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European Federation of Pharmaceutical Industries and Associations

The EFPIA Disclosure Requirements for HCPs
Your Questions Answered

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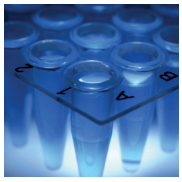



Working together: why do the pharmaceutical industry and healthcare professionals work together?

1 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.

2 What services to health professionals does the industry provide?

Industry works with healthcare professionals to advance patient care. 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.

Companies can shape their future research programmes based on the scientific and medical expert opinion of HCPs. For example, ensuring studies are developed in the right way to enable a meaningful assessment of clinical benefit.

Understanding how a medicine would be used in clinical practice can help companies provide the right information, education and training, to support the introduction of a new medicine, to ensure the best outcomes for patients.

About the Disclosure provisions in the EFPIA Code

3 What are the Disclosure provisions in the EFPIA Code?

The Disclosure provisions in the EFPIA Code require all EFPIA member companies and companies that are members of EFPIA member associations to disclose transfers of value to HCPs, HCOs and POs. Under these provisions, EFPIA member companies will have to disclose the names of HCPs and HCOs 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.

Since 30 June 2016, companies disclose transfers of value made to HCPs, such as consultancy and advisory boards, speaker fees, and sponsorship to attend meetings. This transformational step in the relationship between industry and health professionals is a result of the EFPIA Disclosure Requirements.

4 Why has EFPIA introduced 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.

5 Which countries does the EFPIA Code cover?

The EFPIA Code covers the 36 countries within its membership (see 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.

6 What types of payments are disclosed?

Companies 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.

7 Does the system cover all payments to healthcare professionals at an individual level?

No. Payments made for research and development activities are disclosed in aggregate. For the purposes of the disclosure, 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 18.01 of the EFPIA Code*).

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

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

The EFPIA Disclosure 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 is disclosed in aggregate.

9 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.

10 How does the 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 were made on 30 June 2016, for payments made in 2015.

11 How are payments disclosed?

In the majority of countries in Europe, payments are disclosed on company websites. In countries such as Belgium, Denmark, France, Greece, Portugal, national legislation requires disclosure on a governmental central platform.

National Associations that disclose payments on a central platform through self-regulation: Czech Republic & UK.

National Associations that disclose payments on a central platform through co-regulation with the healthcare professional community: The Netherlands.

National Associations that disclose payments through Gateways: Bulgaria, Croatia, Cyprus, Finland, Germany, Ireland, Latvia, Lithuania, Norway, Poland, Romania, Serbia, Sweden, Switzerland.

12 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 France or Denmark, 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 the Netherlands, Czech Republic, 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.

13 What is the definition of "healthcare professional" in the context of the EFPIA Disclosure?

The EFPIA 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/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Europe. For the purpose of this Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP.

14 What do healthcare professionals and healthcare organisations need to do under the 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, and if the company based its disclosure on consent, healthcare professionals 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.

15 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, disclosure is made in the country where the HCP/HCOs holds their principal practice.

16 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.

About Data Privacy

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

This will depend on the applicable national legislation in the HCP's principal place of work.

The processing of personal data is subject to EU General Data Protection Regulation and to relevant national legislation. The GDPR provides a number of bases on which personal data may be processed including consent, legitimate interest and legal obligation. The legitimate interest ground is the subject of a balancing test. Where the publication of personal data is deemed in the light of the interests of the industry and the wider societal interest in transparency, to outweigh the individuals right to privacy, legitimate interest can provide a legal basis for publication.

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, healthcare professionals will retain the right to withdraw their consent and other rights, such as rectification. Individuals also have the right to challenge the processing of their data where this is carried out under legitimate interest. Individuals must be informed of their rights.

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

18 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 legitimate 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 number 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.

19 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 legitimate interest), then under data protection legislation, when a healthcare professional withdraws their consent for the information to be publicly disclosed, the data controller (the company) is obligated to remove the data related to payments made to that individual from the public domain. Instead the data related to 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 number 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.

20 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.

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

Companies set their own policies and criteria for working with healthcare professionals within the applicable legislative and regulatory frameworks and in this case, the freedom of consent.

22 If health professionals simply cannot give their consent to disclose payment information, will the 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?

No. Where legitimate interest or national legislation has negated the need for individual consent, then the data will be automatically published. Where individual consent is used as a basis for publication (rather than legitimate interest), 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.

HCPs divide their working time in different ways. Some may devote more of their time to research, clinical practice, private practice or other activities. As a consequence the time spent and income earned working with pharmaceutical companies will vary.

General Information and Questions

25 Do 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.

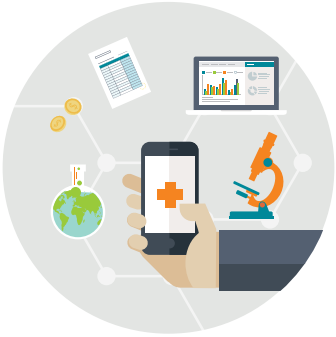
26 Does the number of HCPs giving their consent vary between countries?

Yes, the EFPIA Disclosure Code applies to HCPs across 36 countries, each with different cultural, socio-economic, healthcare and regulatory environments. As a consequence, disclosure rates vary between countries.

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

The first port of call for information is the pharmaceutical company with which a healthcare professional is working. For more general information on disclosure, healthcare professionals can contact the national association in the country in which they are working. You can access a list of EFPIA member associations at www.efpia.eu/about-us/membership.

For information on disclosure from EFPIA please go to www.efpia.eu/relationships-code/



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