



The Sun Shines on Europe

Transparency of financial
relationships in the healthcare
sector

The Sun Shines on Europe:

Transparency of financial relationships in the healthcare sector

May 2017

Ancel.la Santos

Senior Policy Advisor

Acknowledgements

Alice Fabbri, Signe Mezinska, Barbara Mintzes and Shai Mulinari for providing guidance regarding the development of this paper. We also thank contacts in reported countries who helped to clarify questions about Sunshine Act initiatives.



Published by:
Health Action International
Overtoom 60 (2) | 1054 HK Amsterdam | The Netherlands
Tel: +31 20 412 4523 | www.haiweb.org

Licensing:
This report is licensed under the Creative Commons Attribution-NonCommercial 4.0 International Licence.
To view a copy of this licence, visit <http://creativecommons.org/licenses/by-nc/4.0/>.



This publication received funding under an operating grant from the European Union's Health Programme (2014–2020).

The content of this publication represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency, or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

Pharmaceutical companies employ a wide range of promotional activities to increase medicines prescription rates and maximise their profit. Some of the strategies companies use to influence healthcare professionals include the provision of hospitality to attend events, free meals and gift-giving. At the same time, healthcare professionals might be part of companies' advisory boards and receive speaking fees. At the core of the issue around these types of activities is the reality that financial conflicts of interest raise serious concerns about the objectivity of medical research and the commitment of healthcare professionals to patients' best interest [1].

In recent years, several countries have enacted laws to increase the transparency of financial relationships between the healthcare industry and providers. In 2010, after more than ten years in the making, the United States (U.S.) adopted the Physician Payments Sunshine Act ("Sunshine Act") as part of the Affordable Care Act [2]. The Sunshine Act was implemented to allow patients to make better-informed decisions about healthcare professionals and treatment, and deter inappropriate financial relationships that may lead to increased healthcare costs [3]. Under these rules, manufacturers of drugs, medical devices, biologicals or medical supplies participating in federal healthcare programs have to report direct or indirect payments or other transfers of value of \$10 or more to physicians and teaching hospitals. This data is submitted to the Open Payments program, managed by the Centers for Medicare and Medicaid Services. The first reporting period covered the last months of 2013 and the results were published on the Open Payments website in September 2014. The U.S. Sunshine Act also mandates companies to report certain ownership interests held by physicians and their immediate family members. There are some exemptions, including: meals offered at large conferences, product samples, independent certified and accredited continuing medical education, and educational materials that directly benefit patients [4]. Failure from companies to comply with reporting requirements may result in penalties of up to \$1,000,000 [5].

European Union (EU) laws regulating pharmaceutical promotion [6] do not include any provisions like those found in the U.S. Sunshine Act, but some Member States have adopted these rules in their national legislative framework. Following the Mediator (benfluorex) scandal, France adopted a new health law in December 2011 with specific provisions to increase the transparency of relationships between the industry and healthcare providers [7] [8]. This information was firstly disclosed at the end of 2013 on companies' websites and at the site of the French National Medical Council (reporting period 2012) [9]. As of June 2014, disclosures have been available on a centralised database managed by the Ministry of Social Affairs and Health [10]. These reporting

requirements apply to a range of industries. For example, companies producing or marketing medicines, medical devices, cosmetic products and breast milk (milk banks). Covered beneficiaries are healthcare professionals and representative associations, students, medical centres, universities and patient organisations amongst other stakeholders. Those consulting the centralised database can find certain information about agreements entered into between companies and providers and the value of cash or in-kind benefits valued at €10 or more. However, an implementing decree exempted companies from reporting the actual fee for services provided to a given beneficiary. In 2015, following a complaint from civil society groups, the French Council of State ruled that this type of information also needs to be published [11] [12]. According to a new decree issued at the end of 2016, companies will have to report all granted fees of €10 or more and, with respect to agreements, report some additional information such as the precise subject matter of the contract. These new requirements should be applied by no later than 1 July 2017 [13]. In general, non-compliance by companies with disclosure requirements may result in fines of up to €225,000 and additional sanctions (e.g. suspension of business activities).

Similar legislative initiatives have been implemented in other EU countries. Portugal adopted mandatory Sunshine Act rules in 2013 [14]. At present, information on subsidies, grants, sponsorship, occasional consultancy fees and other benefits granted by the pharmaceutical and medical devices industries can be viewed in a centralised database managed by Infarmed, the Portuguese National Authority for Medicines and Health Products [15]. In this case, reporting requirements apply to both donors and beneficiaries* (e.g. healthcare professionals and representative organisations, medical centres, patient organisations). A minimum reporting threshold of €60 applies (or €25 if the transfer of value was made before 6 October 2014).

Other examples of EU Member States with legislative Sunshine Act provisions are Greece, Romania, Latvia and Denmark [16] [17]. Disclosure requirements in Denmark have been in place for several years and were expanded at the end of 2014 [16] [18]. Since then, both pharmaceutical and medical devices companies have to forward an annual report to the Danish Medicines Agency (DMA) with details of proprietary pharmacists, doctors, nurses and dentists with whom they have had a professional affiliation (either with or without remuneration) the year before. This group of healthcare professionals are also obliged to notify the DMA of their professional affiliation with a company, or even to seek prior permission depending on the type of activity (e.g. participation in advisory boards) and they have to specify remuneration received. Based on the notifications received from these healthcare professionals, the DMA publishes on its website information about

*The new Decree-Law 5/2017 – which extends the transparency requirements to the medical devices industry – has replaced beneficiaries' duty to notify Infarmed about received benefits (double-notification system) by their obligation to proceed to validate the information submitted by companies. These changes were applied in February 2017.

the type of affiliation and the value of the remuneration received [19]. Information on ownerships (e.g. shares) is also available. In addition, a larger group of healthcare professionals and certain professionals engaging in the buying and selling of medicinal products and medical devices shall notify the DMA if they receive payment for expenses (sponsorship and hospitality) relating to activities taking place outside Denmark and this is also published on the website in a different register [19].

In Romania, pharmaceutical companies are also mandated by law to declare sponsorship and other benefits provided to healthcare professionals and organisations to the Ministry of Health and the National Agency for Medicines and Medical Devices (AMND) [16]. Reporting obligations also apply to beneficiaries. At present, declarations from sponsors for the 2014 reporting year are available on AMND's website, as well as declarations from sponsors and beneficiaries for the 2015 reporting year [20]. Greece also passed a new law at the end of 2014 that includes provisions to increase the transparency of financial relationships between the pharmaceutical industry, healthcare professionals and healthcare organisations. The law mandates disclosure on companies' own websites and on the website of the National Organisation for Medicines [16]. Following a 2016 opinion from the Greek Data Protection Authority, at least three companies have reported publishing transfers of value executed in 2015 to healthcare professionals on an aggregate basis [21] [22] [23]. At present, disclosures are available on companies' websites. Latvia also adopted legislative reporting requirements in 2014. Pharmaceutical companies submitted to the Health Inspectorate of Latvia the first reports on transfers of value to individual healthcare professionals, associations, foundations and healthcare institutions that were made in 2015. The information was published in March 2016 on the Health Inspectorate's website [17].

In other EU countries, disclosure is primarily managed through self-regulation. The Netherlands is a special case amongst these countries, as it involves a self-regulatory approach with some government involvement. In 2009, the then acting Minister of Health initiated talks about the establishment of a system similar to that of the U.S. Sunshine Act. The parties involved expressed a preference for self-regulation and the rules on the disclosure of financial relationships ended up being implemented by the Foundation for the Code of Pharmaceutical Advertising (CGR) in 2012 [24]. The CGR is a multi-stakeholder, self-regulatory organisation comprised of pharmaceutical industry and healthcare provider associations. The centralised payments database was set up with financial support from the Dutch Ministry of Health and is managed by the Transparency Register Foundation (established at the initiative of the CGR) [25]. Information on certain transfers of value from the pharmaceutical industry has been publicly available since 2013. The CGR code sets a very high threshold amount: companies only have to report financial support when it exceeds €500 per beneficiary, per calendar year. Reporting requirements also apply to beneficiaries, although it was agreed

that the main responsibility to report to the register the financial relationships entered into within the Netherlands lies with pharmaceutical companies [25]. Information on transfers of value from the veterinary industry has been available in the registry since 2014 and from medical devices companies since 2016.

In June 2013, the European Federation of Pharmaceutical Industry Associations (EFPIA) adopted a Code on the 'Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations' [26]. The Code mandates EFPIA national member associations to transpose the rules into their own codes (in full, except where its provisions are in conflict with national laws and regulations). The deadline for the first disclosures was at the end of June 2016 (reporting year 2015). The EFPIA Code says that disclosures have to be done on companies' own websites or "on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or a Member Association..." [26, p.6]. Companies have to report support provided to healthcare organisations (e.g. donations, grants, sponsorship, hospitality and fee for service) and to healthcare professionals (e.g. hospitality and fees for service). EFPIA encourages companies to seek recipients' consent to individual disclosure (not applicable to transfers of value related to research and development activities, which are reported in an aggregated way).

While some national industry associations had already introduced self-regulatory provisions to enhance transparency of financial relationships several years ago (e.g. in Sweden and the United Kingdom to a certain degree), the EFPIA Code has expanded disclosure practices in Europe. The EFPIA initiative might be more relevant in countries with non-existing disclosure rules or less ambitious self-regulatory provisions, but less in those countries where there have been legislative developments on disclosure.

Expected benefits of Sunshine Act rules

Several studies examining data from the Open Payments program in the U.S. and Medicare Part D prescription data have revealed connections between the receipt of industry support and prescription patterns more aligned with commercial interests than with patient interests. A study from ProPublica, published in 2016, found that physicians in five common medical specialities who accepted industry payments in 2014 were two to three times as likely to prescribe high rates of brand-name drugs compared with others in their speciality [27]. Amongst those who received payments, the group receiving larger payments had on average a higher brand-name prescribing rate. Another analysis of almost 342,000 physicians from 12 specialties with documented payments in the Open Payments program, revealed a relationship between the level of payment and the level of prescribing costs per patient. Similar associations were observed regarding the proportion of brand-name prescriptions written for patients [28].

Likewise, DeJong et al (2016) found that receipt of industry-sponsored meals was associated with an increased rate of prescribing the brand-name medicine that was being promoted [29]. This is possible because information on the type of drug being promoted is available on the Open payments database. All of these studies indicate an association between the provision of financial assistance to healthcare professionals and their prescribing habits. These patterns are strongly suggestive of causality, although more research is needed.

Besides helping to uncover the extent of financial relationships between the industry and healthcare providers and their impact on prescribing patterns,

Sunshine Act rules can serve as a deterrent. Indeed, transparency can help to dissuade healthcare professionals from entering into inappropriate relationships that could negatively affect clinical practice and increase healthcare costs. Patients can also use information on payments to make more informed decisions on healthcare professional choice and treatment [3]. The extent to which this happens will partly rely on the comprehensiveness of Sunshine Act initiatives. Although this paper has not addressed, in detail, the initiatives mentioned above, some initial conclusions can be drawn, and general recommendations issued, with the purpose of ensuring that Sunshine Act initiatives are implemented in ways that maximise their potential.

General recommendations for more effective Sunshine Acts

1. Adopt a comprehensive legislative approach towards the disclosure of financial and professional relationships

Under self-regulation, pharmaceutical industry associations or multi-stakeholder organisations (representing a group of affected sectors) develop their own codes and put in place procedures to respond to complaints [30]. Self-regulatory bodies are, in principle, responsible for ensuring that members are in compliance with the rules and that corrective measures and sanctions are applied as needed. A study of self-regulation of pharmaceutical promotion in Sweden and the United Kingdom (UK) between 2004 and 2012 found that a total of 46 companies were ruled to be in breach of the industry code for a serious offence at least once in the two countries combined, and seven companies were in serious violation more than ten times each [31]. There was little indication of deterrence, with charges incurred by companies equivalent to only 0.014% and 0.0051% of annual sales revenues in Sweden and the UK, respectively. The authors concluded that “the prevalence and severity of breaches testifies to a discrepancy between the ethical standard approved by companies and codified in industry codes of conduct and the actual conduct of the industry”[31, p18].

It is important to note that self-regulation by the industry brings an intrinsic conflict of interest in and of itself, whereas governmental action predominantly focuses on public health outcomes. Instead of relying on self-regulation, the EU and Member State governments must take the lead and enact mandatory rules for the disclosure of relationships between the healthcare industry, healthcare professionals, healthcare organisations and other entities working in public health (e.g. patient associations). Disclosure rules should be applicable to all the industries operating in the healthcare sector (pharmaceutical and medical devices industries) and with a potential for detrimental effect on public health (e.g. nutrition, cosmetics). Disclosures should be in a searchable, centralised database managed by the government.

2. Mandate disclosure of transfers of value on an individual level

Evidence shows that all gifts—big or small—create feelings of reciprocity and self-serving bias, which negatively influences prescribing practices [32] [33]. To allow for an accurate overview of the extent of industry influence, companies should report any transfer of value (direct or indirect), regardless of its worth. At a minimum, the database should display the value and type of support provided (e.g. grant, gift, hospitality, fee for service), the name of the company’s product or products that are being promoted and some general information about agreements entered into between companies and beneficiaries. Since there is a public interest in disclosure, consent by beneficiaries to publish the data on an individual level should not be required. This is already the case in countries such as France, Portugal, Denmark, Romania, Latvia and The Netherlands. The contrasting option involves putting in place an opt-out clause, which allows for incomplete disclosure. In the United Kingdom, for example, the Association of the British Pharmaceutical Industry reported in 2016 that 70% of healthcare professionals who allowed their details to be disclosed received less than 50% of the total amount of money paid. This means that those who received the highest payments from the industry preferred to remain anonymous [34]. Clearly, opt-out clauses are inconsistent with the intent of transparency.

Another recommendation that we make is to offer beneficiaries the opportunity to review the data. In the case of a disagreement with the company, the data can be marked as being disputed in the database. In any case, reporting deadlines must always be respected.

3. Improve monitoring and compliance

Governments must actively monitor compliance with reporting requirements. The main responsibility of data disclosure must lie with the industry, but governments should also encourage and facilitate reporting from beneficiaries so that the data can be cross-checked. Non-compliance by companies with reporting requirements should result in the application of effective sanctions that deter future offenses.

Transparency not an end in itself

Although transparency of professional and financial relationships between the healthcare industry and healthcare professionals is important, it cannot be perceived as an end in and of itself. Exposure to information from pharmaceutical companies negatively affects prescribing and professional behaviour, with potentially detrimental effects on patient health. Stricter regulation of pharmaceutical promotion is therefore needed. In addition, it is important for healthcare professionals to better understand the implications of companies' promotional activities and to know how to critically appraise promotions in ways that ensure good clinical practice. Education on pharmaceutical promotion and conflicts of interest should be adequately addressed in the medical curriculum and in continuing medical education.

To further capacitate healthcare professionals and medical students, Health Action International has published the following educational guides: 'Fact or Fiction? What Healthcare Professionals Need to Know about Pharmaceutical Marketing in the European Union' (2016) and 'Understanding and Responding to Pharmaceutical Promotion: A Practical Guide', published in collaboration with the World Health Organization (2009). More information about our work on pharmaceutical promotion can be found on our website: <http://haiweb.org/what-we-do/pharmaceutical-marketing/guides/>.

Overall, a multi-faceted approach that combines robust regulation with education is the best way forward for ensuring that financial relationships between pharmaceutical companies and healthcare practitioners do not affect prescribing habits or have negative health outcomes for patients.

References

- [1] Institute of Medicine (2009). *Conflict of Interest in Medical Research, Education, and Practice*. Washington, DC: The National Academies Press.
- [2] Santhakumar S, Adashi EY (2015). The Physician Payment Sunshine Act. Testing the value of transparency. *JAMA*, Vol 313 (1): 23-4
- [3] Centers for Medicare and Medicaid Services (2013). Medicare, Medicaid, Children's Health Insurance Programs: Transparency reports and reporting of physician ownership or investment interests. *Federal Register*, 78 (27) 9457- 9528.
- [4] American Medical Association (2016). *Sunshine Act: Physician financial transparency reports*. American Medical Association, 21 March 2016. Available at <https://www.ama-assn.org/sites/default/files/media-browser/specialty%20group/washington/sunshine-act-brochure.pdf>
- [5] Centers for Medicare and Medicaid Services. *Audits and Penalties*. [Online] Available at <https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Audits-and-Penalties.html>
- [6] European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311
- [7] Libération (2011). Après le Mediator, la loi remède de Bertrand. *Libération*, 1 August 2011 http://www.liberation.fr/societe/2011/08/01/apres-le-mediator-la-loi-remede-de-bertrand_752578
- [8] Law No 2011-2012 of 29 December 2011 on the Strengthening of Health Protection for Medicinal and Health Products
- [9] Ordre National des Medicines. [Online] Available at <http://www.sunshine-act.ordre.medecin.fr/>
- [10] Ministère des Affaires sociales et de la Santé. *Base Transparence Santé* [Online] Available at <https://www.transparence.sante.gouv.fr/flow/main?execution=e2s1>
- [11] Borde JS (2015). Décrets du sunshine act : Décisions contrastées du Conseil d'État. Formindep, 6 Mars 2015. Available at <http://www.formindep.org/Decrets-du-sunshine-act-Decisions.html>
- [12] Fernandez Rodriguez L (2016). Base Transparence Santé : où en est-on ?. *LesEchoes.fr*, 24 February 2016. Available at https://www.lesechoes.fr/24/02/2016/lesechos.fr/021717793386_base-transparence-sante---ou-en-est-on--.htm
- [13] McCully S (2017). French sunshine obligations clarified and extended. CHCUK, 30 January 2017. Available at <http://www.chcuk.co.uk/french-sunshine-obligations-clarified-and-extended/>
- [14] Decree-Law n° 20/2013 of 14 February 2013 and Decree-Law n° 128/2013 of September 2013
- [15] Infarmed. Comunicações ao INFARMED, I.P., no âmbito da Transparência e Publicidade. Perguntas Frequentes. [Online] Available at <https://placotrans.infarmed.pt/Faq.aspx>
- [16] Campbell DJ, Sharkey BP (2015). *Ready Or Not, Full Speed Ahead For The Global Transparency Movement*. Porzio Life Sciences. Available at https://s3-us-west-2.amazonaws.com/porzio/media/1432/porziols-white-paper_august-2015.pdf
- [17] Health Projects for Latvia (2016). *Farmācijas industrijas sponsorētie profesionālās un zinātniskas ievirzes pasākumi veselības aprūpes speciālistiem: informācijas caurskatāmība un nepieciešamie uzlabojumi*. Health Projects for Latvia, Available at http://www.veselibasprojekti.lv/upload/Petijumi/Zinojums%20VIM%20par%20industrijas%20maksajumiem%20arstiemi%202015.g._17.11.16.pdf
- [18] Horten (2014). *Update: The Danish HCP Affiliation/Sunshine Act*. Horten, 2 September, 2014. Available at <http://en.horten.dk/News/2014/September/Update-The-Danish-HCP-Affiliation-SunshineAct>
- [19] Danish Medicines Agency (2017). Collaboration between healthcare professionals and companies. [Online] Available at <http://laegemiddelstyrelsen.dk/en/licensing/collaboration-with-companies/>
- [20] National Agency for Medicines and Medical Devices. [Online] Available at http://www.anmdm.ro/anmdm/med_publicitate_declaratii.html
- [21] GSK. *Disclosure of transfers of value by GlaxoSmithKline A.E.B.E., in accordance with article 66 par. 7a of Law 4316/2014, SFEE and EFPIA Disclosure Code* [Online] Available at <http://www.gsk.com/en-gb/responsibility/our-behaviour/engaging-with-healthcare-professionals/europe/greece/>
- [22] Servier (2016). *Methodological Note*. Servier Hellas, Servier

- [Online] Available at http://www.servier.gr/sites/default/files/Servier_Methodological%20Note_ENG.pdf
- [23] Pfizer. *Ευρωπαϊκή Ομοσπονδία Φαρμακευτικών Βιομηχανιών και Ενώσεων (EFPIA) Κώδικας Δημοσιοποίησης* [European Federation of pharmaceutical industries and associations (EFPIA) Code to disclosure] [Online] Available at <http://www.pfizer.gr/content/disclosure-code>
- [24] Stichting CGR. Transparency. [Online] Available at <http://www.cgr.nl/en-GB/Transparantie>
- [25] Stichting Transparantieregister zorg. *About the Transparency Register*. [Online] Available at <http://www.transparantieregister.nl/en-GB/Over-het-Transparantieregister>
- [26] European Federation of Pharmaceutical Industries and Associations (2014). EFPIA HCP/HCO Disclosure Code. *EFPIA Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations*. EFPIA, 6 June 2014.
- [27] Jones RG, Ornetein C (2016). *Matching Industry payments to Medicare prescribing patterns: an analysis*. Pro Publica, March 2016
- [28] Perlis RH, Perlis CS (2016) Physician Payments from Industry Are Associated with Greater Medicare Part D Prescribing Costs. *PLoS ONE*, 11(5): e0155474. doi:10.1371/journal.pone.0155474
- [29] DeJong C, Aguilar T, Tseng CW et al (2016). Pharmaceutical industry-sponsored meals and physician prescribing patterns for Medicare beneficiaries. *JAMA Intern Med*, 176(8):1114-10.
- [30] World Health Organization & Health Action International (2009). *Understanding and responding to pharmaceutical promotion: A practical guide*. Health Action International, Amsterdam.
- [31] Zetterqvist AV, Merlo J & Mulinari S (2015). Complaints, complainants, and rulings regarding drug promotion in the United Kingdom and Sweden 2004-2012: A quantitative and qualitative study of pharmaceutical industry self-regulation. *PLoS Med*, 12(2):e1001785.
- [32] Sah S & Fugh-Berman A (2013). Physicians under the Influence: Social Psychology and Industry Marketing Strategies. *Journal of Law, Medicine and Ethics*, 41(3): 665-672.
- [33] Smith SR, Hams M & Wilkinson W (2013). Conflict of interest policy guide for medical schools and academic medical centers. *Community Catalyst*. Toolkit series (www.communitycatalyst.org/initiatives-and-issues/initiatives/prescription-reform/conflict-of-interest-policy-guide)
- [34] Torjesen I (2016). Doctor and pharmacist payments by pharma revealed in database. *The Pharmaceutical Journal*, 1 July 2016. Available at <http://www.pharmaceutical-journal.com/news-and-analysis/news/doctor-and-pharmacist-payments-by-pharma-revealed-in-database/20201381.article>