Disclosure D-Day Draws Near In Europe

- WHERE BUSINESS MEETS POLICY -
PharmExec.com

Apr 12, 2016
By Julian Upton [1]
Pharmaceutical Executive
Volume 36, Issue 4

In line with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code, June will see member companies across Europe required to publish data concerning their 2015 transfer-of-value transactions to healthcare professionals (HCPs). The EFPIA Code has been looming for four years and much of Europe appears to be ready for the imminent deadline.

In France and Denmark, for example, disclosure of payments on a central platform is already a legislative requirement: in the UK, the Association of the British Pharmaceutical Industry (ABPI) began disclosing aggregate payments to HCPs in 2014; and in Portugal, US "Sunshine"-type rules took effect in February 2013.

European companies have also had over a year to monitor the US experience of the physician payment program, which went live in September 2014. The Sunshine Act was, of course, tailored to a market with it own particular challenges, but US pharma's experience of Open Payments has, nonetheless, flagged up some useful pointers, and European companies would do well to take heed.

US problems concerning consistency of reporting, for example, will likely be amplified across Europe, and the media's focus on and reaction to some of the data is something for which European life sciences organizations should be prepared.

Code concerns

Ahead of those challenges, however, is the concern that some countries and companies may not be ready for the EFPIA Code to come into force at the end of June. In November last year, results from a pan-European survey on customer data in the life sciences industry by Veeva stated that two-thirds (73%) of companies surveyed said they did not have the data to successfully manage HCP activity across borders, with 66% revealing that their data resided in "multiple systems" that are not yet integrated.

Speaking to *Pharm Exec*, Veeva's Guillaume Roussel explained that companies have been developing their information systems incrementally over time, "just adding new systems on top of older ones," and

this “has created an architecture that is difficult to streamline from a transparency

“Companies are investing tremendous amount of time and resources in order to get to the point of reporting, but this is not sustainable over time.”

perspective.” However, countering the somewhat alarming findings of his company’s survey, Roussel believes that companies will be ready to meet the EFPIA reporting deadline, as many of them are implementing “temporary solutions.” But, he adds, “The question is, at what cost?” He explains: “Companies are investing tremendous amount of time and resources in order to get to the point of reporting, but this is not sustainable over time.”

EFPIA’s Communications Director Andrew Powrie-Smith suggests that a survey of the industry’s disclosure efforts published more than six months ahead of the Code deadline might better have asked who *will* be ready, rather than who is ready. Making an agreeable analogy, he asked attendees at a meeting in early December, “Who is ready for Christmas?” Not too surprisingly, no hands went up; most of the audience simply proffered a slightly nervous chuckle. Powrie-Smith’s point was thus made, although one could argue that leaving a short time to buy gifts, defrost a frozen turkey, and decorate a tree is not really comparable to the pressure of a last-minute completion of all the legal and administrative legwork needed to fulfill the requirements of the Disclosure Code.

Nevertheless, Powrie-Smith later told Pharm Exec, “We must remember that it’s a requirement that EFPIA companies are ready by a certain date, and companies are taking this requirement seriously. All our companies have been working hard, and that process continues until the end of June.” He does concede, however, that we can expect to see reporting inconsistencies at the “go-live” date: “You’re looking at countries that can be very different in terms of their cultural, socioeconomic and legal frameworks, so you’re going to have variances.” Ironically, Veeva’s Roussel says that adoption of EFPIA guidelines “is actually very consistent across the board—there is no striking difference between north and south, or east and west.”

Indeed, some measure of inconsistent reporting is virtually guaranteed when the European data is published; even the US’s one-language, one-culture market still has a way to go before it has this problem in hand. When the US’s Open Payments system went live in September 2014, “one of the things that was most notable was the inconsistency across companies in how they interpreted things and in how they chose to report them,” notes Christine Bradshaw, Vice President, Porzio Life Sciences, LLC.

While Bradshaw believes companies were reporting in good faith, the inconsistencies “made it very difficult to look at one company’s information and compare it to another’s, to answer questions such as

who's spending more on research, who's spending more on commercial, what do the fees look like for consulting agreements, things like that." This was particularly frustrating, she adds, not just because making the data transparent and accessible for analytics were key among objectives of the Sunshine Act in the first place, but also because of the "exorbitant amount of time and money" companies had spent in getting ready for it.

In Europe, in terms of analysis of the data, Powrie-Smith agrees that "we're going to see the same thing in the short term." But, he adds, "that's one of the benefits of the transparency project as a whole: we get to see at a detailed level what a relationship looks like and understand it better."

Of course, a wider public understanding of industry–HCP relationships is one of the overriding social goals of the shift toward transparency. But amid the general lack of understanding among the public at present, we can be certain that new systems of openness will bring a new level of critical scrutiny, at least in the short term. Where pharma has seen many incremental changes in the way that industry and HCPs work together over the last decade, Powrie-Smith points out that the push for full disclosure of transfer of value "is more of a transformational step, a significant change, so inevitably it's going to put a level of focus on relationships that hasn't been there in the past."

He anticipates questions like "what are these payments for, what's this relationship about, what is an advisory board, why do people speak at meetings?" But it is the industry's job, he says, "to explain how those relationships work, what the value is, who benefits, and so everyone can see what those relationships are and have confidence in them."

Jane Griffiths, Company Group Chairman, EMEA, Janssen, told *Pharm Exec*, "It's no secret that when Sunshine first went live in the US, there was an initial media focus on some of the higher earning HCPs and maybe that will happen in Europe." For Griffiths, the important thing is that the relationship between the industry and HCPs is seen in context. How new medicines are developed and how innovation is brought to patients are not models that are well understood by the public, she explains.

"Transparency is very important, but as an industry we need to communicate the way the model works more extensively than we do," Griffiths says. "This would put transparency around clinical trials and transfer of value into more context."

Griffiths is keen for the public to reach a greater understanding of what the industry does, of how research is conducted and what is involved in it, and

> "Transparency is very important, but as an industry we need to communicate the way the model works more extensively than we do."

why companies have interactions with HCPs beyond the sales and marketing of medicine. She explains: "This is a journey, an evolution; we've set the EFPIA date and done a lot of educating, but that education will continue far beyond the deadline. The aim is that society and patients in general see an open and transparent relationship between companies and the people who prescribe the medicines."

Trust and transparency

Educating the public (and the mainstream media) about "what the industry does" remains key to gaining its trust, or in some cases establishing trust in the first place. But negative headlines could continue for some time yet, if not when the European transfer-of-value data is sliced and diced in the press later this year, then probably when the results of a major investigation by Transparency International (TI) into pharma and healthcare corruption filter through to the media.

TI, a global anti-corruption non-governmental organization (NGO) currently best known for its Corruption Perceptions Index, announced its investigation into pharma last year, following a 2013 survey of 17 countries which stated that "45 per cent" of the public believed that medical and health services were "corrupt or extremely corrupt."

TI will begin by focusing on five priority areas: procurement and distribution, marketing practices, manufacturing (including counterfeits), registration processes, and R&D. Ominously, the organization's UK executive director, Robert Barrington, told an audience of pharma execs at CBI's Compliance Congress in Munich in November 2015: "We will challenge you, and we expect this to be disruptive to your industry." However, somewhat more charitably, he added that he thinks pharma's reputation is in "a rescuable position."

Speaking to *Pharm Exec*, Sophie Peresson, Director of Transparency International's Pharmaceuticals & Healthcare Program, is not ambiguous when setting out TI's stall. "Every day, all around the world, people suffer and die due to corruption in the pharmaceutical and healthcare sector," she begins.

Peresson goes on to list a litany of pharma crimes and misdemeanors that comprises "patients denied access to medicines because they cannot afford to bribe, the effect of counterfeit drugs with no medicinal value, the theft of a national health budget by a corrupt public official, [and] the distortion of regulatory decisions through inappropriate lobbying."

She explains that TI is aiming "to make corrupt officials think twice about accepting bribes, but also

provide the real structural reforms that create transparency and limit the scope for corruption to take root." Achieving this will be no mean feat; accordingly, Peresson estimates that TI's investigation "will need at least 10 years to make an impact."

So will the upcoming EFPIA disclosures, and those already accessible in the US Open Payments system, help TI's investigation? Peresson is ambivalent. There are "pockets of good work" being done, she says, but "the response is hugely disproportionate to the threat" and the sector is "under-served by anti-corruption programming as a whole." Arguably, she explains, Sunshine and the EFPIA Code will "provide a benchmark to measure performance, but compliance is box-ticking and it is, therefore, essential to ensure that implementation really happens."

While the US and European regulation will help facilitate TI's work in the geographical regions that the regulation covers, Peresson reminds us that "large parts of the world are not covered and, therefore, at a higher risk of corruption vulnerabilities." What is needed is a "holistic approach driven by multi-stakeholder groups operating at various levels," she says. "Real change will only be achieved if the private sector is prepared to be bold, commit to change, and take a leading role."

This is not to say that TI is entering the transparency fray gunning for industry from the outset. Peresson looks forward to dealing amicably with pharma as the investigation gets off the ground. "We have been successful in developing a very good relationship with many industry players and we hope to continue doing so," she adds.

The long run

No one is denying that the road to full transparency will be a rocky one, especially during the journey's early stages. As Bradshaw says, "One of the things that we in the US have learned is that the process takes longer and requires more time and support than anyone anticipated." She adds that factoring consent into the transfer-of-value disclosure mix "means more nuance in the preparation process," and the European challenge of data privacy will constitute another layer of complexity.

But the biggest lesson from the US, says Bradshaw, "is probably making sure you have the support and participation of different business units in the company." The project may be owned by the compliance team, "but it is so critical that the team has connections with the right people to make sure things are being done consistently, that they have, or can quickly access, all the information they need."

Respective teething problems aside, there is broad consensus that both the US and European transfer-of-value disclosure codes will succeed in

The ultimate goal of the TI investigation is to provide the industry with "a chance to repair its reputational damage."

changing attitudes and behaviors across the pharma industry in the long run. Although Roussel points out that many European companies have been implementing temporary solutions ahead of the EFPIA deadline, he believes that eventually they "will feel more comfortable in terms of selecting the tools and implementing the proper processes for future disclosure reporting."

Future surveys will be interesting in showing how company interactions with physicians are evolving, Roussel says. "Will companies, for example, move further away from face-to-face, science-oriented meetings? Transparency will affect and accelerate this transition, in that the focus is completely disconnected from commercial incentives and more about adding value to the physician's knowledge."

Even if TI's qualified praise of Sunshine and the EFPIA Disclosure Code suggests that pharma's efforts in promoting full transparency so far have been somewhat short-sighted in the face of the enormous task at hand, it is worth remembering that the ultimate goal of the TI investigation is to provide the industry with "a chance to repair its reputational damage and build trust within the patient community again."

And while EFPIA's Powrie-Smith recognizes that the Disclosure Code represents just the start of the journey, and that the industry is being required to "go straight from 'zero' to a new era of transparency," over time, he says, full disclosure will "progress from a standing start to becoming the way that industry and health professionals operate together."

Such sentiments echo the words of the 19th Century poet and physician Oliver Wendell Holmes, who famously asserted, "The great thing in this world is not so much where we stand as in what direction we are moving."

Julian Upton is *Pharm Exec*'s European & Online Editor. He can be reached at julian.upton@ubm.com [2]

Source URL: http://www.pharmexec.com/disclosure-d-day-draws-near-europe

Links:

[1] http://www.pharmexec.com/julian-upton

[2] mailto:julian.upton@ubm.com%20