

Snapshot of Sunshine Rules in EU Countries for The Pharmaceutical Industry

PART I – JUNE 2014





Executive Summary

Since the enactment of the Physician Payments Sunshine Act (US Sunshine Act) by the United States, a number of EU Member States have adopted similar rules or strengthened pre-existing regulation in order to improve the transparency of relationships between physicians and health care companies.

The purpose of this guide is to identify EU countries that have implemented a Sunshine Act or sunshine rules and to provide a brief overview of these regulations.

This guide focuses on the main rules that apply in 12 EU countries and does not provide a full analysis of any codes of ethics that may apply in addition to national Sunshine Act or sunshine rules.

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I. – EFPIA Rules

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. In 2013, EFPIA adopted a disclosure code binding its member companies and its member associations, and their constituent members (the Disclosure Code).

Under Article 1 of the Disclosure Code, *Subject to the terms of this Code, each Member Company shall document and disclose transfers of value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 3.*

Each member falling within the scope of the Disclosure Code must therefore disclose direct and indirect transfers of value to or for the benefit of health care professionals (HCPs) or health care organisations (HCOs) within six months after the end of a relevant reporting period. The first reporting period is the calendar year 2015, with disclosure required in July 2016.

Implementation is carried out by national industry associations, which must have procedures in place for receiving and processing complaints and imposing sanctions if necessary.

As regards the application of the Disclosure Code in the countries referred to below, please note that

- Each of these countries has a national pharmaceutical business association.
- These national associations have implemented a national code of ethics.
- Such codes only apply to members of these national associations.
- It is not, however, compulsory for pharmaceutical companies to join those associations.

II. – EU Countries That Have A Sunshine Act

FRANCE

French law n° 2011-2012 on the Strengthening of Health Protection for Medicinal and Health Products, dated 29

December 2011 entered into force once the implementing Decree n° 2013-414 was adopted on 21 May 2013, followed by a Circular dated 29 May 2013.

Under the French regulatory framework, any company manufacturing or commercialising products in France must disclose

- Agreements entered into with HCPs and HCOs.
- Advantages in kind or in cash exceeding €10, provided directly or indirectly to HCPs and HCOs.

As of 19 December 2013, this information must be disclosed on a specific website, no later than

- 15 days after the signing of each agreement.
- 1 August for benefits granted during the first half of the year.
- 1 February for benefits granted during the second half of the precedent year.

A draft decree is in preparation to amend the 21 May 2013 Decree. The French Government is planning minor changes relating to the wording of the 21 May Decree and a few substantial modifications related to the deadline and the content of the information relating to events that must be disclosed on the website.

Companies that “knowingly fail to fulfil the obligation to publicly disclose” face a fine and sanctions.

Article 20 of the bill on the future of agriculture, food and forest extends the scope of disclosure obligations to companies that manufacture or sell veterinary medicine or provide associated services. The bill was voted on during its first reading by the National Assembly on 14 January 2014 and by the Senate on 15 April 2014. It now has to be discussed at its second reading.

The French national pharmaceutical industry association (LEEM) has adopted a code of ethics that implements the Disclosure Code. This code of ethics applies to all companies that are members of the LEEM.

PORTUGAL

Decree-Law n° 128/2013 of 3 September 2013 replaced provisions of Decree-Law n° 176/2006 of 30 August, in force

since 31 August 2006, which applied to medicinal products for human use.

Under the new regulatory framework, the disclosure of transfers of value exceeding €25 between pharmaceutical industries and HCPs and HCOs is mandatory.

The provisions of Decree-Law n° 20/2013 and Decree-Law n° 128/2013 are designed to cover not only pharmaceutical manufacturers and sellers, but any natural or legal person referred to in the regulation who takes part in the product cycle, including the holder of a marketing authorisation.

When sponsoring any congress, symposium or scientific or marketing event directly or indirectly, health care companies must

- Be mentioned in the promotional documents associated with events, such as marketing/promotional materials, as well as in the attendees' documents and published papers or reports resulting from the event.
- Keep records of the documents concerning each of the events directly or indirectly sponsored or organised for the last five years, and make them available for inspection by the legal authority, *i.e.*, Infarmed.
- Make these documents available for inspection by the legal authority, *i.e.*, Infarmed.
- Notify the national health regulatory authority before any transfers of value exceeding €25 to HCPs and HCOs related to events, with a few exceptions.

Infringement of these rules is punishable by a fine.

The Portuguese national pharmaceutical industry association (APIFARMA) has adopted a code of ethics that implements the Disclosure Code. This code of ethics applies to all companies that are members of APIFARMA.

SLOVAKIA

Slovak Act No. 362/2011 of 13 September 2011 on medicinal products and medical devices relates to benefits granted to HCPs but does not apply to agreements entered into with HCPs.

Under Act No. 362/2011, pharmaceutical companies that hold a marketing authorisation must submit an annual report to the Slovakian Ministry of Health, stating the value of

advertising and marketing expenses and non-financial, in-kind benefits given to HCPs either directly or indirectly. The report must include the name and address of the recipients and the value of the expenditure or benefits.

III. – EU Member States With Sunshine Rules

BELGIUM

Belgium has a number of rules on transparency that are enshrined in legislation (*Arrêté Royal fixant les conditions dans lesquelles la remise de médicaments à usage humain sous forme d'échantillons peut être effectuée, Loi sur les Médicaments, Arrêté Royal relatif à l'information et à la publicité concernant les médicaments à usage humain*).

Belgian law imposes transparency requirements on pharmaceutical companies in relation to internal recordkeeping and samples given to HCPs.

In particular, companies that have a marketing authorisation or a registration authorisation for medicines on the Belgian market must

- Report information related to samples given to HCPs to the Agence Fédérale des Médicaments et des Produits de Santé (AFMPS) by 1 March every year.
- Keep an up to date file containing all the details necessary for the AFMPS to verify business relationships with HCPs. The file must include details relating to gifts, benefits, financial support and payments for services.
- Comply with the authorisation requirements prior to product launches or sponsorships of scientific events. Failure to comply with these requirements may result in the sponsoring company and the recipient HCPs incurring a fine or imprisonment.

Although there is no Sunshine Act equivalent in Belgium, the Belgian industry association for pharmaceutical companies (Pharma.be) adopted a code of ethics in March 2014. This code implements the Disclosure Code and applies to all companies that are members of Pharma.be.

DENMARK

Under Danish law, pharmaceutical companies and HCPs are obliged to publicly disclose certain connections.

The main burden of disclosure rests on the HCPs, who are obliged to obtain permission from the Danish Health and Medicines Authority (Sundhedsstyrelsen) before they can establish a relationship or connection with a pharmaceutical company.

Pharmaceutical companies that have a marketing authorisation for a pharmaceutical or medical product that can be legally sold or prescribed in Denmark, and companies that have authorisation from the Health and Medicines Authority to produce, import, export, store, distribute, dispense or package a pharmaceutical or medicinal product in Denmark are obliged to report annually to the Health and Medicines Authority which HCPs they have been connected with during the previous year.

Failure to submit the annual report is punishable by a fine.

The current legislation is expected to be amended to make the regime more all-encompassing. The following are some of the main changes that are expected:

- The laws on disclosure will apply to both pharmaceutical and medical device companies.
- A reporting requirement and an authorisation requirement will be introduced, although they will not directly impose reporting obligations.
- The amount of information that must be made publicly available will be expanded to include financial information.

GERMANY

German legislation does not impose any specific disclosure obligations on producers of licensed pharmaceutical products. Certain regulations do, however, impose some more general disclosure obligations:

- The German Medical Products Act (Arzneimittelgesetz) imposes disclosure obligations in relation to observational drug studies for the purpose of gathering knowledge on the safety of authorised or registered pharmaceutical products.
- Employed HCPs who enter into service contracts with, or receive benefits from, pharmaceutical companies will almost always be obliged to disclose the relationship to their employer or principal (the

doctrine of employer consent).

- Under the physicians' codes of professional conduct (Berufsordnung-Ärzte and MBO-Ä), certain disclosure obligations apply when making transfers of value, especially when sponsoring a medical event or entering into agreements where HCPs receive a fee or remuneration.

Although there is no Sunshine Act equivalent in Germany, the German association of research-based pharmaceutical companies (FSA) does have a code of ethics. This code implements the Disclosure Code and applies to all companies that are members of FSA.

ITALY

Italian law does not have general transparency rules that are similar to the Sunshine Act.

Article 124 of Legislative Decree No 219 of 24 April 2006, on the notification and authorisation requirements for hospitality during scientific events does, however, include sunshine rules through a disclosure obligation that applies specifically to pharmaceutical companies.

Companies holding the authorisation to produce, import or market pharmaceutical products in Italy, and companies that commercialise such products in Italy by means of an agreement with a company that holds the relevant authorisation, must inform Italy's Medicines Agency (AIFA) when organising or contributing to an event connected with a matter related to a product commercialised in Italy.

In some cases, the company's participation must be authorised by AIFA. Events organised in breach of the rules may be cancelled by AIFA and pharmaceutical companies may be fined.

Although there is no Sunshine Act equivalent in Italy, the Italian association of pharmaceutical companies (Farmindustria) does have a code of ethics. This code implements the Disclosure Code and applies to all companies that are members of Farmindustria.

SPAIN

Spain does not have rules that can be considered similar to the Sunshine Act.

Some transparency regulations have, however, been enacted in Spain comprising, in particular, the Spanish Act 29/2006, dated 27 July, on the Guarantee and Reasonable Use of Medicines and Health Products (*Ley 29/2006, de 27 de Julio, de garantías y uso racional de los medicamentos y productos sanitarios*) and the Spanish Royal Decree 1416/1994, dated 25 June, on Publicity of Medicines for Human Use (*Real Decreto que regula la publicidad de los medicamentos de uso humano*).

These regulations state that

- Pharmaceutical companies must make publicly available details of benefits they have given to HCPs and HCOs in relation to conferences, congresses, study trips and similar events by, for example, the publication of those offers on the company's website.
- Conference programmes and sponsored publications must mention the financing source and the funds granted by companies in support of the conference or publications.
- Companies must notify the relevant public authority (to be determined by further legislation) of their involvement in any materials produced for the attention of HCPs that mention medicines, at the time of their publication or broadcasting. Such materials include scientific magazines, books, blogs or any other similar publications published either in hard copy or by any kind of audiovisual or electronic means.

Although there is no Sunshine Act equivalent in Spain, the Spanish association of pharmaceutical companies (Farmaindustria) does have a code of ethics. This code implements the Disclosure Code and applies to all companies that are members of Farmaindustria.

IV. – EU Member States That Have No Sunshine Act Nor Sunshine Rules (Yet)

THE NETHERLANDS

There is no statutory legal obligation in the Netherlands for pharmaceutical companies to report payments made to HCPs or HCOs.

The Dutch pharmaceutical industry association (Nefarma) has a code of ethics that implements the Disclosure Code and applies to all companies that are members of Nefarma.

POLAND

At present, Poland has no plans to introduce any new laws regulating the transparency of the pharmaceutical sector.

The Polish pharmaceutical companies association (INFARMA) has approved the Disclosure Code and adopted a code of good practice in the pharmaceutical sector. This code will apply all companies that are members of INFARMA from 2016.

SWEDEN

There is no direct statutory legal obligation in Sweden for pharmaceutical companies to report payments made to HCPs or HCOs. Applicable industry rules do, however, apply indirectly as a result of, for example, the Medicinal Products Act (1992:859) and anti-corruption rules under the Criminal Code (1962:700).

The Swedish research-based pharmaceutical industry (LIF) has a code of ethics that implements the Disclosure Code and applies to all companies that are members of LIF.

UNITED KINGDOM

Current UK law prohibits the supply, offer or promise of any gift, pecuniary advantage or benefit in connection with the promotion of medicinal products, to HCPs or suppliers. The Bribery Act 2010 introduced the new corporate offence of "failure to prevent bribery", which applies to all businesses the trade association that represents manufacturers of prescription medicine in the United Kingdom (ABPI) has implemented the Disclosure Code through a code of practice it adopted in 2014. This code applies to both members of ABPI and affiliate members.

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