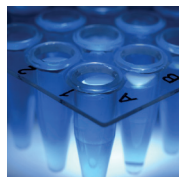




European Federation of Pharmaceutical  
Industries and Associations

## EFPIA Disclosure Code: Your Questions Answered

March 2016





# Working together: why do the pharmaceutical industry and healthcare professionals work together?



## Why does industry pay health professionals to provide services?

Collaboration between industry and healthcare professionals benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives. Industry and health professionals collaborate in a range of activities from clinical research, sharing best clinical practice and exchanging information on how new medicines fit into the patient pathway.



## What services to health professionals does the industry provide?

As the primary point of contact with patients, healthcare professionals offer invaluable and expert knowledge on patient outcomes and management of diseases. This plays a crucial role in informing the pharmaceutical industry's efforts to improve patient care, treatment options and patient outcomes.

Health professionals also may be paid to contribute to medical education meetings. Sharing information and best practice on state-of-the-art treatments is a driver of better healthcare and improving patient outcomes.

As with any professional group providing services it is fair and appropriate to remunerate healthcare professionals for their time and expertise.



# About the EFPIA Disclosure Code



## What is the EFPIA Disclosure Code?

The EFPIA Disclosure Code is a code of conduct that requires all EFPIA member companies and companies that are members of EFPIA member associations to disclose transfers of value to HCPs and healthcare organisations (HCOs). Under the Code, EFPIA member companies will have to disclose the names of healthcare professionals and organisations that have received payments or other transfers of value from them. They will also have to disclose – by HCP or HCO – the total amounts of value transferred, by type of activity, which could consist of, for instance, a grant to an HCO, a consultancy fee for speaking, payment for travel, or registration fees to attend a medical education congress.

The first disclosures will be made by 30 June 2016, for payments made in 2015. This information will be published on a public platform, which could be on the company's own website or in some countries, a central platform combining data from different companies.



## Why is EFPIA introducing the public disclosure of payments to health professionals?

Collaboration between industry and health professionals benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives. Industry and health professionals collaborate in a range of activities from clinical research, sharing best clinical practice and exchanging information on how new medicines fit in to the patient pathway. Bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Society has increasingly high expectations for transparency, none more so than in healthcare. We want to ensure we meet those expectations going forward.



## Which countries does the EFPIA Disclosure Code cover?

The EFPIA Code covers the 33 countries within its membership (see [www.efpia.eu](http://www.efpia.eu)), EU, EEA and EFTA countries and beyond, as well as countries that decide to voluntarily abide by the Code - it covers the geographical area from Portugal to Russia, from Turkey to Iceland, and from Greece to Scandinavian countries.



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## What types of payments will be disclosed?

Companies will disclose payments made to health professionals such as consultancy, advisory boards, speaker fees and sponsorship to attend meetings.

More specifically, donations and grants (to organisations only; grants and donations are not legally allowed to individual healthcare professionals), fees-for-service & consultancy, where a contract is in place for activities such as speaking at, or chairing meetings, attending advisory boards and media consultancy, coverage of costs to participate in events (including registration fees, travel and accommodation) and research & development transfers of value, which are disclosed in aggregate.



## Will the new system cover all payments to healthcare professionals at an individual level?

No. Payments made for research and development activities will be disclosed in aggregate. For the purposes of the Code, these activities are defined as transfers of value to HCPs or HCOs related to the planning or conduct of:

- **non-clinical studies** (as defined in OECD Principles on Good Laboratory Practice);
- **clinical trials** (as defined in Directive 2001/20/EC); or
- **non-interventional studies** that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the HCP Code).

Meals and drinks will not be disclosed, but a threshold has been applied in each country, limiting hospitality under a certain value. The Code does not require items of medical value, information and educational materials designed for patients and which are inexpensive, samples and activities solely relating to over the counter medicines, to be disclosed.



## Why are payments made for research and development not included in the disclosures?

The EFPIA Disclosure Code focuses on transfers of value for the provision of services, such as speaking at events or attending advisory boards and for attending educational meetings. This is a significant step in bringing greater transparency to the relationship between industry and the health professional community.

It is worth noting that research and development, and in particular clinical trials, are subject to transparency legislation under the EU Clinical Trial Regulation (2001/20) and the European Medicines Agency Transparency Policy (Policy 0070). The names of investigators working on industry-sponsored trials will be publicly disclosed in the Clinical Study Reports published by the EMA.

Company spending on research and development will be disclosed in aggregate.





## Why are meals and drinks not included in the disclosures?

Very often these transfers of value are for small amounts such as a coffee or sandwich. Disclosing these small transactions would place a disproportionate administrative burden on industry and HCPs, for little value. Instead, a threshold has been applied in each country, limiting hospitality under a certain amount. These amounts are outlined in country national codes of practice.



## How does the new system work?

Payments made to health professionals are recorded throughout the year and publically disclosed by the 30 June, of the following year. The first disclosures will be made by 30 June 2016, for payments made in 2015.



## How will payments be disclosed?

In the majority of countries in Europe, payments will be disclosed on company websites. In countries such as France, Denmark and Portugal, national legislation requires disclosure on a central platform.

Belgium, Czech Republic, Ireland, Sweden, the Netherlands and the UK have opted to make disclosures on a central, online platform in each country, through self-regulation, often in partnership with stakeholders.

Denmark, Estonia, France, Greece, Latvia, Lithuania, Portugal, Romania, Serbia, Slovakia and Turkey have either existing legislation or legislation in development covering the disclosure of payments to health professionals.



## Why are some countries disclosing payments through a central platform for disclosure and some just disclosing on company websites?

In some cases, such as in Denmark, France or Portugal, disclosure of payments on a central platform is a legislative requirement. The decision to disclose payments on a central platform through self-regulation or co-regulation with the healthcare professional community, such as in Belgium, Czech Republic, Ireland, Sweden, the Netherlands and the UK, is a national decision reflecting the differing stakeholder, technical and resource environments. In the majority of countries in Europe, payments will be disclosed on company websites.





### What is the definition of “healthcare professional” in the context of the EFPIA Disclosure Code?

The EFPIA Disclosure Code defines healthcare professionals as any member of the medical, dental, pharmacy or nursing professions, or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.



### What do healthcare professionals and healthcare organisations need to do under the new system of disclosure?

Healthcare professionals and healthcare organisations will be informed by the company or companies they work with of the intent to disclose. In order for the disclosures to be made public, healthcare professionals and in the case of Austria and Switzerland, healthcare organisations, need to give their consent for the information to be made public. This usually will be managed through a clause in the contract between the healthcare professional/ healthcare organisation and the company.



### If an HCP lives on one country but is paid to provide a service in another country, where will the payment be disclosed?

In order to make the system meaningful for patients and other interested parties, disclosures will be made in the country where the HCP/HCOs holds their principal practice.



### What consultation has there been with healthcare professionals about this initiative already?

EFPIA has reached out to the healthcare professional community in Europe at an early stage.

A broad range of stakeholders, including several leading European healthcare professional representative organisations, endorsed the [Principles for Good Governance in the Pharmaceutical Sector](#). The principles, published in 2012, contain a section on transparency that requests stakeholders to “have, or develop, a policy on transparency regarding conditions under which professional relations in this area are made accessible to the public”.

EFPIA Member Associations have conducted a range of activities, consulting with healthcare professionals, on the issue of disclosure such as surveys, consultations and meetings. EFPIA continues to engage with European professional bodies on the issue and has launched a social media platform to engage with individual healthcare professionals.



# About Data Privacy



Will individual healthcare professionals need to give consent for information about their payments to be disclosed?

It depends where your principle place of work is.

The collection and use of personal data is subject to EU Directive 95/46. The Directive is transposed into data protection legislation in each country. The Directive means that companies, as the data processors, must comply with the relevant data protection laws in each country. As part of these obligations, companies have the right to retain data but there are strict rules around how data is obtained, recorded, stored, used and published. Where the publication of data is deemed to be in the public interest, this can outweigh the individuals right to privacy and form a legitimate basis for publication. This approach is being adopted in countries such as Denmark, France, the Netherlands and Slovakia.

Gaining an individual's consent to process and publish their personal data is an alternative way that data processors can show that they are handling data fairly.

In order for it to be valid, any consent from healthcare professional must be:

- Freely given
- Specific
- Unambiguous
- The result of an informed decision

Where individual consent has been used as a basis for publication (rather than public interest), then healthcare professionals will retain the right to refuse to disclose their information and will retain their right under the law to seek a correction of mistakes or deletion of their information.

The process of obtaining consent will usually be managed through a clause in the contract between the healthcare professional/healthcare organisation and the company.

Bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Industry is being proactive, based on its commitment to this relationship.

Our hope is that health professionals will also recognise the benefits of greater transparency and grant consent to disclose the data.



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### What happens if an HCP refuses to give consent for information about their payments to be disclosed?

Where individual consent has been used as a basis for publication (rather than public interest) and healthcare professionals do not grant consent to disclose payments, then the payments will be disclosed on an aggregate basis. Each company will disclose the percentage of health professionals that did not grant consent and the total amount paid to them.

However, bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Industry is being proactive, based on its commitment to this relationship. Our hope is that health professionals will also recognise the benefits of greater transparency and grant consent to disclose the data.



### What happens if an HCP withdraws consent for their information to be disclosed?

Where individual consent has been used as a basis for publication (rather than public interest), then under the data protection legislation, when a healthcare professional withdraws his consent for the information to be publicly disclosed, then the data controller (the company) is obligated to remove payments made to that individual from the public domain. Instead the payments will be added to the aggregate total of payments made to health professionals that have not given consent to disclose and this aggregate figure will be published along with the percentage of healthcare professionals that did not give consent.

However, bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Industry is being proactive, based on its commitment to this relationship. Our hope is that health professionals will also recognise the benefits of greater transparency and grant consent to disclose the data.



### What happens if an HCP does not agree with the payment information a company holds?

Healthcare professionals should contact the company. Where mistakes have been made or inaccurate data posted, companies will revise the payment information once the correct figure has been agreed.





**Will companies refuse to work with health professionals that do not give their consent to disclose payment information?**

This is an individual company decision. Companies set their own policies and criteria for working with healthcare professionals within the applicable legislative and regulatory frameworks.



**If health professionals can refuse to grant their consent to disclose payment information, will the new system of disclosure really bring greater transparency?**

We believe that a more open, transparent relationship is in the best interests of patients, healthcare professionals and systems. Bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Industry is being proactive based on its commitment to this relationship. Our hope is that healthcare professionals will also recognise the benefits of greater transparency and grant their consent to disclose the data.



**Are you taking away HCPs' rights to privacy?**

Where public interest or national legislation has exempted the need for individual consent, then the data will be automatically published. Where individual consent is used as a basis for publication, health professionals retain the right to withhold their consent to disclose transfers of value or withdraw their consent to disclose at anytime. However, we believe that a more open, transparent relationship is in the best interests of patients, healthcare professionals and systems. Bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Industry is being proactive, based on its commitment to this relationship. Our hope is that health professionals will also recognise the benefits of greater transparency and where needed, grant consent to disclose the data.



**Does this show that industry does not trust health professionals to manage conflicts of interest appropriately?**

No, we believe that a more open, transparent relationship is in the best interests of patients, healthcare professionals and systems. Bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Society has increasingly high expectations for transparency, none more so than in healthcare. We want to ensure we meet those expectations going forward. We believe healthcare professionals can manage their conflicts of interest, and transparency is an additional tool in this process.



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## General Information and Questions



### Will the amounts disclosed vary between countries?

Yes, every healthcare system in Europe is different. Industry and HCP activity is shaped by different legislation, self-regulation and guidance. There is also significant variation in resources, infrastructure, income and expertise between countries.

For example the availability of funding for, and access to, medical education differs across Europe. Taking these factors in to account, it is likely there will be some variation in the transfers of value to health professionals in countries across Europe.



### Does the number of HCPs giving their consent vary between countries?

Yes, the EFPIA Disclosure Code applies to HCPs across 33 countries, each with different cultural, socio-economic, healthcare and regulatory environments. As a consequence, disclosure rates are likely to vary between countries. Industry is keen to work with individual health professionals and their representative bodies to maximise the rates for disclosure across Europe.

Bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Industry is being proactive, based on its commitment to this relationship. Our hope is that health professionals will also recognise the benefits of greater transparency and grant consent to disclose the data.



### Who can an HCP contact for more information or questions?

The first port of call for information is the pharmaceutical company a healthcare professional is working with.

For more general information on disclosure, healthcare professionals can contact the national association in the country they are working in. You can access a list of EFPIA member associations at [www.efpia.eu/about-us/membership](http://www.efpia.eu/about-us/membership).

For information on disclosure from EFPIA please go to [www.transparency.efpia.eu/downloads](http://www.transparency.efpia.eu/downloads).





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