

Ensuring data protection in the implementation of the EFPIA disclosure code: key challenges and how pharmaceutical companies are addressing them

Speed read

The EFPIA Disclosure Code will, from 2016, require pharmaceutical companies to disclose details of payments and transfers of value made to healthcare professionals and healthcare organisations. The Code aims to promote, through transparency, greater trust in the relationships between pharmaceutical companies on the one hand and healthcare professionals and organisations on the other.

Compliance with the Code, because it involves the disclosure to the public of personal data, presents challenges to compliance with data protection laws. Pharmaceutical companies must have a lawful basis for disclosures under data protection law, which for most companies will involve ensuring transparency (i.e. making HCPs/HCOs aware of the purposes and nature of processing, as well as the legitimate basis for disclosures) and obtaining a form of consent (i.e. as a minimum, giving HCP/HCOs the opportunity to opt-out of disclosures). Achieving compliance with these and other requirements presents many challenges.

This article examines some of the issues and contains the results of a small benchmarking exercise we carried out, which looked at the approach that a number of pharmaceutical companies are taking to address these challenges.

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Background

On 24 June 2013, the European Federation of Pharmaceutical Industries and Associations (EFPIA) issued a Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations (the Code). The Code requires member companies to disclose to the public specific data regarding their relationships with healthcare professionals (HCPs) and organisations (HCOs). EFPIA explains the purpose of the Code as follows:

“In recent years there has been growing public interest in the pharmaceutical industry’s relationships with HCPs and HCOs. Critically, the public want to know that such relationships do not influence clinical decisions and that they can trust their HCP to recommend, administer or purchase appropriate care and treatments based solely on clinical evidence and experience. This demand will be supported by this push towards transparency, which in turn will create greater trust.”

The Code gives rise to specific challenges to ensuring compliance with data protection and privacy laws, including in particular national laws implementing the Data Protection Directive (95/46/EC). This is because compliance with the Code involves the processing, and significantly the disclosure to the public (on a pharmaceutical company website or a central government platform), of personal data concerning HCPs and individual representatives of HCOs, including not just their address and registration details, but more significantly the amounts paid to those individuals by pharmaceutical companies in any year, aggregated by category (eg hospitality, fees, expenses). These disclosures will be on a massive scale, affecting hundreds of thousands of HCPs and HCOs across the 33 countries covered by the Code.

What are the challenges to compliance with the code under data protection law?

The Code states that it must be implemented in accordance with applicable national data protection laws. This statement underplays somewhat the challenges that compliance with data protection law presents. It represents a voluntary code that does not have the force of law, so it does not override in any sense the rights and obligations arising under data protection laws.

In the EU, to ensure compliance with data protection will require, in particular, that pharmaceutical companies making disclosures (i) establish a legitimate basis for the processing of the personal data of HCPs/HCOs and (ii) ensure the provision of “fair processing information” to individuals regarding the processing of the personal data of HCPs/HCOs.

Pharmaceutical companies must also consider their other obligations under national laws implementing the Data Protection Directive, including to ensure that personal data is adequate, relevant and not excessive, to ensure it is accurate and up-to-date, to ensure it is kept secure,

not to transfer it to non-adequate jurisdictions outside the EEA without implementing adequate safeguards, and to provide a right of access to personal data and a right to object to processing. Within the EU, until such time as the General Data Protection Regulation is adopted and enters into force, which is likely to take a further three to four years, the specifics of these requirements will vary based on differences between the national laws implementing the Data Protection Directive.

Outside the EU – EFPIA has member associations across not just the 28 EU Member States but also Russia, Serbia, Switzerland, Turkey, and Ukraine – the data protection and privacy requirements will vary more greatly. And further afield still, similar transparency initiatives exist in many other non-EFPIA countries (e.g. the “Sunshine” Act in the US) and the data protection and privacy laws of those countries will often pose similar challenges, which must be addressed by pharmaceutical companies operating internationally.

Is there lawful basis for making disclosures under the Data Protection Directive?

The Data Protection Directive sets out six alternative criteria for making the processing of personal data legitimate. Those criteria include: (i) the data subject has unambiguously given his consent; (ii) the processing is necessary for compliance with a legal obligation; (iii) the processing is necessary for the purposes of legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject.

Any of the three criteria listed above could potentially be relevant to disclosures pursuant to the Code. In countries where the Code, or equivalent obligations, are transposed into local law such that disclosure represents a legal obligation. Elsewhere, pharmaceutical companies must look to one of, or a combination of, consent and legitimate interests as a basis for disclosure.

What are the challenges with seeking consent?

Seeking the consent of the HCP/HCO will seem to many the most appropriate and fair means by which to ensure compliance with data protection laws in implementing the Code. Indeed, the guidance notes accompanying the Code specifically recommend that pharmaceutical companies seek consent from HCPs and HCOs and certain national associations (e.g. the ABPI) have already proposed model consent wording for use to obtain consent from HCPs/HCOs.

Consent offers a potentially strong basis for making a disclosure. Obtaining consent makes it much less likely that an individual or authority would later object to a disclosure. It is recordable and auditable and provides a degree of certainty to the pharmaceutical company. However, it presents many challenges.

Obtaining valid consent can be practically difficult. As summarised by the Article 29 Working Party in its Opinion 15/2011 on the definition of consent, a consent must be “specific”, “informed”, “unambiguous” and “freely given”. As such, an individual must be provided with clear information about the scope of processing proposed, such that they understand what it is they are agreeing to, and they must clearly signify their agreement to that processing. They must also be able to withdraw that consent at any time in future.

Pharmaceutical companies thus face the challenge of communication of information to the HCP/HCO, in a format that meets the specific requirements of local data protection laws, then implementing a process to record the choice (whether on an opt-in or opt-out basis) of those individuals to consent, or not, to the proposed processing. This requires that a business process is established, which for larger companies will have to deal with tens or even hundreds of thousands of individuals in any year.

A valid consent must also be “freely given”. In the context of a relationship between a large pharmaceutical company and an HCP, a careful balance must be struck. There must be genuine choice available and in particular there should be no adverse consequences as a result of a refusal to consent. As such, it may be unwise, for this and other reasons, for any pharmaceutical company to adopt an approach whereby it refuses to work with HCPs/HCOs that do not consent to disclosures pursuant to the Code – it would risk invalidating the consent of those that do.

Pharmaceutical companies must then deal with the challenge of making disclosures pursuant to the Code while respecting the choice made by HCPs/HCOs. This requires the anonymisation, by means of aggregation, of the details of annual payments and transfers of value made solely by category rather than by HCP/HCO. A system must therefore be implemented to ensure that disclosing entities are aware whether or not the data of a specific HCP/HCO can be disclosed, based on the choice made, and to ensure that data of non-consenting HCPs/HCOs is not disclosed other than on an aggregated basis. As the disclosing entity will often not be the same as the paying entity, and those entities may be located in different jurisdictions, this means that the system and processes established must operate across group companies and also across borders.

The HCP/HCO must also consider whether the aggregation of data is sufficient to ensure anonymisation, such that the individuals cannot be re-identified. This could present particular challenges where small groups can be identified in relation to certain aggregated disclosures by category. Due to the proliferation of information and IT, ensuring effective anonymisation is increasingly difficult, as recognised by the Article 29 Working Party in its Opinion 05/2014 on Anonymisation Techniques.

What are the challenges with relying on a legitimate interest?

There is a clear public interest purpose underlying the Code. Further, the non-disclosure of data, as a result of aggregation or withholding of data, on the basis of lack of consent, would clearly undermine to some extent the achievement of the principal objectives of the Code.

As such, the “legitimate interests” would likely comprise on the one hand those of recipients of the information (i.e. the public), in transparency, accountability and avoiding conflicts of interest, all of which are promoted by the Code, and on the other those of the pharmaceutical company, in complying with the Code and in promoting confidence in its relationships with HCPs/HCOs.

However, the legitimate interests must be weighed against the interests, fundamental rights and freedoms of the data subject, taking into account the nature and source of the legitimate interest, the impact on the data subjects and any additional safeguards which are put in place. The Article 29 Working Party, in its Opinion 06/2014 on the notion of legitimate interests of the data controller, recommend a pragmatic approach that allows the use of practical assumptions based primarily on what a reasonable person would find acceptable under the circumstances and based on the consequences of the data processing activity for data subjects.

Notwithstanding the apparently strong basis for a legitimate interest in the circumstances, the fact that information will be disclosed publicly is a factor to take into account in weighing up the impact on the HCP/HCO. It could conceivably lead to third parties obtaining the information and using it for additional purposes not contemplated by the pharmaceutical company or the individual concerned, the extent and impact of which is hard to predict. On the other hand, the data disclosed is limited, not comprising any sensitive categories of data (e.g. health data, political beliefs, etc.) and comprising only annual amounts paid. Furthermore, HCPs/HCOs are generally likely to be highly educated professionals acting in a professional capacity, who will appreciate the purpose of disclosures pursuant to the Code, particularly given extensive work has been undertaken by EFPIA and member associations in order to raise awareness among healthcare practitioners of the forthcoming implementation of the Code.

The basis for relying on a legitimate interest can be strengthened by offering HCPs/HCOs an opportunity to opt-out of disclosures, in circumstances where the criteria for obtaining a valid consent, as discussed above, have not otherwise been satisfied.

Nevertheless, there is no avoiding the fact that relying on legitimate interests as a sole basis for disclosure is clearly inherently unattractive for any pharmaceutical companies contemplating disclosures pursuant to the Code, due to the lack of certainty that a pharmaceutical company can have as to whether or not the balancing test weighs in favour of disclosure, and given the importance to pharmaceutical companies of maintaining strong relationships with HCPs/HCOs. Further, some data protection authorities take a particularly strict approach to interpretation of the

legitimate interests ground, so it is unlikely to be accepted as a lawful basis across some Member States.

What information must be provided to HCPs/HCOs about disclosures?

The Data Protection Directive sets out certain information that must be provided to data subjects. A pharmaceutical company is therefore required to provide HCPs/HCOs with the following information: (a) the identity of the controller and of his representative, if any; (b) the purposes of the processing for which the data are intended; (c) any further information such as (i) the recipients or categories of recipients of the data, (ii) whether replies to the questions are obligatory or voluntary, as well as the possible consequences of failure to reply, (iii) the existence of the right of access to and the right to rectify the data concerning him, in so far as such further information is necessary, having regard to the specific circumstances in which the data are collected, to guarantee fair processing in respect of the data subject.

Pharmaceutical companies must therefore find a means to make appropriate information available to HCPs/HCOs. In some cases, this may be something which can be achieved as part of an existing process, particularly where the pharmaceutical company will be entering into an agreement with the HCP/HCO in relation to the payment of an appearance fee or travelling expenses, for example. However, in other contexts, where the relationship between the paying entity and HCP/HCO is less formal and not documented in an agreement, e.g. hospitality, it will likely be necessary to implement a new business process to ensure the provision of information to the HCP/HCO. Most companies will wish to ensure provision of information in a manner which, while meeting the requirements of local law, is as consistent as possible.

What approach is the industry taking?

We carried out a benchmarking exercise involving a small number of pharmaceutical companies, large and small, on their proposed approach to overcoming data protection challenges to compliance with the Code.

The key findings were as follows:

- *The majority (80%) of companies surveyed were planning to seek consent of all HCPs/HCOs across each of the 33 EFPIA member countries*

None of the companies surveyed proposed to rely solely on legitimate interests as a sole basis for disclosure. There was a clear desire to ensure consistency across jurisdictions and equal treatment of HCPs/HCOs across different jurisdictions. Many made the point that, regardless of whether or not strictly required by law, it was important to maintain a good relationship with HCPs/HCOs. However, a minority (20%) of respondent companies indicated that they did not

plan to seek consent in those countries where the Code had been transposed into local law, such that disclosure was a legal requirement.

- The majority (80%) of companies surveyed propose to adopt an “opt-out” / implied consent approach, rather than seek opt-in / explicit consent

The clear majority of companies surveyed planned to use a form of implied or tacit consent, whereby HCPs/HCOs would be taken to have signified agreement by entering into an agreement with the pharmaceutical company or by continuing to work with the pharmaceutical company. This would be combined with an opt-out process, whereby that consent could be withdrawn at any time.

A minority proposed to go further and to seek explicit consent in all cases, whereby HCPs/HCOs would be asked to make a “yes” / “no” choice at the outset as to whether or not to give consent. However, the majority of companies proposed to adopt an explicit consent approach only in those countries where it was strictly required by law.

- All companies surveyed propose to develop standard consent clauses, which are tailored to meet local law requirements

The consent would be obtained either by inclusion of consent clauses in agreements with HCPs/HCOs, such that by entering into the agreement they will be taken to have signified consent, or by incorporating a similar provision into a stand-alone notice provided to the HCP/HCO (e.g. in correspondence, on information leaflets, on event attendance forms, etc.). The majority of companies surveyed planned for the paying entity to be responsible for obtaining the consent from the HCP.

- All companies surveyed propose to continue to work with HCPs/HCOs that refuse or subsequently withdraw consent

All companies noted that they would, or would in principle, continue to work with HCPs/HCOs that refuse or withdraw consent to disclosures. However, a number commented that they believed others in the industry may be proposing to take a stricter approach whereby they would not deal with HCPs/HCOs that refused to agree to disclosures, so some were waiting to see whether a standard approach develops across the industry.

What happens next?

The first disclosures under the Code will be due in the year 2016 (by 30 June 2016), in respect of the year 2015. Pharmaceutical companies must therefore act quickly to implement new business processes and systems, likely to involve the provision of certain information to, and obtaining of consent of, data subjects, to ensure disclosures relating to the period 2015 can be undertaken in compliance with local data protection and privacy laws.

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