Global Transparency

2013 International Medical Device Conference
Warsaw, Poland
May 17, 2013
Panel

- Moderator:
  - Diane Biagianti, VP/Chief Responsibility Officer, Edwards Lifesciences

- Panelists:
  - Laure Le Calvé, Partner, LCH
  - Katsumi Kojima, Director, Regional Compliance Officer, Edwards Lifesciences
  - Christopher L. White, Esq., Sr. EVP, General Counsel, AdvaMed
  - David Wysocky, Director, Medical Device Compliance, PwC
  - Holger Diener, Managing Director, Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA)
**Introduction**

- There has been growing public interest in greater transparency into interactions between the healthcare industry and healthcare professionals (HCPs) and organizations (HCOs).
- In response, nearly two dozen countries have enacted, or are considering, laws or industry guidelines requiring some degree of transparency of transfers of value to third parties involved in the provision of healthcare.
- Life sciences companies have been developing aggregate spend programs over the last three to five years with a focus on US State and Federal reporting and more recently to non US emerging requirements.
The global movement to transparency

We have witnessed significant acceleration of legislation and codes of conduct throughout the world related to the interactions that manufacturers can have with Healthcare Professionals and Institutions (HCIs). Most notably is the proposed EFPIA legislation requiring how, and how much, companies are spending money on health care professionals, organizations and other related entities to be disclosed in all 30 membership countries.
Legislative timeline

**Legislative Trends** - Increasing....

- Reporting at the individual HCP-level
- Inclusion of cross-border activity in reports
- Reporting of more types of customer interactions/spend activity
- Reporting at a more granular level of data

* Dates represent the beginning of data capture

**EFPIA Requirements**

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech
- Denmark
- Estonia
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Malaysia
- Norway
- Poland
- Portugal
- Romania
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- UK

**Higher Complexity**

- US States: MA, MN, VT, WV, and DC
- *France Bertrand Act*
- Belgium
- Japan ABPI
- Japan
- JPMA
- AUS Code 17
- Japan JFDMA
- US Sunshine Act
- UK ABPI

**Lower Complexity**

- Norway
- Denmark
- UK
- Austria
- Estonia
- Italy
- Latvia
- Lithuania
- Russia
- Ukraine
- Turkey
- Belgium
- France
- Lithuania
- Russia
- Ukraine
- Bulgaria
- Croatia
- Cyprus
- Czech
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Malta
- Norway
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- UK

* Dates represent the beginning of data capture
Global requirements timeline

The following countries should be considered countries of priority for reporting based on the timing of the disclosure requirements and your business operations/model.
Australia


• Outlines minimum standards for which member organizations must satisfy
  - Requires HCP interactions to conform to professional and ethical standards and serve to enhance medical knowledge
  - Prohibits certain “inappropriate” HCP interactions
  - Applicable only to Member Companies

• Reporting Requirements
  - Educational meetings and symposia sponsored by the Member Company
    ◦ Educational Event Report due twice each year (Oct-Mar and Apr-Sept)
    ◦ Due within 30 days of end of each period
  - Consulting arrangements with Australian HCPs
    ◦ Summary of consultancy services each calendar year due within 30 days of end of year
  - Advisory boards
    ◦ Advisory Board Report due twice each year (Oct-Mar, and Apr-Sept)
    ◦ Due within 30 days of end of each period
  - Listing of HCOs that receive financial and significant non-financial support
Slovakia

- Act on Medicinal Product & Medical Devices (2011)

- Details reporting requirements for certain marketing expenditures and benefits provided to HCPs

- Reporting Requirements
  - Provision of promotional materials, marketing materials, and in-kind items directly and indirectly to HCPs
    - Report a list of amounts of items by January 31 of each year for the previous year
  - HCP participation in educational seminars and congresses
    - Report a list of HCP attendees of educational seminars and congresses after presented
  - Provision of financial and non-financial contributions to patient organizations
    - Publish list of patient organization recipients on Company website by March 31 each year
FRENCH SUNSHINE ACT UPDATE

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The purpose of the Law

- 2010 Médiator® - sanitary scandal – off label prescription
- New law debated and voted under an urgent process (draft August – publication of the law December... of the same year)
- Purposes: more transparency (« copy of the US Sunshine Act »), safety and more information for patients and HCPs
- New Agency: ANSM replaces AFSSaPS (agence nationale de sécurité des médicaments et des produits de santé)
Category of payments to be disclosed

- The “existence” of conventions
- All “advantages” whether in kind or in cash, provided directly or indirectly
Category of payments to be disclosed

- All types of convention regardless of the services provided, whether services are paid or not

- The “existence” of the conventions must be disclosed:
  - pending issue: **not the remuneration?**

- Definition of advantages? In practice = travelling costs, meals, lodging expenses ...
Definition of an healthcare professional

List of individuals/entities concerned by the transparency obligations:

- Health care professionals and students intended to practice a health care profession
- Associations of health professionals/students
- Patients associations
- Healthcare institutions
- Foundations, Health societies ("société savante"), service providers
- Press and media companies
- Software developers (for medicinal drug)
- Medical universities
The exemptions

- Two exemptions:
  - when the “existence” of the agreement is published, its purpose is drafted in order to protect industrial and commercial secrecy
  - selling agreements
- Waiting for the decree
- Drafts decree have provided thresholds of:
  - 1 euro
  - 15 euro
  - 60 euro
  - Disclosure of the exact amount per “advantage” or disclosure of total amount of advantages over 6 months
Publication place and frequency

- To be clarified under the decree:
  - French company’s website?
  - Group of companies’ website?
  - Paperbook?
  - Website of professional trade union?

- Time for Disclosure:
  - every six months, within a 45 day period
- Waiting for the decree
- Retroactive as of January 1st, 2012
Sanctions

- **Criminal sanctions**: € 45 000 fine in case of deliberate omission of disclosure for an individual (€ 225 000 for a company)

- **Other sanctions**: posting of sanctions, prohibition to manufacture products, ban to participate to public tenders
Thank you
Any questions?

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Edwards Lifesciences
Director, Regional Compliance Officer APAC/JAPAN
Katsumi Kojima
May 17, 2013 Warsaw Poland
Purpose of Law/Code

• Name of Code:
  – “Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations”

• Purpose:
  – To gain public understanding that the industry conducts business activities with a high level of ethics by transparency.
  – To avoid Conflicts of Interest.
  – To follow Global Trends.
Requirements

1. Category of payments to be disclosed

- A. Research and development expenses
  
  Total Annual Amount
  
  - Joint Research Expenses
  - Contract Research Expenses
  - Clinical Trial Expenses
  - Post-marketing clinical study expenses
  - Nonconformity and infection case reporting expenses
  - Post-marketing surveillance expenses
Requirements

1. Category of payments to be disclosed

• B. Academic research support expenses
  – Scholarship donations
    Department, university, number of cases, amount
  – General donations
    University/foundation, number of cases, amount
  – Academic conference donations
    Conference number, amount
  – Academic co-sponsoring expenses
    Conference number, seminar, amount
Requirements

1. Category of payments to be disclosed

• C. Manuscript writing fees, etc.
  – Lecturers fees
    Professor/director, department, university/hospital, number of cases, amount
  – Manuscript writing/supervising fees
    Professor/director, department, university/hospital, number of cases, amount
  – Expenses for the consignment of services, including consulting
    Professor/director, department, university/hospital, number of cases, amount
Requirements
1. Category of payments to be disclosed

• D. Expenses related to information provision
  – Lecture expenses
    *Total annual number of cases and amount*
  – Seminar expenses
    *Total annual number of cases and amount*
  – Expenses for the provision of medical/medical engineering-related literature, etc.
    *Total annual amount*
Requirements
1. Category of payments to be disclosed

• D. Expenses related to information provision
  – Lecture expenses
    Total annual number of cases and amount
  – Seminar expenses
    Total annual number of cases and amount
  – Expenses for the provision of medical/medical engineering-related literature, etc.
    Total annual amount
Requirements
1. Category of payments to be disclosed

• E. Other expenses
  – Reception expenses

  \textit{Total annual amount}
Definition of HCP

- Individual HCPs
- Hospitals, Clinics
- Medical schools, Medical Conferences
- NO medical students and patients 'associations
Requirements

3. Exemptions

• NO exemptions.
Requirements
4. Threshold

• NO minimum threshold.
Requirements
5. Publication place and frequency

• Publication place
  – Company Websites or Other Methods (National Newspaper or Official Government Gazette).

• Frequency
  – Once a year.
Requirements
6. Timing

• Timing of Disclosure
  – FY2013 HCPs spending data will be disclosed in FY2014.
Global Transparency Panel

17 May 2013
International Medical Device Industry Compliance Conference
Warsaw, Poland

Christopher White
Senior Executive VP, General Counsel
The Advanced Medical Technology Association
The U.S. Sunshine Law

**Patient Protection and Affordable Care Act (PPACA)**
- Signed into law March 23, 2010
- P.L. 111-148
- Section 6002: “Transparency Reports and Reporting of Physician Ownership or Investment Interests”
- First report due March 31, 2013 [now delayed]
- Information submitted will be available to the public on-line
- Effective January 1, 2012, the federal law preempts state laws requiring disclosure of same type of information, but not state laws requiring information outside scope of PPACA

**Proposed Rule: “Transparency Reports and Reporting of Physician Ownership or Investment Interests”**

**Final Rule: “Transparency Reports and Reporting of Physician Ownership or Investment Interests”**
- 78 Fed. Reg. 9458 (February 8, 2013)
The U.S. Sunshine Law

Main Elements of Sunshine Law

• Requires medical device manufacturers to report “payments or other transfers of value” to “covered recipients”

  • *Payments or other transfers of value* means a transfer of anything of value. Certain identified payments/transfers excluded, e.g., those less than $10/$100 annual aggregate, certain educational materials, in-kind items for charity care

• *Covered Recipients* are limited to physicians and teaching hospitals

• Reportable information includes name and address of covered recipient, amount + date of payment, form of payment (e.g., cash, stock), nature of payment (e.g., consulting fees, gift, entertainment)

• PODs. Requires “any applicable manufacturer or applicable group purchasing organization” to report information regarding any physician ownership or investment interests
Exemptions may apply to:
- TOVs less than $10, up to $100/year
- Samples
- Educational materials
- Demo/evaluation/loaners
- Warranties
- Discounts
- Charity care
- Dividend/profit distribution from a publicly traded company
- Employee health care
- Expert witnesses

Nature of Transfers of Value:
- Consulting
- Comp for other than consulting
- Honoraria
- Gifts
- Entertainment
- Food
- Travel (and destination)
- Education
- Research
- Charitable Contributions
- Royalties/Licenses
- Ownership & investment
- Compensation for med ed speaker/faculty
- Grants
- Anything else described by Secretary
The U.S. Sunshine Law

U.S. Sunshine Scheme

1. Applicable Manufacturer (AM) Reports
   • For each Transfer of Value (TOV)
   • For each Covered Recipient (CR)
   • Identity Data (name, address, stakeholder, etc.)
   • Amount of TOV
   • Nature of TOV (what is TOV for?)
   • Form of TOV
   • Covered Product Name
   • Eligible for Delayed Disclosure?
   • Optional Context
   • Signed Attestation

2. CMS Aggregates data and sorts by individual CR

3. CMS Posts on Secure Site for AM and CR pre-release review; Dispute Resolution

4. CMS Publicly Posts Non-Deferred Data in Searchable Database with Context (TBD)

5. Follow on Reports to Congress and States
The U.S. Sunshine Law

CMS’ Template Forms

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
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<td>5. Manufacturer or Supplier of Substance</td>
<td>Kriya products unless the manufacturer or supplier of substance</td>
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<td>Swaha products unless the manufacturer or supplier of substance</td>
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<td>10</td>
<td>7. Manufacturer or Supplier of Substance</td>
<td>Shanti products unless the manufacturer or supplier of substance</td>
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<td>10 Char</td>
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<td>8. Manufacturer or Supplier of Substance</td>
<td>Dehaka products unless the manufacturer or supplier of substance</td>
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</tbody>
</table>

Subsection B: Information (All sections from here to end of template contain data elements that are reported once per payment/transfer of value)
The U.S. Sunshine Law

Sunshine Final Implementation Timeline

Deferred Implementation Date  
Aug 1, 2013

First Report Due to CMS  
Mar 31, 2014

Secretary submits reports to states including summary of payments made to covered recipient in each state  
Sept 30, 2014

Information made public through website; in subsequent years, information made public June 30  
Sept 30, 2014
The U.S. Sunshine Law

Key Considerations

- **Attestation.** Attestation statements must be provided at original submission of data, as well as any time the data is updated or changed.

- **Penalties.** Civil money penalties may be imposed for failure to report information in a timely, accurate or complete manner. This applies to entire transactions as well as certain fields related to a transaction. CMS does not intend that errors corrected during the review, correction, and dispute resolution periods will be subject to penalties for failure to report in instances when the original submission was made in good faith.

- **Preemption.** Preemption determinations must be analyzed on a case-by-case basis.
AdvaMed’s New Sunshine Brochures

Value of Industry-Provider Collaborations

Collaboration and interactions between medical technology companies and health care providers are essential to advancing new, safe and effective medical technology that benefit patients. AdvaMed recognizes that this goal must be balanced against the obligation of health care providers to make independent decisions regarding the care and treatment of their patients. AdvaMed and its member medical technology companies are committed to transparency with patients about interactions between providers and industry. For this reason, AdvaMed supports the Physician Payment Sunshine Law.

The Physician Payments Sunshine Law and You: building stronger industry-physician interactions

What Is the Nature of Payment Categories that must be used to describe Payments and Transfers of Value?

The Payment/Transfer of Value must be categorized as one of the following:

- Consulting fees
- Compensation for services as facility or as a speaker for an accredited CME program
- Compensation for services as a speaker for an unrelated forum (unrelated to the Sunshine Law)
- Compensation for services other than consulting, including serving as facility or as a speaker for an unrelated forum (unrelated to the Sunshine Law)
- Entertainment, Travel, Lodging or Other Indirect Benefits
- Honorarium
- Payment/Transfer of Value provided to the Physician owner or investor

How are companies preparing for compliance with the Sunshine Law?

Manulife and other companies are preparing to track the required payment data beginning on August 1, 2013. Can physicians review the data and make connections, if necessary?

When information is publicly posted, a physician has 45 days to either submit dispute notices or to request disclosure of the information. The physician will then have 30 days to either request disclosure of the information or to disclose it to the Physician. The information must be disclosed within 90 days of the request.

How will the information be disseminated?

The Physician must be able to search on a public website by name of the Physician. The physician can request disclosure of the information by name of the Physician. The information must be disclosed within 90 days of the request.

What are the penalties for non-compliance?

The reporting deadline is May 4, 2012, for all transactions in 2011 and February 1, 2013, for all transactions in 2012. Non-compliance may result in penalties ranging from $1,000 to $5,000 for each payment or transfer of value not reported, and

$1,000,000 for “knowingly” failing to report a payment or transfer of value.

The maximum penalties which may imposed against a manufacturer or GPO are $25,000 per year.

What will be done with the reported information?

What is being provided to thePhysician?

The information will be published annually on a public website that is searchable. The Secretary of HHS will be responsible for ensuring that the data is accurate and complete.

In subsequent years, information made public on June 30. For example, the information will be published annually on a public website that is searchable. The Secretary of HHS will be responsible for ensuring that the data is accurate and complete.
QUESTIONS?

Christopher White
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(202) 434-7217
Voluntary Self-Regulation for the pharmaceutical Industry (FSA)

Global Transparency Panel
Introduction of country legislation and industry self-regulatory efforts

EFPIA and EUCOMED Approaches

2013 International Medical Device Conference
Warsaw, 17 May 2013

Dr. Holger Diener, Managing Director
DRAFT EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

(EFPIA HCP/HCO DISCLOSURE CODE)

• EUCOMED White Paper on Transparency & Disclosure
  (Approved by the EUCOMED Board on 12 September 2012)
I. Purpose of EFPIA Draft Code / EUCOMED White Paper

- Self-regulation needs to respond to the evolving demands of the society for transparency. In particular, there is a growing expectation that interactions between corporations and society are not only conducted with integrity but are also transparent.

- EFPIA hopes that, a transparency code can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stake-holders in the pharmaceutical industry.

- Transparency is one of the core principles of the Eucomed Code of Ethical Business Practice

- Transparency is a crucial element ensuring that all kinds of cooperations are appropriate and beyond criticism in view of any conflict of interest.

- Self-regulatory scheme prefered
II. Category of payments to be disclosed

- Research and Development
- Grants and Donations
- Contributions to costs related to events (sponsorship agreements, registration fees, travel and accommodation)
- Fees for Service and Consultancy
- Research and educational grants to institutions;
- Charitable donations;
- Direct sponsorship of HCPs to congresses (i.e. congress fee and related costs);
- Hospitality, travel and accommodation provided to HCPs, in accordance with the provision of the Eucomed Code, and above a reasonable threshold.
- Consulting agreements (e.g. honorarium, proctoring);
- Compliant gifts and give-aways
III. Definition of HCP

• Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

• HCPs are defined as “individuals (clinical or non-clinical, including but not limited to physicians, nurses, technicians and research co-ordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members’ medical devices”
IV. Exemptions and thresholds (1)

- Food and Beverage

- Fee-for-service, honoraria and payments to HCPs below a reasonable threshold per year per HCP

- Hospitality, travel and accommodation payments, made in accordance with the Eucomed Code and applicable legislation, and below a reasonable threshold per year per HCP, do not have to be collected and reported.

- Compliant gifts/give-away, samples and items of limited value, as defined by the Eucomed Code, below a reasonable threshold per year per HCP, do not have to be collected and reported.
IV. Exemptions and thresholds (2)

- ToV solely related to over-the-counter medicines
- ToV which are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and an HCP

- Disclosure requirements should not include reporting of discounts, rebates, or other pricing information
V. Publication place and frequency

- Disclosures must be made on an annual basis (cover full calendar year; first reporting year: 2015)
- Within 6 months after the end of the relevant reporting period
- Information shall remain in public domain for a minimum of 3 years
  - Member Company’s website or central platform
  - Depending on the physical address of the Recipient
  - In the language prescribed by the relevant (national) Code

- Reporting should take place once a year for the payments made in the previous calendar year

- Eucomed strongly recommends that disclosure takes place via a unique national reporting platform, like a website, rather than on individual company websites
VI. Timing (1)

- Timing is up to the member companies and associations of EUCOMED
VI. Timing (2)

EFPIA General Assembly adopts changes to EFPIA Code 24-25 June 2013

Codes Committee Review of Code transposition (report to the Board) April 2014

EFPIA Board to approve “pre-final” wording for changes to EFPIA Code 15 February 2013

Member Associations’ deadline for transposition into Code of Practice 31 December 2013

Individual disclosure period begins

Data collection by member companies for individual disclosure

Questions?

Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.

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Fax 030 / 88728 – 1705
h.diener@fs-arzneimittelindustrie.de
Approaches and considerations for Global Transparency

May 2013

pwc
European landscape

- Initiatives to date are country-specific
  - Local country laws, regulations and
  - Industry codes
    - Focusing on companies payments and other transfer of values to healthcare professionals, organizations and other related entities, each with different sets of external reporting requirements.
- Industry initiative aiming at harmonizing transparency/disclosure initiatives within the region in FY16 on FY15 data.
- Some countries are still facing difficulties in enacting their Transparency laws (France adjusted the legislation multiple times in 2012 and is still pending a final decree).
- Data Privacy Laws must also be honored (HIPAA, EU Data Protection).
Key questions to address while defining the program

- What is our company common interpretation of applicable set of laws and industry guidelines?
- What are the gaps in current data collection compared to evolving requirements?
- What is the scope and implication of cross border transactions?
- What is the optimal governance framework?
  - Global, regional or local
- What are the optimal short/long term solutions to the gaps (personnel, processes, systems and policies)?
- What are the funding and timing requirements?
**Key mobilization considerations to improve likelihood of success in implementing governance**

- Define ownership and sponsorship
- Define an achievable scope
- Identify country points of contact
- Define a baseline for activities and data
- Promote individual country transparency initiatives
- Leverage internal transparency expertise
These components of a Transparency Program must be addressed. Each component has cross-border and geographic considerations.

- **Governance**: Clearly defined ownership and accountability of the activities necessary to execute and comply with reporting obligations.
- **Reporting**: Consistent processes and systems for consolidating transactional data, applying business rules, generating reports, and conducting reviews and certification.
- **Master Data Management**: Successfully maintaining profile data to uniquely identify HCPs and HCOs.
- **Data Sources and Supplement/Remediate Data**: Standard terms, definitions, processes, and sources to capture transaction data.
- **Efficient and complete tracking and reporting of transfers of value to local HCPs / HCOs incurred outside a country's borders.**

The pyramid illustrates the hierarchical nature of these components, emphasizing the importance of addressing each level to ensure comprehensive transparency and compliance.
What do organizations need to understand

**Scope**
- Which country regulations or industry codes impact you
- How are you engaging covered recipients (i.e., HCPs/HCIs) within these countries
- Are you engaging in cross-border contracting of covered recipients

**Current landscape**
- Policies, processes, procedures
- Enabling technologies
- Available data
- Organizational structure, governance and oversight

**Future State Vision**
- Evaluate Global vs. Regional vs Local approaches for each global aggregate spend component
### Summary of transparency program options

<table>
<thead>
<tr>
<th>Approaches</th>
<th>Challenges</th>
<th>Solution</th>
<th>Impact</th>
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<tbody>
<tr>
<td><strong>Local Approach</strong></td>
<td>Gather and report data to comply with the minimum requirements for each country&lt;br&gt;Aligning across siloed business units</td>
<td>Implement piece-meal short term Transparency solutions in each country</td>
<td>Adequate level of Compliance per each country’s legislation</td>
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<tr>
<td><strong>Cross-border Approach</strong></td>
<td>Gather and report data across countries to comply with the minimum requirements for other countries&lt;br&gt;Aligning across siloed business units and countries</td>
<td>Common definitions, Data stewardship, Common Platform</td>
<td>Synergies and learnings across borders, single point of contact for cross-border spend</td>
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<tr>
<td><strong>Regional Approach</strong></td>
<td>Gather and report data to comply with the requirements for each country’s&lt;br&gt;Aligning across the enterprise&lt;br&gt;Different reporting requirements and specifications including covered recipients, reportable activities, required data, and deadlines</td>
<td>Flexible approach to capture majority of requirements</td>
<td>Realizable benefits and ROI, standardized data collection and reporting improves accuracy and can yield business insights.&lt;br&gt;Regional controls reduce the risk of inaccurate reporting, fines, and penalties</td>
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</table>
What does this mean for the industry?

As a result, companies are starting to take a complete HCP Spend Management approach from the initiation of an activity and budget planning through reporting to enable consistency and compliance through the entirety of the business process.
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