



WHITE PAPER

The Ongoing Global Transformation in Life Sciences Transparency

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The global trend toward transparency in the life sciences industry has accelerated over the past six months. On February 1, 2013, the Centers for Medicare and Medicaid Services released the final regulations implementing the Sunshine Act provisions of the Patient Protection and Affordable Care Act.¹ Similarly, on May 21, 2013, the French government issued a long-awaited decree² to implement its Sunshine Act, which was passed on December 29, 2011.³ The French decree requires pharmaceutical and medical device companies to report on agreements that they have with healthcare professionals, as well as benefits that they provide to them. Several aspects of the decree are controversial, especially in terms of the low thresholds for reporting and the onerous burdens that the reporting requirements impose on life sciences companies.

Industry, too, has entered the fray, seeking to instill practicality and uniformity into the regulations. On June 24, 2013, the European Federation of Pharmaceutical Industries and Associations (“EFPIA”) adopted a new code, “EFPIA Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations” (“Disclosure Code”),⁴ which requires pharmaceutical companies to publicly disclose, in 2016, their 2015 financial relations with healthcare organisations and healthcare professionals.

With this recent activity, the momentum for increased transparency within the life sciences industry continues to build. As the trend accelerates, it is accompanied by a vigorous

¹ 42 CFR Parts 402 and 403.

² Décret n° 2013-413 du 21 mai 2013 portant approbation de la charte de l'expertise sanitaire prévue à l'article L. 1452-2 du code de la santé publique (the “May 21, 2013 Decree”).

³ LOI n 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé (the “French Sunshine Act”).

⁴ *EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA HCP/HCO Disclosure Code)*, EFPIA.EU, available at <http://transparency.efpia.eu/uploads/Modules/Documents/GA%20240613%20A5%20EFPIA%20Codes%20Annex%201%20Disclosure%20Code%20FINAL.pdf>.

debate about how to best achieve the goals of transparency. While some governments⁵ have adopted legislatively-imposed reporting requirements, other countries (and, in some instances, regions) rely on requirements created by industry associations. There is an obvious tension between these two approaches: supporters of transparency legislation claim that their model will result in cost savings and a reduction in corruption, whereas advocates of industry self-regulation emphasize that their approach is more efficient and could lead to global uniformity across borders.

The trend toward more transparency, and the fight between supporters of governmental action and advocates of industry self-regulation, is occurring throughout the world. This article will touch upon some of the global “hot spots” and highlight some recent developments.

Europe

France, Portugal, Denmark, and EFPIA are four of the “hottest” spots in Europe, but for different reasons. In December 2011, France enacted 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”).⁶ The French Sunshine Act requires broad disclosure by pharmaceutical and medical device companies of agreements with healthcare professionals (“HCPs”) and benefits provided to HCPs and various entities. The details of those public disclosure requirements were to be spelled out by an implementing decree that was required to be in effect by August 1, 2012. Several draft decrees were circulated in early 2012, but the final decree was not issued until May

⁵ Countries with legislative mandates include Denmark, France, Portugal, Slovakia and the United States.

⁶ The French Sunshine Act, *supra* note 3.

21, 2013.⁷ The Ministry of Health and Social Affairs also published a Circular, dated May 29, 2013, that provides additional guidance about certain portions of the final decree.⁸

The final decree imposes two main types of disclosure requirements on pharmaceutical and medical device companies: 1) all agreements, except for commercial sales agreements of goods and services, that they have with specified individuals and entities; and 2) certain benefits given to those individuals and entities. Specifically, companies must disclose the existence of agreements with and benefits provided to the following:

- 1) Healthcare professionals (e.g., physicians, nurses, but the disclosure requirements do not apply to the reporting company's employees);
- 2) Associations of healthcare professionals and associations of students for relevant occupations;
- 3) Students for relevant occupations;
- 4) User associations of the health system (public or private);
- 5) Health facilities;
- 6) Foundations, learned societies, and consulting companies or organisations in the health sector;
- 7) Publishing companies: press, radio, television, and on-line media;
- 8) Editors of prescription and dispensing software; and
- 9) Legal entities contributing to the initial training of healthcare professionals.

There are some similarities, but also some differences, with respect to the information that companies must reveal about agreements they have with the aforementioned recipients and the benefits they provide to them. For agreements, companies must reveal the following:

- the identity of the parties to the agreement:
 - For healthcare professionals: name, professional address, qualifications, title, specialty, and registration number with the relevant professional board;
 - For healthcare students: name and educational institution;
 - For legal entities, like associations, health institutions, etc.: name, corporate purpose, and registered address;
- the date the agreement was signed;
- the subject matter of the agreement (which can be phrased in such a way as to protect confidential and trade secret information);

⁷ The May 21, 2013 Decree, *supra* note 2.

⁸ Circular No. DGS/PF2/2013/224 of May 29, 2013 regarding the application of Article 2 of LOI n 2011-2012 of December 29, 2011 increasing the safety for health purposes of drugs and healthcare products.

- if the agreement involves a promotional or scientific event, the program of the event.

As to benefits, companies must disclose all benefits that they provide, whether direct or indirect, in kind or in cash, to the aforementioned recipients if the benefits are equal to or exceed ten euros, inclusive of VAT. Benefits worth less than ten euros do not have to be disclosed. In disclosing benefits, companies must identify the recipient and the recipient's personal information in the same manner as for agreements (e.g., name, address, title); the amount of each benefit; the date and nature of each benefit; and the time period (either the first six months of a year or the latter six months) during which the benefit was received.

The Circular elaborated upon the definition of benefits, as it provides that benefits include in-kind benefits like donations of equipment, invitations, hospitality expenses, or payment for trips. Additionally, benefits include commissions, discounts, rebates, or repayment of expenses. As to the indirect aspect of benefits, the Circular makes clear that benefits include money or in-kind support given to family members of a covered recipient or groups of which the recipient is a member.⁹

All of this information about agreements and benefits will eventually be disclosed, in French, on a to-be-established public website. The website will be created and operated by a public authority, and the information will be available for a period of five years.

In terms of timing, companies must report the pertinent information for 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. Once the public website is operational, the

⁹ *Id.*

information about benefits provided and agreements made during the first part of a calendar year will be made public by October 1 of that year, and benefits provided and agreements made during the second part of a year will be published by April 1 of the following year.

Because the public website is not yet operational, the decree provides for a different reporting scheme until the website is ready. Specifically, the decree provides that by June 1, 2013 (ten days after the decree was issued), companies were to submit all reportable benefits provided and agreements made during calendar year 2012 to the appropriate national council of the healthcare professionals association (e.g., National French Medical Association). Companies were to provide the reportable information for agreements concluded and benefits provided during the first six months of 2013 to the appropriate national council by August 1, 2013. All of this information covering both 2012 and the first six months of 2013 is then to be published by October 1, 2013, on two separate websites: the website of the reporting company (or a common website shared by several companies for that purpose), and the website of the relevant French national council.

Although the decree provides important details about the French transparency system and imposes significant reporting requirements on life sciences companies, several important issues remain unclear or ambiguous. For example, the decree requires that the value of benefits be disclosed, but does not impose a similar requirement for agreements. This distinction between reporting the value of one type of interaction, but not that of a different type of interaction, might be addressed, and the inconsistency reconciled, in a future decree or in further guidance from the government. Moreover, it is unclear if the decree applies only to companies established in France or more broadly to companies that are doing business in France or are otherwise interacting with French healthcare professionals. The operational details of the public website,

among other matters, are also expected to be clarified by additional decrees or guidance. Thus, the life sciences industry will once again be waiting for further clarification while simultaneously having to proceed with its reporting obligations in France. As it monitors any such developments, the life sciences industry will also be closely watching to see if healthcare professionals or organisations challenge the decree, which could lead to further delay or complications for the industry.

The French decree will have an immediate, direct, and enormous impact on transparency reporting in France, but it may also serve as a model for other countries that are pursuing, or considering, a legislative approach to transparency. In that regard, it is likely that governments in other countries will enact laws that are at least as strict as, or similar to, the French system, as no country wants to be viewed as soft on industry. Thus, the recent issuance of the French decree could serve as a seminal moment in the global transparency movement.

Portugal entered the transparency fray earlier this year with the publication of Decree-Law n. 20/2013 of February 14,¹⁰ which was an amendment to the Medicinal Products Act.¹¹ As with the French law, the Portuguese amendment addressed a wide range of topics relating to many aspects of drug safety, but also established new reporting requirements for several actors in the healthcare field. Under the amendment, pharmaceutical companies must report to Infarmed (the Portuguese National Authority of Medicines and Health Products, which is a government agency accountable to the Health Ministry) on the grant of any financial support provided to patient organisations. Significantly, the amendment also requires patient organisations, scientific associations, and health professionals (including doctors, dentists, pharmacists and nurses), to submit to Infarmed information about subsidies, grants, and other financial support that they

¹⁰ Decreto-Lei n.º 20/2013 de 14 de Fevereiro, *available at* www.dre.pt/pdf1s/2013/02/03200/0079900912.pdf (in Portuguese).

¹¹ Decreto-Lei n.º 176/2006 de 30 de Agosto.

receive from pharmaceutical companies if such support exceeds twenty-five euros. It is too early to evaluate the effects of Portugal's government-based approach to transparency, but it will be interesting to observe how the pharmaceutical industry and the key stakeholders in Portugal react to and comply with these new reporting requirements.

Denmark is somewhat unique, in that it already has governmentally-imposed disclosure requirements, but is expected to adopt an additional legislative scheme this year. Currently, healthcare professionals are required to obtain permission from the Danish Health and Medicines Authority before they can establish a relationship with or collaborate with a pharmaceutical company.¹² In turn, pharmaceutical companies must annually report to the Danish agency by January 31 all doctors, dentists, or pharmacists with whom they have collaborated. Although pharmaceutical companies must provide certain information about the doctors, dentists, and pharmacists with whom they have worked (e.g., name, address, dates of collaboration), they are not required to list any information concerning any financial compensation or benefits that were provided to those healthcare professionals.

The current system, which identifies relationships between industry and professionals but does not provide for any financial transparency, is expected to be modified by new legislation in 2013. This legislation is expected to be applicable to both pharmaceutical companies and medical device companies. Under the anticipated legislative scheme, it is the healthcare professionals – not the life sciences companies – who will have the primary reporting obligation. Healthcare professionals are expected to have to disclose the amount of fees they receive for research (e.g., clinical research); fees for education/speaking; fees for consultancy (e.g., advisory boards); fees for market research; events; and other sponsorships. Further, it is anticipated that

¹² The Danish Pharmacy Act (Bekendtgørelse af lov om apoteksvirksomhed), *available at* <https://www.retsinformation.dk/Forms/r0710.aspx?id=120537> (in Danish).

the Danish Health and Medicines Authority will disclose this individual data on its website. Again, as with France, the life sciences industry should be paying close attention to the legislative process in Denmark, as it will be important to see if the legislation places the primary reporting burden on the healthcare professional, as in Portugal, or if it is shifted to industry, as in France.

In contrast to, and, some suggest, in direct response to, the legislative approach taken by some European governments, EFPIA has been acting aggressively to implement an industry-driven solution to this issue. EFPIA is the representative body of the pharmaceutical industry in Europe, and it includes forty pharmaceutical companies and the national industry associations of thirty-three countries. Prior to its adoption of the Disclosure Code in June 2013, EFPIA had two relevant codes: 1) EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions With, Healthcare Professionals;¹³ and 2) EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations¹⁴ (together, the “pre-2013 Codes”). The pre-2013 Codes, like the Disclosure Code, apply to EFPIA member companies, their subsidiaries, and any companies affiliated with EFPIA member companies or their subsidiaries, if such affiliated companies have agreed to be bound by the pre-2013 Codes. The pre-2013 Codes contain minimum standards that all national industry associations must have in their own national codes. The pre-2013 Codes permit national organisations to impose stricter obligations or requirements upon member companies.

¹³ *EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with Healthcare Professionals*, EFPIA.EU, available at http://www.efpia.eu/uploads/Modules/Documents/efpia-code_promotion_hcp_-_11.06.14_final_editing_07-08-11-mcp-20110630-002-en-v1_1.pdf, (“Code on Interactions with Healthcare Professionals”).

¹⁴ *EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations*, EFPIA.EU, available at http://www.efpia.eu/uploads/Modules/Documents/po_code_-_sga_14_june_2011-20110627-004-en-v1_0.pdf, (“Code on Interactions with Patient Organisations”).

The current EFPIA Code on Interactions With Healthcare Professionals, which was most recently amended in June 2011, does not contain reporting or disclosure requirements, but encourages companies to make publicly available information about donations, grants, or benefits in kind made to institutions, organisations, or associations comprised of healthcare professionals or that provide healthcare or conduct research. The EFPIA Code on Relationships with Patient Organisations, also most recently amended in June 2011, contains reporting requirements. The requirements apply to activities commenced as of or ongoing on January 1, 2012, with the first reports required to be made public by the end of the first quarter of 2013.

EFPIA, however, revolutionized its approach to transparency at its 2013 Annual Meeting when it adopted the Disclosure Code. In a July 2, 2013, press release announcing the adoption of its Disclosure Code,¹⁵ Richard Bergstrom, the Director General of EFPIA, declared that

[t]his is an important step for our industry, as we demonstrate our commitment to transparency and secure the trust of the patients our industry serves. This code is EFPIA's delivery on the guiding principles set forth last Autumn, in which we committed to working together with relevant stakeholders to establish a clear approach to transparency of financial transactions and other declarations of interest.

We know that by making this a success, we can improve the relationship between industry, HCO's and HCP's in a way that ultimately benefits the people that all three of these stakeholders aim to serve – patients.

(emphasis in original)

EFPIA's intent in is also evident from the Preamble of the Disclosure Code, wherein EFPIA declares that it

believes that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe a medicine is one of the pillars of the healthcare system. EFPIA recognises that interactions between the industry and healthcare professionals can create the potential for conflicts of interest.

¹⁵ Press Release, EFPIA, Pharmaceutical Companies to Disclose All Financial Relations with Healthcare Professionals, *available at* <http://www.efpia.eu/mediaroom/108/44/Pharmaceutical-Companies-to-Disclose-All-Financial-Relations-with-Healthcare-Professionals>.

Consequently, professional and industry associations, including EFPIA and its member associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

Under EFPIA's Disclosure Code, pharmaceutical companies must publicly disclose, in 2016, their 2015 financial relations with healthcare professionals and healthcare organisations. The Disclosure Code provides that company 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. To assist companies with their disclosure obligations, EFPIA adopted a template – a multi-colored, multi-column, and multi-row XL spreadsheet – that provides a structure by which all the information must be reported. The Disclosure Code requires that companies make their disclosure in one of two ways: 1) on their own website; or 2) on a central platform, which could be developed by the national member association. 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.

As to the substantive requirements of the Disclosure Code, companies must report, on the individual level, their transfers of value provided to healthcare professionals and healthcare organisations in the following categories: donations and grants (for healthcare organisations only); contributions to costs related to events (registration fees; travel and accommodation, to the extent permissible; and, for organisations only, sponsorship agreements to manage an event); and fees for service and consultancy. Transfers of value include direct and indirect transfers, whether in cash, in kind, or otherwise. Companies must also report, for those same categories, the aggregate amounts they spend during the reporting period. Moreover, companies are required to report, on an aggregate basis, their research and development transfers of value during the

reporting period. Such transfers of value – to both healthcare professionals and healthcare organisations – are defined by the Disclosure Code to include support relating to the planning or conduct of: 1) non-clinical studies, as defined in OECD Principles on Good Laboratory Practice; 2) clinical trials, as defined in the governing directive of the European Commission; and 3) non-interventional studies pursuant to EFPIA’s HCP Code.

EFPIA is requiring formal transposition of these new requirements into the national codes of its member associations by December 31, 2013, a process that will be closely monitored by the pharmaceutical industry. Member associations are expected to incorporate the provisions of the Disclosure Code into their own national codes in full, except when the Disclosure Code’s provisions conflict with governing national laws or regulations. In such instances, EFPIA has indicated that it will tolerate deviations from the provisions of the Disclosure Code, but only to the degree needed for compliance with the controlling national legislation. Likewise, EFPIA has acknowledged that to the extent a company’s compliance with governing national legislation would make adherence to the Disclosure Code impossible, then such lack of adherence will not be considered a breach of the Disclosure Code.

The Disclosure Code also requires EFPIA’s member associations to include sanctions for violations of the disclosure provisions, with such sanctions to be proportionate to the nature of the violation. Although the Disclosure Code suggests that a combination of publication and fines would be the most effective sanction, it ultimately delegates the responsibility to member associations to decide the most appropriate sanction scheme.

The EFPIA approach holds tremendous potential for achieving some degree of uniformity across Europe. The critical variable will be the nature and extent of the differences in how national industry associations implement EFPIA’s provisions.

While the recent revisions to the EFPIA codes may have the most significant long-term consequences for transparency within the pharmaceutical industry in Europe, there are a number of countries in which significant reporting has already taken place. For example, the code of the Netherlands industry group requires its members to report in 2013 on amounts spent in support of healthcare practitioners – on an individual level – in 2012.¹⁶ Under the Dutch code, companies are required to disclose two different types of financial relationships with healthcare professionals: 1) service agreements; and 2) sponsorship agreements of meetings between a company and associations of professionals/institutions that directly or indirectly improve healthcare to patients or promote medical science. There are five types of service agreements: 1) consulting; 2) advisory; 3) speaker; 4) non-speaker research; and 5) other.

The substance of the mandated disclosure depends upon the nature of the agreement, service, or sponsorship. For a service agreement, the company must provide the personal information of the healthcare professional, including: name; specialization; work address; amount paid to the professional; and name, business address and/or registration number of the association or institution that employs the healthcare professional. For sponsorship agreements, the company must disclose the name, business addresses and registration number of the recipient group, along with the amount paid to the group during the calendar year. Not all financial relationships between companies and Dutch healthcare professionals must be disclosed. Rather, the Dutch Code set the threshold amount at five hundred euros per calendar year.

The first reports have already been submitted by companies to a central register set up by the Dutch pharmaceutical group. Disclosures were made pursuant to the following disclosure schedule:

¹⁶*Code of Conduct Disclosure*, FOUNDATION FOR THE CODE FOR PHARMACEUTICAL ADVERTISING (CGR) (effective January 1, 2012).

-- companies were to upload the requisite information to the central register by the end of the first quarter;

-- healthcare practitioners and healthcare organisations could review the accuracy of the information submitted by pharmaceutical companies until April 12;

-- to the extent there were any disputes or discrepancies regarding the reporting of financial support, they were addressed between April 12 and April 19;

-- the register was made available to the public on April 25 on the website www.transparantieregister.nl.

The website can be searched by healthcare practitioner, but it cannot be searched by company. Thus, if a person were interested in learning how much (fictional) “Dr. John Smith” received from pharmaceutical companies in 2012, that person could search for Dr. John Smith and see how much support was given to him. However, a person interested in learning how much (fictional) “Pharma Company X” spent on Dutch healthcare professionals in 2012 cannot perform a similar company-based search on the website.

The Dutch industry group issued a press release on April 25, 2013 – the day the register was made available to the public – to tout its success in achieving a system that provided greater transparency into the relationships between the pharmaceutical industry and healthcare professionals.¹⁷ In that regard, the press release pointed out that the Dutch system actually provided more transparency than the scheme promulgated in the United States under the Sunshine Act. The release also stressed that the Netherlands was leading the way in Europe with respect to self-regulation and that other countries, including the United Kingdom, were looking to the Dutch scheme as a model.

¹⁷ Press Release, CGR, Transparency, *available at* <http://cgr.nl/getattachment/Nieuws/Nieuwsbrieven/2013/Nr-2-2013-Transparantieregister/CGR-nieuwsbrief-2-2013.pdf.aspx> (in Dutch).

Not only did the press release trumpet the development of the Dutch transparency system, it also provided data about the financial information that had been disclosed by companies to the register. According to the press release, more than fifty pharmaceutical companies submitted reports. Combining those reports from all the reporting pharmaceutical companies revealed the following: 1) there were approximately 7,600 financial relationships reported involving more than 2,100 physicians and 1,200 institutions and associations; 2) the total reported value of those relationships was more than thirty million euros; and 3) of the approximately thirty million euros, approximately 4 million went to individuals and 28 million to institutions and associations. While acknowledging the success of its system, the Dutch industry group acknowledged that there could be minor errors in the registry, but pledged to work with all the relevant stakeholders to clarify any unclear issues and to further improve the system.

Like their Dutch counterparts, members of the Association of the British Pharmaceutical Industry (“ABPI”) disclosed their relationships with healthcare professionals for the first time in 2013.¹⁸ The ABPI requires companies to disclose the support they provide healthcare professionals in several categories, including payments for consulting services and sponsorship of healthcare professionals to attend events sponsored by third parties. Unlike Dutch pharmaceutical companies, however, members of the ABPI do not have to report on the individual level but rather only in the aggregate, and they do not need to identify the names of the particular professionals that they support.

In an April 5, 2013 press release, the ABPI announced that, based on the 2013 disclosures of its members, it estimated that the pharmaceutical industry spent approximately £40m in 2012

¹⁸ *Code of Practice for the Pharmaceutical Industry Second 2012*, THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY (ABPI), available at http://www.abpi.org.uk/_layouts/download.aspx?sourceurl=/our-work/library/guidelines/Documents/ABPI_Code_2012.pdf (“ABPI Code”).

on such support.¹⁹ Commenting on those figures and the collaboration between the pharmaceutical industry and healthcare professionals, the ABPI Chief Executive stated:

The industry is proud of its collaboration with healthcare professionals. Working closely with healthcare professionals has helped the industry to consult with, and listen to, clinical expertise and develop medicines which are in the best interests of patients. Full transparency about these relationships is right and appropriate and we have taken the lead to make this a reality. By publishing these figures industry's aim is to ensure these vital relationships are open and transparent. It is right that professionals are reimbursed fairly for the time and expertise they regularly provide the industry in developing the next generation of medicines. These figures also show another way in which the pharmaceutical industry adds value to [the National Health Service "NHS"] by supporting training and development and medical education. This support is particularly important at a time when NHS budgets are under increasing pressure. It is right that companies are transparent about the support they provide and it is important that we also recognise the benefits this delivers the NHS.

The establishment of the aggregate reporting requirements in the British ABPI Code in 2012, and the ABPI's members' public reports, did not signal the end of the British group's involvement with transparency; in fact, in January 2013 the ABPI announced the launching of a consultation by the Ethical Standards in Health and Life Sciences Group ("ESHLSG") (which is a group of twenty organisations that work collaboratively to improve the relationship between the life sciences industry and healthcare professionals) to promote greater transparency between industry and healthcare professionals. Specifically, the ESHLSG will study the feasibility and process associated with establishing a public register of payments made to healthcare professionals on the individual level. In a press release announcing the launching of this initiative, the Chief Executive of the ABPI stated that:

[t]he ABPI welcomes the new consultation launched today by the [ESHLSG], which seeks the views of the healthcare community and the commercial healthcare sector on the important issue of payments to healthcare professionals.

¹⁹ Press Release, ABPI, Pharmaceutical industry takes the lead on transparency, *available at* <http://www.abpi.org.uk/media-centre/newsreleases/2013/Pages/050413-a.aspx>.

There is lots of work to do to lead us to individual disclosure and we need to hear views on the best way to implement a workable solution. Therefore, we believe this consultation will be an instrumental step in the co-creation and development of a system of disclosure and the move towards greater transparency.²⁰

The ABPI's efforts to further develop its transparency system have been somewhat complicated, however, by EFPIA's June 2013 adoption of its Disclosure Code. As a member of EFPIA, the ABPI must ensure that its code is consistent with EFPIA's new code – and the ABPI is already working to harmonize its approach with that of EFPIA.

On July 8, 2013, Heather Simmonds, the Director of the Prescription Medicines Code of Practice Authority (“PMCPA”), which administers the ABPI Code, sent a letter to ABPI Member Companies, ABPI R& D Affiliates, ABPI General Affiliates, and ABPI Honorary Members discussing recent proposals to amend the ABPI code. While many of the proposed changes are unrelated to transparency and the EFPIA code, Ms. Simmons noted that some “changes are needed to the ABPI Code [] as a result of the new EFPIA Code []. ... The proposals to implement the EFPIA Disclosure Code are in relation to what information companies should collect in 2015 for disclosure in 2016.” Ms. Simmons stressed that the proposals did not include how the disclosures would be made in 2016, in terms of whether they would be on company websites or a central database, as the ABPI is not expected to decide that issue until the end of 2014.

Ms. Simmonds's letter also includes a schedule for adoption of the new ABPI Code. On July 8, the date of her letter, the proposals were sent to ABPI members and affiliates and were made available to the public on PMCPA's website. The consultation period will close on September 5, and final proposals will be agreed to by the ABPI Board of Management by

²⁰ Press Release, ABPI, Consultation launched to promote greater transparency between healthcare professionals and industry, *available at* <http://www.abpi.org.uk/media-centre/newsreleases/2013/Pages/Payments-to-HCPs-consultation.aspx>.

October 1. By November 5, proposals will be presented to the BPI Half Yearly General Meeting, and the new code will take effect on January 1, 2014.

Another European hot spot is Greece. In December 2012, the Hellenic Association of Pharmaceutical Companies (“SFEE”) announced a new and updated Code of Ethics for its members, which took effect in February 2013.²¹ With respect to disclosure requirements, the Greek Code provides that members must publish annually on the SFEE’s website information about donations, sponsorships, or provisions in kind they make to foundations, institutions, organisations, or associations comprised of healthcare professionals. In addition, the SFEE Code limits the amounts that companies can give to 1% of their total turnover. Similarly, the SFEE Code establishes a maximum annual limit of five thousand euros (gross payment, excluding VAT and legal withholdings) that can be paid to a healthcare professional for consulting services. Separate and apart from those disclosure requirements and limitations, the SFEE Code includes a more structured and rigorous approach to conferences and scientific events. Among other things, the SFEE Code establishes restrictions on the number of physicians that can attend conferences and events, as well as limits on how much companies can expend on such sponsorship. The SFEE Code also requires companies to obtain the approval of the National Organisation for Medicines in order to sponsor certain types of scientific events.

These types of reporting requirements and limitations are not unique to the Greek Code, as many other national industry groups in Europe have similar provisions. For example, the code of the German pharmaceutical industry group, which was most recently amended in August 2012, requires that companies publish the donations, or other monetary support, that they provide

²¹ *Code of Practice on the Promotion of Prescription Only Medicinal Products*, HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES (SFEE), available at http://www.sfec.gr/files/page/20130308_ENG.pdf.

to institutions, organisations, or associations whose members are healthcare professionals, when the support is greater than ten thousand euros per benefit recipient per year.²²

Another related area that many national industry codes address concerns gifts to healthcare practitioners. Many codes include restrictions on whether and how gifts may be provided to healthcare professionals, and some Codes include monetary limitations. The Code of the pharmaceutical industry group for the Czech Republic, which was most recently amended in September 2012, is an example of one such code, as it limits gifts, pecuniary advantages, or benefits in kind during the promotion of products to healthcare professionals to a nominal value of less than 200CZK.²³ Gifts of medical literature, however, are permissible up to a limit of 1,500CZK per piece, but the total value of all gifts, pecuniary advantages, or benefits provided to a single healthcare professional cannot exceed 1,500CZK per year. In Norway, the gift limit is NOK 1000, and only one such item may be distributed per doctor per year.²⁴

Unlike EFPIA and other European national industry associations, Eucomed, which represents the medical device industry in Europe, has not been aggressive in imposing reporting requirements on its members. Eucomed represents approximately 25,000 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment, and amelioration of disease and disability.²⁵

Although Eucomed is committed to high ethical standards for its members and works to ensure that its members adhere to the highest ethical and professional standards when they

²² *Code of Conduct on the Collaboration with Healthcare Professionals (Code of Conduct Healthcare Professionals)*, VOLUNTARY SELF-REGULATION FOR THE PHARMACEUTICAL INDUSTRY (FSA), available at http://www.fs-arzneimittelindustrie.de/securedl/0/3519298585/71c778ace31b43f8a1c7ca527e8ac9ec2e1f79e5/fileadmin/medien/Code_of_Conduct.pdf.

²³ *Code of Conduct*, ASSOCIATION OF INNOVATIVE PHARMACEUTICAL INDUSTRY (AIFP), available at <http://www.aifp.cz/cz/clanek-detail.php?clanek=72>.

²⁴ *Rules for Marketing of Medicinal Products*, ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY IN NORWAY (LMI), available at <http://www.lmi.no/media/1208123/rules-for-marketing-of-medicinal-products.pdf>.

²⁵ *About Us*, EUCOMED.ORG, <http://www.eucomed.org/about-us> (last visited July 1, 2013).

collaborate with healthcare professionals, its Code of Ethical Business Practices does not mandate reporting of interactions with healthcare professionals.²⁶ In September 2012, Eucomed issued a White Paper titled, “Transparency and Disclosure: Interactions between Industry and Healthcare Professionals (HCP)”.²⁷ In that paper, Eucomed acknowledged the growth of the transparency movement and cited the laws passed in France and Slovakia, as well as the transparency schemes in the United States, Australia, and Japan. Nonetheless, Eucomed expressed the view that if a country were to pursue reporting requirements, whether through legislation or a voluntary industry code, several important factors and issues must be evaluated and accounted for before adopting such a scheme. For example, Eucomed’s White Paper recommends that companies should only have to report on payments made above “a reasonable threshold per year per HCP”, and that reporting should take place only once a year, to reflect the payments made during the previous calendar year, rather than multiple times during the course of a given year.

The Pacific Rim

In Australia, the pharmaceutical industry is represented by Medicines Australia, which, among other things, promulgates and implements the Medicines Australia Code of Conduct (“Australia Code”).²⁸ The Australia Code, first established in 1960, has been revised numerous times and is currently in its 17th Edition as of January 2013.²⁹ Under that most recent edition, companies are required, for the first time, to report on the aggregate fees they pay to healthcare professionals who provide services, including, for example, preparing promotional materials and

²⁶ *Code of Ethical Business Practice, Eucomed Guidelines on Interactions with Healthcare Professionals*, EUCOMED.ORG, <http://www.eucomed.org/key-themes/ethics> (last visited July 1, 2013).

²⁷ *Transparency and Disclosure: Interactions between Industry and Healthcare Professionals (HCP)*, EUCOMED.ORG, September 20, 2012, available at http://www.eucomed.org/uploads/Modules/Publications/20120920_transparency_position_final.pdf.

²⁸ *Medicines Australia’s Code of Conduct, Edition 17*, MEDICINES AUSTRALIA, available at <http://medicinesaustralia.com.au/files/2010/01/20130328-PUB-Edition17-FINAL.pdf>.

²⁹ See *id.*

participating in advisory boards. Although companies are required to submit a number of details about their payments, the names of the consultants do not have to be identified. Moreover, the Australia Code requires member companies to submit reports that provide detailed financial information about educational meetings and symposia that they sponsor, as well as payments made to speakers to attend and present at education meetings, but the names of the individual recipients of such sponsorship and payments do not have to be identified.

While this aggregate reporting scheme is similar to what has been adopted in some countries, the Australian industry group's approach was not enough for one Australian legislator, Senator Richard Di Natale. On February 28, 2013, Senator Di Natale introduced legislation that would essentially replace the Australia Code and totally re-shape the relationship in Australia between pharmaceutical companies and healthcare professionals.³⁰ In that regard, the proposed legislation prohibits payments to healthcare professionals to attend specific educational seminars and scientific conferences and limits gifts and hospitality that can be given to healthcare professionals. Furthermore, unlike the Australia Code's reporting requirements, the proposed legislation requires pharmaceutical companies to report the amounts spent on individual recipients and to identify those recipients. Under the proposed legislation, on an annual basis pharmaceutical companies would be required to report, among other things, the amount or value of payments made to individual recipients, the names of the recipients, the nature of the payment, and the reason the payment was made.

On March 21, 2013, the legislation was referred to the Senate Finance and Public Administration Legislation Committee (Senate Finance Committee). The reason for the referral was "[t]o receive evidence on the need for regulation of pharmaceutical industry conduct with

³⁰ Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013, *available at* <http://www.comlaw.gov.au/Details/C2013B00029>.

regards to interactions with the medical profession, and the appropriateness of the provisions in the bill that place restrictions on these interactions.”³¹ The committee invited interested individuals and stakeholders to provide written submissions by April 19, 2013, and received twenty-four written submissions, most of which expressed opposition to the legislation.³² The opponents included thirteen pharmaceutical companies, as well as Medicines Australia. In its sixteen-page submission opposing the legislation, Medicines Australia identified four primary reasons why the legislation should not be passed: 1) an effective transparency system is best achieved through industry self-regulation, and its Code was comprehensive, avoided red-tape, had stakeholder support, and was self-funded and not dependent upon any taxpayer funds; 2) in its ongoing work to further increase transparency, Medicines Australia had consulted with key stakeholders, like clinicians, who would be impacted by the proposed legislation, but had not been consulted regarding it; 3) the government and industry have already been working together to develop policy responses to the concerns that motivated the legislation; and 4) the legislation would endanger the legitimate and appropriate informational and educational interactions between industry and healthcare professionals.³³

In addition to individual pharmaceutical companies and Medicines Australia, the following groups also submitted written opposition to the legislation: the Australian Medical Association; the Australian Self-Medication Industry; GMiA (Generic Medicines Industry Association Pty Ltd.); and the Australian government’s Department of Health and Ageing. In its submission, the Department of Health and Ageing stated that the “Government supports self-

³¹ The Senate Finance and Public Administration Legislation Committee: Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 (the “Australian Senate Report”), available at http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Committees?url=fapa_ctte/therap_goods_amend_bill_2013/report/report.pdf.

³² *Id.*

³³ Submission in Response to The Senate Finance and Public Administration Inquiry into the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013*, MEDICINES AUSTRALIA, available at <http://medicinesaustralia.com.au/files/2010/02/Medicines-Australia-submission-19-April-2013.pdf>.

regulation of industry conduct and provided funding in the 2012-2013 Budget to strengthen the self-regulatory framework. An Advisory Group with representatives from industry associations, health professional and consumer organisations has responsibility for progressing this work.”³⁴ Moreover, the Department concluded that “[t]he proposed amendments appear to raise issues in relation to their scope and enforcement and alignment with the current scheme of the *Therapeutics Goods Act 1989*.”³⁵

On April 29, 2013, the Senate Finance Committee conducted a hearing on the proposed legislation, and heard testimony from representatives of the Australia Medical Association, GlaxoSmithKline, Medicines Australia, and the Department of Health and Ageing, as well as supporters of the legislation. On June 17, 2013, the committee issued its report on the legislation, which recommended that the legislation not be passed.³⁶

In its report, the committee outlined its inquiry process, provided an overview of the legislation, and analyzed various provisions of the legislation. In addition, the committee examined the Australian government’s approach to transparency, as well as the pharmaceutical industry’s self-regulatory experience in the country. After briefly addressing the “overseas experience,” the committee’s report identified a number of concerns about the legislation, including its timing, its limited application, and its potential impact of limiting or otherwise restricting appropriate interactions between the pharmaceutical industry and healthcare professionals. In conclusion, the committee declared

it is important that health consumers are confident that the medical practitioner, from whom they are seeking assistance and advice, maintains an ethical and

³⁴ Submission to the Senate Finance and Public Administration Legislation Committee: Inquiry into the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING, *available at* <https://senate.aph.gov.au/submissions/comitees/viewdocument.aspx?id=0a187863-efab-4310-8aa7-44c10939658b>.

³⁵ *Id.*

³⁶ The Australian Senate Report, *supra* note 30.

transparent relationship with pharmaceutical companies. The committee notes that since 2010 this relationship has been the subject of examination and consideration. Recommendations have been made to the Government to improve transparency of this relationship. The Government has responded by funding the implementation of some of the recommendations including the strengthening of self-regulation through industry codes of conduct.

The committee considers that it is appropriate that the relationship between medical practitioners and pharmaceutical companies be regulated through industry codes. Further, the committee notes that some aspects of the Bill are weaker than the existing Medicines Australia code of conduct. The committee therefore does not support the Bill.

The Australian Greens members of the Senate Finance Committee dissented from the committee's position and supported passage of the legislation. The dissenters issued a statement which responded to various points made by the committee and concluded by asserting that "[t]he inquiry made it clear that there are serious concerns regarding the transparency and integrity of the therapeutic drugs sector in Australia. This Bill would address those concerns by bringing Australia up to world's best practice in terms of transparent disclosure and reduction of conflicts of interest arising in the medical profession as a result of their interactions with industry."

Although passage of the Therapeutic Goods Amendment is highly unlikely at this point, its introduction represented a pivotal moment for the life sciences industry. It is the first time that a well-established industry transparency code was challenged by more intrusive legislation. The likely demise of the proposed legislation may influence, in favor of industry, the on-going global debate between those who support governmental reporting schemes and those who favor a self-regulatory approach.

The trend toward increased transparency is expanding beyond Australia and throughout Asia, with Japan serving as an illustrative example. In Japan, disclosure requirements have been implemented by the Japan Pharmaceutical Manufacturers Association ("JPMA") via the "JPMA Guidelines on Transparency on Corporate Activities with Medical Institutions and Healthcare

Professionals” (“JPMA Guidelines”).³⁷ Under the JPMA Guidelines, which were issued in March 2011, members must do two things. First, they must establish a transparency policy to govern activities in accordance with the Guidelines. Second, they must publicly disclose payments to medical institutions and healthcare professionals by uploading data on their websites. Payments made in fiscal year 2012 are to be disclosed in fiscal year 2013. There are five categories of payments that must be disclosed: 1) research and development-related costs; 2) grants/donations; 3) honoraria (speaking, writing and consulting); 4) information exchange costs (i.e., speaker programs); and 5) meals and hospitalities provided to healthcare professionals.

Between March 2011, when the JPMA Guidelines were announced, and the summer of 2012, there was very little reaction among key stakeholders in Japan. However, by late summer 2012 physicians and their associations became concerned about some of the aforementioned disclosures, including most especially the honoraria category and the identification of how much financial support individual healthcare practitioners received. Over the next several months, physicians and their associations forcefully criticized the JPMA Guidelines, while the JPMA defended its code. Ultimately, the two camps met to try to resolve their widely divergent views on how and whether the honoraria disclosure should occur.

In March 2013, the JPMA announced that all disclosures, with the exception of certain honoraria disclosures, would proceed as outlined in the JPMA Guidelines. For honoraria, the JPMA announced that a compromise had been reached: healthcare practitioner-specific reporting for honoraria would be delayed until 2014, while the 2013 reports would list the amount of funds companies expended on honoraria in the aggregate to all healthcare practitioners. Although the amounts of 2012 honoraria need not be reported on the practitioner-

³⁷ *Transparency Guideline for the Relation between Corporate Activities and Medical Institutions*, JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION, available at http://www.jpma.or.jp/english/issues/pdf/transparency_gl.pdf.

specific level, JPMA members must list the names of all healthcare practitioners who received honoraria.

It will be important for the pharmaceutical industry to monitor how the Japanese approach continues to develop and whether other countries may pursue a similar course. Industry groups are well-advised to include healthcare practitioners and their representative bodies early in the process of developing reporting requirements to ensure their cooperation with and support for industry-mandated disclosure.

Industry groups in China (the China Association of Enterprises with Foreign Investment R&D-Based Pharmaceutical Association Committee) and India (the Organisation of Pharmaceutical Producers of India) also amended their respective codes in 2012, with the Chinese code taking effect on July 1, 2012,³⁸ and the Indian code becoming effective on December 31, 2012.³⁹ Although neither code includes reporting requirements, both codes embrace the general topic of transparency and have provisions that regulate interactions between pharmaceutical companies and healthcare professionals. For example, both codes closely govern a company's ability to sponsor events, what a company is permitted to pay for at such events, where such events can take place, who can attend such events, and what materials and information can be provided at such events. Similarly, both codes permit companies to engage healthcare professionals as consultants, but place a number of restrictions on these relationships, including that the compensation for the services must be reasonable and reflect the fair market value of the services that are rendered.

³⁸ *Code of Practice 2012*, R&D-BASED PHARMACEUTICAL ASSOCIATION COMMITTEE (RDPAC), available at http://www.ifpma.org/fileadmin/content/About%20us/2%20Members/Associations/Code-China/RDPAC_Code_of_Practice_2012_print_final_web.pdf

³⁹ *Code of Pharmaceutical Practices 2012*, THE ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA (OPPI), available at <http://www.indiaoppi.com/OPPI%20Code%20of%20Pharmaceutical%20Practices%20%20-%202012.pdf>.

Before departing Asia, it is also significant to note that there is pending legislation in the Congress of the Republic of the Philippines that would require the filing of reports by both pharmaceutical and medical device companies concerning gifts made to healthcare practitioners.⁴⁰ This legislation was introduced on September 20, 2010, and assigned to the Health and Demography Committee on September 28, 2010, where it has remained since its referral. Under this legislation, pharmaceutical and medical device companies would have to report, on an annual basis, any gifts, whether in the form of money, service, loan, travel, entertainment, hospitality, thing or promise, or in any other form, made to a healthcare provider. Those reports would include the following information: 1) the name, address, and telephone number of the manufacturer; 2) an itemized list containing a description of each gift; 3) the name, address, and telephone number of the healthcare provider who received the gift; 4) the monetary value of the gift; and 5) other information deemed necessary by the Secretary of Health. The legislation provides for a number of potential monetary sanctions for violation of its provisions. Although this legislation has been quietly pending for several years, it should not be ignored, especially with respect to the possibility that the global transparency movement could energize supporters of the legislation.

Latin America, The Middle East and Africa

The transparency movement has been slower to take hold in Latin America than it has in Europe and some of the other countries previously discussed. However, that appears to be slowly changing.

⁴⁰ Senate Bill No. 2528, Disclosure of Gifts Provided by Pharmaceutical Manufacturers (September 20, 2010), available at http://www.senate.gov/ph/lis/bill_res.aspx?congress=15&q=SBN-2528.

In Mexico, the pharmaceutical industry group, Cetifarma, amended its code in 2012.⁴¹ The revised code, which became effective on April 1, 2013, includes a number of reporting requirements. For example, companies must make publicly available information about the donations they make. Companies must also, upon Cetifarma's request, make available to Cetifarma information about the financial support they provide to patient organisations. Moreover, upon the request of Cetifarma, a member company must provide information about educational programs it supports; consulting arrangements it has with healthcare practitioners; and services provided by healthcare practitioners to patient organisations that are funded by the member company.

The most recent amendment to Brazil's industry code took effect on July 1, 2012.⁴² Although, the Code does not include reporting requirements, it requires members to keep a list of supported patient associations. The list must include a brief description of the nature of each project, the corresponding value of the support, and various other details. Additionally, the Code contains a number of restrictions with respect to a company's ability to contract with healthcare professionals for consulting services, as well as the circumstances under which a company can sponsor events and contract with healthcare professionals to speak at or attend such events. Moreover, the Code establishes a number of conditions with which a company must comply in order to offer a gift to a healthcare professional.

Although transparency has not yet garnered widespread support in the Middle East and Africa, it is only a matter of time until industry groups or governments focus on this area. For example, Mecomed, which was formed in 2007 and is an associate member of Eucomed, is the

⁴¹ *Codes of the Pharmaceutical Industry Established in Mexico*, COUNCIL OF ETHICS AND TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY (CETIFARMA).

⁴² *Code of Conduct*, INTERFARMA.ORG, available at http://www.ifpma.org/fileadmin/content/About%20us/2%20Members/Associations/Code-Brazil/Brazil_-_Interfarma_Code_of_Conduct_2012_-_English_version.pdf.

trade association for the medical device and diagnostic industry in the Middle East. Mecomed, which represents twenty medical device and diagnostic companies in the Middle East, adopted its own transparency code, which was amended in March 2012. The preamble of the Mecomed Guidelines on Interactions with Healthcare Professionals states that its provisions are based on the Principle of Transparency, whereby “[i]nteraction between industry and Health Care Professionals must be transparent and comply with national and local laws, regulations or professional codes of conduct.”⁴³ Moreover, the Guidelines include a number of limitations on arrangements between companies and consultants, as well as on how medical device companies can provide product training, education and support for third-party educational conferences.

Conclusion

The movement toward transparency in the life sciences industry has gained momentum throughout 2012 and the first seven months of 2013, highlighted by the long-awaited issuance of the final Sunshine Act regulations in the United States and the decree implementing the French Sunshine Act. The French decree, in particular, has generated significant controversy in the life sciences community because it is not only retroactive in requiring the disclosure of information dating back to January 2012, but also because it imposes aggressive deadlines that will be difficult for companies to satisfy.

The remainder of 2013 promises further significant developments. Much of that activity will be driven by EFPIA’s push to have its member associations adopt their versions of the Disclosure Code by the end of the year. That process will be watched closely both by supporters of governmental regulation and those who prefer a self-regulatory approach. An as-of-yet unanswered question is whether European supporters of governmental regulation will sit idly

⁴³ *Code of Business Practice, Mecomed Guidelines on Interactions with Healthcare Professionals*, MECOMED, available at <http://www.mecomed.com/common/pdf/code.pdf>.

during 2014 and 2015 to see the results of the EFPIA-mandated 2016 reporting. Advocates of industry self-regulation argue that legislators should determine the efficacy of the EFPIA Disclosure Code before taking additional action. However, any new scandal could motivate regulators to act and impose more stringent, and immediate, reporting requirements. Moreover, the medical device industry, which has lagged behind pharmaceuticals in adopting voluntary reporting requirements, may be more likely to do so if EFPIA's approach is well received by governments.

In short, the transparency landscape is quickly changing, ever-evolving, and unpredictable. Companies in the life sciences industry must be aware of all the latest developments because the one definite, predictable effect of the transparency movement is that there will be more – not less – reporting requirements, leading life sciences companies to devote more time and resources to ensuring compliance and transparency.