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Is pharma ready to disclose its payments to doctors in Europe?

From 2016, pharma will have to make public its payments to doctors and healthcare organisations in Europe: it will be not just a huge technical challenge, but also a major cultural shift.

Just how transparent and 'above board' are the pharmaceutical industry's relationships with healthcare professionals? Many people in the sector would argue that it has come a long way in recent years – but the momentum for greater openness is continuing, and even growing.

The push for greater transparency in pharma has grown steadily over the last decade, and 2015 marks the start of a new era in Europe.

Starting this year, pharma companies will have to record all payments or so-called 'transfers of value' (see definition below) to healthcare professionals and healthcare organisations, and then make this data publicly available in 2016.

Complying with the EFPIA Code on Disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organisations will be a very complex business. This is not least because each of the 33 countries involved has its own slightly different approach to complying with the Code.

The EFPIA Disclosure Code

- European Federation of Pharmaceutical Industries and Associations (EFPIA) member companies will have to disclose the names of healthcare professionals (HCP) and organisations (HCO) 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 transfer or value 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.
- This information will be published on a public platform, which could be on the company's own website or a central platform combing data from different companies.

Another complicating factor is that, while the EFPIA Code is essentially industry self-regulation, each individual country has its own laws to regulate interactions between pharma and healthcare professionals. How legal requirements and the Code should be reconciled within one framework is less than clear – a major headache for companies not wanting to be caught not complying with the new rules.

The European industry has been gearing up for the 2016 deadline since mid-2013, but the experience of similar regulations in the US show it is a major undertaking: creating a robust accounting and IT infrastructure to ensure the right data is collected and assembled is just one side of the story. Equally important is understanding just how big a cultural shift the changes are within pharma companies, and indeed among healthcare professionals and healthcare organisations in Europe.

Underpinning it all are two important principles. Firstly, pharma must not just comply with the letter of the law, but live by the spirit of the law – otherwise pockets of misconduct will be allowed to continue unchallenged, and more damaging scandals could emerge again.

Secondly, it's vital for the pharma industry to preserve good relationships with healthcare professionals across Europe - this is fundamental to all aspects of its business, from research to marketing. The new transparency should, if implemented properly, help maintain and even increase mutual confidence within these relationships. However there is clearly a fear that clumsy implementation, or unintended consequences from the new disclosure rules, could permanently damage relations.

"Pharma must not just comply with the letter of the law, but live by the spirit of the law – otherwise pockets of misconduct will be allowed to continue"

At a recent roundtable convened by life sciences software specialists Veeva in Barcelona, experts in the field warned that many companies were not sufficiently prepared for the changes, both in organisational and in cultural terms.

The Mediator case – the impact on France and beyond

Alexandre Regniault, a Paris-based lawyer at Simmons & Simmons specialising in life sciences, said France had already introduced its own legislation obliging disclosure of payments, launched in 2014.

France's *Loi Bertrand* is strict new legislation introduced after the scandal around Mediator (benfluorex), the Servier drug withdrawn in 2009. The drug was on the market for decades before being linked to heart valve problems.

Legal investigation in connection with the case is still ongoing, public prosecutors accusing the operating company of knowing about the drug's dangers. There are also allegations that the company's 'cosy' relationships with prescribing doctors and regulators allowed the danger signals to go unheeded.

This has put relationships between pharma and doctors and the country's medicines regulator under intense scrutiny, and has led to a complete overhaul of medicines regulation there, including the new transparency requirements.

The Mediator affair also directly influenced new EU laws on pharmacovigilance, and is certainly one of the biggest driving forces behind the pan-European EFPIA Code.

Newly introduced, France's own legislation-based transparency regulations are still causing consternation and confusion, especially among healthcare professionals. From 2016, these will also have to be reconciled with the EFPIA Code. Alexandre Regniault says this illustrates the huge cultural shift that needs to happen.

"One healthcare professional said to me – why would I want to be transparent? Transparency is a quality you expect from a jellyfish – why is it a good thing?!"

He adds that, despite resistance from some quarters, everybody in France now knows the rules are here to stay.

"Everybody accepts that there is no going back. You will have to live with the new rules, so you may as well make the most of them. That includes companies seeing it as an opportunity to understand their business and relationships better, and use it as a means of competitive advantage."

Francis Geysermans is co-founder and general manager of BMI, a company specialising in regulatory compliance software for the life sciences sector.

Geysermans has an anecdote which illustrates the huge gulf between current practices in some parts of the pharma industry, and where it needs to be. He says he recently presented his company's compliance software to someone on the sales side in a pharma company. After the practical aspects of the system had been explained, including how to enter different kinds of data – the person asked: "Where can I enter onto the spreadsheet that I have taken them to the cinema?"

Geysermans naturally told them this wasn't possible – not for technical reasons, but because this kind of hospitality shouldn't be happening in the first place.

He says the response was "Oh, that's a shame, the only way I can engage with them is by taking them to the cinema." This is perhaps an extreme case, but one Geysermans feels illustrates how far behaviour still needs to change.

"I would say that currently in France, only 25 per cent of companies have grasped the importance of this change," he says. "Only that proportion are well prepared to deal with what it means in practical terms – collecting the data, complying with the rules. There is also the cultural question, the way in which relationships with healthcare professionals must change."

Pascale Paimbault is a former senior director, of Compliance and Ethics at Bristol-Myers Squibb and Wright Medical Inc for the EMEA region, and is now the founder and independent consultant in compliance, risk management and business ethics, at Consulting Alley.

She is slightly more optimistic about the level of preparedness in the industry, but agrees that pharma will need to work hard in 2015 to be ready for the 2016 deadline.

"The bottom line is that pharma needs to be compliant with the disclosure rules, but it also needs to ensure its relationships with healthcare professionals are also protected.

"At the same time, the new system has to be seen to be doing the right thing in the eyes of the public – balancing all of these demands will be challenging."

She adds: "The industry and healthcare professionals need to continue working together, so the new rules should support, not undermine these relationships."

Guillaume Roussel, director of strategy for Veeva Network in Europe says the experience in France has been made more difficult because of a lack of dialogue between healthcare professionals and the industry. He says the more 'consensual' approach taken in the Netherlands, where doctors and pharma discussed the new requirements, would serve as a better model for other countries.

Nevertheless, Roussel says a 'mosaic' of different interpretations of the EFPIA Code will inevitably emerge across Europe, something which pharma companies will have to take into account when managing compliance.

Broadly speaking, around half of the 33 countries involved are transposing the EFPIA Code directly into their national codes with a minimum of customisation. This of course leaves pharma the task of understanding the idiosyncrasies of all the other nations – all told, a hugely complex undertaking.

Even in those countries which are 'cutting and pasting' the EFPIA Disclosure Code, things aren't always straightforward.

Rais Amils is a Barcelona-based lawyer with Clifford Chance. She says that, as the Code is voluntary in nature, data privacy regulations are especially important, and will prevail. This implies that it will be necessary to request express consent from doctors for data disclosure, and it is likely that, at first, Spain's doctors will be reluctant to reveal personal data.

There is relatively low public awareness of these transparency issues in Spain, in comparison with France. That means it is difficult to predict what the public reaction to the disclosure will be. Rais Amils says that the new rules are going to be a revolution in Spain, as there were few regulations relating to transparency before. The future direction will depend on the public, which, in her opinion, will have to be shown and educated as to why greater transparency is beneficial for everybody.

Corporate leaders were also urged not to see the new Code purely as a business compliance issue, but as an opportunity to understand better their relationships with healthcare professionals, and how money is spent on these relationships.

New systems and cultures needed

Most agree that existing software systems – including accounting and CRM platforms – cannot be adapted to accommodate the needs of payments compliance. This means investment in new systems – but also new organisational structures to ensure someone is responsible for making sure this data is collected, is accurate, and meets the requirements of the particular territory.

"If this obligation is seen only as an organisational headache, then it will never be successfully integrated into the company's business"

Everyone agrees, if this obligation is seen only as an organisational headache, then it will never be successfully integrated into the company's business, and this neglect would risk not complying properly.

Pascale Paimbault says the success of this very much depends on how the compliance officer is positioned within the company – this person needs to be seen not just as a trouble-shooter for when something goes wrong, but someone with a strategic, proactive role.

"The compliance officer needs to carve out a proactive role and take the lead on making sure the company has its own business ethics, and puts those ethics into practice," says Pascale.

"All pharmaceutical companies are ultimately geared to producing medicines for the benefit of patients – a very ethical goal – so all the company's behaviour needs to reflect that.

The other way of making the compliance valued in an organisation is to see it not just as an obligation, but as an opportunity – having collected all this data on who you are paying, and for what, a company can then analyse that data and correct inappropriate spending, analyse risks, and judge upon future relationships.

An end to 'inappropriate relationships'?

So can the new rules really help pharma clean up its act once and for all? GlaxoSmithKline (GSK) hit the headlines repeatedly in 2014 because of serious allegations of bribery and misconduct across a number of markets, most notably China. Another existing danger is in using third parties to manage your relations with key opinion leaders and doctors – this is common practice today, but if they break the rules, it is the pharmaceutical company that will be held accountable, not the service company.

In the US, GSK has introduced a new incentive model for its US salesforce whereby they are no longer incentivised on revenues, but on the quality of their interaction with healthcare professionals.

Pascale Paimbault says there are a number of companies moving towards this kind of quality-based model, and thinks this could help foster healthier relationships.

However one of the key ways to ingrain ethical business behaviour is to engage the leadership team, including the chief executive.

"Compliance officers are leading and implementing, but these business ethics should belong to the business," she says. "If you get an active input from the CEO, that buy-in will filter into to the whole company, its ethos and its day-to-day practices."

Related links

Veeva Systems and BMI SYSTEM Partner to Deliver Complete EFPIA Compliance Management Solution

Responsible Transparency – EFPIA's website devoted to explaining the code in detail
http://transparency.efpia.eu/

Should drug firms make payments to doctors? (BBC)
http://www.bbc.co.uk/news/magazine-26890072

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