



**Global HCP
Transparency Study**
Regulatory disclosure
challenges and program
guidance for life
sciences companies

Overview

Deloitte has executed a Global HCP Transparency Study to provide insights into countries' current and anticipated regulatory requirements for tracking payments and transfers of value that life sciences companies make to health care professionals and organizations (HCP/O).

While U.S. pharmaceutical manufacturers have been dealing with the federal Sunshine Act and state-level transparency laws for some time, new and pending legislation such as France's disclosure law, *Loi relative au renforcement de la sécurité sanitaire du médicament et des produits de santé*, which was passed in December 2011, and the European Federation of Pharmaceutical Industries and Associations' (EFPIA) draft Code on Disclosure of Transfers of Value from Pharmaceutical Companies to HCP and HCO, which is scheduled to go into effect in 2014, are the latest in a series of transparency-related legislation and industry codes being instituted around the globe (Figure 1). In fact, we estimate that over 70% of pharmaceutical sales will occur in countries which have HCP Transparency regulations in place by 2015. (Figure 2)



Figure 1: Global transparency laws

This table summarizes the fundamental elements of a number of existing and/or proposed regulations requiring the disclosure of payments to health care providers and organizations.

Jurisdiction	Regulatory body	Law/industry code	Timing	Scope — HCP/OS	Scope — transactions	Threshold/unique ID
US	US government	Law	Anticipated start January 2013	Physicians and teaching hospitals	All payments or value exchanges, with some exceptions	NPI for each HCP/O \$100 threshold
U.K.	PMCPA/ABPI code	Industry code	Payments made in 2012	HCPs — MD, DDS, pharmacists, nurses, admin staff HCO — Medical assoc., patient orgs, hospitals, trusts, group practices	HCOs — Granular payments HCPs — Aggregate payments	None specified
France	French government	Law	Subject to government decree being adopted, latest December 2012	Broad definition including physicians, hospitals, students, software developers, media, etc.	All “advantages;” no exclusions	Threshold under discussion. RPPS is unique HCP/O ID
Slovakia	NCHI & MOH	Law	December 2012		Expenditures on marketing & benefits granted to HCPs	None specified
Netherlands		Industry code	January 2012	Not defined	HCP granular payments, meals, etc., excluding R&D	Threshold €500/yr
Japan	JPMA (pharma) JFMDA (device)	Industry code	JPMA — collection 2012 JFMDA — collection 2013	Broad definition including physicians, hospitals, hospital employees, patient groups, group practices, etc.	R&D expenses, grants, conference expenses, consulting arrangements, hospitality	None specified
Europe	EFPIA	Industry code	Anticipated start January 2015	Individuals (HCP) and organizations (HCP companies and organizations)	R&D-related transfers of value; donations & grants; sponsorship, events and hospitalities (excluding trivial transfers below threshold); fees for service & consultancy	Threshold under discussion
Australia	Medicines Australia (MA)	Industry code	First disclosure in June 2013	Member of a medical, dental, pharmacy or nursing profession and any other person who may prescribe, supply, or administer a prescription medicine	Consulting, speaking, sponsorships, hospitality, grants to patient groups	None specified

Note: Only countries with payment disclosure requirements are listed. Many other countries have restrictions on payments and value exchanges which can be made and others have rules relating to conference sponsorships but these countries do not have disclosure requirements and are, therefore, not listed in the table.

Sources:

[UK] <http://www.abpi.org.uk/our-work/library/guidelines/Pages/code-2012.aspx>

[France] <http://www.sante.gouv.fr/transparence-en-matiere-de-promotion-des-produits-de-sante-sunshine-act.html>

[Japan] http://www.jpma.or.jp/english/parj/pdf/2012_ch02.pdf

[EFPIA] <http://www.efpia.eu/>

[Australia] <http://www.fs-arzneimittelindustrie.de/schiedsstelle/verfahrensordnung/>

The proliferation of these regulations is prompting life sciences companies to consider important questions, such as:

- Will more laws/regulations be passed? Where? When?
- How should we address the new laws? Should we implement a global solution, or should each country's offices manage efforts locally?
- How much can we leverage the systems and data investments we have made in the U.S. and other countries to develop global capabilities?
- What controls should we put in place to make certain that the data we are collecting is complete and accurate?
- Who in our organization should own this responsibility?
- What are other organizations doing?

To help answer these questions, Deloitte conducted primary research on the current state of HCP/O transparency regulations and guidelines and conducted interviews in June 2012 with the Chief Compliance Officer or the lead for global HCP transparency at a dozen large and medium size life science companies. (Interview data was "blinded" and aggregated.) Data from these

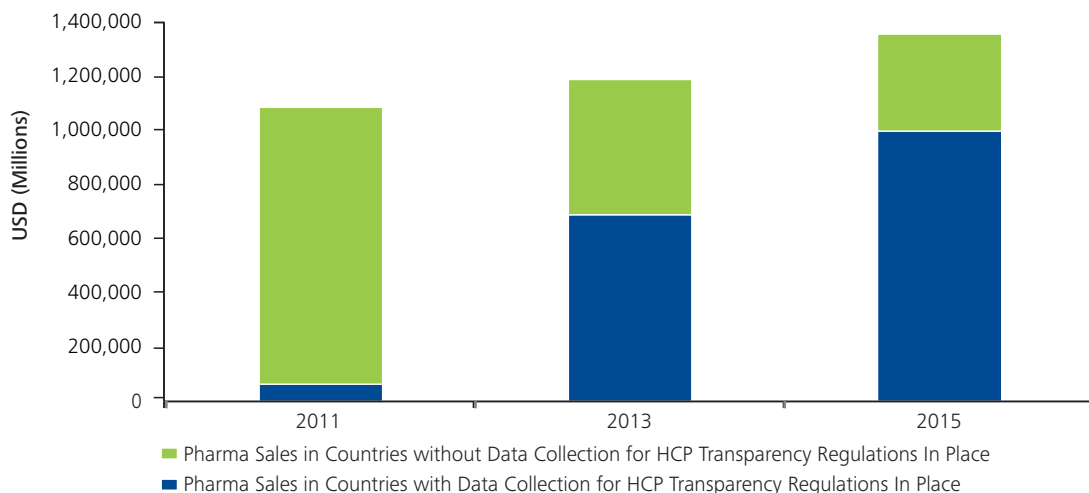
interviews was combined with the primary research and additional insights gained by our field work on similar global initiatives.

This report summarizes our findings and provides guidance for life sciences companies on how to address global HCP transparency challenges.

One of the important observations is there is a great deal of redundancy in the data, IT capabilities and processes required to meet the disclosure requirements by each country with applicable regulations. This redundancy has led many companies to begin development or consider future development of a center of excellence with shared capabilities to service several or all countries with HCP Transparency requirements within a company.

We believe there might be a further opportunity to coordinate across the industry to develop data, IT capabilities and operations which can be shared by multiple companies. Several of our survey respondents noted that HCP Transparency is a good opportunity for sharing capabilities across the industry and might be a good candidate for an industry consortium.

Figure 2:
By 2015, over 70% of pharmaceutical sales will occur in countries with HCP Transparency regulations



Source: 2012 The Economist Intelligence Unit.
 2011: US States only: CA, MA, MN, WV, VT
 2013: Japan, UK, France, Australia, Croatia, Slovakia, US (anticipated), France (anticipated)
 2015: 2013 countries plus EFPIA (anticipated)

Background

Beginning with the enactment of U.S. state legislation in the mid-2000s, government and industry transparency regulations have spread to countries around the globe. While each market's set of regulations is different and contains nuances of which life sciences companies should be aware and work with local legal teams to understand, there are significant similarities that span countries and should provide a measure of reassurance that the task of compliance is not insurmountable if companies develop a methodical, coordinated, approach:

Similarities	Nuances
<ul style="list-style-type: none">• Data elements — The overlap in required data for the various regulations is significant, which lends itself to standardized data capture from each market.• Interaction types — Many of the regulations require reporting commercial and educational activities such as speaking, consulting, hospitality, gifts, sponsorships, etc.• Granularity — Providing itemized lists of transactions by date is common across virtually all of the regulations.• Frequency — Many reports must be posted or submitted on an annual basis.• Technology components — The technology needed to develop reporting is consistent across current requirements and with technology typically existing in organizations today.• Fundamental capabilities — The business, legal, and technology capabilities are fundamentally consistent across country requirements.	<ul style="list-style-type: none">• HCP/O Definition — The type of vendors and customers that are required to be tracked are typically the same (e.g., doctors, dentists, pharmacists, etc.) but there are some differences; for example, in some countries, students and/or nurses must be tracked. There are also differences in the types of HCOs that should be tracked.• Exclusions — Each regulation tends to provide its own list of activities or amounts that need not be disclosed; for example, discounts, specific types of loans, amounts under a certain threshold (e.g., France - €10).• Cross-border — Regulations differ as to whether transactions should be disclosed based on the HCP/O's country or the country which initiates the value transfer. Currently, the trend is for transactions to be disclosed for an HCP/O, no matter where they originated.

In general, the data required for disclosure is fairly straightforward and similar across countries' regulations. Our study and field experience suggest that creating a standard core model for all countries (Figure 2) would likely provide benefits to both local and global compliance teams.

Our experience: Number of Data Elements required for Global HCP Transparency reporting is small

The data set necessary to support the current HCP transparency reporting requirements is relatively small. In fact, our analysis of the reporting requirements indicates that the collection and management of 10 data profile elements related to HCP spend transactions is what is needed to meet current regulations.

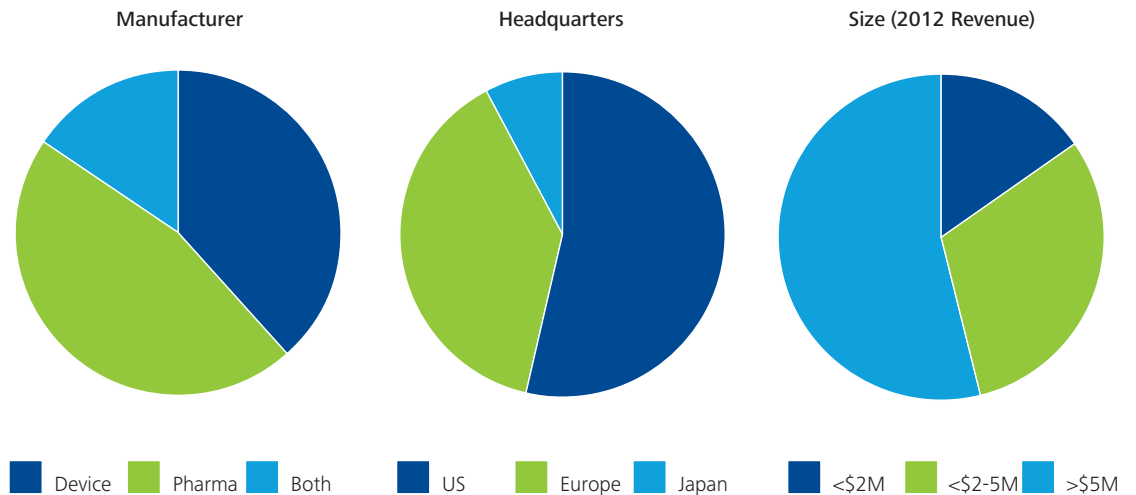


Methodology

Deloitte conducted interviews in April - June 2012 with the Chief Compliance Officer or the Global Compliance Lead at a dozen large and medium-size life science companies. (Interview data was “blinded” and aggregated.)

The participating companies, profiled in Figure 3, provided responses to this benchmark study’s questions and feedback on additional questions to ask in subsequent editions of the study.

Figure 4
HCP/O transparency study participants



In addition to conducting interviews, we conducted a review of HCP Transparency projects Deloitte has been involved in during the past 5 years. These projects included strategy assessments, compliance audits, process design projects and system implementations. We combined data from these interviews with additional insights gained through our work on similar global initiatives to generate the following findings and observations.

Study objective and findings

The objective of Deloitte's benchmark study of global HCP/O transparency is to provide insights that life sciences companies can use to make smart decisions about the direction of their HCP/O transparency programs. The study offers an analysis of the current issues that companies are facing as well as pragmatic approaches to addressing those issues.

This study addresses three considerations facing life sciences executives:

1. **Does a global HCP/O transparency program make sense?** As is the case with many of these types of questions, "It depends ..."
2. **What is the preferred implementation approach?** If a centralized, global capability is the selected option, what is the preferred path to implementation and how much is the project going to cost?
3. **Who should lead this effort?** What organization(s) and function(s) should be responsible for implementation, roll-out and ongoing operations?

Among the study's specific findings:

- The number of regulations for HCP/O transparency is growing and coverage is expanding into some of the world's largest markets. However, there are similarities among existing and proposed regulations that support centralizing a company's response capabilities and programs.
- The applicability of a global, centralized HCP/O transparency service — including policy, process, and solution components — depends on company factors such as risk tolerance, cost avoidance, and maturity of local processes and controls.
- Any global solution requires an upfront investment of defining global data standards and the governance for the standards. Even though there may be a limited number of data attributes to consider, stakeholders from across the globe need to be involved in defining the standards and in participating in ongoing governance activities.
- Change management is critical to the effective implementation of this type of project given the breadth and variety of stakeholders impacted by policy, process, and solution changes at both the local and global levels.
- Defining project ownership, governance, and ongoing operations can be a challenge for organizations given the complexity and scope of these requirements. Therefore, governance is a critical factor; steps should be undertaken early to align stakeholders around accountability and responsibility for specific activities.

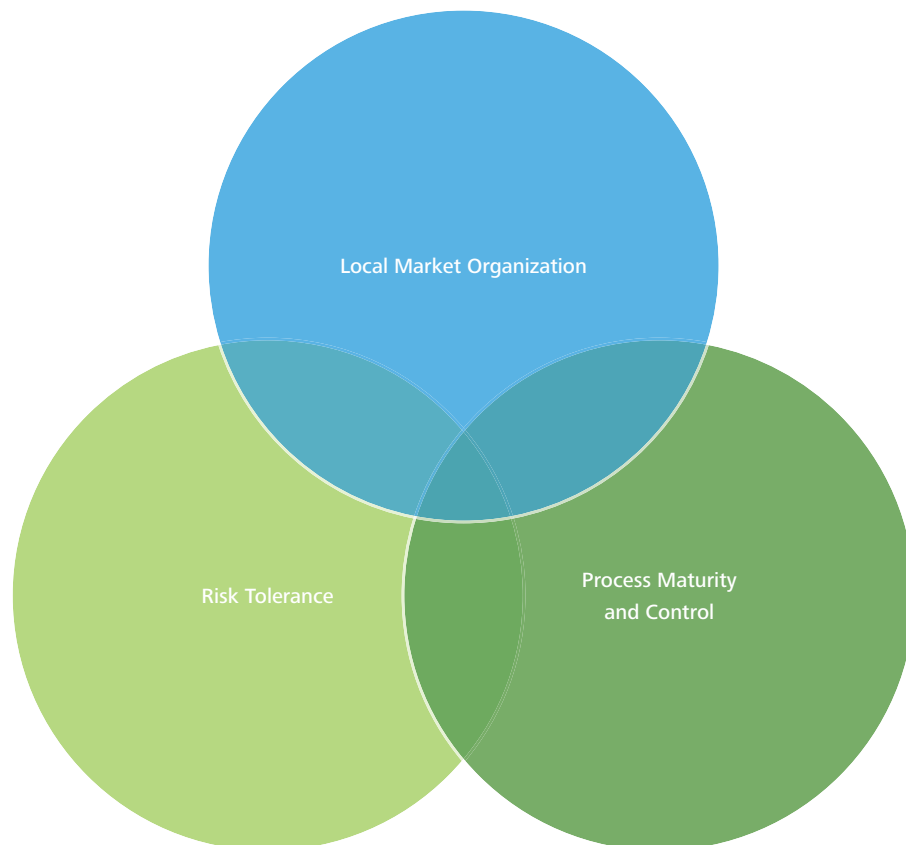
Life sciences companies should address transparency requirements in a prompt yet methodical manner. Data commonality offers a strong argument for centralizing systems and services to achieve improved quality, lower costs, and more efficient operations. However, companies also should recognize each country's different compliance needs and the importance of driving accountability to the right stakeholders in the organization; therefore, a mix of global and local capabilities and governance may be the preferred solution.

A global program: Does it really make sense?

As mentioned earlier, the number of regulations that require detailed disclosure of payments and transfers of value to HCPs and HCOs is increasing across the globe. The positive news is that different countries' regulations tend to be quite similar in their structure and requirements; life sciences companies, therefore, may only need to deal with "nuances" in the regulations rather than completely disparate rules. Even given these similarities, however, it is important for companies to carefully consider the question, "Does it really make sense to implement a global HCP/O transparency program when dealing with country-specific regulations?" In our recommendation, the answer to this question depends on three factors that drive a company's vision for global HCP/O transparency (Figure 4):

1. The relative autonomy of the company's operations in the markets where transparency is required, which may increase redundancy and, therefore, the cost of disparate solutions
2. Risk tolerance of the global organization to the potential negative impacts of data that is not perceived as being accurate and complete
3. Maturity level and control of the end-to-end process of HCP engagement that is required in each market based on a current-state assessment.

Figure 5
Driving factors for global HCP/O transparency vision

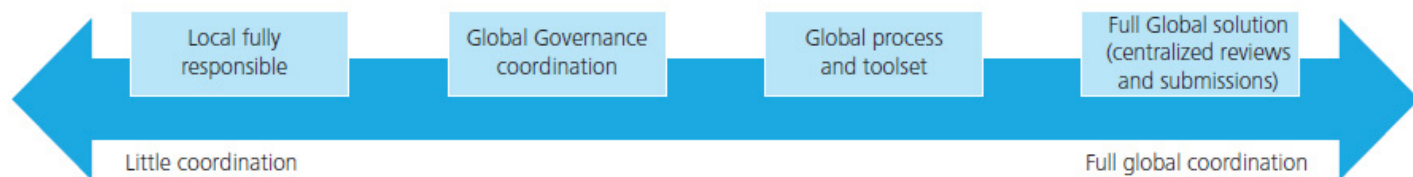


What are the alternatives?

Depending on a particular company's vision for global HCP/O transparency, the future state (e.g., in three years) program alternatives can be visualized along a continuum of organizational coordination in responding to transparency — from "Local Fully Responsible" to "Full Global Solution" (Figure 5):

- Local Fully Responsible — Assumes that it is each market's responsibility to react to transparency regulations. The global organization does not need to be aware of submissions' status or quality; also, redundancy of efforts and additional costs in each market are not a concern.
- Global Governance Coordination — Assumes that there is a benefit to the global organization providing oversight into process changes, communications, quality, and status of submissions; however, assigning a resource or a small team from the global organization is sufficient. Redundancy of efforts and additional costs in each market are not a concern.
- Global Process and Toolset — Assumes that there are cost savings and risk-reduction benefits in standardizing processes, and in providing a set of software tools (e.g., reporting database, repository of HCP/O profile information, data monitoring routines) which can be leveraged (perhaps as a service) by all countries with reporting requirements.
- Full Global Solution — Assumes a central group has a mandate to collect, aggregate, and report on HCP interactions in all countries where regulations exist.

Figure 6
Global HCP/O transparency continuum

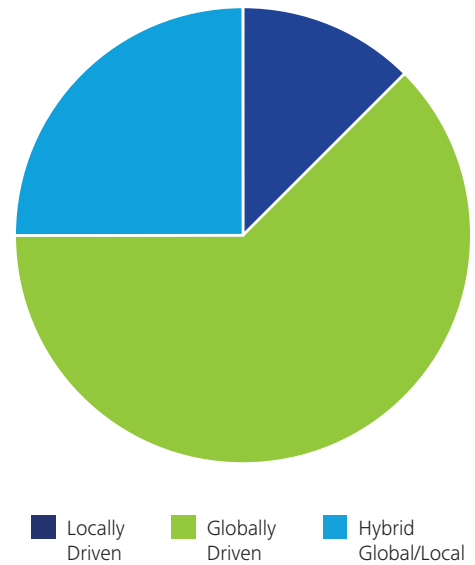


What is driving companies' choice of implementation options?

According to the HCP/O transparency study results, most life sciences companies are considering global implementation options (Figure 6). What is driving companies' choice of approach? The most common driver that study participants cited was government fines, despite the fact that the United States and France are the only countries that have specified the potential for fines. Brand/reputational harm was the second most common driver that participants mentioned. Interestingly, business transparency, which was cited as a longer-term benefit, was not identified as a driver for implementation efforts at this time.

Of the surveyed companies moving forward with global initiatives, current status ranges from assessing whether or not a global solution is feasible; to initiating either policy or process changes; to initiating solution implementation (Figure 7).

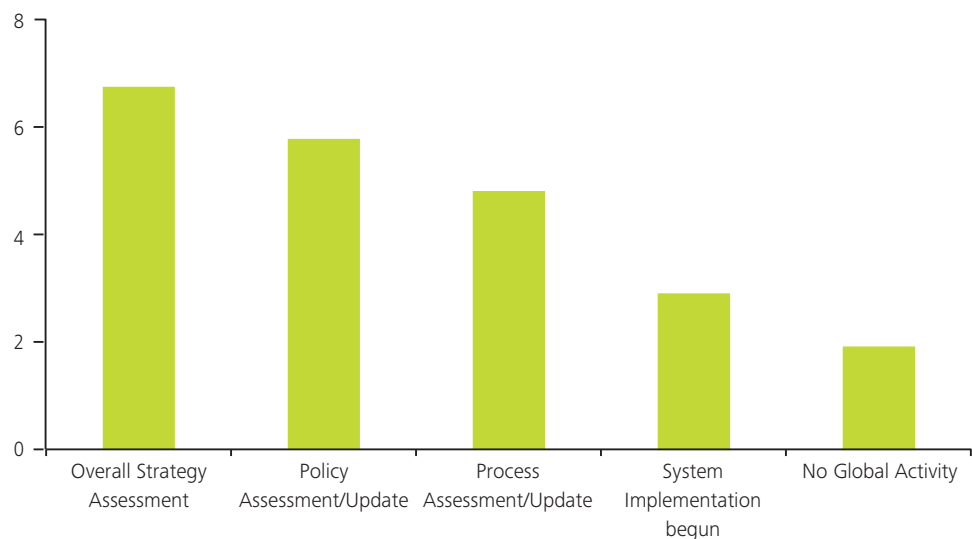
Figure 7
Implementation options



Our Experience: Over time HCP Spend data often begins to provide value beyond regulatory reporting

As the process of aggregating and internally reviewing data matures, the issues of reputational harm and business transparency often begin to drive collaboration and solution coordination. That is, once internal stakeholders and leaders begin to truly see the data in internal reporting systems or pilots, the level of insight and reputational obligation often becomes a more distinct driver for the broader solution.

Figure 8
Current global initiatives



Global approach is often a sound option

Based on the study results and the potential operational efficiencies and cost savings that may be realized, implementing a global approach to HCP/O transparency is often a sound option. This approach may help life sciences companies manage current U.S. “Sunshine” legislation and accelerate their ability to respond to potential future global regulations.

In our opinion, one of the most important benefits of a global approach is that it may help a company avoid increased operational overhead that results from a decentralized program’s redundancies and lack of information sharing among countries/affiliates. In addition, a global approach encourages collaboration and the leveraging of business intelligence across divisions, functions, and countries in the pursuit of shared compliance goals (Figure 8).

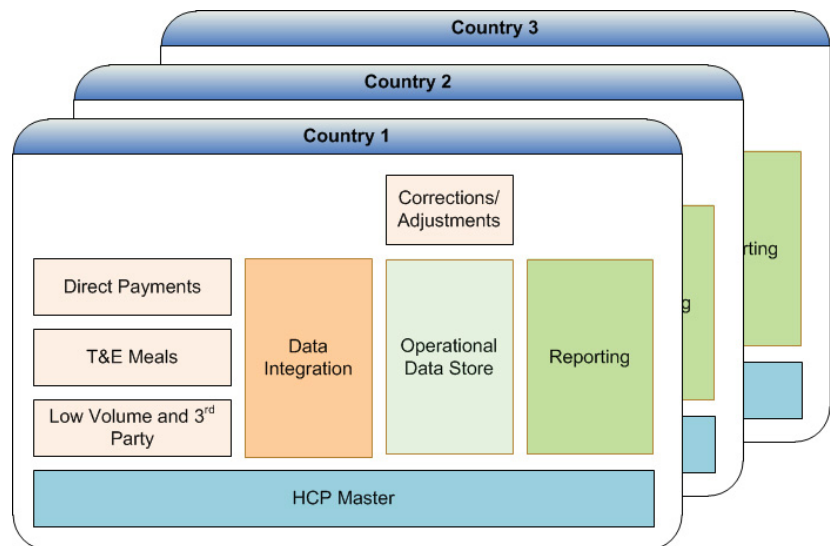
Our Experience: HCP Transparency capabilities are redundant and there is an opportunity to “build once and use multiple times” across countries, divisions or even companies

Not only are individual companies creating systems and processes that are redundant across countries and divisions/business units, the systems and processes being created across companies are often highly redundant. There is an opportunity for companies to work together — perhaps under an industry consortium — to develop systems, processes, data, and services which can be shared by multiple organizations. Many compliance executives we have spoken to do not feel that base HCP transparency capabilities are sources of competitive advantage, so cross-industry collaboration might be an attractive alternative to individual companies developing their capabilities.

Our Experience: Not all operational activities can or should be centralized

If a global approach is selected, it is not necessary or advisable to centralize all operational activities; rather companies should identify those activities and functions which should be managed at an enterprise-wide level as well as those which should be managed locally. For example, program management, enterprise policy definition, and data standards may be more effective if managed centrally, while legal interpretation, HCP payments, and meeting management and customer support may require local management and maintenance.

Figure 9:
Redundancies in Systems and Processes



Smart first steps

Once a life sciences company has decided that a centralized, global capability for HCP/O transparency is the preferred approach and that the long-term vision includes both disclosure reporting and HCP/O interaction management, Deloitte suggests the following smart first steps to implement this vision.

Our Experience: HCP/O Master data management is a challenge and some aspects of managed centrally over time

Although study respondents did not rank “managing accurate HCP/O lists” as a high-priority challenge, we have found that master data management for HCP/Os is a challenge. Many business units in many countries have some type of HCP/O list in their customer relationship management (CRM) solution but few have a central list which is used by all systems where HCP interactions are tracked (e.g., meeting management tools, vendor master lists in ERP systems, etc.).

It is important to have a centrally stored list of HCP/Os to properly aggregate HCP spend and meet the reporting requirements of each country. However, it is not necessary or even recommended to manage the HCP master centrally, at least in the immediate term. HCP master data management is more effectively left to local country resources because they have enhanced knowledge of the HCP’s attributes; in addition, HCP master data is used by local offices for purposes other than HCP transparency reporting. It is feasible to begin considering how and where it might make sense to leverage a central HCP repository, but as a starting point, this scope will likely pose considerable risk to completing required reporting in a timely manner.

1. Obtain team alignment on answers to questions such as:

- To which portions of the end-to-end process of interacting with an HCP or HCO do we want to add or improve controls to facilitate improved HCP/O transparency? These could include...
 - Identification and selection of HCP/Os
 - Approval to interact based on the company’s Code of Conduct or promotional policies
 - On-boarding/due diligence of the HCP or HCO as Key Opinion Leader (KOL) or vendor or when hiring third parties
 - Expense, invoice, or payment processing for HCP/Os
 - HCP master data enrichment and cleansing
 - Dispute management
- Do we already have a stable platform that addresses HCP/O disclosure requirements, perhaps from our U.S. experience? Do we have a standard platform for Business Process Management or externally available web portals that we can or should leverage?
- Have we properly prioritized our Year 1, Year 2, and Year 3 activities and deployment by those countries most in need, including identifying a proper pilot?
- Do we deeply understand the nuances of local processes so that global standards do not place an onerous burden on local operational teams?
- Have we developed a clear, direct communications and training plan for each of the impacted stakeholders, including local commercial operations, local finance, local sourcing, local legal/compliance, and (as applicable) global compliance and finance teams?
- Have we prioritized capabilities needed for a global system, taking into account which capabilities are needed for high-priority countries?

2. Identify potential challenges

Study participants were asked to rank the challenges to achieving their vision of global HCP/O transparency. The results show that over 50 percent of respondents believe that “Driving Adoption and Change in the Business” and “Collecting Data from 3rd parties” will be the primary challenges to achieving their goals (Figure 9). The lowest-ranked response was “Maintaining HCP/O lists.” These challenges suggest that the HCP/O transparency plan, from inception, should include strong change management leadership to target the right audiences in the right ways and at the right times.

3. Consider and plan program elements

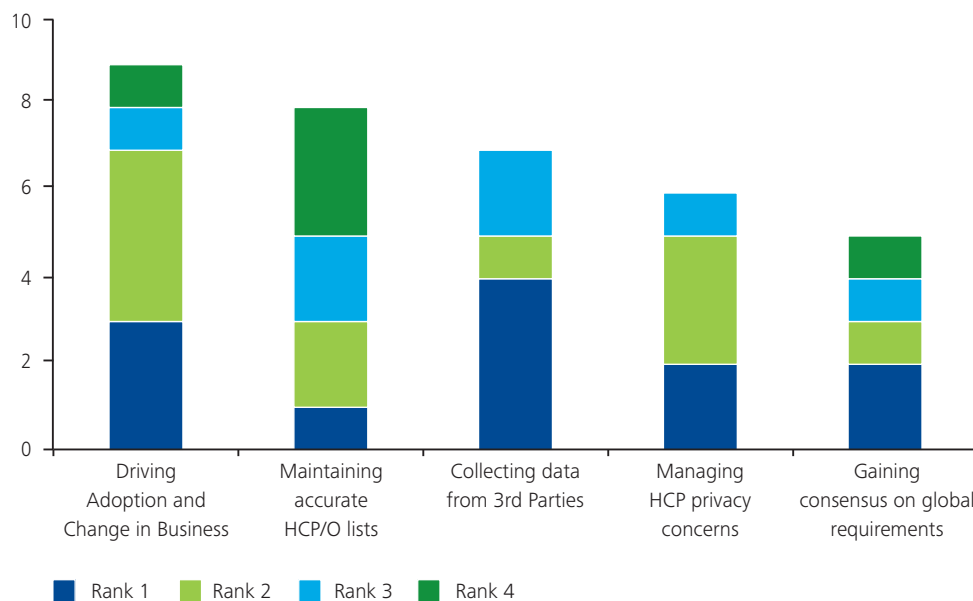
Once the project team is aligned around providing a centralized capability, it needs to develop a roadmap for implementation. In our conversation with survey participants we learned that many companies are taking a programmatic approach to capability roll-out, i.e., the first countries targeted for a rollout are the countries with regulations already in place followed by the countries with regulation planned or pending.

Another consideration is where a local country office or affiliate already has a solution in place. Some survey respondents noted that the initial focus was on countries which had regulations but did not have an acceptable solution in place.

Our Experience: Costs of developing HCP Transparency solutions could cost \$10-15 million to operate in large life science companies

Although many of the study participants said they believe that implementing a solution will cost less than \$5 million, our experience shows that, depending on the size of the organization, implementation costs can be as high as \$10-15 million over a two-to-three year period. Although the cost to implement a central capability for HCP transparency may seem high, it may not be when compared to the cost of implementing individual systems in individual countries. As noted earlier in this paper, the systems, processes, capabilities, and services required to meet HCP transparency are often highly redundant across countries; therefore, there is an opportunity to “build once and use multiple times.”

Figure 10
Challenges to success



4. Allocate and monitor budget

A large majority of study participants stated that they plan to spend between \$1 million and \$5 million to develop the policies, processes, and tools required to address global disclosure regulations (Figure 11). Respondents also indicated that a majority of this budget would be allocated to IT capital investments and consulting support for policy, process, and system integration efforts. Generally, many companies do not fully consider all the potential costs of such a comprehensive program, so continually monitoring expenditures against plans is an important function for the project team.

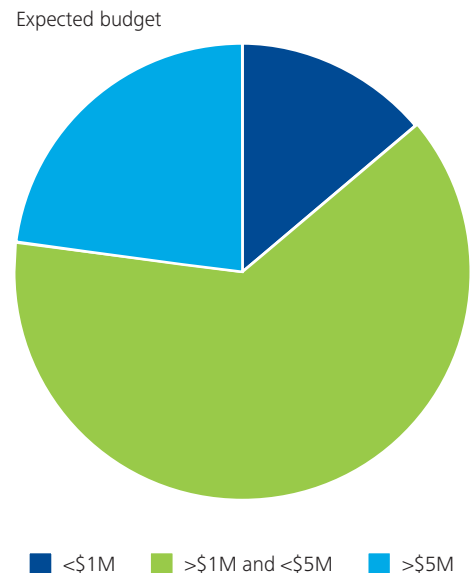
5. Assign governance responsibilities

Global HCP/O transparency is a growing challenge for life sciences companies. For many organizations, identifying who should assume governance responsibilities from a global perspective is difficult because the work involved — collecting data from many different sources, identifying problems with the data and getting it corrected, managing HCP lists — isn't typically among the traditional skills of compliance professionals.

On the other hand, collecting data about what payments are made to HCPs is often a natural extension of activities that compliance departments govern: confirming that needs assessments exist before a contract is created; performing Fair Market Value (FMV) calculations for services provided; and issuing guidelines on what constitutes a "reasonable" meal or lodging location.

The question of which department should fund Global HCP/O transparency initiatives often generates discussion about which department should own the program, as it is a leading practice for the organization that is responsible for a capability to take a leadership role in defining its processes, systems, and governance. Most of the study participants indicated that the Global Chief Compliance officer is leading their company's efforts to develop a global HCP transparency solution (Figure 11).

Figure 11
Disclosure program budget



Our Experience: Global HCP Transparency governance is challenging because activities required for compliance may go beyond the scope of most CCOs.

While it makes sense for the Global Compliance Officer to lead/own global HCP/O transparency programs, we have found that the scope of activities (across sales, marketing, R&D, etc..) and the systems that house the value exchange data (many of which are financial systems) often go beyond the scope of control that many CCOs' feel that they can influence. This poses a challenge when determining the roles, responsibilities, and overall governance of programs in which enterprise-wide coordination is required.

Other observations

Most companies (70 percent) in the Global HCP Transparency study indicated that they are in the assessment phase of a global HCP/O transparency project; few, therefore, have determined which activities should be centralized, what skills are needed to complete the activities, and what volume of work is required to execute them. Below is partial list of activities which could be centralized:

1. Monitor environment for new regulations
2. Interpret disclosure regulations and translate into system requirements
3. Define/update guidelines or policies, business processes and standard operating procedures (SOPs)
4. Train individuals on new policies, procedures and SOPs
5. Build technology capabilities based on approved requirements
6. Enter HCP/O spend data entry into source systems
7. Monitor data quality
8. Correct data errors in source systems
9. Maintain HCP/O master data
10. Develop and execute communication plan
11. Execute/produce draft disclosure reports
12. Review disclosure reports prior to submission internally
13. Review HCP spend data with HCPs and make updates to data, if needed
14. Submit disclosure report (or post on web)
15. Support technology.

Many, but not all, of the activities listed above can and should be centralized; however, companies should calculate the associated skills and work effort needed; designate a department or function to execute these activities; and communicate the project's goals, processes, and timeline across the organization.

At the executive level, it is appropriate for the CCO to lead the global HCP/O transparency effort, but many of the implementation activities listed above should reside within another organization (e.g., technology support resides in IT). Clearly identifying roles, assigning accountability, communicating regularly with stakeholders, conducting appropriate training, and monitoring the project's progress and budget are critical to instituting a high-quality corporate disclosure capability.

Study conclusions

There are many global HCP transparency regulations in place or planned for the near future. Although these regulations differ in subtle ways, the core set of data, processes, and technologies needed to support transparency requirements are often the same. Many life sciences companies have recognized this commonality and are in the planning phase of developing a global solution. The business driver for this approach is often reducing redundancies across countries, which should result in reduced compliance risk and lower overall costs.

Implementing a global solution does not imply that all activities are centralized. One of the elements of achievement is determining which functions should be centralized and which should be left in local hands. As is the case with many complex, global programs, numerous factors should be included in a company's plan for moving forward, including operational model design, data quality analysis, process design, systems integration, and change management for communications and role-based training.

Closing thoughts

Can the game be changed? Is there an opportunity for the life sciences industry to come together — formally — to develop a global HCP transparency solution?

HCP transparency requirements are similar in many countries which have existing laws and industry codes: the data elements are similar; the processes to collect and report the data is similar; and the roles and responsibilities required to operate a HCP transparency reporting solution are similar. Despite these similarities, however, we have observed that many companies are building essentially redundant systems, processes, and organizations in each country with a current or pending HCP transparency regulation.

The more logical and cost-effective approach may be for companies to analyze what capabilities can be built and housed centrally and offered as a service to individual countries. Once a collaborative team establishes global data standards and local country offices are able to collect and submit data to a central repository using those standards, a central group can execute data quality routines (communicating errors back to the countries), aggregate data using a copy of local HCP master data, and store the data in a reporting repository which can be accessed by the local countries.

Industry Consortium: What would it look like?

We believe that there is a real opportunity for the life sciences industry to consider forming a consortium to address global HCP transparency reporting needs and solutions. Such a consortium could:

- Monitor regulations globally and define reports and business rules
- Publish standards for meeting the data requirements
- Provide a central data repository (partitioned by company) and accompanying reports
- Provide a means of assigning and managing different HCP Identifiers (HCP IDs) to each transaction
- Leverage purchasing influence over third-party data providers.

The benefits the consortium could provide include:

- Consistent approach and data definitions across companies, which makes analysis by external interested parties easier and could result in less inquiries to companies
- Lower total cost of ownership to individual companies, as the cost of building the capabilities would be spread across participants
- Ability of regulators to review and analyze data across different companies.

As Deloitte completed our analysis of this benchmark study's data and reflected on what an ideal future state might look like, we concluded that an industry consortium on global HCP transparency makes sense.

We are interested in hearing your opinion. Please contact the individuals below to share your thoughts.

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