Global Transparency
The content of these slides and the presentation that goes with it are personal views and opinions of the panel and do not necessarily reflect the views of their respective employers.
Analyzing trends within global physician spending and reporting
Transparency on Physician Spend will continue to expand globally.

As well as the U.S. state requirements of:
West Virginia, Vermont, Minnesota, D.C, California and Massachusetts
# Global Transparency Requirements

<table>
<thead>
<tr>
<th>Country</th>
<th>Regulation</th>
<th>Description</th>
<th>Status</th>
<th>Products covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Industry Code (Medicines Australia)</td>
<td>Code of Conduct: Each company must make publicly available on its website, a list of Health Consumer Organizations to which it provides financial support and/or significant direct/indirect non-financial support.</td>
<td>Enacted</td>
<td>Prescription Only</td>
</tr>
<tr>
<td>Denmark</td>
<td>Danish Pharmacy Act</td>
<td>Requires pharmaceutical companies to annually disclose any the name, address, civil registration number and period of association of any doctors and dentists associated with them; the Danish Medicines Agency may require that they further disclose nature and extent of relationship and amount of remuneration.</td>
<td>Enacted</td>
<td>All Pharmaceuticals</td>
</tr>
<tr>
<td>France</td>
<td>French “Sunshine Act”</td>
<td>All financial relationships and agreements between manufacturers, physicians, experts, healthcare firms, patients' associations and specialized media will have to be disclosed.</td>
<td>Decree announced end 2011 but still going through discussions with industry and government</td>
<td>Pharmaceuticals and Medical Devices</td>
</tr>
<tr>
<td>Slovakia</td>
<td>Act on Medical Aid no.362/2011</td>
<td>Pharma companies must report on advertising and marketing expense and non monetary benefits (direct or indirect) to HCP’s – report to MOH by Jan 31st for previous year. MOH to publish on their website</td>
<td>Enacted</td>
<td>All Pharmaceuticals</td>
</tr>
<tr>
<td>India</td>
<td>Industry Code</td>
<td>The companies must maintain a detail record of expenditure incurred on all promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events.</td>
<td>Voluntary Self-Regulation – Code of Marketing Practices for Indian Pharmaceutical Industry</td>
<td>All Pharmaceuticals</td>
</tr>
</tbody>
</table>
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<td>Japan</td>
<td>JPMA Transparency Guideline</td>
<td>JPMA members to have Transparency Policy in place and publicly disclose payments to HCPS and Medical institutions. Includes all clinical and non-clinical.</td>
<td>Enacted in 2011– first report 2013</td>
<td>All Pharmaceuticals (Med devices expected 2013)</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Central Group combining Industry and Associations</td>
<td>Reporting to central agency all service agreements (and Monies) related to non-clinical activities (consulting, advisory, speaker etc)</td>
<td>Enacted Jan 2012 - first report 2013</td>
<td>All Pharmaceuticals</td>
</tr>
<tr>
<td>UK</td>
<td>Pharmaceutical Industry Code (ABPI)</td>
<td>Self reporting on public website of expenditure on non clinical activities such as speaker fees, travel/hotel, consulting, advisory boards</td>
<td>Enacted Jan 2012 - first report 2013</td>
<td>All Pharmaceuticals</td>
</tr>
<tr>
<td>Estonia</td>
<td>Medicines Act</td>
<td>Pharma companies must report (on paper) to Ministry of Health any non Clinical HCP engagement where expenditure was greater than 6.48 Euros</td>
<td>Enacted</td>
<td>All Pharmaceuticals</td>
</tr>
<tr>
<td>Ireland and Hungary</td>
<td>Regulation</td>
<td>Each company must make public any financial support (direct or indirect) to patient associations</td>
<td>Enacted – first report 2013 for FY 2012</td>
<td>Patient Associations</td>
</tr>
<tr>
<td>Turkey, Philippines and Thailand</td>
<td>Laws in Discussion</td>
<td>All countries are currently discussing transparency type legislation</td>
<td>Not yet enacted</td>
<td>Unknown at this time</td>
</tr>
</tbody>
</table>
Trends - Summary

- Governmental spend on Healthcare continues to increase across the world, as population ages and science develops - leading to increased focus on the cost of drugs and hence Pharma spend and physician interactions.
- All EU countries are looking at UK, FR and NE and will follow suit (if EU Gov.t does not act first – EFPIA/EUCOMED already starting on pan Europe voluntary code)
  - Government changes (e.g. France) will potentially slow progress but will not stop this trend
  - Proliferation of CIA’s and anticipation of PPACA has US ahead in planning – but complexity will be multiplied by global requirements
- The race is on for Associations to build acceptable voluntary codes first, before Laws/Statutes are implemented
- Recent survey at another conference had attendees agreeing that within 3 – 5 years all developed countries would have an aggregate spend / transparency reporting requirement
- APAC starting to develop code and requirements
- No moves seen in LATAM as of yet
Considerations for tracking and collecting physician spend Globally
Before you start thinking this is different ...

• On review of these slides, it becomes clear that a lot of what you need to apply to ex-US spend tracking is not very different from that applied in the US.

• However, how you choose to go about getting this information needs to be carefully thought out, communicated and executed.
Key Considerations

– Understand your business
  • What is your organization structure ex-US?
– What is the scope?
– Who owns Global Spend tracking?
– Can you leverage global systems?
– Global Master Data and Data Privacy
– Budget Approach, Program model and management
– Can you leverage best practices/lessons learnt from US experience?
Understand your business

• Is your company driven by one central entity or are regions / countries autonomous?
• What Executive decision bodies do you need to work through?
• Is Compliance a Global group or a loose framework of regional Compliance representatives?
• Is Compliance seen as an asset to doing safe business or ‘the business prevention department’?
• What license do regions have to drive their own IT strategy?
  – What ability do they have?
• Do you have a harmonised training platform and strategy?
• There needs to be respect that each country knows their business better than you do!
What is the scope

- Right size the approach to the scope
  - Manual or Automated or somewhere in between
- Make sure you focus on building robust and repeatable processes first.
- Only then consider automation: the ability to automate and the need to automate are very different things
- Your Strategy depends upon a number of factors
Who should own Spend tracking?

- Compliance?
- Finance?
- Marketing?
- Operations?
- Legal?

- A lot of companies are deciding on a stand alone team that work alongside all of the above, but are independent and responsible for
  - Process, Systems and Strategies for Aggregate spend
  - BUT ... This only works if the team understands how your company works, has a global remit and access to Global contacts
The Village known as ‘Agg. Spend’

• Getting this done globally requires a virtual village.

• Compliance, Finance, Sales and marketing, Legal etc. all need to be aligned to ensure
  – Consistency
  – Accuracy
  – Completeness
Can you leverage a Global system?

• Understand your business and scope
• Look at the risk, the cost and the ROI and make a balanced decision
• Think about all the elements — Meals, meeting costs, travel, engagement fees etc.
• Does your company have the ability, the desire and the need?
The Data Disparity Dilemma

Expense System

Trial Payment System

Purchasing System

HCP’s

Trial Mgrs

Vendors

Entities

Hotels, Airlines..

Third Parties

Charitable Donations

Manual Entries

AGGREGATE SPEND REPORTING SOLUTION

?!?
The Data Disparity Dilemma

Trouble is ... in most companies the processes and systems used in different countries do not always look the same nor have the same data dictionary.
Intention:
-HCP master data is managed in Global MDM solution and all transactions are bought into a single data cube
- Facilitates reporting at all levels
- Provides Company with business analytics up to a Global scale
- Allows local/regional interpretation of local/regional requirements in flexible modular solution
Integrated Global Compliance Platform

Global Master data Management

Global Data Cube

- U.S.
- EAME
- LatAm
- Canada
- AP
- R&D
- Med Aff.
- Other

- Annual operating plans
- Event Management
- Contracts
- Grants / sponsorship
- Spend Tracking
- Clinical Trials

Global reporting
Regional reporting
Local reporting
Business Analytics
Readiness for a Global system

As well as the risk, consider where your organisation is maturity wise

Chaotic
- Isolated people
- Different processes
- Disparate local systems
- No international meeting coordination

Reactive
- Loose affiliation of people
- Some shared processes
- Disparate regional systems
- Some international meeting coordination

Proactive
- Network of people
- Majority shared processes
- Some global systems
- Regional IT decisions
- Commonality in regulations / requirements
- International meetings through a central body

Repeatable
- Globally coordinated people
- Standard processes
- Global systems
- Global IT governance
- Standard regulations / requirements
- International meetings through a central body
- Global capabilities in support operations

ABILITY TO EXECUTE A GLOBAL SYSTEM

POTENTIAL FOR INVESTMENT RETURN
Global Master Data and Data Privacy

• Data privacy
  – Safe harbor certification
  – Design with intent
  – Notice & consent
  – Consult the experts...

• Clean Global Master Data is ideal
  – or at least single sources of truth

• Tracking of licensed HCPs X-US
  – Proactive vs. Reactive
  – How?
  – Who owns this?
Interactive Data Protection Heat Map

- **Most restrictive**
- **Restrictive**
- **Some restrictions**
- **Minimal restrictions**
- **Pending legislation**
- **No legislation or no information**
- **Caution due to government surveillance**

Source: US Department of Commerce and country specific legislation

Source: Forrester Research, Inc.
Data Privacy Considerations

– More and more vigilance is required around data privacy
– Safe Harbor is not always seen as adequate
– What data, where you use it, how you use it, who uses it all need to be understood and allowable
– Have a DP expert aligned with the team
– Preferred practice would be to have HCP’s contractually agree
Organised Master Data is Critical

- Having a clean, trusted source of master data is critical
- Moving to a Global MDM solution is a large step and given data privacy and disparate solutions strategies can be a difficult proposition
- Many companies are building Data Governance teams
  - Focus initial local efforts on:
    - Cleansing data
    - Removing duplicates
    - Aligning key systems on a single source of the truth
How do I know who you are?

- With the increasing requirements, knowing who you are talking to and where they are licensed ahead of any transfer of value is paramount.
- Consider the systems that Sales and Marketing Teams use in HCP engagement
- Flag licenses against HCP’s in those systems (esp. Canada)
- Alert meeting organisers to any potential conflicts on meals etc.
Key Challenges

• Tracking Cross-Affiliate Spend
  – Guidelines to non-reporting countries
  – Education
  – Process
  – IT Solution

• Culture
  – What is acceptable within a country?

• Language
  – Impact on communication and training
  – Impact on systems
Planning the Event

• Considerations:
  – Potential of a Formal pre-registration process
  – Do you have a Global Marketing group and what is their remit?
  – Potential for Sign off by Regional head on use of ‘their’ HCPs
  – Potential for Sign off by Compliance head (in country) to ensure code is not breached
  – Ensure that any travel is booked through your approved agents (not direct by HCP)
During the Event

• Considerations:
  – Have one person within your company who is the designated “Event Owner”
    • They need to understand the responsibilities involved and be the single point of contact for that event
  – Consider auditing all events managed by third parties (to start off)
    • Then lower the auditing rate if they pass
  – Ensure that all hotel, travel, meals etc will be clearly broken down into attributable costs
    • You will not get this after the event
After the Event

• Considerations:
  – A Formal pre-registration process can be followed up for post event spend information
  – Plan early for any reporting milestones as HCP’s are not the fastest at invoicing!
  – If you have dispersed systems or paper processes and have to chase down data, start early.
  – Befriend your finance team, as they will help you uncover unreported spend
Ad Hoc Meals

• From a completeness perspective, collecting spend on ad-hoc meals can be taxing
• Does your company have a Global single expense system?
• Is the expense system linked to your ‘HCP source’?

More time and effort will be spent reconciling ad hoc meals – at very least automate the name entry (against a source of truth)
Cultural Considerations

• What Constitutes an HCP Engagement
  – Ensuring the ‘Transfer of Value’ concept is understood is key.
  – Not all conferences are run the same way, AP / Latam / EAME cost elements can be very different.
    • Also what the company has to pay for can be different
  – A common ‘data dictionary’ for HCP engagements and transfer of value definition is a good way forward.
Getting past the ‘why me’

• When broaching PPACA requirements with international colleagues the first question is “What has this got to do with me – I’m not in the US”

• Need for cascaded messaging from the top down, through regional leadership to all to explain the implications on a Global workforce

• Backed up by training programs – targeted at individuals who will be engaging with HCP’s
Language

- How many of your Korean sales team speak English?
- Many non-English speakers will find it offensive if you do not offer training (for example) in their native language.
  - EU alone is 27 countries, 26 official languages and another 60 additional languages recognised.
- Adoption and adherence to policies is at high risk if training is not delivered in local language.
- However you plan to update a Global workforce, take time to consider the best method and ensure that your people are met on their terms.
Summary

• Take a good look inside and truly understand how your business works – and what works for your business

• Tailor your strategy and solutions to:
  – The size of the risk (internally and externally)
  – Your company culture(s)

• When it comes to HCP engagement, know who you are doing business with as soon as possible

• Automate what makes sense to automate
Other Regulatory Considerations
Regulatory Considerations

• Every country has its own pharma code
  – Ensure that the pharma code of both the home country of the physician and the host country of the meeting are considered when planning
• Ignorance is not going to be an excuse
• Train your meeting organisers to understand the above and check that they do follow it
Regulatory Considerations

• If using an HCP from one country to ‘do work’ in another country
  – Consider contractual legality
  – Consider Visa requirements
  – Consider Payment and Tax requirements

• A lot of companies are moving towards a process where contract and payment are made in the country of residence of that HCP
  – But understand implications on resources, systems etc
In summary

- Aggregate spend requirements will expand
  - In detail
  - In geography

- Communicate, collaborate, coordinate

- Fit the solutions to
  - The risk
  - The ability
  - The desire
Case study 1
Strategic Approach

• Developed a “Hybrid” approach
  – Local ownership of data collection and report submission
  – Global ownership of aggregation and reporting tool
• Focus on countries with requirements
• Develop a robust and repeatable process for on-boarding countries as they get requirements
• Global MDM & data governance as a key dependency
Conceptual Model: Global approach with local components

**Key Business Opportunities**
- Create one view of all transactions with HCPs and HCOs at a local level
- Improve or develop consistent and effective business processes
- Quality business intelligence for effective internal spend analysis to drive strategic decisions
Program Management Structure

• Global program management office
  – Support of Executive Sponsors & Steering Committee

• Global lead role
  – Lead PMO
  – Provide strategic direction
  – Share best practices/lessons learnt from US
  – Identify synergies and opportunities to leverage processes & solutions X-Affiliate
Global Transparency Program Management Organization

- Executive Sponsors
  - Overall ownership of initiative
  - Optional attendee of program update meeting

- Global Steering Committee
  - Monitor overall progress
  - Provide resources
  - Resolve escalated risks/issues
  - Attend Program Update Meeting every other month

- Global Program Management Office
  - Overview
  - (Global Lead, Project Leads, IT, Finance, Legal)

- Project 1: US
  - Global Project Lead
  - Local Project Leads
  - Note: US projects that are in phase II of data quality checks and enhancements

- Project 2: France
  - Global Project Lead
  - Local Project Lead
  - Work streams:
    - Legal/Regulatory
    - Finance
    - IT
    - Business

- Project 3: Japan
  - Global Project Lead
  - Local Project Lead
  - Work streams:
    - Legal
    - Finance
    - IT
    - Business

- X-Program Activities
  - Build of Aggregate Spend Repository
  - Implementation of tool for Reporting
  - X-Affiliate Spend Collection
  - Sustainable Support Model

- Corporate Services
  - Capture/Aggregate/Report
  - Internal Reports & Analytics
  - Sustainable Organization Model
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Global Concepts

• Global fields & definitions
  – Working with Legal
  – Leveraging existing policies
  – Recipient Level
  – Transactional Level
  – Identifying Exceptions to the Global rule

• Flexibility for adjustments in requirements…
  – Sunshine
  – France
  – EPFIA
**Example of Identified Global Data Fields – Recipient Detail**

<table>
<thead>
<tr>
<th>Covered Recipient Type</th>
<th>Covered Recipient Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Individual</td>
<td>- Internal Record #</td>
</tr>
<tr>
<td>- Entity</td>
<td>- Name</td>
</tr>
<tr>
<td>Physicians</td>
<td>- Individual</td>
</tr>
<tr>
<td>Teaching Hospitals</td>
<td>First Name</td>
</tr>
<tr>
<td>Hospitals</td>
<td>Last Name</td>
</tr>
<tr>
<td>Non-profit hospital organizations</td>
<td>Middle Name (If Available)</td>
</tr>
<tr>
<td>Licensed Insurance Carriers</td>
<td>Suffix (If Available)</td>
</tr>
<tr>
<td>Health Benefits Plan Manager/Administrator</td>
<td>Professional</td>
</tr>
<tr>
<td>Nursing Facilities</td>
<td>Designation/Credentials</td>
</tr>
<tr>
<td>Clinics</td>
<td>Affiliated Organization Name</td>
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<tr>
<td>Pharmacies</td>
<td>- Entity Name</td>
</tr>
<tr>
<td>Nursing Homes</td>
<td>- Address</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>Address Lines 1</td>
</tr>
<tr>
<td>Academic institutions</td>
<td>City</td>
</tr>
<tr>
<td>Professional/educational and patient organizations representing or serving healthcare professionals or consumers located in or providing services in Vermont</td>
<td>State</td>
</tr>
<tr>
<td>Members of the Green Mountain Care Board</td>
<td>Postal/Zip Code</td>
</tr>
<tr>
<td>Front-Office Staff</td>
<td>Region</td>
</tr>
<tr>
<td>Others</td>
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<tr>
<td></td>
<td>- Contact</td>
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<td>- Identities</td>
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<td>ID Type</td>
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<td></td>
<td>Region</td>
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<tr>
<td></td>
<td>Country</td>
</tr>
<tr>
<td></td>
<td>- Primary Therapeutic Area/Specialty</td>
</tr>
</tbody>
</table>
Case study 2
Organic Approach

• Develop robust processes and build local solutions relative to the requirements
  – Suits a company with strong geographical independence

• Manage cross border use manually
  – Relies on strong communications and relationships

• Informal steering team advising others and sharing best practices
**Conceptual Model**

**Local Data Capture**
- **Localized** business process, data collection & data quality checks
- **Country 1 - US**
- **Country 2 - France**
- **Country 3 - UK**

**Cross Border Capture**
- **Manual** cross-affiliate spend captured manually
- **Manual forms completed for cross border usage**

**Report & Analyze**
- **Localized** reporting & analysis
- **Country-specific Reporting and Analysis**

**PROS**
- Low operational cost (while requirements low)
- Geographical independence
- Low entry cost as requirements develop

**CONS**
- Manual cross border tracking needs constant work
- Not scalable beyond a few countries
- Potential for high risk as requirements develop or countries expand

**Sharing of best practice globally but complete local ownership**
In Summary
In Summary

• Moving towards more transparency than less
• Keep an eye on the world
• Bring in the experts for Data Privacy & Disclosure requirements by country
• Be thoughtful - Take the time to build a strategy that works for your company
• Recognize that your affiliates know their business best
• Work towards a sustainable and scalable solution
Thank you