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Europe adopts "Sunshine"; Pfizer US gets tough

Not to be outdone by Sunshine Acts passed into law in the US and France, the European Federation of Pharmaceutical Industries and Assns. (EFPIA) has adopted a public disclosure code that will apply to national codes in 33 countries, and therefore to member companies. A pmlive report says that data collection will start in 2015 for disclosure in 2016; UK and the Netherlands have already started.

Codes will vary from country to country, but all will require the name and address of the healthcare provider (HCP), the amount of payment and details of the sponsorship. The report suggests that data will be reviewed by, among others, US and UK law enforcement agencies, competitors seeking information on relationships with HCPs, and potential whistle-blowers.

In the US, the Pfizer department for independent grants announced that CME providers can no longer use grant funding for food or beverage at any CME event -- or even at a planning meeting.

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Public disclosure under the spotlight

With the final approval of the EFPIA Disclosure Code at the end of June and the implementation of the US Sunshine Act starting in August, transparency requirements and public disclosure become a reality for pharmaceutical companies

It is important to compare the two regulations prior to their application: firstly to see how equivalent they are and secondly, to assess how different they are on key aspects, which may lead to serious trouble for organisations seeing these regulations as identical.

Because the EFPIA Code applies to local member associations, it does not directly constrain organisations and its enforcement will be different in each of the 33 member countries. As an example of what national differences can be, this article will discuss the French regulation for transparency, as laws on relationships with third parties have already been in place for more than twenty years in this country.

Full light of day

In the US, the Patient Protection and Affordable Care Act (PPACA), enacted in March 2010, imposed a variety of reporting obligations on various players in the healthcare industry. One major component of these new rules requires 'applicable manufacturers' of covered 'drug, device, biological or medical supply' to report annually to the Secretary of the United States Department of Health and Human Services on certain types of payments to doctors and teaching hospitals.

In Europe, the initiative started in 2001, when the European Commission defined Corporate Social Responsibility (CSR) as 'a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis'. In 2010, the Council and the European Parliament both called on the Commission to develop this CSR policy further.

Thus, in the Europe 2020 Strategy, the Commission made a commitment to renew the EU strategy to promote CSR. In the field of pharmaceuticals this has led to the creation of the Platform on Ethics and Transparency. Following this EU Commission initiative on Ethics & Transparency, this multi-stakeholders' platform – including EFPIA (European Federation of Pharmaceutical Industries and Associations) – has adopted a 'List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector'.

In line with these Guiding Principles, EFPIA has therefore decided that its existing Code on the Promotion of Prescription-Only Medicines to Healthcare Professionals and Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals (HCPs) and organisations.

In a similar approach, several European countries have already started to publicly disclose

payments made by individual companies to HCPs or healthcare organisations. This is already the case in the Netherlands, Slovakia and the UK (only at an aggregate level). In France, a law adopted by the end of 2011 also recently came into force. It has supplemented a previous law ruling the relationships with HCPs – the 'DMOS' law which had been in place since 1993.

Setting the pace

The **Sunshine Act** is set to be the first regulation to be enforced, with organisations having to start collecting data from August this year. While the law initially required the reporting to commence in March 2013, because of delays in issuing the implementing regulations, companies covered by the statute and regulations must now commence reporting in early 2014.

> **“ The Sunshine Act ... could influence the way European pharma companies approach transparency ”**

This first move for disclosure at such a large scale could influence the way European pharmaceutical companies approach transparency. In February, the EFPIA approved the final draft for the disclosure code for transfers of value from pharmaceutical companies to HCPs and healthcare organisations (HCOs); it is required to be transposed into national Codes by 31 December 2013. It will apply to the 33 EFPIA European member countries.

All EFPIA member associations will be required to transpose this Code into their national codes of practice, except where its provisions are in conflict with the applicable national law or regulation, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation.

In April 2014, the Codes Committee Review will evaluate the transposition of disclosure requirements in each European national Code. Member companies will then start collecting data in 2015 for a first disclosure to take place in 2016. Because of specific national requirements, some countries have already started the disclosure (the UK, the Netherland) or will start soon (France).

Regarding the American Sunshine Act, as enacted, section 6002 of PPACA requires all 'applicable manufacturer[s]' that 'provide[d] a payment or other transfer of value' to a doctor or teaching hospital to report those payments to the Secretary of Health and Human Services; failure to provide these reports exposes the 'applicable manufacturer[s]' to civil monetary penalties of up to $1,000,000.

> **“ Companies shall declare any contribution to HCPs for costs relating to events and fees for services and consultancy ”**

The US Congress specifically defined 'applicable manufacturer' to mean 'a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States'. Congress also specified that 'the term 'covered drug, device, biological, or medical supply' means any drug, biological product, device, or medical supply for which payment is available', under either the Medicare programme (the federal programme for the elderly and disabled in the US) or the Medicaid programmes (jointly funded federal and state healthcare programmes in the US for the poor). As enacted by Congress, these transparency reporting requirements would appear to apply to all manufacturers of any drug or medical device or medical supply for which payment is made by either the Medicare or the Medicaid programmes, including, for example, manufacturers of over-the-counter (OTC) drugs and producers of items like wheelchairs, crutches and beds.

However, when issuing regulations, the Secretary of Health and Human Services narrowed the reporting requirements to certain kinds of drugs and devices, for example, just those drugs and biologicals that require a prescription from a doctor to be dispensed, thus excluding all OTC drugs and biologicals. Similarly, the Secretary limited the reporting requirements to manufacturers of Class II and III medical devices; these are devices that require either premarketing approval from the FDA, or notification to the FDA through the filing of a premarket clearance (such devices are typically called 510(k) devices).

In Europe, all member companies of a local association responding directly to the EFPIA Board will be subject to the new disclosure requirements and will be required to make sure

they supply the necessary information to their national association. So it will apply to companies undertaking research, development and the manufacture in Europe of medicinal products for human use.

The stakeholders concerned by the disclosure are HCPs and HCOs (institutions, organisations or associations of HCPs providing any type of services to a member company).

This scope may vary according to existing national regulations. As an example, in France, the scope is much broader since:

- It concerns all companies providing healthcare products (medicines, medical device, cosmetic product, etc)
- The concerned stakeholders are also consulting firms and press agencies working in the healthcare area.

Content of the disclosure
In Europe, according to the EFPIA Code, transfers of value shall be disclosed on an individual basis and concern any transfer made by a company to an HCP or to a HCO. Such transfers of value may be aggregated on a category-by-category basis.

For transfers of value to an HCP, companies shall declare any contribution to costs related to events and fees for service and consultancy. The same level of detail is expected for payments made to an HCO, including the donations and grants made to associations. R&D transfers of value in each reporting period shall be disclosed by each member company on an aggregate basis.

The details of disclosure for individual HCPs or HCOs are still to be reviewed but so far they cover:

- Full name and address (address of registration for a HCO)
- A unique identifier, where applicable
- The amount of the payment with details of the sponsorship.

Requirements can go further in some countries, as in France, where according to the law, all nature of gifts and advantages, including meals and beverages, must be disclosed.

Concerning the US, the Patient Protection and Affordable Care Act requires, among other things, the disclosure of the following:

- The name and address of the doctor, including an identification of his or her specialty
- The amount of the payment; where the payment is made to a group or another entity for distribution to a doctor, those details must be disclosed
- The date or dates of the payment and the nature of the payment (eg whether a consulting fee, compensation for speaking, a gift, for entertainment or an honorarium)
- The covered drug, biological or device 'related to each payment or transfer of value'.

The US' rules also apply to payments for research, but allow for delayed publication. Once received by the Secretary, the information will be published on a website and thus made publicly available. The minimum threshold value is very low – set at $10.00 – and accordingly virtually everything must be reported.

The reporting requirements are designed to provide transparency on potentially corrupting payments made by a manufacturer of a drug, device, or medical supply, to a doctor. Companies selling non-OTC drugs and Class II and III medical devices in the US must have data collection processes in place so that they can begin making the required reports next year.

Main issues to address
These new requirements arise from a need to display to the public the clear relationships taking place between pharmaceutical companies and third parties. All companies making the required reports should expect the reported data to be extensively reviewed and researched by, among others: US law enforcement, lawyers representing potential whistle-blowers, media, patients, and US Congressional investigators. It is likely that US and UK investigators may

scrutinise European data for use in Foreign Corrupt Practices Act (FCPA) and UK Bribery Act investigations. Companies can also expect their competitors to 'mine' this data. Indeed, the data will provide the first ever window into each company's relationship with HCPs, thus allowing everyone to identify the HCP a company employs, as well as the purpose for the employment.

All companies making the required reports should expect more legal enforcements, following enhanced transparency, as well as subjection to potential public scrutiny. One possible cascading impact of the new rules will be an escalation in the adoption, by institutional providers, of prohibitions on employee-HCPs from receiving funds from drug and device companies. Finally, companies can expect a slow expansion of the adoption of such rules in other countries around the globe.

These issues will be shared by European companies once the EFPIA Disclosure Code is enforced, but there will also be challenges associated with the requirements of specific countries; these regional differences will require companies to implement country specific collection and reporting procedures. These regional and country differences might come from:

- Pre-existing transparency regulations (such as in France) with differences of perimeters and information to disclose
- Differing cultures in the organisation and management of relationships with HCPs and HCOs as a result of national differences in medical culture and HCOs (the first difference being the definition of an HCP in each country)
- Differing tools used to disclose information (centralised websites, third party websites, pharma companies' websites...) as each member of EFPIA will choose its own way to make data available.

> **“ These arise from a need to display to the public the clear relationships between pharma and third parties ”**

One thing to recognise is that while transparency is a global trend in the healthcare industry, the requirements for transparency will retain local characteristics, as well as local rules, of disclosure. The challenge for pharmaceutical companies will be not to adopt a single 'best' global transparency process, but rather to acknowledge the similarities and differences existing in each market and to implement in each of them an appropriate tool that insures company compliance. At the same time, this should allow management to make a global review of the company's relationships with HCPs and HCOs.