





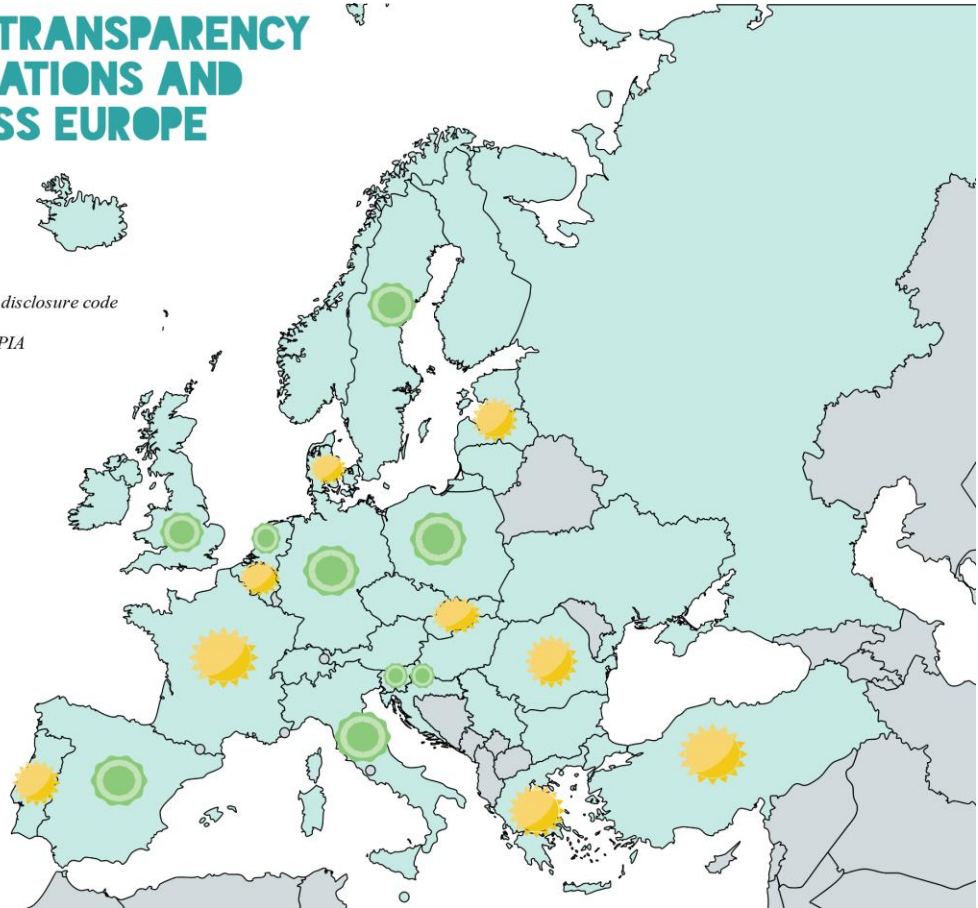
# SUNSHINE & TRANSPARENCY LAWS, REGULATIONS AND CODES ACROSS EUROPE

 Countries covered by EFPIA disclosure code

 Countries not covered by EFPIA disclosure code

 Sunshine law / Regulation

 Transparency / Anti corruption laws



April 2017

**Shedding light on the relationship between Pharma and the healthcare profession:  
 A mapping of Sunshine and transparency laws, regulations and codes in Europe**

Country	Sunshine laws/regulations	Covered by EFPIA code	Transparency/ anti-corruption laws
Austria	-	Yes	-
Belgium,	Yes – full law	Yes	-
Bulgaria	-	Yes	-
Croatia	-	Yes	Yes
Cyprus	-	Yes	-
Czech Republic	-	Yes	-
Denmark	Yes -full law	Yes	-
Estonia	-	Yes	-
Finland	-	Yes	-
France	Yes – full law	Yes	-
Germany	-	Yes	Yes
Greece	Yes -regulation	Yes	-
Hungary	-	Yes	-
Iceland	-	Yes (voluntarily)	-
Ireland	-	Yes	-
Italy	-	Yes	Yes
Latvia	Yes-regulation	Yes	-
Lithuania	-	Yes	-
Luxembourg	-	-	-
Malta	-	Yes	-
Netherlands	-	Yes	Yes
Norway	-	Yes	-
Poland	-	Yes	Yes
Portugal	Yes- full law	Yes	-
Romania	Yes -regulation	Yes	-
Russia	-	Yes	-
Slovakia	Yes – full law	Yes	-
Serbia	-	Yes	-
Slovenia	-	Yes	Yes
Sweden	-	Yes	Yes
Switzerland	-	Yes	-
Spain	-	Yes	Yes
Turkey	Yes -regulation	Yes	-
Ukraine	-	Yes	-
UK	Yes- contract rules	Yes	Yes

## Introduction

Mental Health Europe (MHE)<sup>1</sup> is concerned about the influence the pharmaceutical industry (Pharma) has over healthcare actors including healthcare professionals and organisations (HCPs and HCOs), families, patients, service providers and the general public. MHE believes that this influence has contributed to overreliance on the purely biomedical model as well as over-medicalisation in the field of mental health. In particular, this influence is deeply ingrained in the relationships, which are too often financial, between the pharma industry and mental health professionals and organisations and can impact on their independence, leading to unethical and biased decision-making in mental healthcare. For this reason, since its inception, MHE has always had a firm position on never accepting funding of any kind from Pharma. Up until a few years ago, there was little regulation governing these relationships and Pharma companies did not need to disclose whether they, for example, sponsored events or made transfers of value (ie donations, gifts etc) to HCPs or HCOs.

Following the introduction by the US of the ground-breaking Physicians Payments Sunshine Act in 2010, the transparency landscape has rapidly shifted in Europe. This mapping aims to give a glimpse into the progress in Europe where many States have introduced Sunshine Laws, Regulations and Rules which require transparency around 'transfers of value' between Pharma and HCPs. The legislation and rules adopted vary throughout Europe with some opting to place the burden on HCPs who come under anti-corruption legislation while others require Pharma and other companies that sell and promote goods to the healthcare profession to report on their affiliations and financial relationships. There have also been attempts at better self-regulation from Pharma and the healthcare profession including through the adoption of voluntary Disclosure Codes which have been transposed by industry and HCOs across Europe but it should be noted that these codes are not legally binding.

## At European level

In 2013, the European Federation of Pharmaceutical Industries and Associations (EFPIA) responded to calls for greater transparency by adopting a self-regulatory Disclosure Code (the European Disclosure Code). This new code represents a significant and welcome step forward in transparency in the healthcare sector.<sup>2</sup> The new code mandates the disclosure of all transfers of value, both direct and indirect, on a public platform ie company websites, by its members to HCPs and HCOs as of 1 January 2015.<sup>3</sup>

It should be noted that in many countries, HCPs can refuse to let their details be communicated on privacy grounds except in some countries where this is permitted in the public interest (ie Denmark). This limits the utility and effectiveness of the Disclosure Code. EFPIA informs that it has done outreach to HCPs both at EU level and national levels to try to encourage HCPs to disclose this information to ensure that information provided in the annual disclosures is as complete as possible. Additionally, MHE has learned from some actors that further work could be done on the accessibility of the disclosure documents. We hope that EFPIA will work with its members to ensure that these documents are accessible for users of services and the public.

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<sup>1</sup>Mental Health Europe (MHE) is a European non-governmental network organisation committed to the promotion of positive mental health, the prevention of mental distress, the improvement of care, advocacy for social inclusion and the protection of human rights for (ex)users of mental health services, their families and carers. MHE's membership includes associations and individuals active in the field of mental health in Europe, including people with (a history of) mental health problems, as well as volunteers and professionals in a variety of related disciplines. MHE's work is funded through financial support received from the European Union Programme for Rights, Equality and Citizenship. The views expressed herein should not be taken to reflect the official opinion of the European Commission. MHE has gathered the information for this mapping with the help of its members as well as external actors including EFPIA, Health Projects for Latvia, national Pharmaceutical Associations, Health Action International, Medtech Europe, Medicines for Europe, CPME and the European Psychiatric Association. **MHE intends for this document to be updated depending on developments so please contact MHE Shedding Light Project Coordinator, Marcin Rodzinka, ([marcin.rodzinka@mhe-sme.org](mailto:marcin.rodzinka@mhe-sme.org)) if you have if you have further information on the situation in your country.**

<sup>2</sup>EFPIA has also adopted other transparency codes including on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals and the Practice on Relationships between the Pharmaceutical Industry and Patients Organisations. However, this document will focus specifically on transfers of value and, as a result, Disclosure Codes.

<sup>3</sup>For more info on the European Disclosure Code, please see: <http://transparency.efpia.eu/the-efpia-code-2>.

EFPIA members operate in 33 European countries.<sup>4</sup> National Pharma industry associations have been obligated by EFPIA to transpose the Disclosure Code into their own national code, in line with national and EU regulations, and ensure that it is implemented. You can read more about how EFPIA members have transposed the Disclosure into their own codes of conduct [here](#). Where States have adopted legislation in this area, EFPIA does not expect its members to transpose the Disclosure Code and are granted 'deviations' although MHE is aware that in some countries there are two disclosure systems run by the State and by the industry (ie Latvia). It should be noted that not all Pharma companies are members of national associations and therefore may not be bound by the Disclosure Codes although according to EFPIA there are European States where the coverage of the Disclosure Code is at 100%.

Several other health industry actors at European level updated their codes in light of the EFPIA Disclosure code. In December 2015, Medicines for Europe, which represents the generic and biosimilar industry in Europe, followed suit and adopted a Code of Conduct which governs its members' interactions with all health actors with a similar Disclosure obligation which applies to HCPs, HCOs and patient organisations and will require disclosure by 2018.<sup>5</sup> All members of Medicines for Europe must either adopt the Code of Conduct or a 'comparable' code which is at least as strict. You can find a list of the members of Medicines for Europe [here](#).

MedTech Europe, which represents the European medical technologies industry, adopted an updated Code of Ethical Business Practice<sup>[1]</sup> in December 2015 which introduced a number of new provisions including a joint independent enforcement mechanism and Disclosure Guidelines which require disclosure of transfers of value to HCOs in relation to educational grants as the Code no longer allow for transfers of value in relation to Third Party Organised Educational Conferences directly to HCPs. The main change to this Code means that Medtech members will no longer be allowed to provide sponsorship to HCPs in relation to the attendance at conferences organised by third parties. This will be done through Educational Grants to HCOs who will select the HCPs benefiting from the Grant independently. The Code requires members of Medtech Europe to internally transpose the provisions by December 2016 with a view to ceasing direct sponsorship and beginning reporting on disclosures on a Medtech operated pan European Platform (TransparentMedTech) in 2018. However, it should be noted that where other legal obligations relating to disclosure are in place, Medtech Europe does not require its members to disclose on the TransparentMedTech platform. Medtech Europe also do outreach to healthcare organisations and professionals and carry out trainings on their Code. You can find a list of Medtech Europe members [here](#).

From the side of HCOs at European level, the Standing Committee of European Doctors (CPME) has adopted [Guidelines](#) on transparency which are quite general and are not binding on its members. CPME has also collaborated with EFPIA on a [joint-statement](#) on cooperation between Pharma and HCPs which is likely to be revised in the future. The European Psychiatric Association also has an internal disclosure rule which relates to their headline event – the European Congress of Psychiatry. The rules were adopted in 2009 and request speakers to disclose conflicts of interest in line with the WHO's definition which outlines situations which must be declared including those linked to financial relationships with commercial entities like Pharma companies.

During research undertaken for this mapping, MHE learned that in some European countries, membership organisations of medical professionals have adopted Disclosure Codes but this document does not map these initiatives; although it is acknowledged that commitment from HCPs will be instrumental in improving transparency through the changing of attitudes towards disclosure.

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<sup>4</sup>To check for EFPIA members in your country, please see [here](#). The industry in Iceland has also voluntarily signed on the EFPIA Codes.

<sup>5</sup> You can see the Code of Conduct here: <http://www.medicinesforeurope.com/wp-content/uploads/2016/02/Medicines-for-Europe-Code-of-Conduct.pdf>.

<sup>[1]</sup> Medtech Europe, Code of Ethical Business Practice, available at: [http://www.medtecheurope.org/sites/default/files/resource\\_items/files/MTE\\_Code\\_of\\_Ethics.pdf](http://www.medtecheurope.org/sites/default/files/resource_items/files/MTE_Code_of_Ethics.pdf).

## European States with Full Sunshine Laws

### Belgium

Belgium has several existing laws<sup>6</sup> which impose transparency requirements on pharmaceutical companies in relation to internal recordkeeping and samples given to healthcare professionals. However, in December 2016, Belgium also enacted a new [Sunshine Act](#) requiring Pharma, importers and distributors, as well as retailers and medical device manufacturers, to disclose interactions with HCPs and HCOs through reports. The scope of disclosure is the same as the EFPIA Disclosure Code but the owner and receiver of the report is now Belgium's AFMPS (Agence Fédérale des Médicaments et des Produits de Santé), a department of the Ministry of Health. Research & Development (R&D) spending reports may aggregate all R&D-related transfers of value, however all other types of transfers of value must be reported for each HCP and HCO.<sup>7</sup>

### Denmark

In 2014, Denmark introduced a Sunshine Act<sup>8</sup> which significantly expanded the scope of the regulation of Pharma companies' affiliation with HCPs and the provision of 'economic benefits'. The legislation requires healthcare professionals to seek permission from/notify the Danish Medicines Authority (DMA) about certain types of affiliations. The DMA can then disclose this information to the public. Companies are required to send an annual report to the DMA with the details of who they have been affiliated with during the year. The Sunshine Act also introduces an application scheme for HCPs who wish to acquire shares, above a certain value, in companies marketing pharmaceutical products or medical devices. The new legislation applies to a broader set of HCPs and applies to medical device companies as well as Pharma in terms of economic benefits. The new law obligates companies not to provide unlawful economic benefits to HCPs and abolishes the provision of courtesy gifts and the use of competitions/raffles when promoting pharmaceutical products.

### France

In 2011, France became the first European State to pass a Sunshine Act (the anti-gift Act/Loi Bertrand) following a scandal around the marketing of an amphetamine as a diet suppressant which is believed to have killed hundreds of people in France. The law came into force after an implementing decree was adopted in 2013. Under the French regulatory framework, any company manufacturing or commercialising products, including medical devices, in France must disclose (via a dedicated [website](#)):

- any agreement it enters into with HCPs and HCOs;
- Benefits in kind or in cash exceeding €10, provided directly or indirectly to HCPs and HCOs.

More recently, in January 2017, as part of its strategy on strengthening the prevention of conflicts of interest the French Council of Ministers presented an order amending the French Sunshine Act. Based on Article 180 of Law 2016-41 of 26 January 2016 on the modernisation of the French healthcare system, the order widely extends the scope of the companies and professionals who come under the Act. It also clarifies what is and is not considered a benefit which must be disclosed. It clarifies certain derogations regarding the prohibition of benefits and creates specific regimes for authorising or declaring such benefits in order to strengthen the supervision by professional bodies or competent authorities. In addition, the amount of remuneration paid as part of contracts must also be disclosed.

### Portugal

Several Sunshine laws were adopted in Portugal between 2006 and 2013<sup>9</sup> which make the disclosure of transfers of value exceeding €25 between Pharma companies and HCPs and HCOs mandatory. In

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<sup>6</sup> 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.

<sup>7</sup> For more information about the new Sunshine Act, please see: <http://polarismanagement.com/belgium-introduces-new-sunshine-act/>.

<sup>8</sup> For more information on the act, please see: <http://en.horten.dk/News/2014/September/Update-The-Danish-HCP-Affiliation-SunshineAct>.

<sup>9</sup> Decree-Law n° 20/2013 of 14 February 2013 and 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,

addition, there are rules pertaining to the sponsorship of events (ie congresses, symposiums or scientific or marketing events). The law in Portugal also requires Pharma to report to the Portuguese Medical Authority (Infarmed) about financial support to patient organisations.

## Slovakia

Two Sunshine Acts in Slovakia<sup>10</sup> require transparency in relation to:

- medicinal products and devices and benefits granted to HCPs.
- the submission by pharmaceutical companies, with marketing authorisation, of an annual report to the Ministry of Health which states the value of advertising and marketing expenses and non-financial, in-kind benefits given to HCPs which is then made public by the Ministry.

## European States with Sunshine Regulations

### Greece

In 2014, Greece adopted a law with a sunshine obligation<sup>11</sup> which came into force in January 2016 under which every pharmaceutical organisation is obliged to disclose on its website and on the website of the National Organization for Medicines in the first six months of every year, all benefits provided to HCPs and HCOs including donations, sponsorship, registrations fees to congresses or seminars, accommodation and trip fees, as well as any other benefit relevant to the promotion of prescribed medicines. The benefits relating to research and development and non-interventional studies should be disclosed in totality by every Pharma organisation. Expressly excluded from this obligation are the costs relevant to market research, meals and drinks, as well as objects of negligible value for training and medical use connected with the conduct of the everyday medical practice of HCPs and HCOs. Negligible value is defined as value not exceeding 15 euros.

The Hellenic Data Protection Authority has published a legal opinion relating to the sunshine obligation which limits the scope of disclosures. In this ruling, the Authority found that there were gaps in the relevant legal provisions and concluded that the disclosure obligation only relates to those benefits concerning promotional but not scientific conferences. Furthermore, disclosures should include only essential personal data and excludes information such as Tax Registration Number and Social Security Number. Moreover, the Authority has concluded that the reporting of the amounts of benefits must be carried out in a specific way which ensures the protection of the privacy of HCPs. For example, the creation of profiles for HCPs is prohibited and disclosure must be done in a way that ensures that their personal information does not appear on search engines. As a result of this legal opinion, Pharma companies who had published disclosures with personal data of healthcare professionals on their websites, have subsequently deleted this information.

The Hellenic Association of Pharmaceutical Companies has announced that it will comply with any relevant directive issued by the National Organization for Medicines and other relevant authorities. The National Organization for Medicines has not yet issued any relevant directive regarding disclosures of transfers of value but it has contested the decision of the Hellenic Data Protection Authority and a new decision is expected to be delivered.

### Latvia

Latvia has a national regulation<sup>12</sup> with a Sunshine obligation that requires all Pharma companies to report their payments to healthcare professional associations, foundations, and medical treatment institutions and individual doctors in relation to events with a professional and scientific orientation (ie travel to congresses and conferences abroad). The reports appear on the website of the [Health](#)

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<sup>10</sup> Act No. 362/2011 and Act No. 362/2011 of 13 September 2011

<sup>11</sup> See Law Number 4316/2014 at Article 66, para 7.

<sup>12</sup> Art 32.2, Cabinet Regulation No 378 "Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians", available at: [http://vvc.gov.lv/export/sites/default/docs/LRTA/MK\\_Noteikumi/Cab\\_Reg\\_No\\_378\\_-\\_Advertising\\_Medicinal\\_Products.pdf](http://vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab_Reg_No_378_-_Advertising_Medicinal_Products.pdf)

Inspectorate- state administrative institution supervised by the Ministry of Health. Currently the medical device industry is not covered by this regulation.

## Romania

Romania has a sunshine regulation, implemented since 2015, with some amendments having been made to strengthen the regulation in 2016.<sup>13</sup> Under the regulation, a wide variety of transfers of value to medical doctors must be disclosed with responsibility for implementation delegated to the Ministry of Health through its National Agency for Medicines and Medical Devices. Disclosures appear on the National Agency's website.

## Turkey

In 2015, the Ministry of Health adopted sunshine regulations on the use of promotional activities for medical products which require that transfers of value between holders of marketing authorisation and HCPs and HCOs (including universities, unions and other health related organisations) be disclosed to the Ministry of Health. Transfers of value which exceed 10% of the legal minimum wage must be disclosed to the Turkish Pharmaceutical and Medical Device Agency. The regulation came into force in 2016 and the first disclosures are due at the beginning of 2017, however the regulation is weakened by the fact that disclosure will not be made publicly available and will only be reviewed by the Ministry of Health. One strength of the regulation is that it requires HCPs and HCOs to consent to disclosure before entering into relationships with Pharma but does not cover the disclosure of transfers of value to the general public. Pharma will still therefore need to seek additional consent if they want to more fully comply with EFPIA Disclosure Code.

## United Kingdom

The UK law is quite robust at present as it 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. However, as of last year, Sunshine Rules<sup>14</sup> were also introduced to support the legislation and regulate payments to NHS medical staff by suppliers of drugs and other medical products as a response to a journalistic investigation which revealed that many NHS workers were economically benefiting from relationships with Pharma. As of April 2016, there has been a change to the NHS contract requiring senior doctors and a range of other personnel (but not including medical residents/junior doctors and nurse practitioners) to declare payments or other benefits in kind to be put on a searchable database which is to be managed by NHS clinical commissioning groups and NHS hospital trusts.

### **European States with anti-corruption/ transparency legislation**

## Croatia

In Croatia, there are punitive laws that could potentially cover corruption by Pharma companies, however these laws have never been used for this purpose due to lack of transparency around their work, making it difficult to investigate any suspicions for the purposes of criminal prosecution.

## Germany

German legislation does not impose any specific disclosure obligations on Pharma but rather places the burden on HCPs. Certain regulations impose general disclosure obligations; for example, all HCPs who enter into service contracts with or receive benefits from Pharma companies are obliged to disclose this to their employer. The German Medical Products Act imposes disclosure obligations in relation to observational drug studies. Germany adopted a new anti-corruption law which came into force in 2016 and makes it illegal for all HCPs, including General Practitioners, to accept gifts in return for prescribing medicines.<sup>15</sup> This law was amended in the summer of 2016. The amendments are based on a decision of

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<sup>13</sup>The regulation is governed by two ministerial orders: OMS 874/2015 and OMS 194/2015.

<sup>14</sup>For more information on the newly adopted Sunshine Rule, please see: <https://www.theguardian.com/healthcare-network/2016/may/03/sunshine-rule-quick-guide>.

<sup>15</sup> More info is available at: [https://www.aok-bv.de/hintergrund/gesetze/index\\_14879.html](https://www.aok-bv.de/hintergrund/gesetze/index_14879.html).

the Federal Supreme Court made in 2012 and refer to anti-corruption practices in the health system. In the course of the making of these amendments, it was noted that some corruption standards (§§299, 311ff of the German Criminal Code) were not applicable to doctors in private practice and that consequently these doctors could not be prosecuted for accepting 'benefits' during their professional activity. In response, §§299a, 299b and 300 were added to the German Criminal Code which now refer explicitly to all members of the healing professions and unequivocally anchor corruption in the health system as a criminal offence. The aim is to sanction bonus marketing -the influencing of doctors regarding their prescribing practice via the payment of bonuses- by pharmaceutical companies. At present, uncertainty surrounding the new standards is problematic. Under the amendments many forms of cooperation and the drawing of 'benefits' could be interpreted as being prohibited. More concrete details will need to be elaborated by the legislator.

In terms of self-regulation, under the physicians' codes of professional conduct, 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. Our German members report that organisations and institutions have adopted their own codes and initiatives to minimise collaboration with Pharmaceutical companies. For example, there is a movement among German psychiatrist called: I pay for my own lunch (Mein Essen bezahle ich selbst).<sup>16</sup>

### Italy

Italian law does not have general transparency rules akin to a Sunshine Law. However, one legislative Decree,<sup>17</sup> on the notification requirements for scientific events does include transparency rules with a disclosure obligation that applies to Pharma companies. Companies holding the authorisation to produce, market or import pharmaceuticals in Italy, and companies that commercialise such products must inform the Italian 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 can be cancelled by AIFA and pharmaceutical companies may be fined.

### Poland

A limited disclosure obligation does exist in Polish law under the Act on Consultants in Healthcare but only covers national health consultants, of which there are few, who carry out a state function in the area of health. The disclosure obligation rests on national consultants rather than Pharma who must issue individual declarations in which they disclose transfers of value (over 380 złoty) as well as other interests. These disclosures have been publicly available on a government [website](#) since 2013. Poland has a number of other laws which help to regulate and make the relationships between Pharma and healthcare professionals more transparent including the law on public tenders, which covers the healthcare sector, and the Pharmaceutical Law which has a measure which prohibits Pharma from giving, offering or promising any 'material benefits' worth over 100 złoty (approx. 20E) to doctors unless they are related to their medical practice.

### The Netherlands

There is no statutory legal obligation in the Netherlands for Pharma companies to report payments made to HCPs or HCOs. However, the Dutch Medicines Act contains articles regarding advertising to the public and advertising to professionals and inducements. Advertisement, for public and for professionals, is forbidden for any medicines that are only available on prescription. The Medicines Act also prohibits 'inducements' unless certain conditions are met.

Besides legislation there is a self-regulatory [transparency register](#). This offers insight into certain financial relationships between Pharma and HCPs. The register was initiated by umbrella organisations of HCPs,

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16 <https://www.mzis.de/mzis-auf-englisch/>

<sup>17</sup> Legislative Decree No 219 of 24 April 2006.



HCOs, the industry and the Minister for Health who was inspired by the US Sunshine Act. Financial relations above € 500 must be reported.

### Spain

Spain does not have a full sunshine law but does have some relevant transparency regulations in the general law devoted to medicines and other health products.<sup>18</sup> These regulations require Pharma companies to make public details of benefits given to healthcare professionals and organisations in relation to conferences, congresses, study trips and similar events. 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 of their involvement in any materials produced for the attention of healthcare professional that mention medicines, at the time of their publication or broadcasting. Complementary regulations aimed at implementing these directives have not yet been fully developed.

### Sweden

There is no direct statutory legal obligation in Sweden for pharmaceutical companies to report payments made to healthcare professionals or organisations. However, other anti-corruption legislation could be applicable including the Medicinal Products Act and anti-corruption rules under the Criminal Code.

### Slovenia

Slovenia does not have a specific sunshine law but the Medicinal Products Act<sup>19</sup> requires holders of marketing authorisation for medicinal products to keep records in relation to advertising of medicinal products as well as training of HCPs and it prohibits the giving, offering or promising of gifts, financial advantage or material benefits to persons qualified to prescribe or supply medicinal products over a certain amount. Slovenia has anti-corruption legislation which might also apply in some circumstances.<sup>20</sup>

## Conclusion

There is a clear trend emerging across Europe towards greater regulation in the area of transparency around the relationship between Pharma and HCPs. The EFPIA Disclosure Code and other transparency codes adopted by industry represent a substantial step forward. However, self-regulation through these Disclosure Codes cannot ensure full transparency with regard to transfers of value for a number of reasons including the limitations of membership coverage and the obstacle that the need for consent from HCPs poses in many European countries. In addition, there are anti-corruption laws which might apply in terms of inappropriate financial relationships between Pharma and HCPs, however many of these have gone untested in this arena.

**MHE is in favour of the adoption of clear and robust Sunshine and transparency Laws, which are legally binding, to ensure that there is full transparency around the financial relationships between these two important health actors who are often at the heart of how our mental health policy is formed and how our mental health systems function.**

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<sup>18</sup> The Spanish Act 29/2006, dated 27 July, on the Guarantee and Reasonable Use of Medicines and Health Products Spanish Royal Decree 1416/1994

<sup>19</sup> The Full Act is available at the following: [http://www.firdpc.com/en/Legislation/Medicinal\\_Products\\_Act\\_March\\_2014/](http://www.firdpc.com/en/Legislation/Medicinal_Products_Act_March_2014/).

<sup>20</sup> <http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO5523>