



Ready Or Not, Full Speed Ahead
For The
Global Transparency Movement

WHITE PAPER

D. Jeffrey Campbell, JD
Brian P. Sharkey, JD
Porzio Life Sciences, LLC

AUGUST 2015

Introduction

For the past several years, we have published an annual White Paper¹ analyzing the evolution of the global transparency movement. A primary catalyst for the rapid acceleration of the transparency movement was the adoption by the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), which is comprised of thirty-three national member associations and forty pharmaceutical companies, of the "EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations" ("Disclosure Code"). Data collection under the Disclosure Code began on January 1, 2015, and companies are gathering the necessary information to complete their first reports by the June 2016 deadline.

The transparency movement goes well beyond EFPIA, however, as there have been legislative reporting developments recently in France, Denmark, Portugal, Romania, Greece, England, and Scotland. Geographically, the global transparency movement extends to the Pacific Rim, as the Japanese and Australian pharmaceutical industry groups modified their individual-level reporting requirements in 2015.

Transparency of HCP interactions is affecting not only innovative pharmaceutical companies but other parts of the life sciences industry as well. In December 2014, the European Generic and Biosimilar Medicines Association, which is the official representative body of the European generic and biosimilar pharmaceutical industry, adopted a Code of Conduct that puts that industry on the path to self-regulatory transparency reporting similar to EFPIA. In contrast,

¹ D. Jeffrey Campbell, Esq. & Brian P. Sharkey, Esq., White Paper, *Do Start Believin': The Life Sciences Industry's Journey to Global Transparency* (2014); Campbell & Sharkey, White Paper, *The Ongoing Global Transformation in Life Sciences Transparency* (2013); Campbell & Sharkey, White Paper, *The Trend Towards Global Transparency: A Challenging New World for the Life Sciences Industry* (2012). In this year's White Paper, we will focus on developments that occurred over the past year and direct your attention to our prior White Papers for more information about the history and details of the global transparency movement.

Eucomed, which represents the European medical device industry, rejected the EFPIA reporting system and instead embraced a different approach to transparency.

There were also many developments over the past year in the United States, the birthplace of the transparency movement. Most significantly, in 2014 companies reported on five months of 2013 data under the Transparency Reports and Reporting of Physician Ownership or Investment Interests (section 6002 of the Patient Protection and Affordable Care Act) (“US Sunshine Act”), and in 2015 companies reported on the full year of 2014 data, all of which was released to the public by the federal government.

United States

The US Sunshine Act requires "applicable manufacturers," namely pharmaceutical companies and medical device companies that satisfy certain statutory requirements, to report to the Centers for Medicare & Medicaid Services ("CMS"), part of the federal government's Department of Health & Human Services ("HHS"), any direct or indirect payment or other transfer of value to a "covered recipient" or any payment provided to a third party on behalf of a covered recipient during a calendar year. "Covered recipients" include 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 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.

CMS issued final regulations for the US Sunshine Act that took effect in April 2013,² and data collection for the first reporting period ran from August 1, 2013, until December 31, 2013. Companies were required to submit their detailed 2013 payment data by June 30, 2014. The review, dispute, and correction period followed thereafter, and on September 30, 2014, CMS published the first round of Sunshine Act data on its Open Payments website. According to CMS, the released data for the five-month reporting period in 2013 included "4.4 million payments valued at nearly \$3.5 billion."³ In December 2014, CMS revised the Open Payments dataset, and thereby increased the amount of reported payments to a total amount of approximately \$3.7 billion paid by 1,303 reporting companies to 546,000 individual physicians and 1,360 teaching hospitals.⁴

One of the life sciences industry's concerns about reporting was whether the government would impose penalties for Sunshine Act violations. CMS provided its answer in its April 2015 "Annual Report to Congress on the Open Payments Program For Fiscal Year 2014".⁵ In the section of the Report titled, "Penalties for Noncompliance", CMS declared that, pursuant to its powers under the Sunshine Act, it

will launch targeted audits to identify applicable manufacturers and [Group Purchasing Organizations] that should have submitted payment information but did not for 2013.

As of the date of this publication, CMS is engaged in an effort to increase submission compliance of specific entities that did not submit the data. The near-term objectives of the Open Payments compliance strategy are focused on alerting applicable manufacturers and GPOs to their failure to register and submit data in the Open Payments system. Beyond the first program year, applicable manufacturers and GPOs will be notified of their failure to report in a timely,

² 42 CFR Parts 402 and 403.

³ CMS.GOV, *CMS Makes First Wave of Drug & Device Company Payments to Teaching Hospitals and Physicians* Public, PRESS RELEASE (September 30, 2014), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-09-30.html>.

⁴ *Id.*

⁵ CMS ANNUAL REPORT TO CONGRESS ON THE OPEN PAYMENTS PROGRAM FOR FISCAL YEAR 2014 (APRIL 2015).

accurate and/or complete manner. To date, CMS has not imposed any [civil monetary penalties] against applicable manufacturers or [group purchasing organizations].⁶

CMS is not the only federal government agency interested in ensuring US Sunshine Act compliance. In a report titled, "Fiscal Year 2015 WORK PLAN: Mid Year Update/May 2015", the HHS's Office of the Inspector General ("OIG") highlighted its role with respect to the US Sunshine Act.⁷ In that report, the OIG observed that it

will determine the number and nature of financial interests that were reported to CMS under the Open Payments Program. We will also determine the extent to which CMS oversees manufacturers' and group purchase organizations' ... compliance with data reporting requirements and whether the required data for physician and teaching hospital payments is accurately and completely displayed in the publicly available database. ... The Open Payments program provides public transparency about provider-industry relationships; it is important that the information be complete and accurate to service the needs of consumers making educated decisions about their health care choices.⁸

In terms of the legislative and agency response to the first round of reporting, on May 19, 2015, the House of Representatives introduced House Bill 6 ("H.R. 6"), which would amend the US Sunshine Act to exclude from the reporting requirement "peer-reviewed journals, journal reprints, journal supplements, medical conference reports, and medical textbooks." Currently, those materials are not excluded from reporting. On July 10, 2015, the House of Representatives passed H.R. 6 with bipartisan support and it is now pending in the Senate.

CMS has also been active in changing the rules governing reporting and improving the Open Payments program in general. In 2014, CMS published a final rule that amended the

⁶ *Id.* at p. 17.

⁷ OIG, WORK PLAN MID-YEAR UPDATE FOR FISCAL YEAR 2015. The OIG of the HHS is an office that was created to protect the integrity of HHS programs and operations and to hold responsible individuals and entities who do not satisfy HHS program requirements or violate federal health care laws.

⁸ *Id.* at p. 59.

Sunshine Act's regulations⁹ and deleted the continuing education exclusion in its entirety. This means that companies will be required to report compensation provided to physician speakers at continuing education events unless the payment or other transfer of value is specifically excluded. Although the final rule took effect as of October 31, 2014, CMS will not implement the changes until the 2016 program year for reporting in 2017. CMS has also announced a number of enhancements and planned improvements for the Open Payments program, many of which are designed to address stakeholder feedback.

Another major concern of industry and physicians was how the release of data would be received by the media and public. Both sides expressed unease that if the payments information was released without the proper context, the data could be easily misinterpreted, resulting in the public being confused and potentially misled about how and why industry interacts with physicians. Not surprisingly, CMS's release of the payment information in 2014 was greeted with numerous news articles that cast either, or both, industry and physicians in a negative light. Here are just a few examples of headlines from major publications: "Doctors Net Billions From Drug Firms: Companies Paid At Least \$3.5 Billion in Last Five Months of 2013"; "Financial Ties Between Doctors and Health Firms Are Detailed"; and "Drug Companies and Their Ties to

⁹ CMS.GOV, *Policy and Payment Changes to the Medicare Physician Fee Schedule for 2015*, FACT SHEET (October 31, 2014), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-10-31-7.html>.

Doctors, Data Released".¹⁰ In addition, John Oliver, on his HBO program *Last Week Tonight*, utilized Open Payments data to skewer the relationship between industry and HCPs.¹¹

While reporting in 2014 covered only five months of 2013 data, in 2015 companies had to report a full year's worth of data to account for all of their 2014 covered payments. Although the annual deadline for the submission of reports is March 31, CMS extended the deadline until April 3. The review and dispute period for physicians and teaching hospitals began on April 6 and ran until May 20. The data correction period started on May 21 and expired on June 5.

On June 30, 2015, CMS published the 2014 Open Payments data. Overall, 11.41 million total records were published that were attributed to 607,000 physicians and 1,121 teaching hospitals. The total amount reported was \$6.49 billion. Of that \$6.49 billion, \$2.56 billion was for general payments, \$3.23 billion was for research payments, and \$703 million was for ownership or investment interests.¹² The release of this data was once again greeted by headlines that cast a suspicious eye upon the relationship between industry and physicians, including the following: "Industry Payments to Doctors Are Ingrained, Federal Data Show"; "Federal tool details financial links between doctors, medical industry"; and "U.S. doctors, hospitals reap \$6.5 bln from drug and device makers".¹³

¹⁰ Peter Loftus, *Doctors Net Billions from Drug Firms: Companies Paid At Least \$3.5 Billion in Last Five Months of 2013*, WALL ST. J. (Last updated Sept. 30, 2014, 7:29 p.m. ET), <http://www.wsj.com/articles/u-s-agency-reveals-drug-makers-payments-to-doctors-1412100323>; Katie Thomas and Rachel Abramsoc, *Financial Ties Between Doctors and Health Care Firms are Detailed*, N.Y. TIMES (Oct. 2, 2014), http://www.nytimes.com/2014/10/03/business/financial-ties-between-doctors-and-health-care-firms-detailed.html?_r=0; Mike Oliver, *Drug Companies and Their Ties to Doctors, Data Released*, AL.com (Last updated Oct. 1, 2014, 8:33 a.m.), http://www.al.com/news/index.ssf/2014/09/drug_companies_and_their_ties.html.

¹¹ *Last Week Tonight with John Oliver: Marketing to Doctors* (HBO television broadcast Feb. 8, 2015), available at <https://www.youtube.com/watch?v=YQZ2UeOTO3I> (Last visited Aug. 12, 2015). Please be advised that this is a "Not Suitable For Work" viewing experience.

¹² CMS.GOV, *The FACTS About Open Payments Data*, OPEN PAYMENTS, (Last updated June 30, 2015), <https://openpaymentsdata.cms.gov/>.

¹³ Charles Ornstein and Ryann Grochowski Jones, *Industry Payments to Doctors are Ingrained, Federal Data Show*, NPR.ORG (July 1, 2015, 4:16 pm ET, last updated July 8, 2015), <http://www.npr.org/sections/health-shots/2015/07/01/419206613/industry-payments-to-doctors-are-ingrained-federal-data-show>; Steven Moore, *Federal Tool Details Financial Links Between Doctors, Medical Industry*, LAS VEGAS REV. J. (Last updated July 2,

Since the 2014 data has only been publicly available for a little over a month, it is too early to draw any definitive conclusions about how the Open Payments program will be impacted and whether there will be a legislative or regulatory reaction, or possible investigations and audits by the CMS, OIG, or other governmental actors.

European Self-Regulation

While companies are collecting 2015 data to satisfy their 2016 US Sunshine Act reporting obligations, many of those same companies are also collecting data for the first round of EFPIA reporting. EFPIA's Disclosure Code provides that data collection was to begin on January 1, 2015, and first reports are due by June 30, 2016. Before analyzing the Code, it is important to note that the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA"), which represents the research-based pharmaceutical industry globally, is also involved in the transparency movement.

Although the IFPMA Code, which was most recently amended in 2012, does not include transparency reporting requirements, the IFPMA nonetheless supports the idea of transparency in the relationships between industry and HCPs. In that regard, in November 2014, the IFPMA released a Position Paper titled, "Interactions in the Healthcare Sector: Disclosure of Transfers of Value"¹⁴ in which it agreed with the principle that "instilling and maintaining trust in the healthcare sector is essential."¹⁵ The paper noted that transfer of value reporting systems had been implemented in several countries in a variety of ways, from the enactment of national laws

2015, 11:09 pm), <http://www.reviewjournal.com/news/las-vegas/federal-tool-details-financial-links-between-doctors-medical-industry>; Bill Berkrot, *U.S. Doctors, Hospitals Reap \$6.5 billion from Drug and Device Makers*, REUTERS (Last updated June 30, 2015, 6:41 pm ET), <http://www.reuters.com/article/2015/06/30/us-usa-healthcare-payments-idUSKCN0PA30K20150630>.

¹⁴ IFPMA, INTERACTIONS IN THE HEALTHCARE SECTOR: DISCLOSURE OF TRANSFERS OF VALUE (November 2014).

¹⁵ *Id.* at p. 1.

to the adoption of self-regulation via an industry code. While acknowledging the general importance of transparency in the healthcare field, the IFPMA pointed out that

[t]hese initiatives ... have proven to be complex and resource intensive. Therefore, if disclosure systems are undertaken, it is important to ensure that their value is measured in the context of wider health system needs, that they are appropriate and proportionate to the national context and beneficial to patients and society.¹⁶

The paper then listed a number of factors that must be considered to achieve a successful disclosure system, including: 1) the collaboration of many stakeholders (e.g., HCPs, industry, government officials) should be sought before a reporting system is enacted; 2) disclosure measures should apply to all industries, including generic pharmaceuticals and medical devices; and 3) all HCPs and associations should participate in the disclosure process. Not only should all of those factors be considered, the paper identified several issues that should be resolved prior to the creation of a disclosure program: 1) type of disclosure platform (e.g., governmental or industry-based); 2) type of reporting (individual or aggregate); 3) whether there is a threshold for reporting; 4) who are the covered recipients; 5) the categories of payments to be reported; 6) the timelines (e.g., period of data collection); and 7) the protection of intellectual property rights and compliance with other relevant laws (e.g., privacy, tax, fair competition). Finally, the IFPMA stressed that a successful disclosure system would have to: 1) "[e]nsure that no harm is brought upon patients and that mutual respect and trust between stakeholders is protected"; 2) "[p]rovide appropriate contextual information with the published data so that interactions between [HCPs and industry] are well understood by patients and the public"; 3) "[r]eport the transfers of value in a form that is readily accessible, adds value and is meaningful to the public"; 4) "[e]nable the

¹⁶ *Id.*

information to be reviewed by [HCPs] prior to publication to ensure accuracy"; and 5) "[e]xclude business-to-business trading arrangements relating to the purchase of medicines etc."¹⁷

The IFPMA did not endorse a specific reporting system, but instead emphasized that such systems must ensure that

concerns about the legitimate relationship between healthcare professionals and companies are addressed. If disclosure of transfers of value is to be considered as helpful to these aims, it is important that arrangements are appropriate to the national context and are conducted in collaboration with all relevant stakeholders. Commitment from governments, patients, healthcare professionals and the healthcare industry is essential to ensure a credible, balanced, and pragmatic approach that brings practical benefit to all stakeholders including patients.¹⁸

Before highlighting developments from the past year concerning the EFPIA Disclosure Code, it is helpful to briefly review the key provisions of the Code. Companies must publicly disclose, for the first time in 2016, their 2015 transfers of value to HCPs and healthcare organisations ("HCOs").¹⁹ 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,²⁰ 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

¹⁷ *Id.* at p. 2.

¹⁸ *Id.*

¹⁹ EFPIA Disclosure Code, EFPIA.EU, <http://transparency.efpia.eu/the-efpia-code-2> (June 6, 2014; Last updated July 11, 2014). "Transfers of value," "HCPs," and "HCOs" and other terms discussed *infra*, e.g., research and development transfers of value, are defined both in the Disclosure Code, *supra*, as well as in our prior White Paper, *Do Start Believin': The Life Sciences Industry's Journey to Global Transparency* (2014).

²⁰ 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.

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 to maintain such records for at least five years, unless a shorter period is required under local law.

EFPIA adopted a reporting template that provides a structure by which all the information must be reported. 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 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, for HCOs only, sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an event); and 3) fees for service and consultancy. Unlike the US Sunshine Act approach, 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 EFPIA wants as much individual-level reporting as possible, there are two instances in which companies will report at the aggregate level. The first is when certain information cannot be disclosed at the individual level for legal reasons. Because the Disclosure Code is a voluntary form of self-regulation and not a law, and because of the data privacy

protections afforded to European Union ("EU") citizens under the governing EU Directive and national laws,²¹ 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.²² When companies are unable to obtain consent, 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.

The second instance when companies can report at the aggregate level is for research and development transfers of value. Specifically, companies are required to report all of their transfers for research and development in a calendar year, which includes costs related to events that are clearly related to research and development 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

²¹ There have also been recent developments with respect to the governing law in Europe for data protection. In June 2015, the European Council ("Council") agreed to a "General Approach" with respect to data protection reform at the EU level. The EU currently 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. For several years, the EU has been working on reforming its data protection system; significantly, the EU is working to adopt a Regulation in place of the existing Directive. This is a major difference because a Regulation is similar to a national law and it is applicable in all EU countries. The EU's goal in adopting a Regulation to replace the Directive is to achieve a greater level of uniformity and consistency across all Member States with respect to data privacy. The Council's "General Approach" is a significant development on the road to reform because the Council now has a political agreement that can serve as the basis for it to begin negotiations with the European Parliament and European Commission, with the goal of reaching an overall agreement on new EU data protection rules, ideally sometime in 2015.

²² 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."

companies make their "methodology" public. This methodology note is similar in concept to the assumptions document that companies have the option to submit under the US Sunshine Act, but the Disclosure Code mandates that all companies prepare and make public the methodology that they utilized in preparing their disclosure reports. Specifically, the Disclosure Code provides:

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.

As originally adopted in June 2013, the Disclosure Code required EFPIA's national member associations to transpose the disclosure requirements into their own national codes by December 31, 2013. The Disclosure Code envisioned that national member associations would both enact provisions for Code violations and incorporate EFPIA Disclosure Code 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 for compliance with the controlling national legislation.

EFPIA's approach to transparency, as articulated in the Disclosure Code, has the potential to result in some level of disclosure reporting consistency across Europe, although it is impossible to achieve absolute consistency for two main reasons. First, the various national disclosure laws, discussed *infra*, take precedence in those countries over industry's self-regulatory approach, and those laws have different reporting requirements. Second, in transposing the Disclosure Code into their national codes, EFPIA's member associations have taken slightly different approaches to some issues. Although EFPIA's member associations have

almost uniformly adopted the categories of transfers of value that must be reported at the individual or aggregate levels, there have been variations among countries on other subjects.²³

Over the past year, EFPIA has actively promoted its Code to garner support for its reporting provisions from industry, HCPs, and other stakeholders. In May 2014, EFPIA announced the launch of an on-line and social media campaign to publicize the Disclosure Code which included a new website, www.pharmadisclosure.eu, focused on developments related to the Disclosure Code. Since then, numerous articles have appeared on www.pharmadisclosure.eu discussing transparency developments in countries like Poland, Greece, Ireland, United Kingdom, Germany, and the Netherlands.²⁴

Richard Bergström, the Director General of EFPIA, posted two articles on the website titled, "Learning the Lessons from the US on Disclosure" and "Making Moves to Avoid Unintended Consequences of Disclosure."²⁵ In the former, Mr. Bergström examined how the US Sunshine Act experience "got off to a less than happy start" and contrasted the US model with the EFPIA disclosure model. Because of the voluntary nature of the EFPIA Code and the data privacy rights afforded to EU citizens, Mr. Bergström emphasized that it is critical for companies to engage with and inform HCPs about the disclosure process and give HCPs "sufficient time to review their data[.]"²⁶ In the latter article, Mr. Bergström discussed the work that EFPIA members were engaged in with respect to data collection, but he expressed concern about reports

²³ In last year's White Paper we analyzed some of the key variations among countries and focused on the following topics: 1) platform of disclosure; 2) language of disclosure; and 3) consent. The importance of consent to EFPIA's Disclosure Code cannot be overstated. It impacts how companies collect and maintain information, how they interact with HCPs and HCOs, and what information is ultimately reported. Although we will discuss consent throughout this White Paper, it is also helpful to consider a paper that we wrote earlier this year, *C-O-N-S-E-N-T: Find Out What It Means to You* (January 2015), that is devoted exclusively to consent in the EFPIA Disclosure Code context.

²⁴ PHARMADISCLOSURE.EU Website (Last visited Aug. 12, 2015), <http://pharmadisclosure.eu/news/>.

²⁵ Richard Bergström, *Learning the Lessons From the US on Disclosure*, PHARMADISCLOSURE.EU (Last visited Aug. 12, 2015), <http://pharmadisclosure.eu/news/learning-the-lessons-from-the-us-on-disclosure/>; Bergström, *Making Moves to Avoid Unintended Consequences of Disclosure*, PHARMADISCLOSURE.EU (Last visited Aug. 12, 2015), <http://pharmadisclosure.eu/news/making-moves-to-avoid-unintended-consequences-of-disclosure/>.

²⁶ Bergström, *Learning the Lessons From the US on Disclosure*, *supra*, note 25.

that HCPs may not consent to disclosure. On that point, Mr. Bergström observed that HCPs should consent because of the "importance of transparency in underpinning open collaboration between the industry and the medical profession[.]"²⁷

Beyond writing and posting articles, EFPIA sponsored an event on January 29, 2015, in Rotterdam titled, "Going Live: Implementation of the Disclosure Code"²⁸ and conducted a webinar on September 16, 2014, titled, "The EFPIA Code 'Moving the Industry/Health Care Professional Partnership Forward'".²⁹ And in June 2015, EFPIA released its "Annual Report 2014" in which it stated that

[t]here remain a number of challenges ahead. EFPIA is working with national associations to assess the impact of national law and regulations on the implementation of the Disclosure Code. Engagement with the health professional community to communicate the process, rationale and benefits of greater transparency is of paramount importance. The requirement for health professionals to give consent to disclose transfers of value makes it critical that we generate support in the healthcare community for disclosure. As we look forward, EFPIA's priority will be to support member companies and associations to engage with stakeholders on the issue, sharing the importance of transparency and developing relationships to drive up the rates of consent. We will continue to produce communications materials to support the project and engage at a pan-European level with key healthcare organisations.³⁰

EFPIA also provided guidance about the Code's provisions in the form of a Frequently Asked Questions document ("Disclosure Code FAQs").³¹ On the cover page of that document, EFPIA recommends that companies "carefully consider the content of their Methodological Notes to ensure they address some of the complex situations that cannot always be addressed in

²⁷ Bergström, *Making Moves to Avoid Unintended Consequences of Disclosure*, *supra*, note 25.

²⁸ Event - *Going Live: Implementation of the Disclosure Code: How Does the Pharmaceutical Disclosure Code Affect Health Care Providers?*, January 29, 2015, <http://pharmadisclosure.eu/events/event-going-live-implementation-of-the-disclosure-code-2/> (Last visited Aug. 12, 2015).

²⁹ Webinar: *The EFPIA Code: "Moving The Industry/Health Care Professional Partnership Forward"*, September 16, 2014, <http://pharmadisclosure.eu/events/webinar-the-efpia-code-moving-the-industryhealth-care-professional-partnership-forward/> (Last visited Aug. 12, 2015).

³⁰ EFPIA 2014 ANNUAL REPORT, *available at* <http://www.efpia.eu/annual-report-2014>.

³¹ EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS (EFPIA HCP/HCO DISCLOSURE CODE) - FREQUENTLY ASKED QUESTIONS (FAQS) (Published Dec. 19, 2014).

FAQs."³² The cover page also advises companies that when there is doubt about whether a particular interaction is reportable, "the reasonable solution is to disclose unless the Transfer of Value is clearly out of scope. *Companies would not be criticized for over-disclosure, but are likely to be in breach of national codes for under-disclosure.*"

The Disclosure Code FAQs document includes several "Points of Clarification and Definitions." Among other things, this section of the document addresses "Privacy law & regulations" and "Cross Border Payments". As to the former topic, the document focuses on the intersection between the Disclosure Code and national data privacy laws, and observes that "[a]s a general rule, each Member Company will ... need to obtain the consent of each HCP (or HCO when privacy regulation also apply to organisations) to disclose their personal data." In this section, EFPIA also explains that there is no "prescribed process" for companies to deal with inquiries from HCPs or HCOs, nor are companies required to "validate data" with recipients before disclosure. However, EFPIA recommends, as a matter of good practice, that companies establish procedures to deal with such inquiries and to inform HCPs and HCOs in advance what data will be disclosed about them.

There are a total of sixty-eight FAQs that are organized to correspond with the relevant sections of the Disclosure Code. The topic that has the most questions (twenty-four FAQs) is Section 3.01: Individual Disclosure. Other subjects addressed in multiple FAQs include consent, cross-border payments, and third parties/indirect payments. While it is beyond the scope of this White Paper to scrutinize all of the Disclosure Code FAQs, it is important to highlight a few points, as EFPIA makes clear that: 1) it will not be developing a unique database of

³² The significance of the Methodological Note is reinforced by the fact that over twenty answers direct companies to explain how they dealt with a particular issue in their Methodological Note.

HCPs/HCOs; 2) it will not be providing a list of specialties and professional designations that fall within the definition of HCP; and 3) it will not develop unique identifiers for HCPs/HCOs.

The actions of EFPIA's member associations have largely mirrored EFPIA's activities, as several national member associations have developed FAQs about the disclosure requirements in their countries. For example, the Spanish association adopted a revised Code of Practice in the summer of 2014,³³ which includes as an annex, "Queries (questions and answers) on the interpretation of the Code of Practice." Twenty-seven of the one hundred eleven questions and answers are devoted to the Code's disclosure provisions.

On the topic of consent, the Spanish FAQs articulate several key principles: 1) pursuant to Spanish data privacy laws, HCPs – but not HCOs – must give express, written consent to the disclosure of their individual data; 2) companies can decide to obtain consent on an activity level or HCP level basis, though the Spanish group recommends that companies obtain a general consent from HCPs for all of their collaborations; 3) if a HCP only gives partial consent, then all transfers of values to that HCP must be reported in the aggregate; 4) consent can be revoked at any time; 5) companies must have an internal procedure in place to ensure that all data privacy issues comply with governing law, and companies must be able to prove that a HCP has consented to disclosure; and 6) although companies do not have to obtain consent from HCOs to report their information at the individual level because Spanish data protection law only applies to natural persons, the Spanish industry group nonetheless recommends that companies inform HCOs of the data they will be disclosing.

³³ *Code of Practice for the Pharmaceutical Industry*, FARMAINDUSTRIA (June 2014).

In 2014, the German industry group released a FAQ document devoted to disclosure.³⁴ Although many of the eighty-eight questions and answers are similar to the EFPIA Disclosure Code FAQs, the German group also includes some additional topics. For example, the FAQs make clear that it is the payment date, as opposed to the date that a service was provided, that is the relevant date for reporting, and that when an event participant is a "no-show," the related expenses do not have to be disclosed because no payments were made to the "no-show" HCP.

The German FAQs also extensively address consent. One such question asks: "In principle, for companies that are 'organisations,' the Federal Data Protection Act does not apply. But what happens if an 'organisation' refuses to sign the transparency clause? ... [In that situation] is collaboration ... possible, but the relevant amount must be disclosed on an aggregate basis?" The German group answered that question as follows:

In principle, it should be noted that, in implementing the EFPIA Disclosure Code, even the [German] Transparency Code does not distinguish between "organisations" and "healthcare professionals" as recipients. The Code stipulates an explicit exception for the general transparency obligation for recipients of transfers of value only "legal reasons". In general, companies can ensure the required level of transparency for collaboration with "organisations" through individual contract negotiations. In practice, though, it is still possible that, despite intensive efforts, an "organisation" may not be willing to consent to a relaxation of the confidentiality of the major terms of an agreement. Based on the fundamental assessment of the EFPIA Transparency Code that, above all, transparency must not render collaboration impossible, such refusal may constitute a "legal reason". That said, one will of course have to place exacting demands upon companies' serious and intensive efforts during the individual contract negotiations; these demands must be documented and substantiated by the companies.³⁵

On that topic, the national member associations for Sweden and Slovakia have indicated in FAQs or other guidance that consent from HCOs is not required. Similarly, in Norway, the

³⁴ *Q&A on the FSA Code of Conduct on Transparency of Collaboration with Healthcare Professionals*, FREIWILLIGE SELBSTKONTROLLE FÜR DIE ARZNEIMITTELINDUSTRIE E.V." (FSA) (Last updated March 13, 2014).

³⁵ *Id.* at p. 28, Q&A 76.

industry group released a document titled, "The EFPIA Disclosure Code – Facts for Healthcare Professionals,"³⁶ that addresses that subject in the following way:

Pharmaceutical companies must comply with requirements for handling and safeguarding personal data and information. Publishing information about health care professionals requires their consent. Transfers to health organisations do not normally require consent. Information that cannot be published individually for legal reasons will be published at an accumulated level. Health care professionals are entitled to receive a copy of published or archived information and have any potential errors corrected. They can withdraw consent at any time and they have the right to have this information deleted. All the information will be handled in accordance with the Norwegian Personal Data Act.

In contrast to how the Spanish, Norwegian, Swedish, and Slovakian industry groups resolved whether HCOs were required to provide consent, the Lithuanian industry has advised that consent is required for both HCPs and HCOs. The Swiss industry group addressed the issue of HCO consent in a Recommendation in which it explains that companies must obtain consent from both HCPs and HCOs in order to comply with Swiss data protection law.³⁷ The Recommendation states that "**[i]f an HCP or an HCO declines to consent to disclosure, without a justified reservation, any pharmaceutical company concerned is advised not to sign an agreement** because individual disclosure is no longer a possibility in this case for reasons of data protection law." The Recommendation stresses that the Swiss Code

does not explicitly stipulate what is to be done if consent to disclosure is not given by a healthcare professional or by a healthcare organisation. **In such cases, this qualified silence leaves open the possibility for the companies either to continue cooperation without any payment of pecuniary benefits or to make provision for a summarised disclosure and, in that case, nevertheless to continue cooperation with an HCP or an HCO.**³⁸

³⁶ *The EFPIA Disclosure Code - Facts for Health Care Professionals: New Rules Concerning Disclosure of Financial Transfers from the Pharmaceutical Industry to Health Care Professionals Commencing on 01.01.2015*, LEGEMIDDELINDUSTRIEN (LMI) (Effective Jan. 1, 2015).

³⁷ *Recommendation No. 1 to the Pharma Cooperation Code: "Failure of Healthcare Professionals and Healthcare Organisations to Consent to Disclosure"*, SCIENCEINDUSTRIES SWITZERLAND (published October 2014).

³⁸ *Id.* at 2.

In Finland, the national association released a six-page FAQ document³⁹ that highlights several points, including: 1) with respect to whether a parent can report for subsidiaries or if different divisions can disclose different data, the Finnish group explains that the company will determine how to disclose but cannot "divide the data so that it will [be] disclosed in parts by the different divisions operating in a country. The practical disclosure can take place in the country chosen as long as the information is freely and readily accessible in the country that constitutes the object of disclosure"; 2) the Finnish group declares that the value of the disclosed transfer of value will be determined on the basis of the expenses incurred by the company, not the value/benefit from the recipient's point of view; 3) the group stresses that companies should try to obtain consent from HCPs using the template form it developed, and that if consent cannot be obtained then information will be reported at the aggregate level; and 4) the Finnish group recommends that the consent form be signed separately from any other agreements.

The Czech industry group issued a twelve-page, twenty-eight question FAQ document.⁴⁰ Like the Finnish group, the Czech group notes that the amount to be reported is the cost incurred by the company in making the transfer to the recipient, not the resulting income/benefit to the recipient. As to indirect transfers, the Czech group explains:

For purpose of disclosure of transfers of value provided to HCP/HCO by third parties, it is necessary to ensure that the contract between the third party and HCP/HCO contains a consent to disclose such transfers of value. The [contract] has to also cover a commitment that pharmaceutical companies will be given information about the value of the transfers of value provided to the final recipient.

³⁹ *Code of Ethics Questions and Answers 2/2: The Disclosure of Transfers of Value* (§ 124–130), PHARMA INDUSTRY FINLAND (PIF) (2014).

⁴⁰ *AIFP Disclosure Code – Frequently Asked Questions*, ASOCIACE INOVATIVNÍHO FARMACEUTICKÉHO PRŮMYSLU (ASSOCIATION OF INNOVATIVE PHARMACEUTICAL INDUSTRY (AIFP)).

The Slovenian group used EFPIA's Disclosure Code FAQs as a foundation and then added comments on certain topics.⁴¹ For example, on the issue of consent revocation, the Slovenian group states that if a HCP withdraws consent prior to publication, that HCP's data will be reported in the aggregate; however, if a HCP withdraws consent after publication, the company is not required to remove the data from its published report.

Turkey and Russia also released FAQs, but they are not as extensive as some of the other countries. The Russian FAQs have only three questions focused on transparency reporting. One question concerns the reporting of payments to third party event organizers:

[s]uch payments shall be disclosed based on the actual circumstances confirmed by documents. The exact distribution of the transfer of values among HCOs could be defined by the sponsorship agreement or by the official correspondence with such HCOs. [The reporting] [c]ompany should document the principle of the split of the transferred values among the HCOs.⁴²

The Turkish group emphasizes its commitment to transparency in its FAQs, explaining that it

has been contributing to the development of an environment of trust, to support improving the quality of life of our society and offer solutions to health problems. Pharmaceutical companies collaborate with healthcare professionals and healthcare institutions and organizations for providing new treatments in the service of medical practice, and the public want to make sure that such relationships do not influence treatment decisions. We believe that publicly disclosing transfers of value will help exhibit these collaborations transparently and serve as a significant step to assure public confidence in them.⁴³

⁴¹ EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS (EFPIA HCP/HCO DISCLOSURE CODE) - FREQUENTLY ASKED QUESTIONS (FAQS) (Published Dec. 19, 2014; FORUM updated Dec. 22, 2014).

⁴² *Questions and Answers to the Association of International Pharmaceutical Manufacturers (AIPM) Code of Practice*, Q&A 6.

⁴³ *Unlocking a World of Transparency: FAQs to the Association of Research-Based Pharmaceutical Companies (AIFD) Code*.

EFPIA's member associations in Germany, Poland, and Bulgaria also followed EFPIA's lead by creating websites devoted to transparency.⁴⁴ Similarly, in 2015 the Irish group launched a section of its website devoted to its Code's transparency provisions that includes educational materials.⁴⁵ The Finnish association sought to publicize its reporting obligations by releasing a video featuring a member of the Finnish Medical Society and two representatives of the Finnish group discussing the transparency initiative.⁴⁶

In addition to trying to build support for the EFPIA reporting system, many EFPIA members have revised various aspects of their disclosure provisions over the past year, some more significantly than others. In 2015, the Swiss industry group revised its disclosure provisions to clarify that writing implements and pads of modest value that are made available to participants at events are excluded from reporting,⁴⁷ while the Ukrainian industry group added a definition for HCO to its Code.⁴⁸ The Turkish industry group added a new section to its Code summarizing its disclosure requirements,⁴⁹ and the Slovenian industry group made a significant change to how its Code addressed the issue of consent. The prior version of the Slovenian Code made it clear that a member company could only transfer funds to a HCP if the HCP provided consent for individual-level disclosure, but the group revised that provision, whereby the current language is more like the EFPIA Disclosure Code. The Slovenian Code now states:

⁴⁴ Germany website, <http://www.pharma-transparency.eu/> (Last visited Aug. 12, 2015); Poland website, <http://kodeksprzejrzystosci.pl/> (Last visited Aug. 12, 2015); Bulgaria website, <http://www.transparencybg.org/index.php?id=306> (Last visited Aug. 12, 2015).

⁴⁵ Irish Pharmaceutical Healthcare Association (IPHA) website, <http://www.ipha.ie/alist/transfers-of-value.aspx?article=552e37ab-fcd4-4d98-aa2a-c303a8f6952a> (Last visited Aug. 12, 2015).

⁴⁶ PHARMACY INDUSTRY FINLAND, Transparency Initiative Video, available at <https://vimeo.com/121233799>.

⁴⁷ *Code of Conduct of the Pharmaceutical Industry in Switzerland on Cooperation with Healthcare Professional Circles and Patient Organizations (Pharma Cooperation Code)*, SCIENCEINDUSTRIES SWITZERLAND (Published Sept. 6, 2013; Revised July 1, 2015).

⁴⁸ *Code of Pharmaceutical Marketing Practices, Consolidated Version 2015*, ASSOCIATION OF PHARMACEUTICAL RESEARCH AND DEVELOPMENT (APRAD) (Effective March 2015).

⁴⁹ *Code of Good Promotional Practice and Good Communication*, Ed. 5.2, ASSOCIATION OF RESEARCH-BASED PHARMACEUTICAL COMPANIES (AIFD) (Last updated Feb. 20, 2015).

Each Member is obliged to acquire consent for disclosure of information from each clearly identifiable HCP prior to such disclosure of payments and other transfers of value. When concluding a contract, which includes a transfer of value to a HCP, members are encouraged to include in the contract provisions relating to HCP's consent to disclose transfers of value in accordance with the provisions of this Code. The same applies to the existing contracts, for which the members are encouraged to include such consent for disclosure at their earliest convenience.

Like the Slovenian industry group, the Latvian industry group revised its disclosure provisions to further align them with the EFPIA Disclosure Code. Specifically, the Latvian disclosure provisions were revised in the following ways: 1) a further exemption from reporting was added to include items of medical utility, meals and drinks, and samples; 2) in the provisions addressing consulting fees and services, the Latvian Code now uses EFPIA's language that they are to be disclosed as two separate amounts; and 3) the Latvian Code now uses EFPIA's language that costs related to events that fall under research and developments activities are to be reported in the aggregate.⁵⁰

The Irish industry group amended its Code during 2014, with the new version taking effect in 2015. For the first time, the Irish group identified the location of disclosure, as its new Code provides that disclosures shall be made on the company's website or on a central platform. The Irish group also modified its language about consent. Under the prior version of its Code, companies were *encouraged* to include consent provisions in their contracts with HCPs and HCOs. However, the revised Code no longer encourages that but instead *mandates* it, as the governing language now states: "When making a Transfer of Value to an healthcare professional/healthcare organisation, and in their written contracts with healthcare professionals/healthcare organisations, companies must include, or refer to, provisions relating to

⁵⁰ *Disclosure Code*, ASSOCIATION OF INTERNATIONAL RESEARCH-BASED PHARMACEUTICAL MANUFACTURERS (AIRP) AND LATVIAN GENERIC MEDICINES ASSOCIATION (Effective Jan. 1, 2015).

the Recipients' consent to disclose Transfers of Value in accordance with the provisions of this Disclosure Code." Furthermore, the Irish group added language from the EFPIA Disclosure Code that consultancy fees and expenses should be reported as two separate amounts and that costs from events related to research and development activities should be reported in the research and development aggregate category.⁵¹

Finally, the Irish group issued its report template. The template looks slightly different than the EFPIA template but there are no substantive differences. It is worth noting, however, that although a "Unique country identifier" is optional, as it is on the EFPIA template, the Irish template contains a note that explains that companies are "strongly encouraged" to use "the relevant Medical Council/Pharmaceutical Society of Ireland/Nursing and Midwifery Board of Ireland/Dental Council of Ireland registration numbers" for such identification.

The Association of the British Pharmaceutical Industry ("ABPI") also made significant changes to its disclosure provisions in 2014,⁵² and as a result its template differs from the EFPIA template. The key changes, and in some instances differences from the EFPIA Disclosure Code, adopted by the ABPI include: 1) its Code requires companies to report on transfers of value that they make to "other relevant decision makers" ("ORDM"); 2) companies must report on transfers of value that they make as part of a "Joint Working" arrangement; 3) its Code provides that reporting will be done via a centralized database; and 4) in a significant change from the EFPIA Disclosure Code, transfers of value to HCOs must be reported on a per activity basis, which is different than EFPIA's requirement that they be reported on an aggregate basis. Transfers of value to HCPs, however, are to be reported on an aggregate basis in the United Kingdom.

⁵¹ *Code of Practice for the Pharmaceutical Industry*, Ed. 8.1, IPHA (January 2015).

⁵² *Prescription Medicines Code of Practice Authority (PMCPA) Code of Practice for the Pharmaceutical Industry 2015*, THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY (ABPI) (Eff. Jan. 1, 2015).

The ABPI template is color coded, as columns/rows in pink are required information; columns/rows in blue are optional; and columns/rows in yellow are to facilitate the reporting process but are not published on the central database. As to the differences from the EFPIA template, the ABPI template has columns for a HCP's middle initial, specialty, and role, but those are color coded blue and therefore optional. Other optional columns pertain to address information and whether companies wish to report total numbers of their disclosures. Other differences from the EFPIA template include a column for Joint Working (which is required); separate reporting rows for ORDMs (in addition to HCPs); and per transaction rows for HCOs (as opposed to aggregate reporting per HCP). As to the yellow (information to facilitate the process but not published on the database), the template has columns for a recipient's e-mail address and for a Local Register ID or Third Party Database ID.

Like many of its EFPIA counterparts, the ABPI has developed flyers, guides, and FAQs about its disclosure provisions, many of which are focused on consent and the operation of the central platform for reporting.⁵³ In that regard, although companies (including non-members who agree to report) will be required to use the central platform for reporting, they are also free to disclose the reported information on their company websites. The ABPI explains that the disclosure process will work as follows:

1. Companies will collect details of relevant payments to HCPs/HCOs and collate into a standard template, modelled on the EFPIA template.
2. The template will be uploaded through a secure system.
3. Payment data from all companies will be consolidated and reconciled. This will entail adding unique identifiers to all HCPs/HCOs. The process will be managed by a third party provider with no additional workload for companies. This ensures the data is clean, complete and up-to-date and crucially ensures accurate search functionality.

⁵³ ABPI website, <http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx> (Last visited Aug. 12, 2015).

4. The data will be stored in a centrally hosted database, which the third party provider will maintain.⁵⁴

The ABPI elaborated on how HCPs would be able to review data about themselves before it becomes public, as the central reporting database will operate in the following manner:

1. When a company allocates spend against the HCP, it generates an automated email informing the HCP that payments have been allocated to their name. Companies may choose to write to HCPs in advance of publishing the data making them aware of the intention to post and the figures involved.
2. If an HCP disputes the figures they can reply to the email in order to resolve the dispute with the company.
3. After the checking period the data will go live on the ABPI website.⁵⁵

Until a HCP dispute is resolved, the data for that HCP is added to the aggregate total of the company's report.⁵⁶ To ensure that all questions and disputes between HCPs and companies can be resolved in a timely manner, company reports must be uploaded to the central database by March 31, 2016, so that all the information will be ready for publication by July 1, 2016.

The Netherlands is also unique, as its industry association, Nefarma, working in conjunction with several other key actors in the healthcare field, has required its members to report on their financial interactions – at the individual level – since 2013 (covering 2012 data), thereby pre-dating EFPIA's Disclosure Code reporting by several years. The Dutch system requires companies to submit their disclosure reports to a central register, that was established by the Dutch pharmaceutical group, within three months of the end of the calendar year. The central register is publicly available and can be searched by HCP, but not by company.

⁵⁴ The Central Platform, ABPI website, <http://www.abpi.org.uk/our-work/disclosure/Pages/The-central-platform.aspx> (Last visited Aug. 12, 2015).

⁵⁵ Disclosure of Payments to Individual Healthcare Professionals – Q&A For Use by the Pharmaceutical Industry with Healthcare Professionals, ABPI, *available on* ABPI website at <http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx>.

⁵⁶ *Id.*

Under the Dutch Code, companies were originally required to disclose their "financial relations"⁵⁷ resulting from the following types of agreements: 1) service agreements with HCPs; and 2) sponsorship agreements with groupings of HCPs and associations of professionals/institutions. However, the Dutch Code was amended so that, as of January 1, 2015, support for patient organisations and agreements in which a company will compensate hospitality costs for a HCP must also be reported.⁵⁸ Lastly, it is important to note that unlike EFPIA's Disclosure Code, which does not set a minimum threshold for reporting, the Dutch system requires that companies report their financial relations with a recipient only if the total sum in a calendar year exceeds 500 euros.

Furthermore, EFPIA Disclosure Code developments expanded in the past year beyond EFPIA's membership, as two national industry associations who are not part of EFPIA, those in Iceland and Luxembourg, adopted EFPIA's Disclosure Code. The pharmaceutical industry group in Iceland is Frumtök. In December 2014, Frumtök announced that it was fully implementing the EFPIA Disclosure Code,⁵⁹ a decision approved by Frumtök's Board without any objection from its members.⁶⁰ Frumtök will publish the disclosure reports on its website, and it has provided its members with suggested language to use in obtaining consent. Similarly, the Association of Pharmaceutique Luxembourgeoise, Luxembourg's pharmaceutical industry group,

⁵⁷ The Code defines financial relations in the following manner: "direct or indirect financial compensation in cash or in kind or otherwise provided by an authorisation holder to healthcare professionals, groupings of healthcare professionals and/or entities in which healthcare professionals participate or by which they are employed based in and/or practicing in the Netherlands or to a patient organisation based in the Netherlands."

⁵⁸ *Code of Conduct for Pharmaceutical Advertising*, Version 1, FOUNDATION FOR THE CODE FOR PHARMACEUTICAL ADVERTISING (CGR) (Eff. Dec. 1, 2014; Revised Jan. 1, 2015).

⁵⁹ See December 2014 Letter Announcement from Frumtök (announcing adoption of *EFPIA HCP/HCO Disclosure Code* (June 24, 2013), Effective Jan. 1, 2015, available on Frumtök website at <http://www.frumtok.is/AboutFrumtok/>).

⁶⁰ *Id.*

in March 2015 adopted EFPIA's disclosure provisions and included them in its Code of Conduct.⁶¹

The European generic medicines industry also took a big step on the path toward transparency reporting this past year. The European Generic Medicines Association ("EGA") adopted a "Code of Conduct on Interactions with the Healthcare Community"⁶² in December 2014, and issued an accompanying "Code of Conduct Questions and Answers" document.⁶³ The EGA Code includes a transparency provision that states:

Promoting transparent relations or interactions between companies and Healthcare Professionals/Organisations to relevant stakeholders assists informed decision-making and helps to prevent unethical and illegal behaviour.

Under various Applicable rules and requirements, companies must disclose engagements, payments and other transfers of value to Healthcare Professionals and Healthcare Organisations, either publicly or directly to specific stakeholders. Companies must therefore adhere to all applicable disclosure rules and requirements.[]

Companies should disclose engagements and transfers of value that could potentially pose a conflict of interest or encourage the recipients of the transfers of value to disclose them, where such disclosure would be in the best interest of patients or the public.

The EGA's Code states that any disclosures must comply with data privacy laws. The EGA's Questions and Answers document sheds additional light on the EGA's approach to transparency, as it makes clear that the exact items and payments for disclosure that will have to be disclosed will be defined at a later stage. The EGA Board is committed to provide guidance for disclosure by December 2015, at which time reporting deadlines will be defined.

⁶¹ *Code de déontologie*, ASSOCIATION PHARMACEUTIQUE LUXEMBOURGEOISE (APL) (Mar. 10, 2015).

⁶² *Code of Conduct on Interactions with the Healthcare Community*, Version 1, EUROPEAN GENERIC MEDICINES ASSOCIATION (EGA) (February 2015).

⁶³ *EGA Code of Conduct Questions & Answers*, Version 1, EGA QUESTIONS & ANSWERS SUB WORKING GROUP (QASWG) (March 2015).

In the face of the European pharmaceutical industry's movement toward transparency reporting, Eucomed chose to go in a different direction. In October 2014, Eucomed announced that it will be recommending to its members to phase out - by January 1, 2018 - direct industry sponsorship of HCPs to third-party organized conferences,⁶⁴ and it will also be introducing stricter rules for indirect sponsorship. These recommendations are being made in conjunction with the European Diagnostic Manufacturers Association ("EDMA"). The recommendations will be included in a joint code that will be known as the MedTech Europe Code of Ethical Business Practice, and will be proposed for adoption at the General Assembly of Eucomed, EDMA, and MedTech Europe in November 2015.

In making this announcement, Eucomed issued FAQs, one of which asks, "Why has the MedTech Industry chosen not to recommend a 'full disclosure' option similar to the one implemented by EFPIA ...?"⁶⁵ Eucomed answered that question by stating:

The option of "full disclosure," as adopted by EFPIA, has been given serious consideration by both the EDMA Executive Committee and the Eucomed Board. However, specifically for the direct sponsorship of HCPs to third-party medical educational conferences, both the EDMA Executive Committee and the Eucomed Board have concluded that such a system may not be the most effective way to address the inherent compliance risk related to providing a benefit to HCPs when supporting them directly to conferences. Both EDMA and Eucomed hold the opinion that the progressive phasing out of direct sponsorship is a more effective approach. The EDMA and Eucomed Codes of Business Practice, which also cover other elements of the relationship between industry and HCPs, are currently being reviewed and will be adapted to reflect the changing legal and compliance environment.

Thus, Eucomed has, in its view, found a "more effective way" than EFPIA to address compliance risks associated with interactions with HCPs. But the Belgian medical device

⁶⁴ Eucomed Press Release, *European MedTech Industry Continues to Reinforce its Codes of Ethical Business Practice*, <http://www.eucomed.com/newsroom/131/187/European-MedTech-industry-continues-to-reinforce-its-Codes-of-Ethical-Business-Practice?cntnt01template=detail-pr> (Oct. 15, 2014).

⁶⁵ *Reinforcing the EDMA and Eucomed Codes of Ethical Business Practice: Questions & Answers*, Q&A 21, MEDTECH EUROPE (Oct. 15, 2014).

industry group, Unamec, broke from Eucomed on the issue of transparency reporting and instead aligned itself with the pharmaceutical industry approach by adopting EFPIA-like reporting.⁶⁶ First reports are not due until 2017 to cover 2016 data. In Belgium, there will be a common, central transparency platform that will include not only reports from Unamec's members, but also from the members of pharma.be, which is the Belgian EFPIA group.

European Legislation

Recent European transparency developments have not been limited to codes and self-regulation; rather, there were significant changes with respect to existing laws, while the possibility of new laws increased in England and Scotland.⁶⁷

In December 2011, France enacted the LOI n 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé (“French Sunshine Act”). The French Sunshine Act, and its implementing decrees, require broad disclosure by pharmaceutical and medical device companies of agreements with and benefits provided to HCPs and various entities. Under the French Sunshine Act, there are two main types of disclosure requirements: 1) all agreements, except for commercial sales agreements of goods and services, that companies have with specified individuals, including HCPs, and entities; and 2) certain benefits given to those individuals and entities. Similar to the reporting process in the United States, companies must report the required information about benefits and agreements to the French government via a web portal. Also similar to the United States, the information that companies report to the French government is made publicly available on a governmental website. In terms of the timing of reports in France, companies must report the pertinent

⁶⁶ *Ethische Code (Code of Ethics)*, UNAMEC (November 19, 2014), available on UNAMEC website at <http://www.unamec.be/code-dethique/code-dethique-2/?lang=nl>.

⁶⁷ In our White Papers from past years, we analyzed the details of legislative requirements in several European countries, including France, Portugal, Slovakia, Romania, and Denmark and direct your attention to those papers for such details.

information on agreements to the public authority within fifteen days of the signing of the agreement. In contrast, for benefits, the relevant information must only be submitted bi-annually: by August 1 for benefits provided from January to June of a calendar year, and by February 1 for benefits provided from July through December of the preceding calendar year.

The biggest development over this past year concerning the French Sunshine Act occurred with the February 24, 2015, decision of the French Supreme Administrative Court (*Conseil d'Etat*), which expanded the scope of reporting. Pursuant to the French Sunshine Act and its implementing decrees, the amount of consulting fees paid to HCPs did not have to be reported; 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. Consequently, prior to the court's ruling, covered companies were only required to disclose the existence of agreements with HCPs, but the court determined that they must also be required to disclose the remuneration paid to French HCPs under such agreements. Thereafter, the French Parliament took up legislation responsive to the Court's ruling, which is pending in the Senate.

Portugal joined the transparency movement in 2013 with the publication of Decree-Law n. 20/2013 of February 14⁶⁸ and Decree-Law n. 128/2013 in September 2013.⁶⁹ Under Portuguese law, pharmaceutical companies and patient scientific associations and health professionals have obligations to report to Infarmed support provided and received.⁷⁰ Originally, the threshold for reporting was twenty-five euros, but in October 2014 Infarmed raised the reporting threshold to sixty euros.

⁶⁸ Decreto-Lei n.º 20/2013 de 14 de Fevereiro, www.dre.pt/pdf1s/2013/02/03200/0079900912.pdf (in Portuguese).

⁶⁹ Decreto-Lei n.º 128/2013, de 5 de Setembro, http://www.infarmed.pt/portal/page/portal/infarmed/legislacao/legislacao_farmaceutica_compilada/titulo_iii/titulo_ii_i_capitulo_i/035-g2_dl_128_2013_vf.pdf (in Portuguese).

⁷⁰ Infarmed is the Portuguese National Authority of Medicines and Health Products, which is a government agency accountable to the Health Ministry.

Denmark has had governmentally-imposed disclosure requirements for several years, and in November 2014 several new requirements took effect. As of that date, both pharmaceutical and medical device companies are required to report, once a year, on the collaborations that they enter into with Danish HCPs. Although companies must provide certain information about the HCPs with whom they have worked, they are not required to list any information concerning any financial compensation or benefits that they provided to those HCPs; instead, that responsibility lies with the HCPs. Before working with companies, HCPs are also required to either obtain permission from, or notify, the Danish Health and Medicines Authority, depending on the nature of the working relationship. Companies have an obligation to advise the HCPs with whom they will be working of the fact that they must notify or seek permission from the Danish Health and Medicines Authority before proceeding with the relationship.

Romania's disclosure law requires pharmaceutical companies to declare to the Ministry of Health and the National Medicines Agency all sponsorship activities and any other costs for doctors, nurses, professional organisations, and patient organisations.⁷¹ Recipients of such benefits also have reporting obligations. The Romanian law charged the Ministry of Health and the National Agency for Medicines and Medical Devices with the responsibility to more fully develop the reporting system, and the agency did so in an Order it issued earlier this year.⁷² The Order requires manufacturers and marketing authorization holders and others to report their sponsorship and other expenses paid for HCPs and other specific recipients. The report format, which is somewhat similar to EFPIA's, requires details relating to the nature, amount, and date of payment and is to be submitted to the Romanian government. Starting with 2016 reports for 2015 data, reports are due by March 31 and will be made public in the second quarter.

⁷¹ The Medicinal Product of Law nr. 95/2006, Art. 7991 (2014), on healthcare reform (Romania).

⁷² Ordinul nr. 194/2015, ORDIN Nr. 194 din 23 februarie 2015, *available at* http://www.anm.ro/anmdm/_/ORDINE/OMS_194_2015.pdf (in Romanian).

On December 24, 2014, Greece enacted Law 4316/2014, which deals with a host of health-related issues and includes provisions that impose disclosure obligations upon pharmaceutical companies.⁷³ According to the law, pharmaceutical companies are required to disclose on their websites and at the official website of EOF (Greece's National Organization for Medicines) benefits provided to HCPs and other specified recipients not later than 6 months from the end of each calendar year. The disclosed information must include, but is not limited to, grants, donations, registration fees for scientific conferences and events, travelling and accommodation expenses, as well as any other benefit based on an agreement between the company and a HCP in relation to the promotion of the prescribed medicinal products. Benefits that relate to research and development activities, as well as non-interventional clinical trials (with or without the application of a medicinal product) are to be cumulatively disclosed by each pharmaceutical company. Costs for market research, meals and drinks, as well as objects of minor value for medical application and training that are directly associated with the conduct of the daily medical practice of HCPs are expressly excluded from the disclosure obligation. "Minor value" is defined as the value of any object that does not exceed in total the amount of fifteen euros (€15), including VAT.

In addition to those developments, whereby laws were enacted or took effect, or existing legislative-based reporting requirements were modified, the possibility of Sunshine laws has arisen in England and progressed in Scotland. In July 2015, *The Telegraph* ran a series of articles about its undercover investigation into the relationship and financial ties between the

⁷³ ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ ΤΗΣ ΕΛΛΗΝΙΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ ΤΕΥΧΟΣ ΠΡΩΤΟ, Αρ. Φύλλου 270, 24 Δεκεμβρίου 2014 (Greek Law 4316/2014, Article 47: Coverage of Medicinal Products Outside the Scope of the Approved Indications (Dec. 24, 2014)).

pharmaceutical industry and senior staff of NHS England.⁷⁴ *The Telegraph's* investigation focused on how NHS England employees who help decide which drugs are used by HCPs and hospitals are being lobbied by and paid to work as consultants for pharmaceutical companies. The articles portrayed the interactions between industry and the government officials as posing serious conflicts of interest for the NHS staff.

In response to *The Telegraph's* investigation, a spokesperson for NHS England stated that

[t]hese are extremely serious allegations so we have immediately directed NHS Protect to launch a full investigation of each and every case identified in this press report. These allegations also raise the question of whether this country should now legislate for a so-called Sunshine Act, requiring full disclosure of any payments made by a pharmaceutical or device company to a health professional or NHS employee.⁷⁵

Moreover, *The Telegraph's* articles noted that Jeremy Hunt, the UK Health Secretary, "is understood to be considering a new law."⁷⁶ The ABPI responded to *The Telegraph's* articles by issuing a press release that explained why industry works with HCPs, that it does so ethically

⁷⁴ Claire Newell, Edward Malnick, Lyndsey Telford, Luke Heighton and Syed Fayaz, *Revealed: The NHS Officials Paid, Wined and Dined on Spa Trip: Health Officials from Across England Attended a Luxury Trip Hosted by a Pharmaceutical Company Trying to Get Its Products Used by the Health Services*, *The Telegraph* (July 24, 2015, 9:40 PM BST), <http://www.telegraph.co.uk/news/nhs/11760923/Revealed-The-NHS-officials-paid-wined-and-dined-on-spa-trip.html>; Edward Malnick, *Doctors May Have to Declare Links to Drug Companies: Medical Professionals Could Be Ordered to Declare Any Financial Ties to Pharmaceutical Companies Under Plans Being Considered by Ministers*, *THE TELEGRAPH* (July 24, 2015, 9:32PM BST), <http://www.telegraph.co.uk/news/nhs/11760922/Doctors-may-have-to-declare-links-to-drug-companies.html>; Malnick, Newell, Telford, Heighton and Fayaz, *NHS Bosses Paid By Drug Firms "Play With Virtual Money": Health Official Exposed in Telegraph Investigation Reveals How He Manages a Budget of £24 million*, *THE TELEGRAPH* (July 24, 2015, 12:30 PM BST), <http://www.telegraph.co.uk/news/nhs/11760376/NHS-bosses-paid-by-drug-firms-play-with-virtual-money.html>; Heighton, Malnick, Newell, Telford and Fayaz, *Lavish Trips Laid On By Drugs Firms to "Sway" NHS Staff: Health Service Officials Earn Thousands Organising and Attending Extravagant Events Where Companies Promote Their Products*, *THE TELEGRAPH* (July 22, 2015, 9:00 PM BST), <http://www.telegraph.co.uk/news/nhs/11755884/Lavish-trips-laid-on-by-drugs-firms-to-sway-NHS-staff.html>; Newell, Malnick, Telford, Heighton, and Fayaz, *NHS Bosses Paid By Drug Firms: Senior NHS Staff Are Being Paid Thousands of Pounds and Taken on Expensive Trips by Drug Companies Lobbying to Get Their Products Used By the Health Service, the Daily Telegraph Can Reveal*, *THE TELEGRAPH* (July 22, 2015, 9:00 PM BST), <http://www.telegraph.co.uk/news/nhs/11755878/NHS-bosses-paid-by-drug-firms.html>; See also Ed Silverman, *UK May Require Doctors to Report Their Financial Ties to Drug Makers*, *WALL ST. J.* (July 27, 2015, 12:36 PM ET), <http://blogs.wsj.com/pharmalot/2015/07/27/uk-may-require-doctors-to-report-their-financial-ties-to-drug-makers/>.

⁷⁵ Malnick, *Doctors May Have to Declare Links to Drug Companies*, *supra*, note 74.

⁷⁶ *Id.*

within the ABPI's self-regulatory framework, and that there will be individual level transparency reporting next year.⁷⁷

Beyond the reporting in *The Telegraph* and the response to that, a June 2015 report by the NHS England's "efficiency tsar" also discussed the possibility of Sunshine-type legislation in England.⁷⁸ In that regard, the report states that

[t]he Sunshine Act in the US requires manufacturers of drugs, medical devices, biological and medical supplies to collect and track all financial relationships with physicians and teaching hospitals and to report this centrally. The goal of the law is to increase the transparency of financial relationships between health care providers and pharmaceutical manufacturers and to uncover potential conflicts of interest. ... [W]e are exploring whether there is a need for a 'Sunshine Act' similar to that in place in the United States.

In Scotland, the potential move toward legislation is being driven by a concerned citizen availing himself of the Scottish public petition process.⁷⁹ In September 2013, 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 has taken evidence and conducted several hearings on the petition, including three in 2015, and requested various entities, including the Scottish government, to respond to points raised by Dr. Gordon. The Scottish government has submitted six separate responses to the Public Petitions Committee, including three this year. In those submissions, the government explains that it is in the process of engaging stakeholders and consulting with them about the best approach to transparency, which could include legislation. According to its most recent submission, the government expects to complete its consultation in the fall of 2015.

⁷⁷ July 24, 2015, ABPI Press Release by Dr. Virginia Acha, *Working with Healthcare Professionals is Critical for the Future of Medicine*, <http://www.abpi.org.uk/media-centre/newsreleases/2015/Pages/240715.aspx>.

⁷⁸ Lord Carter of Coles, *Review of Operational Productivity in NHS providers: Interim Report June 2015*.

⁷⁹ *PEO01493: A Sunshine Act for Scotland*, THE SCOTTISH PARLIAMENT, <http://www.scottish.parliament.uk/GettingInvolved/Petitions/sunshineact> (last visited on Aug. 12, 2015).

The situations in England and Scotland demonstrate the unpredictability of the transparency movement. It could be that legislation is never passed in either country, but it is important to recall that a scandal in France - a public health scandal involving a pharmaceutical company's off-label promotion to doctors and the resulting negative health consequences for patients - led to the adoption of the French Sunshine Act (along with other, broader healthcare reforms). Although it is too soon to predict that *The Telegraph's* investigation will lead to a law, the possibility of a Sunshine Act in England is more of a possibility now than it was before *The Telegraph's* series ran.

Of course, if England enacts a Sunshine Act, that would undermine and seriously jeopardize the entire premise of EFPIA's Disclosure Code and reporting scheme: a consistent, unified self-regulatory approach to transparency reporting across Europe. If other European governments see that England, which has a long and storied history of allowing for and encouraging self-regulation in the pharmaceutical industry, is unwilling to defer to EFPIA's transparency approach and decides to enact its own Sunshine Act, then other European governments may also be unwilling to wait and choose instead to enact their own laws. That is the exact situation that EFPIA has been hoping to avoid, whereby Europe becomes a maze of inconsistent, confusing, and burdensome reporting laws. Thus, it will be important for the life sciences industry to monitor what happens on the legislative front in England and other countries. The adoption of additional laws could result in EFPIA's Disclosure Code reporting being a short-lived and unsuccessful experiment.

The Pacific Rim

Momentum for more transparency has also increased in the Pacific Rim, with Australia being a hub of activity. There, the pharmaceutical industry is represented by Medicines

Australia ("MA"), which promulgates and implements a Code of Conduct. For several years, MA's Code required aggregate reporting only.⁸⁰ On July 2, 2014, however, MA announced that it had submitted an application to the Australian Competition and Consumer Commission ("ACCC") for approval of the next edition of its Code, Edition 18.⁸¹ The new Code, which was approved unanimously by MA's members, includes individual-level reporting for the first time. When it originally adopted Edition 18 of the Code, MA expected the ACCC authorisation process to take approximately six months and that the new Code would take effect in January 2015. However, the journey to ACCC approval did not go as quickly as MA had anticipated.

In October 2014, the ACCC issued a draft determination that conditionally authorised MA's Code.⁸² One condition concerned how the Code dealt with consent. As approved by MA, its Code essentially followed EFPIA's approach. That is, to comply with relevant data privacy regulations, a company would have to get a HCP's consent in order to report his or her information at the individual level; if a HCP refused to consent, then the relevant spend would be reported in the aggregate. However, the ACCC proposed a condition that would require that all relevant transfers of value be reported, namely by providing that if a company did not obtain consent from a specific HCP then the company could not work with that HCP. The ACCC was skeptical of MA's approach because it was concerned that only some, but not all, transfers of value be reported at the individual level and, therefore, the system would not provide an appropriate level of transparency.

⁸⁰ We will not focus on the aggregate reporting requirements that will remain in place until September 30, 2015. Rather, we will focus on the individual-level reporting requirements that take effect as of October 1, 2015.

⁸¹ July 2, 2014, Press Release, *MA submits new transparency reforms to ACCC*, MEDICINE AUSTRALIA, <http://medicinesaustralia.com.au/2014/07/02/ma-submits-new-transparency-reforms-to-acc/>.

⁸² Draft Determination, Applications for Revocation and Substitution of Authorisation Lodged by Medicines Australia Limited in respect of the Medicines Australia Code of Conduct, Edition 18 (Oct. 17, 2014).

In its draft determination, the ACCC also pointed out that it was considering whether to require hospitality reporting, as the Code did not require such reporting.⁸³ Following the draft determination, the ACCC sought comments from interested stakeholders and conducted a pre-decision conference with interested parties about the aforementioned topics, as well as whether MA should create a central database for reporting, as the Code provided that companies were to place their disclosure reports on their websites.

In February 2015, the ACCC announced that it had modified its approach.⁸⁴ Rather than requiring a company to obtain consent from HCPs, the ACCC proposed that a company could not make a transfer of value unless they had taken appropriate steps to inform the HCP of the disclosure obligation, so that the HCP would reasonably expect the disclosure. The ACCC's announcement also touched on other reporting-related requirements, and MA and other interested parties thereafter made further submissions to the ACCC.

Ultimately, on April 24, 2015, the ACCC issued its final determination and ruled that companies do not have to obtain consent from HCPs but that they must ensure, before providing a relevant benefit to a HCP, that the benefit will be able to be individually reported.⁸⁵ Specifically, the ACCC declared that MA had to amend its Code by October 1, 2016, to reflect that disposition. On that point, the ACCC explained:

To address [its concerns about incomplete reporting], and in order to ensure that the potential benefits from the regime are realised, the ACCC has decided to impose a condition to ensure that **all** relevant transfers of value by member companies to individual [HCPs] are reported (which does not include expenditure on food and beverages) and those [HCPs] are identified by name.

⁸³ *Id.* at p. 59. On that point, MA again followed EFPIA's lead and subjected such spend to limits instead of having to be reported.

⁸⁴ February 6, 2015 E-Mail from ACCC seeking comments regarding the conditions of authorisation it proposes to impose on any authorisation of Edition 18 of the MA Code.

⁸⁵ *Applications for Revocation and Substitution of Authorisation Lodged By Medicines Australia Limited in Respect of the MA Code*, Edition 18, ACCC FINAL DETERMINATION (April 24, 2015).

The condition requires member companies to take appropriate steps to ensure that, before making a transfer of value to a [HCP], the [HCP] reasonably expects that the transfer will be disclosed. This approach avoids any difficulty with a consent based approach which might arise where, as identified by [MA] and other interested parties, a [HCP] could provide consent to a transfer of value being reported, receive the transfer of value and then withdraw consent before the transfer has been reported.⁸⁶

Nonetheless, the ACCC is leaving in place for one year – from October 1, 2015-September 30, 2016 – the consent/aggregate reporting approach that MA originally adopted. Specifically, the ACCC noted that it

accepts that this new transparency regime is a significant change to the Code and, therefore, it is important to allow sufficient time for it to be implemented properly. Accordingly, [MA] will not be required to amend the Code to require the reporting of all transfers of value until 1 October 2016. (The transparency regime originally proposed by [MA] will operate from 1 October 2015 until [MA] makes that amendment).⁸⁷

Accordingly, for one year, companies will be able to use the consent/aggregate reporting approach, but after October 1, 2016, that option will no longer be available and companies will have to report on all transfers of value and take reasonable steps to ensure that HCPs will expect that the transfers they receive will be reported. The ACCC also addressed other issues in its final determination, including: 1) companies would not have to report food/beverage expenditure; 2) the transparency data must be published in a common accessible format; 3) the transparency data must be made publicly available for at least three years from the date of first publication; and 4) MA must continue its efforts to establish a central reporting system for reporting the transparency data and it must provide regular update on its progress.

⁸⁶ *Id.* at p. iii.

⁸⁷ *Id.*

MA responded to the ACCC's determination by issuing a press release that welcomed the ACCC's action.⁸⁸ On May 16, 2015, MA's new code, Edition 18, officially went into effect, and it includes the changes compelled by the ACCC. In addition to the Code, MA has released Code of Conduct Guidelines, Version 1, and a Fact Sheet and FAQs about the new individual-level disclosure requirements.⁸⁹

MA's Code requires two types of reports: 1) HCP reports, and 2) sponsorship of third party educational events reports. First, for HCP reports, data collection for this new reporting regime begins with data collection on October 1, 2015. The initial reporting period runs from October 1, 2015-April 30, 2016. Reports must be published on company websites by August 31, 2016. The second reporting period runs from May 1, 2016-October 31, 2016, and reports for that period must be published on company websites by February 28, 2017. Thereafter, reports are on a six-month reporting period cycle, with the due dates for reports being August 31 to cover the November 1-April 30 period and February 28 to cover the May 1-October 31 time period.

As noted, MA complied with the ACCC's determination about consent. Thus, for the first year of reporting, companies must obtain informed consent from a HCP before reporting his or her individual information. If the HCP does not grant consent for reporting, the company must report such transfers of value in the aggregate. Similarly, if a HCP grants and then revokes consent, spend on that HCP must be reported in the aggregate. In terms of what must be reported in the aggregate, companies must report the total number of HCPs for whom personal data cannot be published at the individual level and the total monetary amount paid to such recipients,

⁸⁸ Media Release, *Pharmaceutical industry moves closer to improved transparency with ACCC Code authorisation*, MEDICINES AUSTRALIA (April 24, 2015), <https://medicinesaustralia.com.au/media-release/pharmaceutical-industry-moves-closer-to-improved-transparency-with-accc-code-authorisation/>.

⁸⁹ MA Code of Conduct, Edition 18 (Effective May 16, 2015 and Amended June 11, 2015), and Code of Conduct Guidelines, Version 1 (May 2015), *available at* <https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>; *See also* MA 18th Code of Conduct, Frequently Asked Questions (Last updated Aug. 3, 2015) and 18th Code of Conduct, Enhanced Transparency Fact Sheet (Last visited Aug. 12, 2015), *available at* <https://medicinesaustralia.com.au/code-of-conduct/>.

subdivided into the following categories: registration fees; air travel and accommodation; and fees (e.g., sitting fees, honoraria, consultancy fees). In its Guidelines, MA includes a "Proposed Privacy Statement" that companies can include in their contracts with HCPs.

Beginning on October 1, 2016, however, the informed consent requirement will be replaced by a "reasonable expectation of disclosure of personal information" standard. Rather than asking HCPs to consent to individual-level disclosure, companies will instead be prohibited from making a reportable transfer of value to a HCP "unless they have taken appropriate steps to give notice of this disclosure obligation, so that the healthcare professional would reasonably expect the disclosure."⁹⁰ Because HCPs will no longer have to give consent, they likewise will no longer be able to refuse consent and, therefore, aggregate reporting will no longer be an option for companies. MA includes a "Proposed Collection Statement" in its Guidelines that companies can use to give notice to HCPs of the transparency reporting obligations.

In terms of the substance of the individual level reporting requirements, companies must report on payments or transfers of value that are related to prescription medicines. Thus, companies that have separate operating divisions that do not supply prescription medicines for human use are only required to report on payments or transfers of value that are related to their prescription medicines. Companies do not have to report on payments or transfers of value that they make to HCPs who are their own employees.

The disclosure reports must be published on company websites in the following formats: 1) a searchable table to be viewed on a company's website; and 2) a CSV file available for download from the company's website capable of being supported by spreadsheets and database management systems, including Microsoft Excel. The data in the reporting template must be

⁹⁰ MA Code of Conduct, Edition 18, *supra* note 89, at ¶ 41.3.2., p. 72.

sorted alphabetically by each HCP's family name, then by first name, then by middle initial, then by event date. MA will provide hyperlinks to each company's report from its website.

Similar to the United States, the Code requires that the most senior executive officer of the company provide a signed and dated declaration that the company has published the required report on its website that includes all the required information. The declaration must be provided to MA within seven calendar days following publication of each report.

As to the type of information to be reported, MA combines elements of the US Sunshine Act and EFPIA reporting programs, as companies must report the following transfers of value:

- 1) Fees paid to HCPs in return for speaking at an educational meeting or event.
- 2) Sponsorship of a HCP to attend an educational event. (Reportable items include any airfare, accommodation or registration fees directly associated with the meeting (whether held within or outside Australia).)
- 3) Fees paid to HCP consultants in Australia, or to their employers on their behalf, for specific consultancy services. These services include, but are not limited to, all services provided in relation to educational meetings, preparation of promotional materials or product position papers, and assistance with training or any other advice to the company. Significantly, this does not include payments to consultants in relation to research and development work, including the conduct of clinical trials. (Reportable items include all payments in respect to consulting fees, accommodation and airfares (both within and outside Australia) associated with the provision of the consulting services.)
- 4) Fees paid to HCPs in their role as Advisory Board members. (Reportable items include all payments in respect to Advisory Board sitting fees, accommodation and airfares (both within and outside Australia) associated with the activities of the Advisory Board.)
- 5) Fees paid to HCPs for the purpose of market research if the company knows the identity of the HCP. Reporting is not required when the company contracting the market research is not involved in the selection of participating HCPs and is not aware of the identities of those participating HCPs.

When a HCP requests that payment for any of the foregoing reportable services be made to a third party, such payments must still be disclosed for the individual HCP; however, the report should identify that the payment was made to a third party.

As with EFPIA, and unlike the United States or France, meals and drinks do not have to be reported. Instead, MA has imposed a maximum cost of a meal (including beverages) of \$120 (excluding GST and gratuities). Further, the Code states that the maximum would only be appropriate in exceptional circumstances; in most situations, MA expects that the cost of a meal will be well below that maximum level.

For each individual transfer of value to a HCP that is reported, the following information must be provided according to a template included in the Code's Guidelines:

- Date of the event or provision of service;
- HCP's name;
- Type of HCP (i.e., medical practitioner, pharmacist, nurse practitioner);
- HCP's principal practice address;
- Description of the service (i.e., speaker, Advisory Board member, Chairperson at educational meeting, etc.);
- Description of the event (i.e., company sponsored meeting in Australia; independent meeting held in Australia; independent meeting held overseas; etc.);
- Whether the payment was made to the HCP or a third party;
- The amount of the payment or transfer of value, subdivided (as appropriate) into registration fees, travel and accommodation, and fees for service.

Companies must provide HCPs on whom they intend to report an opportunity to review and submit corrections to their information. The period for review and verification/correction must be at least six weeks. The reported information must remain on company websites for three years from the date of first publication.

Separate and apart from HCP individual-level reporting, MA also requires its members to report on sponsorship of third party educational meetings and symposia. Data collection for third party educational event reports is on the same schedule as HCP consultant reports. That is,

the initial reporting period runs from October 1, 2015-April 30, 2016. The second reporting period runs from May 1, 2016-October 31, 2016. Thereafter, reports are on a six-month reporting period cycle. Unlike HCP reports, third party educational event reports must be submitted to MA, which in turn publishes them on its website two months after receipt. For the first reporting period (October 1, 2015-April 30, 2016), companies must submit their reports to MA by August 31, and MA will publish them by October 31, 2016. For the second reporting period (May 1, 2016-October 31, 2016), companies must submit their reports to MA by February 28, 2017, and MA will publish them by April 30, 2017. For the third reporting period (November 1, 2016-April 30, 2017), companies must submit their reports to MA by August 31, 2017, and MA will publish them by October 31, 2017.

Companies must provide a report on all sponsorships of independent educational meetings and symposia organized by third party organizations in a table set out by MA. The following are examples of the sponsorships that must be reported:

- Financial sponsorship of a third party educational event;
- Providing a lump sum sponsorship to be a gold/platinum/bronze (or similar) sponsor of an event;
- Monetary contribution to support the conduct of grand rounds, department meetings, clinical meetings, or journal club meetings; and
- Purchase space for providing a trade display at an educational event (including if this is the only sponsorship of the event).

When a company only provides hospitality (food and beverages) for an educational meeting, such spend is not reportable. The Code's Guidelines include a reporting table for educational events, which requires companies to provide a description of the event, including duration of educational content delivered; the venue; the professional status of attendees; the purpose of the financial support; the total cost of any sponsored hospitality, travel, and accommodation; the number of attendees; and the total cost of the sponsorship contribution.

While there has been much activity in Australia on the transparency front over the last year, the topic has also garnered attention in neighboring New Zealand. In the March 27, 2015, edition of the *New Zealand Medical Journal*, five HCPs authored an editorial titled, "Let the sunshine in – making industry payments to New Zealand doctors transparent".⁹¹ The HCPs argue that industry payments influence doctors and raise a host of concerns. After reviewing the US Sunshine experience and EFPIA's and MA's push for more transparency, the HCPs recount that there are no transparency reporting requirements in place in New Zealand. Accordingly, the HCPs declare that "[w]e consider that New Zealand should adopt international best practice with respect to transparency over industry payments to individuals. Shining some light on the relationships is likely to be good for our health." Specifically, the HCPs contend that "[t]he time is right for a healthy dose of sunlight to shine on [industry-HCP] relationships, with the preferred method being legislation similar to the US Sunshine Act which would provide greater transparency for New Zealand health consumers."

In response to the editorial, the general manager of Medicines NZ, the pharmaceutical industry group in New Zealand, stated that transparency is occurring around the world and that it is "something we are looking at – how we fit in overall. Transparency is something we take seriously It is on the board and secretariat agenda this year to come up with a position."⁹² More importantly, in terms of whether there will be a legislative or self-regulatory approach to transparency, New Zealand government officials indicated that the government was not interested in a solution that involved governmental legislation or regulation on transparency; rather, the government prefers an industry-led approach.

⁹¹ Cindy Farquhar, Tim Stokes, Andrew Grey, Mark Jeffery, Peter Griffin, *Editorial: Let the sunshine in – making industry payments to New Zealand doctors transparent*, NZMJ Vol. 128 No. 1411 (March 27, 2015).

⁹² Virginia McMillan, *Tell-all transparency sought to show who gets cash from industry*, NZDOCTOR.CO.NZ, p. 2 (March 27, 2015).

Medicines NZ also addressed transparency in its 2014 Annual Review, as it noted that "[a]n emerging issue is disclosure of payments to healthcare professionals with overseas experience showing it is a complex and resource intensive exercise. It is an issue that we will keep a watching brief on in 2015, and further engage with all key stakeholders."⁹³ It will be interesting to see if Medicines NZ follows the lead of MA in the coming year and moves to impose reporting requirements on its members.

Finally, the Japan Pharmaceutical Manufacturers Association ("JPMA") has imposed individual-level reporting requirements on its members for several years. In February 2015, the JPMA revised its "Transparency Guideline for the Relation between Corporate Activities and Medical Institutions." The most significant change is that, beginning with 2016 spend to be reported in 2017, transfers of value relating to research and development spend will have to be disclosed at the individual recipient level.

Conclusion

In the past year the global transparency movement has grown at an accelerating pace. From increased reporting in the United States, to data collection for EFPIA, to amendments to existing reporting laws and the adoption of new ones, life science companies have had to deal with a dizzying array of developments. And the movement has also spread into other sectors, like the generic industry in Europe, and has arisen in new countries, like New Zealand.

It is impossible to predict what will happen next, but reporting under EFPIA's Disclosure Code undoubtedly will be a seminal moment in the transparency movement when reports are submitted in 2016. If EFPIA's self-regulatory approach fails to meet its objectives, if a significant portion of the pharmaceutical industry does not choose to voluntarily report, or if a significant number of HCPs refuse to consent and most of the data reported is at the aggregate

⁹³ MEDICINES NEW ZEALAND 2014 ANNUAL REVIEW, at p. 9 (2014).

level, it is likely that European governments and the public will call for more individual-level transparency. Consequently, more governments may choose to enact transparency laws and thereby doom the future of EFPIA reporting. This is not some remote or far-flung possibility, as the potential that England may enact a Sunshine Act is an ominous warning for the future of self-regulatory reporting. However, if EFPIA reporting succeeds, along with reporting in Australia, that will undoubtedly influence how other industry groups approach transparency and we are more likely to see self-regulatory measures spread to additional corners of the globe.