatives that address corruption risk areas.[215] The ABPI responded in a similar fashion, as it argued that the report is "out of date with our track record for how we research, conduct clinical trials, market and provide our medicines to patients and engage with healthcare professionals." Further, the ABPI contended that the report "fails to take into account many … positive initiatives, nor the ground-breaking work carried out by the industry every day to bring innovative medicines and treatments to billions of patients in the UK and globally."[216] Thus, as the life sciences industry grapples with the ever-expanding global transparency movement, it will be doing so under the watchful eye of groups like TI, along with regulators and other interested stakeholders.

Although we have addressed at length the success, or perceived lack thereof, of the EFPIA reporting experience, it seems unlikely that anyone will be able to make an immediate, conclusive determination on that topic. In the few weeks since the publication of TOV data, there has been ample press coverage of the data, but there does not appear to be a groundswell of support for a legislative replacement. To the extent that such a movement begins to stir in the

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214 *Id*.

215 Press Release, EFPIA, *EFPIA Response to Transparency International UK Report* (June 1, 2016), http://www.efpia.eu/mediaroom/335/43/EFPIA-Response-to-Transparency-International-UK-Report.

216 Dr. Virginia Acha, *ABPI respond to Transparency International report on pharmaceutical industry corruption*, ABPI (June 2, 2016), http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/ABPI-respond-to-Transparency-International-report-on-corruption.aspx.

coming months, it would be prudent for local EFPIA member associations to follow the lead of the Spanish EFPIA member and seek the approval of the necessary governmental authorities to proceed with individual-level reporting without consent.

It is highly likely that there will be more rounds of EFPIA disclosure before a consensus develops on whether EFPIA reporting is a success or should be replaced by a comprehensive legislative solution. It is also all but inevitable that there will be many more developments over the next year, some legislative, some code-based, and some societal, that are currently beyond prediction or anticipation. As these developments play out, we will continue to monitor the philosophical struggle between those who believe that EFPIA's reporting initiative is a milestone on the journey to effective industry self-regulation, and those who see it simply as a dead jellyfish destined to be swept away by a tide of legislative reform.

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