

1 What is the EFPIA Disclosure Code?

The EFPIA Disclosure Code requires all member companies of EFPIA – the European Federation of Pharmaceutical Industries and Associations – disclose payments and other transfers of value made to Healthcare Practitioners and Healthcare Organisations (HCPs and HCOs) in certain categories. The transactions disclosed could consist of, for instance, a grant to an HCO, or a consultancy fee for an HCP speaking engagement.

2 Where did the Code come from – who created it?

EFPIA, as the representative body for the research-based pharmaceutical industry in Europe, has a number of codes and guidelines in place to support transparency in the pharmaceutical sector, including payments made to patient advocacy organisations. The EFPIA Disclosure Code – in full, the EFPIA Code on Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations – was created in order to enhance the transparency surrounding relationships between the pharmaceutical industry and HCPs/HCOs.

3 What was the motivation for EFPIA to create this Code?

In recent years there has been growing public interest in the nature of the pharmaceutical industry's relationships with HCPs and HCOs. Critically, the public want to know that such relationships do not inappropriately influence clinical decisions, that they can trust their HCP to recommend, administer or purchase appropriate care and treatments based solely on clinical evidence and experience.

With the EFPIA Disclosure Code, our goal is to strengthen the legitimate relationship between pharmaceutical companies and healthcare professionals by making these more transparent and therefore better understood by patients and other stakeholders.

4 Why does the pharmaceutical industry need to interact with HCPs/HCOs?

It is essential for the development of new innovative drugs and improvement of existing treatments that the industry interact regularly with HCPs and HCOs. As the primary point of contact with patients, the medical profession can offer invaluable and expert knowledge on patients' behaviour and management of diseases. This plays a big part in informing the pharmaceutical industry's efforts to improve patient care and treatment options – and is essential to improving patient outcomes. A healthy working relationship between the pharmaceutical industry and HCPs/HCOs is in the best interests of patients. Of course, it is only fair to compensate HCPs and HCOs for the valuable insights and time they offer.

5 When will this information be available?

Some disclosure activities are already taking place within certain countries in Europe. The first disclosures required under this new Code will be made in 2016 and will convey information about payments and transfers of value made in 2015.

6 Where will this information be available?

This information will be published on a public platform, which could be on the company's own website or a central platform. Each EFPIA member company will decide how to organise its disclosures. Disclosures should be publicly accessible in the country where the HCP/HCO receiving a transfer of value or payment from industry has their practice. It must be possible for the public to easily find and access the disclosed information in the country where the relevant HCP/HCO practices.

7 Who has to abide by the code? What do you mean by HCP/HCO?

The EFPIA Disclosure Code defines HCPs 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 or administer a medicinal product.

The Member Associations have transposed the EFPIA HCP Code into their national codes. In principle, these codes will include the list of specialities and professional designations that fall into the definition of an HCP, also reflecting healthcare practice in the country – for instance, nurses can prescribe medicines in some countries but are not allowed to do so in other countries.

8 What if a US-based company – a direct member of EFPIA – makes a transfer of value to a doctor in Spain? Who reports this transfer of value? Where will it be reported?

Disclosures are made based on the national code of the country where the HCP/HCO receiving payment or transfer of value has their principal practice. This applies regardless of whether the transfer of value occurs within or outside of that country. This ensures that the patient or interested stakeholder can easily find the information regarding transfers of value to an HCP/HCO he/she has an interest in. The physical address where the HCP practices or HCO is located should be used as the reference when determining in which country the data should be disclosed.

For example, an EFPIA member company's US headquarters sponsoring a HCP whose practice is in Spain for an activity in Germany will be required to disclose the Transfer of Value under the name of the recipient HCP in Spain (following the applicable laws, regulations and the national code in Spain).

9 Doesn't this infringe on the privacy rights of the doctors and healthcare organisations involved? What is the HCP/HCO does not consent to disclosure?

Member Companies must comply with applicable data protection and other laws, which may impose certain limitations on their ability to make disclosures on an individual basis. Data privacy requirements must in each case be checked at the national level (i.e. the jurisdiction of the HCP/HCO receiving payment or transfer of value) by the member company prior. This must be done prior to any disclosure. Companies are encouraged to obtain consent from HCPs/HCOs prior to disclosure, and EFPIA and its Member Associations and Companies are working together with HCPs/HCOs to prepare for the implementation of the Disclosure Code.

10 Where will the Code apply? What happens in cases of non-compliance?

It is a condition of EFPIA membership that member associations adopt all EFPIA Codes in full, and that member companies comply with the national codes (even in those countries where they are not a direct member of the relevant member association). The EFPIA Code applies to all EFPIA members including: Corporate Member Companies; Members of EFPIA Specialised Groups: (i) European Biopharmaceutical Enterprises (EBE) and Vaccines Europe (VE); and Member Companies of Member Associations that are not directly members of EFPIA. You can find a list of EFPIA Member Associations and the countries they operate in, here – <http://efpia.eu/about-us/membership>.

In some cases a national association may have its own Code already in place – or a country may have legislation governing the transparency of relationship between healthcare professionals and organisations, and the pharmaceutical industry. In case a Member Company is found in breach of the applicable code, the Member Association of the country where the HCP/HCO receiving the transfer of value has his/her/its principal practice would sanction the company in question, in accordance with local rules.