CULTIVATING COMPLIANCE IN THE 21ST CENTURY
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By Hae-Won Min Liao, Michele Tagliaferri

Compliance with new standards on disclosure of industry promotional ties to health providers is emerging as a global policy challenge—the United States is no longer an outlier. While pharmaceutical and device companies began tracking payments made to teaching hospitals and physicians on August 1, under the US Physician Payments Sunshine Act (Sunshine Act), a similar trend is underway in Europe. In June 2013, the European Federation of Pharmaceutical Industries and Associations (EFPIA) adopted a code requiring disclosure of certain payments from pharmaceutical companies to healthcare professionals and organizations (Disclosure Code). As pressure for transparency continues across the globe, the costs of compliance are slated to rise for each pharmaceutical and medical device company affected by these initiatives. This column suggests cost-mitigating strategies for companies designed to comply not only with the technical requirements of these global initiatives but also the spirit of the law.

Sunshine precedent
The Sunshine Act requires pharmaceutical and device manufacturers to report annually “any payment or transfer of value” made to physicians and teaching hospitals, who are collectively known as “covered recipients.” The first reports are due to the Centers for Medicare and Medicaid Services (CMS) by March 31, 2014 for the tracking period of August 1 to December 31, 2013.
US law mandates that all transfers of value be reported, unless an exception applies. Important exceptions include:

» Payments less than $10, except when the annual value of such payments to a covered recipient exceeds $100.

» Educational materials that directly benefit patients or are intended for patient use.

Penalties for failure to report in a timely, accurate manner, range from $1,000 to $100,000 per payment not reported, with a maximum penalty of $1,000,000 for each annual submission.

**EFPIA’s Disclosure Code**

Europe has opted to take a self-regulating approach to promotional disclosures but the aims are similar to what is occurring in the United States. The region’s major industry association has endorsed a strong Disclosure Code that requires the constituent members of the EFPIA Associations in Europe and corporate members of EFPIA to disclose annually any transfers of value to healthcare professionals (HCPs) and healthcare organizations (HCOs). The Disclosure Code will be imposed on member companies through the implementing codes that the EFPIA national member associations are required to adopt by December 31, 2013.

The scope of the disclosure obligations is very broad, and includes:

» Transfers to HCOs:
  - Donations and grants
  - Contributions to costs related to events
  - Fees for services and consultancy

» Transfers to HCPs
  - Contribution to costs related to events
  - Fees for service and consultancy

Transfers of value must be disclosed and attributed on an individual basis for each recipient. Disclosures must be made within six months of the end of the relevant reporting period. The first reporting period will be 2015. The Disclosure Code allows companies to disclosure either on their website, or on a central platform, such as the one provided by the relevant government, regulatory body, professional authority, or member association. Unless expressly exempt by the Disclosure Code, transfers must be disclosed on an individual basis.

While the Disclosure Code does not provide for specific sanctions for noncompliance, it calls upon the national member associations to include sanctions for violations of their national codes.

**Surging costs of compliance**

While it is difficult to estimate precisely the total costs incurred by multi-national corporations operating both in the United States and Europe in complying with these transparency initiatives, it is undeniable that these costs have skyrocketed in recent years. CMS predicted that the average labor costs for an applicable manufacturer in complying with the Sunshine Act would be $159,234 in the first year and $119,426 in the second year. CMS estimated that large manufacturers would spend $50,000 in the first year and $5,000 in the second year for infrastructure costs, while small manufacturers would spend significantly less, $4,000 in the first
# Comparison of EFPIA and Sunshine Act

<table>
<thead>
<tr>
<th>EFPIA</th>
<th>US Sunshine Act</th>
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<tr>
<td><strong>Binding Nature</strong></td>
<td>Voluntary code</td>
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<tr>
<td><strong>Applicable Manufacturers</strong></td>
<td>EFPIA Member Companies and other European companies which are members of an EFPIA Association in Europe, as well as their respective parent companies and subsidiaries.</td>
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<tr>
<td><strong>Effective Date</strong></td>
<td>Member associations must transpose the transparency requirements by December 31, 2013. Tracking begins on January 1, 2015. First reports are due by June 30, 2016.</td>
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| **Types of Payments Covered** | All transfers of value in the following categories are covered for an HCO:  
- Donations and grants  
- Contribution to costs related to events  
  - Registration fees  
  - Travel and accommodation  
- Fees for services and consultancy  
  All transfers of value in the following categories are covered for an HCP:  
- Contribution to costs related to events  
  - Registration fees  
  - Travel and accommodation  
- Fees for services and consultancy | All transfers of value in the following categories are covered:  
- Consulting fees  
- Compensation for services  
- Honoraria  
- Gifts  
- Entertainment  
- Food  
- Travel  
- Education  
- Research  
- Charitable contribution  
- Royalty  
- Ownership or investment interest  
- Compensation for speaking at a medical education program  
- Grants  
- Space rental or facility fees |
| **Covered Recipients of Payments** | “Recipient” is defined as any HCP or HCO whose primary practice, principal professional address or place of incorporation is in Europe. “HCP” means a natural person who is a member of the medical, dental, pharmacy, or nursing professions or any other person who may in the course of professional activities “prescribe, purchase, supply, recommend, or administer a medicinal product” and whose primary practice, principal professional address or place of incorporation is in Europe. “HCO” means any legal person that is a healthcare, medical, or scientific association or organization whose business address, place of incorporation or primary place of operation is in Europe or through which one or more HCPs provide services. | “Covered recipient” is defined as: a physician, other than a physician who is an employee of an applicable manufacturer; or a teaching hospital. “Physicians” include US-licensed doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors. A “teaching hospital” is an institution that receives Medicare graduate medical education payments. CMS will annually publish a list of such institutions. |

While both the US and EU regimes focus on payments to “covered recipients,” the meaning of this term is somewhat different. In addition, the Disclosure Code and the Sunshine Act define “transfers of value” broadly, but provide for different exemptions and reporting requirements for different types of payments.
year and $400 in the second year. The threshold size for “small” pharmaceutical manufacturers is 750 employees. Thus, for a pharmaceutical manufacturer, the US government estimated that the cost of implementation would be roughly $200,000 in the first year.

Industry contacts have scoffed at this low estimate, noting the vast resources needed not only for actual tracking but often for purchasing databases. Fellow consultants and company personnel responsible for marshaling a company’s resources have noted figures well above $1 million to comply with this US law in the first year. Based on initial estimates from the industry, the EFPIA Disclosure Code compliance costs are expected to be in the same range.

There are also costs that are difficult to capture, including the loss of opportunity to collaborate with leading physicians or institutions who have instituted a no-industry payment policy, and the financial consequences for noncompliance as a result of enforcement actions. In Europe, new data protection regulations could also affect compliance costs around promotion.

Reducing cost of compliance

The increase in public scrutiny through both voluntary and legally mandated disclosures is designed by both organizations to bolster public confidence in the pharmaceutical industry. Here are a number of recommendations for reducing overall cost while not short-changing the legal obligations around compliance efforts:

Designate personnel with compliance responsibility as early as possible and shop around for experienced outside firms.

- Tracking and reporting accurately is important not only because of the legal fines that can be imposed, but the risk of investigations by the US Department of Justice for Anti-Kickback allegations or potential False Claims Act suits that could arise after publication.
- Determine whether any exceptions apply.
- Does the 10 percent of annual revenues limit apply under the Sunshine Act?
- Can any of your separate divisions be considered exempt from US reporting obligations because it only manufactures non-covered products?
- Does the transfer of value relate to over-the-counter medicines, items of medical utility, meals and drinks, or medical samples which are excluded from EFPIA’s Disclosure Code?

Anticipate strategic growth areas and analyze whether transparency rules will apply to those business sectors. If so, plan compliance efforts early.

There are many additional legislative transparency mandates, spanning countries as diverse as France and Slovakia that companies must monitor. Countries in Asia, such as Japan, have their own transparency initiatives. Pressures and interest to do the same is growing in key emerging country markets like China. We believe this global trend of seeking transparency between manufacturers and providers will require sustained focus on managing these rising compliance costs, in much the same way that companies have tackled the cost burden in product registration and approvals.

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Experts warn that if pharma doesn’t take a tighter grip on its supply chain and yank it into the 21st century, the industry could soon face distribution and logistics crises on an unprecedented scale.

In Pharm Exec’s 2013 end-of-year supply chain roundup, we began with a three-word vision of the immediate future that left little room for ambiguity: “Serialization is coming.” With the impending laws regarding “track and trace” promising to alter the way pharmaceuticals are packaged and shipped, we outlined how global pharma was gearing up to deal with the effects of serialization, and how companies needed to review their own internal practices and those of their outsourcing partners, as the need for technology solutions for both sides of the outsourcing relationship became more evident.

Of course, that message still stands, and it is arguably even more urgent if we are to believe Ian Haynes of 3C Integrity Consulting, who unnerved many in the audience at London’s recent FlyPharma 2015 conference when he said that pharma is still not ready to meet the obligations of track and trace. But since 2013, a number of other concerns—some equally as transparent, others less immediately visible—have emerged to stand alongside the move to serialization as potentially major disruptions in the way the industry operates. Indeed, as we head into 2016, one industry insider believes the pharma supply chain is facing a confluence of challenges “the likes of which it has never seen before.”
Daunting path

Alan Kennedy, director at PartnerSave, pulls no punches when he outlines the litany of challenges that he sees confronting the pharma supply chain over the next five years. He points to “the escalating good distribution practice (GDP) demands on the industry (and the need for greater harmonization); the pressures from the marketplace for cheaper medicines; shifting consumer expectations, with the trend towards more specific, personalized medicines; and rocketing costs.”

The crises are already starting to hit. Kennedy says: “A lot of pharma companies are waking up to the fact that they need to sharpen up their act in terms of compliance with the regulations. But while a lot of the need for change is regulatory driven, it’s also competitive. There’s a lot of lip service paid to the need for reform, but the problem is translating the intention into action.”

One of Kennedy’s “perfect storms” on the horizon is gathering around outsourcing from, and supply to, emerging markets. As these are the markets “where growth is coming from,” he stresses that pharma companies must be better integrated and work more closely with their partners if they are to continue to expand in developing countries. “They’ve got to make sure that the best practices that apply here also apply there. There’s no use having a state-of-the-art facility in the US but not in, say, India or Latin America, where you’re doing business; products have to be reliably protected from start to finish.”

John Menna, vice president of strategy, healthcare logistics, at UPS, often observes companies “doing a fantastic job of maintaining the efficacy of their products from manufacturer all the way to the destination country.” But when the products get to their destination, where there isn’t the same commitment to rigorous procedures, “they end up not being stored at the proper temperature, in the right environment, and with the right protocols.” And companies may be unaware of this, Menna adds. “If
a vice president of supply chain at a big Pharma company flies out to the destination and sees how products are being stored there, they may be in for a shock. Companies need to take a hard look at their supply chain endpoints, and at the providers that they’re using.”

Fast-growing firms must establish their emerging market networks in a “much smarter, more flexible way,” Vitaly Glozman, partner at PwC, told Pharm Exec. Traditionally, big Pharma’s “huge, static networks” have been difficult to change or use effectively. Glozman believes that a “hub-and-spoke” model could provide the key. “By investing in a hub in, for example, Dubai and then outsourcing the hub’s ‘arms and legs’ to local distribution warehouses across the Middle East, a company can minimize its CAPEX investment and achieve flexibility,” he explains. “Or, if things go south, it has the ability to reduce volumes and spend, kind of like transitioning its CAPEX to its OPEX.”

As companies gear up to expand into more countries with more products, however, there will be, accordingly, more threats to data and product security. “A lot of companies are going to be selling so-called drug-device combination products that include data collection capabilities. These products will enable the patient to communicate the results. How that data will be transitioned back to the pharma company or provider presents a big challenge. Companies will not only have to deal with product security but also patient information security,” says Glozman.

The patient ‘pull’

Certainly, pharma seems somewhat unprepared for the supply chain demands of an increasingly patient-focused future. This is largely a result of the healthcare supply chain remaining, says Menna, a “push supply chain, where manufacturers, wholesalers and distributors push products into the channel and downstream to the hospitals, doctors’ offices and ultimately to the patient.”

But things are moving to a point where patients are pulling products through the supply chain for their own consumption. “This is similar to a retail environment; to take an extreme example, it’s like an online purchase of audio-visual equipment to be delivered to the home.” With more personalized medicine procedures being done outside the institutional setting and closer to the patient—either in an outpatient facility or even patients’ homes—logistics solutions will need to start providing for the sending of alerts to patients, allowing them to determine when and how a product is delivered, and facilitating the transportation of critical specimens from the patient to diagnostic labs.

Data: Key cog in chain

As the pharma supply chain evolves from “push” to “pull,” analytics will become a more vital part of the process. Much has been written about analytics and big data, but now more than ever, leveraging the data that pharma has been collecting and investing in predictive and prescriptive analytics will be key to maximizing the promise of data, for issues ranging from temperature tracking to warnings of drug shortages and recalls. “You’ll start to see companies making more use of big data to develop better therapies and leaner supply chains in the next five years,” says Menna. The challenge of analytics begins with determining the different business questions you want the data to answer, Glozman says. “Otherwise, analytics is a very strategic tool that can be misunderstood and misused.” He goes on: “You need bright, capable people managing your supply chain. You don’t just want people who say, ‘Let’s do some analytics.’ They need to say,
‘Wait a second, what is the specific problem we need to understand better? Let’s identify the data attributes and then define our analytics.’”

For Kevin Pegels, VP, global supply chain management – PS Biotech, Bayer HealthCare, there are ongoing issues around end-to-end data availability and decision-making that also need addressing. “There is a gap right now in pharma with regard to the visibility of data concerning suppliers’ capacity and inventory and customer inventory,” he says. “What inventory do customers have? What is patients’ consumption? This information is critical for an efficient supply chain.”

Non-pharma lessons

Pegels formerly worked in the consumer packaged goods business, which he says “is about 15–20 years ahead of pharma in terms of best practice supply chain management” He points out that as soon as consumption is seen, for example, at a Walmart store, that immediately drives orders to the suppliers for replenishment shipments to the Walmart warehouses. “Pharma is long way from that kind of end-to-end visibility, but it is catching up, says Pegels, “because we are finally realizing that the supply chain can add a lot of value.”

Outside of consumer packaged goods, which other industries can pharma look to for lessons on optimizing the supply chain? Alan Kennedy notes that one industry that has been a big advocate of supply chain integration for the last two decades is construction. “The construction industry has the disadvantage of having one of the most complex supply chains out there,” he says. “Every project is a one-off, every project needs a different supply chain, and every one is organized in a different way, all for relatively short periods of time. Construction has all sorts of challenges that are driving real, close collaboration.” The automotive industry’s supply chain management also “is right at the forefront,” says Kennedy, along with retail and electronics.

But while best practices from other industry supply chains can be adopted by healthcare, “it is very important to note that healthcare is different,” says Menna. “The first thing to remember is that at the end of the healthcare supply chain is the patient, whose quality of life will be affected, and hopefully improved, by the treatments he or she receives. So there is a certain level of urgency, because we are talking life or death, or at least quality of life.” Second, the sensitivity of the products and the regulatory environment surrounding their movement and storage “are unlike anything in any other industry.”

Own innovation is vital

Given those dynamics, pharma still needs to find its own solutions for its own supply chain challenges. The “big answer” for Kennedy is that companies have to start integrating more successfully. “An integrated supply chain is more than just a collection of collaborative organizations,” he notes. “If you look at it as a box, within that box you’ve got all the network controls and tools: quality management, shipment visibility, inventory management, regulatory compliance, network communications, education, and training. A properly integrated supply chain addresses all these issues as a unified network.”

For Glozman, cost will become key. “I believe there’ll be a push for the lowest common denominator in terms of cost. I don’t think companies have yet begun to address this issue
properly. Bending the supply chain cost curve is going to be critical.” Glozman also sees more focus on collaborating with regulators. “The industry still currently deals with the regulator as a separate entity rather than as a collaborator,” he says. But with so many changes looming over the next five to 10 years, certainly as far as manufacturing technologies are concerned, “the industry will change to have a much more collaborative relationship with regulators.” Similar to what has taken place in other regulated industries, Glozman sees pharma companies “actually co-locating a regulator staff member within their facility and working with them on new product development.”

The industry “is currently about 30-35% over capacity and it will take a little while to subsume this, because some of this capacity is not ready for the future,” Glozman adds. There will be “a lot more flexible, single-use manufacturing, particularly for complex and biologic products where companies want to minimize the cross-contamination risks.” For more high-volume manufacturing, he adds, “I think we are going to see continuous manufacturing become more of a standard over the next five years.”

Better leveraging of end-to-end data and decision-making will shorten lead times within the pharma supply chain, says Kevin Pegels. He also sees supply chain management gaining more stature within pharma companies. “You may see a chief supply chain officer reporting to the CEO in the next five years,” he says. “With all the competition and downward pressure on pricing, the supply chain needs to play a bigger role to maximize cost efficiency. And just to be part of the game with customers, companies have to have reliable and predictive supply. Pharma is realizing that it has to start investing now.”

Against the clock

The time the industry has to re-engineer its supply chain is hardly in abundance. Is such a revamp of current practices achievable in such a relatively short time? Despite his concerns for the future, Alan Kennedy, for one, is confident that “there’s always someone to take the lead, and some companies will do that. Once that happens, they will see a big competitive advantage coming in their direction. They will see quality improvements, profitability improvements—all the advantages that come with better integration.”

Maybe then pharma’s supply chain reaction will start in earnest.

“THERE IS A CERTAIN LEVEL OF URGENCY, BECAUSE WE ARE TALKING LIFE OR DEATH, OR AT LEAST QUALITY OF LIFE.”

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On June 30, the Centers for Medicare and Medicaid Services (CMS) released the first full year of data under The Affordable Care Act’s transparency program, also known as Open Payments or the “Sunshine Act.” This included about 11.4 million records totaling about $6.5 billion in payments made to 607,000 physicians and 1,121 teaching hospitals by 1,444 reporting entities during 2014. Combined with CMS’s September 2014 release of 2013 data for the period Aug. 1 through Dec. 31, 2013, there are now over 15.7 million payments totaling almost $10 billion publicly available on CMS’s website.

Applicable drug and device manufacturers and group purchasing organizations, collectively known as “reporting entities,” have spent millions building their Open Payments programs, implementing systems to collect payment data, and allocating resources to prepare the data for submission to CMS. While heavier costs are likely to be incurred during the first few years, companies will continue to spend significant dollars complying with this law. But this is not the only issue companies need to consider.

OPEN PAYMENTS: KEY COMPLIANCE CONSIDERATIONS

Five steps companies can follow to best manage and report ‘Sunshine’-sanctioned data

BY EILEE N ERDOS, MICHAEL RICKS
Public perception of promotional activities within the industry is already a concern, and the availability of Open Payments information may result in additional reputational risks for some companies. Open Payments data may also create added challenges for reporting entities in managing relationships with healthcare providers. In addition, CMS plans to audit reporting entities for compliance with program requirements, with potential civil monetary penalties of up to $1,150,000 annually per reporting entity for violations. Such requirements include the submission of timely, accurate, and complete data to CMS, as well as retention of all records related to payments and other transfers of value and/or ownership or investment interest for at least five years from the date of submission to CMS.

It is also possible that Open Payments data could be leveraged by other government agencies, such as the Department of Justice and state Attorneys General offices, during enforcement actions by these agencies. Needless to say, reporting entities need to get it right, which means providing complete and accurate data that is well supported by appropriate documentation. They also need to understand what the data is saying about their practices regarding interactions with physicians and teaching hospitals, and use this data as a means to assess compliance controls associated with these practices.

**Reporting strategies**

Over years of helping companies develop, implement, assess and independently test their Open Payments and similar data, we’ve developed several observations on ways that firms can effectively manage Open Payments processes to enhance compliance efforts and minimize potential risks.

1. **Know Your Data:** What is the breakdown of payments by type and dollar volume? Who are the highest-paid physicians? Are physicians receiving both promotional payments (such as speaker or consulting fees) and research payments? Is one region or brand team averaging greater per-person meal costs than others?

   Understanding what is in the data, including how budgets are being spent from a promotional, research, and investment standpoint, is critical to ensuring the company is allocating resources appropriately to address risks and conflicts. Some companies are surprised by what’s in their data, which is often not evident without significant digging. Some have been surprised when they only learn of certain reported payments when a third party brings it to light publicly. How might individuals use this data to bring lawsuits against the company? How will government enforcement agencies use the data in conjunction with investigative inquiries or enforcement actions? Companies should know their own data better than anyone else.

   The easiest place to start is by performing high-level analyses in order to understand baseline payment patterns and identify potential outliers. Ongoing analysis of the data can be helpful in identifying trends, as well as spotting outliers that might require additional follow-up.

2. **Make Sure Payment Listings Are Accurate:** How accurate is the aggregate payment amount? It is not uncommon for the smallest dollar amount related to a lunch with a physician to be incorrect on the listing, or an honoraria payment to be attributed to the wrong Dr. James Smith in the system. Calculation errors, inconsistent expense practices, system mismatching, and
other issues can quickly turn into inaccuracies in a company’s data. Mistakes that lead to payment inaccuracies occur when company employees do not include the right expenses in the inputs related to physician payments or when the number of physicians associated with an activity is not accurately recorded. This generally results from unclear company policies and procedures, resulting in inconsistent employee behavior and inconsistent compliance with established policies and procedures.

3. CONFIRM THAT SUPPORTING INFORMATION IS AVAILABLE AND COMPLETE: Do you have documentation that supports the detailed transactions that make up each aggregate payment reported? Supporting documentation is a key component to proving that the payments that make up the aggregate amount reported meet federal, state, and company requirements. Ongoing monitoring of supporting documentation for payments is necessary to ensure that it will be available should the company be required to provide it. Missing or incomplete documentation may result in a lack of evidence that the payment met federal, state, and company requirements.

It is important to understand what documentation is required for each payment type and the location of this documentation; to identify who is responsible for maintaining this documentation, including third parties acting on your behalf; and to test the processes used by those responsible for verifying the completeness and accuracy on an ongoing basis.

4. MAKE SURE POLICIES AND PROCEDURES ARE CLEAR: Are company policies and procedures vague or left open for interpretation? Words like “should” or “may” can be understood to mean “nice to have” rather than “required.” While it makes sense for some policies and procedures to guide behavior rather than direct it, companies must think about how they may be interpreted and whether that could result in inconsistent practices.

The most commonly misunderstood policies and procedures are those that address expense reporting. For example, allowable meals may include delivery fees, room/audio/video rental, or administration charges. The company’s position should be clear as to whether these charges are included or excluded from recorded payments to physicians.

Review your policies and procedures to determine whether language could be open for multiple interpretations and clarify as appropriate. Distinguish between language that suggests that a requirement is optional versus mandatory and ensure that language related to tracking and reporting aggregate spend information specifies that the requirements are mandatory. Participate in employee training and ask questions to assess whether employees have a clear understanding of the requirements. Finally, confirm employee understanding by testing payment-related activities to verify consistent application of the requirements across the company.
5. VERIFY THAT EMPLOYEES ARE FOLLOWING POLICIES AND PROCEDURES: For many healthcare companies, policies and procedures are developed, reviewed, and approved with the utmost attention. Many compliance and internal audit departments incorporate compliance auditing and monitoring at the forefront of their annual plans. But how do you really know that employees understand what you expect and are complying with company requirements, especially when it comes to activities that affect Open Payments reporting? To start, you need to understand the different types of payments being reported, as well as the policies and procedures that apply to these payments. This will allow companies to develop criteria that can be used to test whether the policies and procedures were followed, as well as test whether supporting documentation is available and complete.

Payment transparency requirements will expand as international industry associations and other countries, such as France, Australia, and Japan, roll out their versions of Open Payment requirements. This further underscores the importance of establishing effective and consistent processes to collect and report accurate and complete payment information, and to implement policies and procedures that are clear, are understood, and are being followed.

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Increasing demands for transparency have seen the role of chief compliance officer (CCO) evolve rapidly over the last 10 years. But the upcoming shift to cross-border compliance in Europe will present CCOs with their biggest challenge yet.

Compliance, across all industries, thankfully no longer occupies its 1980s position as a “corporate backwater.” Back then, a senior banker recalled for the Financial Times (FT, April 24, 2014), the compliance specialist at one London firm “was also charged with looking after the boss’s wine cellar,” such was the general vagueness and perceived irrelevance of his nominal role. In pharma around the same time, a chief compliance officer (CCO) was a rare commodity indeed. As Ilyssa Levins and Eve Costopoulos write on the Pharmaceutical Compliance Monitor website, before the late 1990s, US companies, for example, simply formulated their business practices on their understanding and interpretation of an anti-kickback statute that was exceptionally broad.
In banking, what the FT calls “the tsunami of regulatory initiatives” that followed the 2007–2009 global financial crisis saw compliance move out of the shadows and toward center stage. Transported through time to 2013, that 1980s banker would no doubt have been astounded to hear a major UK bank (HBSC) announce its plan to hire more than 3,000 compliance officers.

Pharma, of course, has also intensified its compliance activities in the last few years, even if this has been, as with banking, as much a reaction to external regulatory and legislative pressures as a desire to get its house in order.

Recently, we have seen the rollout of the Sunshine Act’s Open Payments database and the European Federation of Pharmaceutical Industries and Associations’ (EFPIA) call for its 33 national member organizations to disclose details of payments made to named individuals and publish them in open registries by 2016. Add to these initiatives a growing emerging market crackdown on bribery and corruption, and it’s fair to say that compliance is an industry hot topic. The Economist Intelligence Unit has predicted that more than 70% of pharmaceutical sales this year will be made in countries with transparency regulations. And aside from GlaxoSmithKline’s widely reported woes in China, pharma companies are currently under investigation for corruption in countries as unlikely as Syria, Iraq, and Lebanon.

In January 2013, Pharm Exec wrote that compliance “is no longer just a box to check—it’s strategic function within the organization is more important than ever.” By extension, we added, “chief compliance officers are gaining momentum and have moved from the background of business operations to the foreground.”

So, two years on, can we confidently say things have moved on for the CCO?

Compliant with compliance?

For David Eves, director of medical affairs and compliance at Chugai Pharma UK, there is a much greater understanding across companies of the centrality of compliance to everyday business activities such as the separation between promotional and non-promotional activities. “Everyone knows the importance of the Code,” he says. “No one has come to me recently and said ‘Can I do this? I’m not sure if this is within the scope of the Code.’ Everyone knows what they can’t do. But there’s a general view now that compliance should not be a business disabler—it should be about finding solutions. There’s an increasing awareness that it’s vital to be an ethical business that is top-down, bottom-up and about perception.”

However, Garineh Dovletian, chief risk officer at The Medicines Company (Parsippany, NJ), a mid-size pharma focused on the acute/intensive care hospital market, believes the boundaries of what fall within compliance are less clearly delineated than they were 10 years ago. “I find it harder

“EVENyONE KNOWs WHA’T THEY CAN’T DO. BUT THERE’S A GENERAL VIEW NOW THAT COMPLIANCE SHOULD NOT BE A BUSINESS DISABLER—IT SHOULD BE ABOUT FINDING SOLUTIONS.”
to define where compliance begins and ends,” she says. “I can recount what the Office of Inspector General (OIG) guidance says, or what the US Sentencing Guidelines say, or what the Organization for Economic Cooperation and Development (OECD) says about what the role should be, but that’s just the starting point.” Whether it’s working with finance and procurement team in terms of Foreign Corrupt Practices Act (FCPA) compliance and proper controls, or with clinical team and activities surrounding research and post-approval, Dovletian believes the role of the compliance officer is getting broader.

But is it taken more seriously? On this point, Siemens’ CCO Dr. Klaus Moosmayer told C5’s online blog (September 2014): “I am optimistic, but I’m not naïve … we are certainly not at the end of the way to achieving this.” He said that the question of whether compliance is seen as bringing business value is still a developing topic. Even now, the major day-to-day challenge of a compliance officer is getting support from middle management. Dovletian agrees: “If you don’t have buy-in from the organization’s mid-level leaders, you’re dead in the water from a compliance perspective,” she says. Mid-level managers are close enough to their employees to set the tone of the day-to-day operations; getting their backing is an issue that, for some companies, still needs more attention.

CCOs still wrestle to get their execs on board. Speaking at CBI’s Compliance Congress in Brussels, Belgium, last year, Abbott’s L. Kathleen Durousseau said she had moved away from trying to get staff to read policy and procedures, favoring instead activity-based tools. “A decision tree helps people understand. It lets the commercial person, for example a senior-level marketer, do a lot of the work themselves,” she explained. Mundipharma’s UK Compliance Officer Kelly Hawson, speaking at the same event, stressed the need for everyone “to take ownership of compliance,” to practice accountable leadership. Failing that, appealing to people’s self-preservation instinct tends to work as a bottom-line approach. Sometimes, added Hawson, “There is a point where you just have to say, ‘These are the company rules.’” As the saying goes, there’s nothing like the threat of jail time to make an executive “get religion.”

These struggles are endemic, however, and, perhaps, to be expected; after all, most heads of department have to be inventive in getting their organization on message. For Polaris Management’s Marc Eigner, a vendor who has long worked with pharma compliance departments, CCOs are now more ensconced in the c-suite than they were a few years ago. He points to the rise of Actavis head Brent Saunders, who began his career in pharma compliance. “To see someone with a compliance background become CEO sends a clear message,” he says. Much of the CCO’s increasing recognition has been down to importance of commercial compliance. “In the past, the commercial aspect of compliance was not as big a deal to the CCO as, say, manufacturing compliance or government pricing,” says Eigner. “But now we’re finding that it has become the most significant part of the CCO role.”

Data from the PwC report Compliance in 2025 reveals that 84% of pharma companies now have a CCO, reporting directly to the CEO. PwC’s Sally Bernstein and Andrea Falcone picture the CCO as “the c-suite star of 2025;” by that time, they write, “the chief compliance officer will sit right at the very center of the seismic shifts reshaping business [and] will be a much closer confidant to the CEO, a permanent member of the leadership team, and a sought-out risk advisor when strategies are being set. Their voice will hold sway, and their wisdom will contribute to the resilience of the organization.”
That all sounds promising, but 2025 is still 10 years away; in the meantime, many compliance departments do still have mountains to climb—even the biggest of big Pharma is a long way from matching HSBC’s pledge for 3,000 compliance officers. Mid-sized Mundipharma, for example, has one full-time compliance officer and 11 part-time. But The Medicine Company’s Dovletian resists the urge to differentiate the compliance officer role based on the size of the organization. “We’re a company of approximately 700 people and we have the same kind of transactional complexity as you would in a large company,” she says.

From a compliance-solution vendor perspective, Eigner agrees: “You might think it is harder for a small company with a smaller budget to get a compliance system in place, but the reality is they have far fewer roadblocks.” Big companies may have larger budgets, but they also have “many more systems and many more people who have been used to doing things the same way for 30 years.” Consequently, explains Eigner, getting things done in a big company can involve a lot of politics.

Eigner notes how, in smaller companies, customer master systems and finance systems are often “in their infancy,” so getting the requirements embedded into these systems upfront can be easier. He points to venture capital-backed pre-approval companies “that are automating the entire end-to-end engagement process even before they have a product.” If you’re a specialty pharma company that wants to eventually be purchased, “the one thing that can thwart your chances is the threat of a $2 billion CIA or FCPA violation.”

For Dovletian, it is “a bit naïve to define the CCO job based on the size of the organization. Whether you have one transaction or 100, you still require competency to do it right.” Indeed, a big company could still be confined to one therapeutic area in one market and have a simple structure. But a smaller firm like The Medicines Company, Dovletian explains, is active in many different countries, many different therapeutics areas, and in different phases of development. Consequently, like the biggest pharma companies, it needs a compliance strategy that can be effectively rolled out globally.

**Is a global compliance strategy possible?**

With regulation of the disclosure of healthcare professional (HCP) spend an increasingly cross-border activity, the question remains of whether a global compliance strategy is really achievable, particularly in high-risk markets such as Syria, Yemen, or Russia, for example.

“It’s very hard to manage a customized approach to each country,” says Dovletian. “So templates should be standardized, and a code of conduct should apply consistently. You need to give people some predictability; if you want adherence to process it can’t be too disjointed.” Dovletian advocates the “grandmother test” as a “go-to test that can be applied consistently” across borders. Basically, you ask yourself the question: “How would I feel about a certain activity if
it was affecting my grandmother?” This “helps you think a little more carefully about the long-term impact of your activities,” she says. But, she adds, if there’s a will to circumvent, it will happen no matter how strict the rules are. “If your incentive structures reward behavior that encourages short cuts or is aggressive, you’re putting people in a day-to-day dilemma.”

The global-standard theory sounds sensible enough, but in practice there remain significant obstacles to streamlining compliance across borders. Europe alone presents enough challenges to keep compliance officers awake at night. Inconsistencies across the region in terms of definitions, templates, and, not least, languages and cultures, will make the integration of the new EFPIA code something of an ambitious task to say the least.

Central to how a European country responds to new disclosure requirements depends on its “historical baggage,” says David Eves. “If you look to Scandinavia and the Netherlands, those countries appear to be more OK with transparency, but elsewhere this can create a major concern at a personal level.” (The Netherlands’ national body, Nefarma, had set up its central database and published its first register by April 2013, more than three years ahead of the required EFPIA deadline). One senior UK compliance officer commented recently that Central and Eastern Europe (CEE) is the region that “makes me most nervous.” She added: “Everyone has a moral compass, but trying to get a message across to staff in CEE that something is wrong when they in fact believe it is OK would take a very long time. You have a brick wall to break through if they think it doesn’t affect them.”

The biggest challenge in Europe is having databases of physicians that are reliable and regularly updated. Where, in the US, “you did not tend to see redundant multiple systems within one company,” says Eigner, “in Europe it’s the norm for a company in one country to have, say, three to five financial systems.” He goes on: “I don’t think I’ve seen a single large company yet that has less than four or five customer masters within Europe.”

Even Western Europe’s heterogeneity and multilingualism can work against it. “Someone from Switzerland could be engaging with a French HCP and not realize it,” says Eigner. “The HCP might have a residence in Switzerland, and everyone is speaking French there, but he or she is a licensed French physician and subject to the demands of the Loi Bertrand (France’s “Sunshine” Act). This is something we’re going to start seeing in the next couple of years.”

All this, adds Eigner, is new territory, even for major pharma companies. “This is the first time you’re really seeing major companies moving to put a global transparency and global HCP engagement strategy in place,” he says. “Even though there might be a global policy in place, the specifics have not been standardized.” CCOs, then, have to ask themselves some questions: Are they solving a specific issue within compliance such as transparency? Or, for example, are they trying get HCO/HCP engagement standardized across the globe? The biggest challenge before formulating a global strategy, says Eigner, is addressing fundamental questions like these.
IT solutions

There is an increasing amount of software available to help companies streamline their payment-tracking processes, manage their sales forces, resolve their legal disputes, and adapt to new code provisions and updates across borders, but Dovletian says the question of what IT tools are available is just one aspect of the process. “There is a lot of software out there, but that’s not really the issue. The issue is: have you stepped back and looked at all the silos and at what your infrastructure looks like generally?” she says. “Do you have a common language for information to flow into your system? Have you identified and connected with all the areas that should be feeding into your systems?”

Certainly, good technology is welcome; the better the systems, the better they can be audited readily and easily. Again, though, smaller companies can face challenges when it comes to equipping staff with the latest IT solutions. Eves says it would be “nice if staff had the means to access guidance in a way that would support decision-making in real time (e.g., via a tablet app for staff in the field). Having access to all the necessary information means that we would be supporting staff at the time since training will not necessarily cover every situation. Compliance often exists within a grey zone where there is not a simple black and white that can be covered in training.”

At a technology-focused compliance event in 2014, one speaker—a vendor of IT solutions—pertinently reminded his audience that “IT solutions don’t solve cultural problems.” In Eigner’s experience, however, a way to make these solutions work across cultures is “to present them as tools to make the business process more efficient rather than specifically a ‘compliance tool.’” Then, he says, the level of acceptance is much higher, especially in countries that do not have direct transparency requirements.

Technology is all well and good, but it seems that time is a commodity that compliance officers need more of. Eves has faith in a patient, organic approach. He is confident that the EFPIA guidance on transparency and member state code changes are right and that, eventually, full disclosure will become the norm. “As an industry we need to work together to be sure there is consistency. The pick-up may be slow, but in time it will be accepted.”

The same can be said about the CCO in pharma. PwC’s State of Compliance Survey 2014 reminds us that the CCO role is only “roughly a decade old and has evolved rapidly.” If it takes another 10 years for the CCO to become, as PwC predicts, “the c-suite star of 2025,” it will still have been a fairly momentous rise to prominence, especially given the plodding pace at which pharma likes to advance. But, increasingly, as US healthcare lawyer Christopher Parrella wrote recently, “The chief compliance officer is viewed as the gatekeeper of a company’s reputation.” In this observation alone we can see the enormity—and importance—of the task ahead.

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The need to collaborate quickly and easily with colleagues and agencies to deliver compliant content to markets across the globe is more pressing than ever; and the explosion of digital and social media alongside the increasing globalization of campaigns is forcing pharmaceutical companies to be more agile and more responsive. Managing accuracy and compliance of content communicated to patients, stakeholders, and customers alike has become more complex. Promotional teams must work smarter and faster; having a software solution in place to facilitate gains at each step of the process cycle is absolutely paramount in driving quality, and realizing ROI in the embedded resources of the end product.

By implementing a totally integrated content compliance and digital asset management solution into marketing workflows, life sciences companies will maximize the time and resource embedded in marketing campaigns. This will facilitate the alignment of marketing with medical, legal, and regulatory (MLR) teams to deliver content to market quickly, accurately, and in a way that is easily transferable for reuse in multiple global geographies, each with unique compliance requirements.

Reaching audiences globally
As the potential audience and client base grows daily with technological advancement and the subsequent expansion of the connected landscape, companies must learn to adapt and effectively manage their digital programs to achieve global distribution. This is increasingly
important as the complexities and challenges of digital programs become an ever-more dominant aspect of the marketing mix, where marketers should embrace every tool available to deliver content to market in a compliant and time-efficient way.

In order to capitalize on this huge market potential, pharma marketers must learn new skills and adopt an alternative way of thinking in order to manage the three key challenges of the digital revolution: quality control in a global market, compliance accuracy, and delivery to market timeframes. Marketers can do this by raising the priority of an integrated digital strategy to the very core of their marketing and overall business objectives. Knowing the right tools and methods for communicating with new and wide audiences is not always straightforward given the plethora of multifaceted social and digital platforms that are emerging. It is such that the explosion in rich digital material and channels is now beginning to displace traditional marketing methodologies, such as face-to-face salesforce contact and print advertising, and is shifting the very way in which integrated sales and marketing campaigns are delivered.

This generality can be seen as a key challenge, and those leading the industry’s advancement into the digital world must learn to realign their perception and become “digitally native” if they are to fully capitalize on the benefits of today’s connected marketplace. To explain this more fully, it is perhaps best to compare against today’s generation, born in an era where digital and mobile technology are totally ingrained into the psyche, and the real and digital worlds are blurred as one and the same. It is simply part of life, rather than a new tool to be added into the mix.

The impact of this can be seen especially within the life sciences sector—an industry giant that has been slow to break the chains of tradition, and has been somewhat unwilling in its uptake of digital technology when compared against other core global market sectors. Yet the pharma giants of today have a very important role to play, and an even more important message to communicate, as the makers of the world’s drugs and medical products. The responsibility is on the sector to adapt quickly to the digital age and communicate as effectively with audiences about the drugs and healthcare products they are making for them.

This is why the role of the marketing teams within the life sciences industry is so dynamic and complex. Programs and campaigns are almost unrecognizable from those of a decade ago, and communications messages must be managed in a totally new way. The digital world demands that marketers learn to embrace a two-way dialogue with their clients, and talk directly with them via public platforms.

**Modern methods for managing the review of digital assets**

Digital content and its accuracy are now key priorities for life science companies. The digital content revolution combines with the increasing globalization of marketing campaigns to drive acceptance and uptake. This is embedded with the added pressure of regulatory compliance that looms constantly in the background of all marketing campaigns where accurate drug information is paramount.

Healthcare providers can only achieve compliance accuracy within an acceptable timeframe if they work to achieve end-to-end collaborative working during promotional content planning, review, and approval. If misaligned, time embedded in developing digital marketing materials can quickly
escalate to damaging levels, impacting both ROI and the overall content quality.

By using a content compliance system, every interaction with an item—including user, actions, comments, and versions—is automatically recorded and available to view at any time. This visibility helps to promote efficiency throughout the internal documentation review process, and will assist teams in easily tracking documents throughout the review process while viewing all user actions, comments, and item versions. The time saved in delivering these applications through review and approval in an efficient manner will deliver ROI for any company, and allow the marketing team to focus on results and real patient healthcare outcomes.

To that end, a content compliance and digital asset management software solution can assist in realizing greater collaboration between a marketing taskforce, by providing a secure access platform that allows team members to communicate openly about compliance objectives and concerns. Through improved clarity and open dialogue, any comments can be addressed and a resolution found in a timely fashion.

Campaign planning is equally impacted by collaboration, and through the use of this type of software, teams located around the world are presented with a single access point where timelines can be created and campaign planning materials can be written, collated, and saved for all to see. It is this unified platform that will allow a taskforce to collaborate effectively despite location, and work efficiently within the same arena.

User profiles can be created and assigned to set jobs, so that each team member can plan their workload, but, more importantly, colleagues can see the demands on the combined resource and plan around potential bottlenecks in the delivery program. This is essential in resource assignment and overall workload planning against objectives and deadlines.

**Dynamic content review**

Dynamic content is becoming the lifeblood of modern marketing—with content types such as HTML5, video, images, website content, app, and social media materials all becoming more common and immediate. Having the essential tools in place to efficiently manage this kind of client-facing promotional asset through review and approval is paramount.

Whereas traditionally marketers will have used screen grabs or static image files to comment on dynamic content, today’s compliance software platforms allow for marketers to upload packaged files containing live video or web platforms that MLR reviewers can then review in a familiar and functional interface. This review suite will allow users to comment against readily available guidance documents, leaving comments and notation where required for the development team to pick up. This kind of functionality allows for smooth review transition of working digital assets, given that total clarity is provided for all team members to see and quickly pick up on.

The added value can be found post-storyboarding and development; the final asset can be reviewed in its entirety and commented on with clarity. Users will then be able to access and download comment summary reports from the route map audit trail, to be satisfied that all pages and issues have been addressed fully by the MLR review team. These will detail all of the comments that will have been made on the asset in question, for total clarity and collaborative working.
**Video uploading and transcoding**

Video content is emerging into the marketing environment at a rapid pace, as the shift from written content towards visuals and interactives becomes more prominent. Therefore, the range of video formats that marketers are dealing with has widened, now often including everything from MP4, WMV, AVI, MKV, MPG, MPEG, FLV, and MOV.

For marketing and MLR teams, it is important to transcode all these common formats into an easily reviewable and compressed format—leading to swift review times. Reviewers will then be able make video review processes smooth and efficient, and will be able to add comments at any point during the video. When doing so, the video will pause, also leaving a time stamp in the timeline bar to show the rest of the review team the precise point at which a comment has been made. These can then be navigated and addressed at a later stage.

By streamlining video formatting and working to a single method each time, video review and approval will quickly become a smooth and routine part of the marketing lifecycle rather than a pain-point.

**E-certification**

Although content accuracy is the central objective, a key concern during review and approval is to have certification signed and stamped in the fastest possible timeframe, reducing time and resource embedded in the job. When dealing with digital assets, a digital asset management system can help to combine content in review with easy access to the required e-certificate, so reviewers can jump to check for requirements and add signatures when a section of the review has been completed.

Modern software platforms can streamline this process for improved user experience, adding simplicity to the overall digital asset management process.

**Benchmarking**

An efficient way of measuring improvement in project delivery is by implementing a system of benchmarking against a number of key performance indicators (KPIs). These metrics can be monitored over time, so teams can measure the impact of their learnings from previous work.

At project conception stages, it is crucial that all parties share and understand business priorities and work with each other to establish KPIs for delivery, as well as review and approval timeframes.

Project status data should be collated and measured at defined intervals, where the team is actively engaged with finding areas for improvement, and where they arise, conducting a deep-dive analysis to look into better process efficiency.

Marketers should, therefore, focus their benchmarking on a number of key areas. The first is the time it commonly takes to develop, review, approve and deliver a document to market. An established baseline here will give specific improvement targets for future work. Secondly, the number of iterations it takes to push the document through this process. Even if a job moves quickly but takes multiple rounds of review and approval, the embedded cost and resource it takes to deliver the material is increased. Lastly, evaluating global re-use capability can uncover potential for cost savings with recreation and agency spend.
Ideally, companies should not just seek to reduce cycle time, but also reduce the number of cycles that content undergoes before delivery to market. Finally, companies should aim to measure the percentage of sharing, from region to region and across departments, repurposing content where possible and, therefore, making savings when volume of sharing is higher.

The value of using benchmarking is that it facilitates more informed analysis of the effectiveness of the team, giving vital insights into ROI and, where required, areas for making improvements in delivery timeframes. By deploying compliance software systems, it is possible to access this data automatically from within the system, allowing users to track data anonymously against industry standards to provide a best practice benchmark.

Future alignment is critical
The relevance of digital marketing is only set to grow. The potential benefits of rich digital content and social media are enormous—empowering patients to take control of the treatment of their disease, enabling the pharmaceutical and healthcare industries to have direct relationships with their customer, and ultimately improving health outcomes.

It is clear that companies need to ensure they make big gains in their use of digital positioning to maximize their outreach and engagement programs by delivering material consistently across multiple channels while staying within regulatory guidelines. With this, comes the need to navigate the complexities of digital materials and communication, including more complex planning, content, and accelerated approvals.

Through building a greater understanding of the digital environment, application areas, and the marketplace, companies can put in place the systems necessary for aligning digital marketing with their overarching business objectives and begin to deliver appropriate, modern communications to their audiences via greater processes efficiency.

Cloud software systems that incorporate digital asset management solutions provide a step change in digital pharmaceutical marketing. They offer the marketer a method to simplify and accelerate critical time-to-market processes, comply with regulation, improve productivity and efficiency, and ultimately be more creative in their marketing strategies.

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European pharma is bracing itself for EFPIA’s June deadline requiring the disclosure of transfer-of-value transactions to HCPs. "Pharm Exec looks at how the industry is preparing for this historic moment.

BY JULIAN UPTON

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 healthcare professional (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 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.”

**Fast Focus**

» With the EFPIA Disclosure Code set to take effect at the end of June, a pan-European survey conducted late last year found that 73% of life science companies did not have the data to successfully manage healthcare professional (HCP) activity across borders. Many companies, however, are implementing “temporary solutions” to meet the reporting deadline, according to executives.

» Experts believe Europe’s new system for analyzing HCP payment data, at least for the short term, will take a page from the US’s “Sunshine” Act. Critical to this shift toward transparency will be establishing a wider public understanding of industry–HCP relationships.

» As the landmark transparency initiative steadily takes shape in Europe over time, it will be important for companies—even though projects may be owned by compliance teams—to ensure they have the support and incorporation of different business units within the organization.
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 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. (See page 34 for more of Pharm Exec’s interview with Sophie Peresson.)

**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,
Transparency International: Rooting Out Pharma Corruption

Pharm Exec spoke to Sophie Peresson, Director of Transparency International’s (TI) Pharmaceuticals & Healthcare Program.

PE: What led Transparency International to make the decision to look at the pharma industry?

SOPHIE PERESSON (SP): Seventeen percent of people worldwide stated they had paid a bribe when dealing with the medical sector in a global survey of 114,000 citizens in 2013, and 45% believed medical and health services to be corrupt or extremely corrupt. Other surveys, such as Transparency International’s Bribe Payers Index, reinforce this finding.

With global spending on health of around US$7 trillion annually, the size of funds flowing through the healthcare sector makes it a lucrative and attractive target for corruption. Estimates of global health public procurement funds lost to corruption range from 10% to 25%. Yet if only 1% of global health spending were lost to corruption, representing US$70 billion, and it was put back into healthcare, this would be US$10 billion more than the sum that would have been needed to achieve the Millennium Development Goals on health.

The pharmaceutical industry has a responsibility to be transparent and accountable and to reduce its role in corruption, thereby increasing health equity.

The purpose of TI’s Pharmaceuticals & Healthcare Program is to achieve genuine change in the pharmaceutical and healthcare sector through reducing corruption and promoting transparency, integrity, and accountability. We will apply TI’s strengths and expertise to contribute to the program’s overall goal of improving global health and healthcare outcomes for the benefit of all people of all ages.

PE: What is the expected timeline for the program? What is to be looked at first?

SP: This will be a long-term project of course; fighting corruption involves both changes in policies but also attitudes. We estimate that we will need at least 10 years to make an impact. We are currently developing the strategy and anticipate that it will be ready in the second half of 2016.

We are aiming for both a long and short-term impact 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.

PE: What stood out from the pilot project as areas of particular interest?

SP: The sector is under served by anti-corruption programming as a whole. There are pockets of good work; however, the response is hugely disproportionate to the threat. It is clear that the problem in the health sector needs a holistic approach driven by multi-stakeholder groups operating at various levels. This includes the private sector, which is so integral to the health systems. Real change will only be achieved if the private sector is prepared to be bold, commit to change, and take a leading role.

There is also a lack of clarity in policy. The regulatory and legislative frameworks at national, regional and global levels are unclear and too often legislation is poorly enforced.

Two areas of the value chain that stood out were procurement and service delivery. Procurement due to the size and number of transactions that happen within health systems, and service delivery because of its direct impact on the individual, often the most vulnerable in society.

PE: What will the geographical focus be in the early stages of the investigations?

SP: The program is a global one but there are regional projects that have been launched (e.g., in Latin America). Moreover, the Health Action Fund (HAF) is helping to support several national initiatives led by TI chapters. The HAF will allow disbursal of grants to TI national chapters from anywhere in the network to fund activities, in whole or in part, that are contributing towards TI’s goals.

PE: Is the global shift to further transparency and — e.g., the US “Sunshine” Act — likely to make TI’s work easier?

SP: Arguably, this can provide a benchmark to measure performance against, but compliance is box-ticking and thus it is essential to ensure that implementation really happens.

Large parts of the world are not covered by compliance legislation and, therefore, face a higher risk of corruption vulnerabilities. Our research has shown that industry works on a self-regulation model, and is quite closed with regards to compliance in, for example, Africa, China, India. These are large markets and corruption here hurts the vulnerable the most.

PE: How does TI plan to work with the industry on finding and combatting corruption?

SP: We have been successful in developing a very good relationship with many industry players and we hope to continue doing so. Asking industry to see the need to combat corruption as going hand-in-hand with their other corporate social responsibility initiatives. It is in their interests to strengthen health systems to make sure the right treatment reaches the right patient at the right price. It’s a chance for the industry to repair its reputational damage and build trust within the patient community again.

In 2016, the program plans to start work on a global Companies Index for the pharmaceuticals and healthcare sector. There is a growing body of indices that seek to evaluate company good performance against, but compliance is box-ticking and thus it is essential to ensure that implementation really happens.

TI produces a number of indices that focus on the private sector, such as the Defence Companies Anti-Corruption Index. These indices involve the assessment of a range of major international companies using well-developed methodologies. TI aims to persuade local, international, and global companies working within the health sector to provide medicines, equipment, and services in a transparent and accountable way so to improve health outcomes.

— Julian Upton
THE ULTIMATE GOAL OF THE TI INVESTIGATION IS TO PROVIDE THE INDUSTRY WITH "A CHANCE TO REPAIR ITS REPUTATIONAL DAMAGE."

“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 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 Powie-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.”

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