
# EFPIA Leads the Self-Regulation Charge to Try to Avoid Government-Imposed Transparency

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As the worldwide trend toward government-imposed transparency in the relationships between life sciences companies and healthcare professionals accelerates, the pharmaceutical industry is aggressively pursuing a different tactic: self-regulation. While advocates of legislative intervention argue that government-imposed disclosure requirements will decrease the cost of drugs and reduce corruption, supporters of self-regulation stress that their approach can lead to world-wide uniformity and a much more manageable, logical, and efficient path to transparency. As the argument between advocates of government action and supporters of industry self-regulation flares, the pharmaceutical industry is seeking to gain the upper hand by enacting self-regulatory transparency measures in a number of key jurisdictions.

Currently, the "hottest spot" for industry self-regulation is the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), which is the representative body of the pharmaceutical industry in Europe. EFPIA's members include forty pharmaceutical companies

and the national industry associations of thirty-three countries. EFPIA revolutionized self-imposed transparency when its Board adopted the "EFPIA Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations" ("Disclosure Code") on June 24, 2013, at EFPIA's Annual Meeting. The Disclosure Code requires pharmaceutical companies to publicly disclose their 2015 financial relations with healthcare organisations and healthcare professionals in 2016.

Prior to June 2013, EFPIA had two relevant codes: 1) EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions With, Healthcare Professionals ("HCP Code"); and 2) EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations (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 Codes. The pre-2013 Codes contain minimum standards that all national industry associations are required to have in their own national codes.

The HCP Code did not contain reporting or disclosure requirements, but encouraged 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. EFPIA's Code on Relationships with Patient Organisations, however, contains reporting requirements that applied 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's adoption of the Disclosure Code is a watershed moment in the debate between self-regulatory supporters and advocates of transparency legislation. In a July 2, 2013, press release announcing the adoption of its Disclosure Code, 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)

As noted previously, under the 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 the structure in 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 that may 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.

The Disclosure Code also mandates that EFPIA's member associations include sanctions in their national codes for violations of the disclosure provisions, with such penalties to be proportionate to the nature of the violation. EFPIA is requiring formal transposition of the Disclosure Code's requirements into the national codes of its member associations by December 31, 2013, a process that will be closely monitored by the pharmaceutical industry.

EFPIA's approach holds great potential for achieving some degree of uniformity across Europe. The critical factor will be the nature and extent of the differences in how national industry associations implement EFPIA's provisions into their own national codes. While the adoption of the Disclosure Code and its incorporation into industry codes across Europe 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, including the United Kingdom and the Netherlands. We will be examining the experience in those countries, as well as industry's approach to transparency in Japan and Australia, as part of **Sunshine Abroad: International Transparency**.