European Transparency **Reporting: Bridging the Cultural Divide**

Beginning this summer, pharma companies will submit full data on payments to European doctors for the first time – but are big cultural differences across the continent complicating matters?

The moment has arrived. This summer the pharma industry will lay bare the extent of its relationship with doctors in Europe, revealing for the first time physicians' names, how much individual pharma companies have paid them, and for what.

As of 30 June 2016, all pharmaceutical companies will be required to publish payments made in the previous year to doctors, nurses, and other healthcare professionals (HCPs), and identify them by name wherever possible. The new rules also require companies to report any payments made to hospitals and other healthcare organisations (HCOs) across 33 European countries.

The new reporting standards are a game changer for pharma's relationship with doctors, and reflect a global move towards greater transparency – the US and Australia having already launched their own "Sunshine Laws".

The European Federation of Pharmaceutical Industries and Associations (EFPIA), the pharma industry representative body for Europe, agreed to this voluntary code with its 33 member organisations across the continent several years ago. Ever since, technology and compliance teams have been hard at work to ensure a smooth first reporting cycle. Meeting new regulatory requirements across such diverse cultures and practices will be a challenge, particularly as the patterns and levels of disclosure reporting vary widely by country.

As the industry moves towards its first transparency-reporting deadline, questions remain about whether companies are ready. Research from Veeva Systems recently revealed fewer than two in five companies feel they are fully prepared to meet the EFPIA requirements. The Veeva research also highlighted concerns about the technical challenge of collecting and reporting data across 33 countries. What's more, as the deadline approaches, some in the industry are raising concerns about the potential negative impact these reports could have on relationships with doctors.

Attempting to manage this change raises questions across the industry: will every pharma company disclose its data on time? Will doctors protest against having their details published? And most importantly, will disclosure actually stoke public suspicions about inappropriate influence, rather than allay fears?

Preparing for change

The EFPIA's head of communications, **Andy Powrie-Smith**, has been grappling with industry reputation issues in the UK and Europe for the best part of a decade. He recognises that for many, naming HCPs in disclosures is a big step, but he believes it's a natural next step for pharma. And it is consistent with a larger trend of society's growing demands for more transparency in public life.

Speaking at a recent Veeva European customer roundtable event, Powrie-Smith said that while European pharma has a coloured history of relationships with HCPs, there have been improvements in recent years. He explained that close relationships between the industry and healthcare professionals will continue to sit at the heart of new drug development, and of the ability to make sure the lifesaving new therapies reach the right patients at the right times.

By proactively showing stakeholders the reality of the industry's relationships with healthcare providers, Powrie-Smith believes the wider society will begin to see more clearly how fully the interests of pharma, HCPs, and patients align.

"We need to move from a conflict of interest to a confluence of interest, and transparency helps to do that," he said.

Another roundtable contributor was **Walter Chmielewski**, transparency manager for Biogen in Europe. Agreeing that the move towards greater transparency was unstoppable, he added: "We live in a world where everybody wants to know everything about you."

Disclosure of data – known as "transfers of value" from pharma to healthcare professionals and healthcare organisations – will one day be a legal obligation, Chmielewski predicts. He argues that in the future, the industry may even welcome European-level legislation as a way to simplify the current reporting structure. The current structure requires companies to collect data, verify its accuracy, and seek consent, which can be awkward if every market has its own interpretation and implementation of the EFPIA code based on different cultural attitudes.

Veronique Monjardet, country manager in France and European lead for pharma compliance specialists Polaris, says that despite agreeing with the need to adopt a common set of rules, the countries have inevitably diverged in how they are implementing the new transparency requirements. Rules about gaining consent are a good example of this: many countries (such as the UK) require pharma to get permission from the HCP to publish the data, but others, such as France and the Netherlands, do not.

These divisions among member-state regulations will play a big role in determining how many names can be published in each country. The EU Data Protection Directive, which sets a minimum standard for privacy, allows countries to set rules that may go further. This has allowed HCPs in some countries to opt out of being identified – and many are likely to exercise this right.

In the UK, a survey of healthcare professionals by the Association of the British Pharmaceutical Industry last year found that 69 per cent would give their consent. While this represents nearly seven in 10 UK doctors and hospitals, nearly one-third of HCPs will remain unidentified. As a result, pharma companies will need to separate aggregate spend totals to account for both named and anonymous recipients.

The consent levels could be even lower elsewhere in Europe. A recent Polish study found average consent of 23 per cent, while a Polaris Management report found Germany is likely to reach 40–44 per cent. In Spain, many doctors are refusing to give consent to be named, as they fear being taxed on the extra income, which in some cases they may not have declared.

Andy Powrie-Smith believes that while the EFPIA disclosure code has nothing to do with anyone's tax affairs, a risk remains that any far-reaching new regulation could produce unintended consequences that would threaten to slow the industry's move toward full transparency.

The EFPIA agreement requires companies to make their "best efforts" to achieve full disclosure. However, drug makers have no choice but to anonymise the payments where consent is not given to release individual names. The industry's hope is that once healthcare professionals see the system in action over the next six months and the benefits of transparency, then the number of participating doctors will rise over time.

Cultural variation across Europe

Veeva's **Guillaume Roussel**, Director of Strategy for Veeva OpenData in Europe and a Veeva regulatory affairs expert, believes cultural differences will inevitably mean considerable variation in the levels of disclosure achieved in Europe.

He predicts that four different "Europes" will emerge this summer when it comes to attitudes to transparency: Scandinavia, north-west Europe, eastern Europe, and southern Europe. He argues that, at a high level, this represents a sliding scale, with Scandinavia the most open, and eastern and southern European countries more resistant to disclosure.

The Scandinavian countries are renowned for having embraced transparency in public life. Examples from Sweden, Norway, and Finland show that public accountability trumps personal privacy regularly in these societies, and in such countries everyone's income and annual tax returns are published and publicly available online. By contrast, countries in southern and eastern Europe, such as Greece, Serbia, and Russia, have histories of corruption between HCPs and officials in pharma companies, which increases scepticism toward any voluntary attempt at comprehensive payment disclosure.

France introduced an entirely new regulatory system, with legislation that made disclosure of payments obligatory after the public scandal around Servier's Mediator in 2009. Portugal, Denmark, and Slovakia have similar laws. Perhaps unsurprisingly, eastern Europe is following France's lead. Estonia, Greece, Latvia, Lithuania, Romania, and Serbia all have legislation in the pipeline to cover disclosure of payments, which will lay a strong foundation to help them eventually overcome HCP wariness to increase transparency and improve the ease of payment disclosure reporting.

Transparency and corporate reputation

Despite concerns and obstacles, early indicators show that the majority of companies will meet the deadline. In part, this is driven by a shift in the industry in which transparency can be a major reputational win for companies.

Collecting data, verifying its accuracy, and gaining HCP consent to publish it is a labourious and long-term undertaking for companies. Walter Chmielewski says central to this is creating single, continent-wide customer data management system for companies to accurately track payments to each individual HCP, regardless of the transfer of value or which division or country affiliate made the payment.

He reports that for Biogen, the drive to meet the deadline came from top management. That meant staff were given the resources and support to make sure the company's first transparency report was delivered on time and complete.

"Our management are very much in favour of embracing transparency. It involves a lot of effort within organisations, with a lot of dollar value and human resources being devoted to it," he said.

As companies submit their inaugural payment disclosure reports this summer, the industry is waiting for the response to its efforts toward open and transparent relationships with doctors. Backlash from doctors and the public seems unlikely at this stage. However, for the industry to repair lost public trust, pharma companies must recognise that the 30 June deadline doesn't represent a "finishing line" for their efforts with transparency and appropriate relationships; rather, it is just the beginning of a new era of open business practices.