Pre-Conference: Global Transparency

FIFTEENTH ANNUAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS

Monday November 3, 2014

Today's Presenters

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All opinions and views expressed today, and included in this presentation, are those of the presenters alone and do not represent those of their Companies.

Agenda

- ***Session 1 - (9:45 – 10:30)***
  - *Laws & Regulations*
  - *Future State*
    - *Open Payments lessons learned*
    - *External Reporting – What's next?*

- ***Break***

- ***Session 2 - (10:45 – 11:30)***
- *Efpia Operationalizing Considerations*
  - *Consent Management* *Data Privacy*
  - *Cross Border* *Data Management*

Global Transparency Overview

Laws, Codes and more Codes..

1. The Why & Current Landscape

2. The Laws:

- France
- Portugal
- Denmark
- Slovakia

3. Existing Codes:

- The Netherlands
- Australia
- Japan

4. Pending Codes for 2015

- EFPIA Disclosure Code
- Examples of National Disclosure Codes

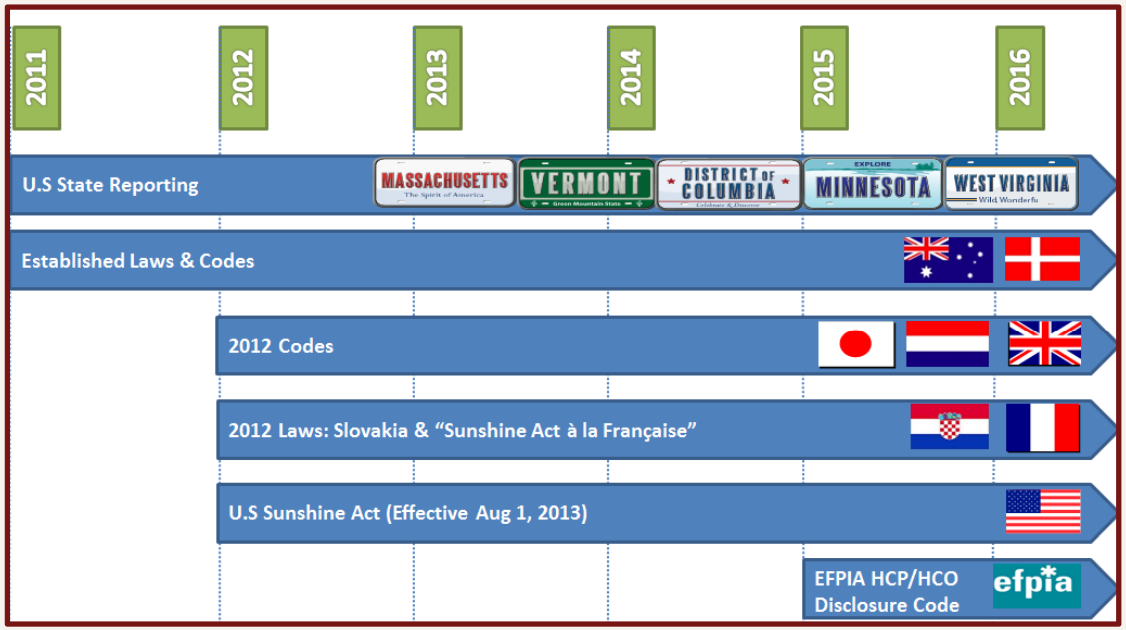
5. Other requirements...

Global Disclosure Requirements:

The Why: The EFPIA Disclosure Code along with other new and developing disclosure requirements are addressing an evolving demand from the public that interactions between companies, healthcare professionals and organizations are not only conducted with integrity but are also transparent.

As a result, these laws and codes are seen as supplementary to existing regulations (government & self-regulations) on interactions with HCPs & HCOs.

The Global Disclosure Landscape:



The Disclosure Law Countries

The Law: France

- **Effective Date:** 2012

- **Scope of Covered Recipients:** Physicians, experts, healthcare firms, patients' associations and specialized media

- **Scope of Covered Transfers of Value:** Report financial relationships and agreements along with all benefits to individuals and entities

- **Key Information:**
  - New implementing decree to be adopted and published according to the Ministry of Social Affairs and Health
  - Next reporting period is February 1, 2015 for benefits granted during the second half of 2014
  - Agreements continue to be reported within 15 days of signing

The Law: Portugal

- **Effective Date:** 2013

- **Scope of Covered Recipients:** Pharmaceutical industries, HCPs, HCOs, Medical Societies & Patient Organizations

- **Scope of Transfers of Value:** Sponsorship, funding or any other sum, money-convertible asset

- **Key Information:**
  - Previous notification of sponsorships of events to Infarmed:
    - ✓ This notification should be made through the electronic platform provided by INFARMED
    - ✓ The use of this platform for prior notifications is available since February 13, 2014
  - Exceptions: Does not cover the salary and other regular contributions, in money or in kind, to which the person is entitled to under a labor relationship or in, the absence of such labor relationship, when said person is financially dependent of the grantor's activity
  - Monetary threshold: 65 Euros

The Law: Denmark

- **Effective Date:** 2008 and updated in 2014
- **Scope of Covered Recipients:** Physicians, pharmacists & dentists
- **Scope of Transfers of Value:** Fees for research, Fees for Education/speakers, Fees for Consultancy, Fees for Market Research, Events, Grants and Donations, Shares & Ownership/Board of Directors
- **Key Information:**
  - The majority of the obligation is on the HCP:
    - Notification (incl. amounts) to the Health Authorities: Education and research
    - Pre-approval (incl. amounts) from the Health Authorities: Advisory activities
  - The pharmaceutical companies (incl. Med Device), will need to notify the authorities in January, who they worked with in the previous calendar year.

  - It is expected that the reporting will be without amount

The Law: Slovakia

- **Effective Date:** 2012
- **Scope of Covered Receipients:** Physicians and pharmacists
- **Scope of Transfers of Value:** Advertising and marketing expenses and non-monetary benefits like grants, gifts and promotional spend
- **Key Information:**
  - Requires notification for non-interventional and other studies
  - No public disclosure, only disclosure to the government
  - EFPIA are currently reviewing the Slovakia law, and will assess if the law fullfils the EFPIA requirements (unlikely)
  - Most likely that there will be a transparency code implemented in parallel with the law
    - AIFP is currently working on a Slovakian disclosure code, but timelines are uncertain

<u>Existing</u> National Disclosure Codes

National Code Requirements: Netherlands

- **Effective Date:** 2012
- **Scope of Covered Recipients:** HCPs
- **Scope of Transfers of Value:** Reporting to central agency all service agreements (and Monies) related to non-clinical activities (consulting, advisory, speaker etc.)
- **Key Information:**
  - Only for activities above 500 Euro
  - Published on a central platform – publically searchable
  - Use the BIG number as the unique identifier for HCPs
  - Includes name of agreement

Australia

- **Effective Date:** 2008/9 – From a transparency perspective, it was significantly updated in 2014 (18th Edition of Code of Conduct) with an effective date of January 1, 2015 with reporting in 2016
- **Scope of Covered Recipients:** HCPs and HCOs (use the Australian Health Practitioner Regulation Agency (AHPRA) database)
- **Scope of Transfers of Valu**e: Similar to US Sunshine Act list of spend categories: Consulting Fee, Speaker Fee, Food & Beverage, Travel & Accommodation, Education, Grant etc...
- **Key Information:**
  - Excludes research
  - Includes payments made by Third Party
  - Identify HCP as the recipient when paying a HCO where applicable
  - Publically available

Japan

- **Effective Date:** 2012 (modified prior to first publication to allow for aggregate disclosure only)

- **Scope of Covered Recipients:** HCPs and Medical Institutions

- **Scope of Transfers of Valu**e: R&D, academic research, writing, information provision-related and other payments

- **Key Information:**
  - Report in the aggregate
  - Publically available

European Federation of Pharmaceutical Industries and Associations

Regional Disclosure Code

EFPIA Disclosure Code Requirements: Timeline

Key Finalized Dates:

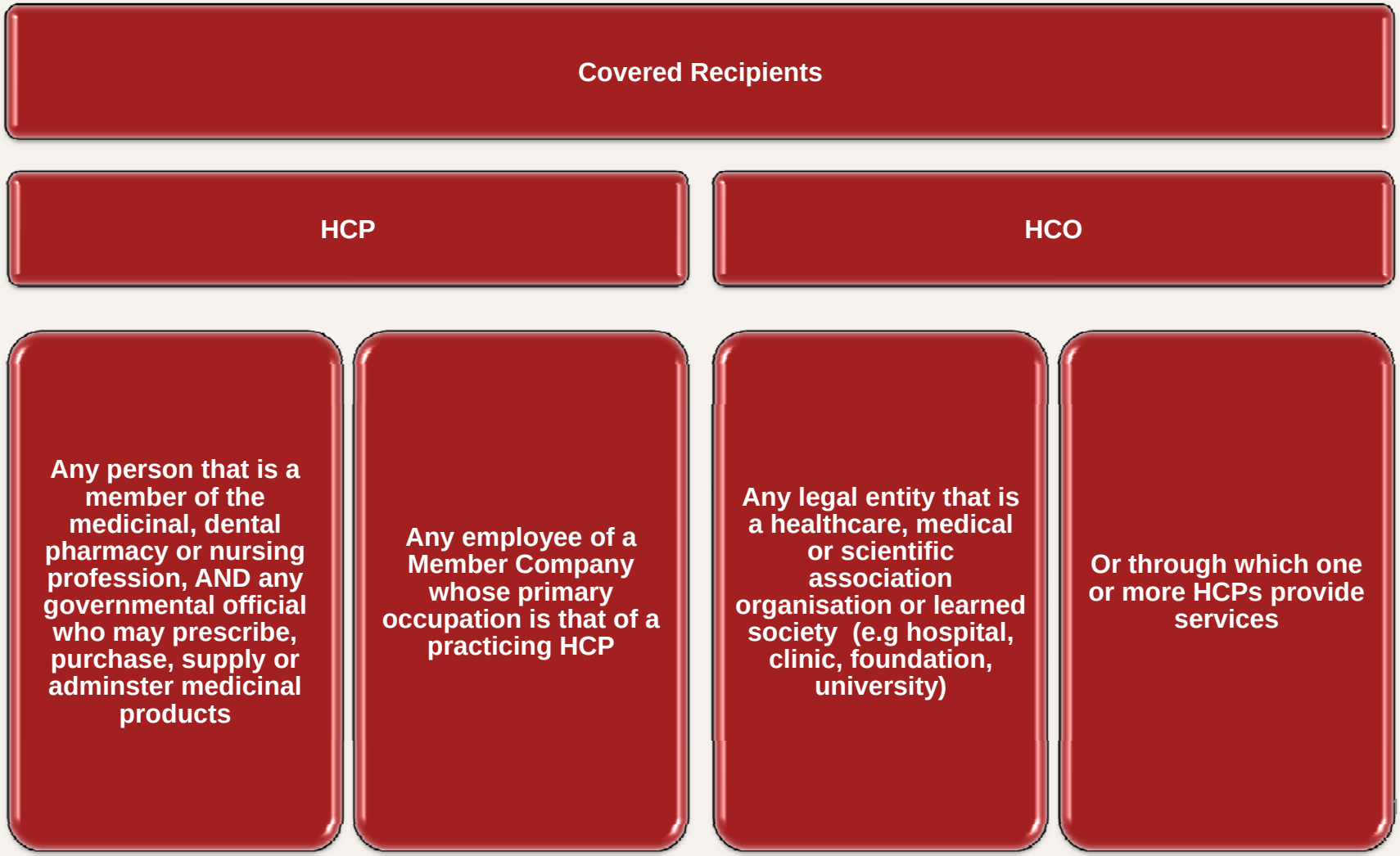
EFPIA Disclosure Code Requirements: Details

- Covers the following countries:

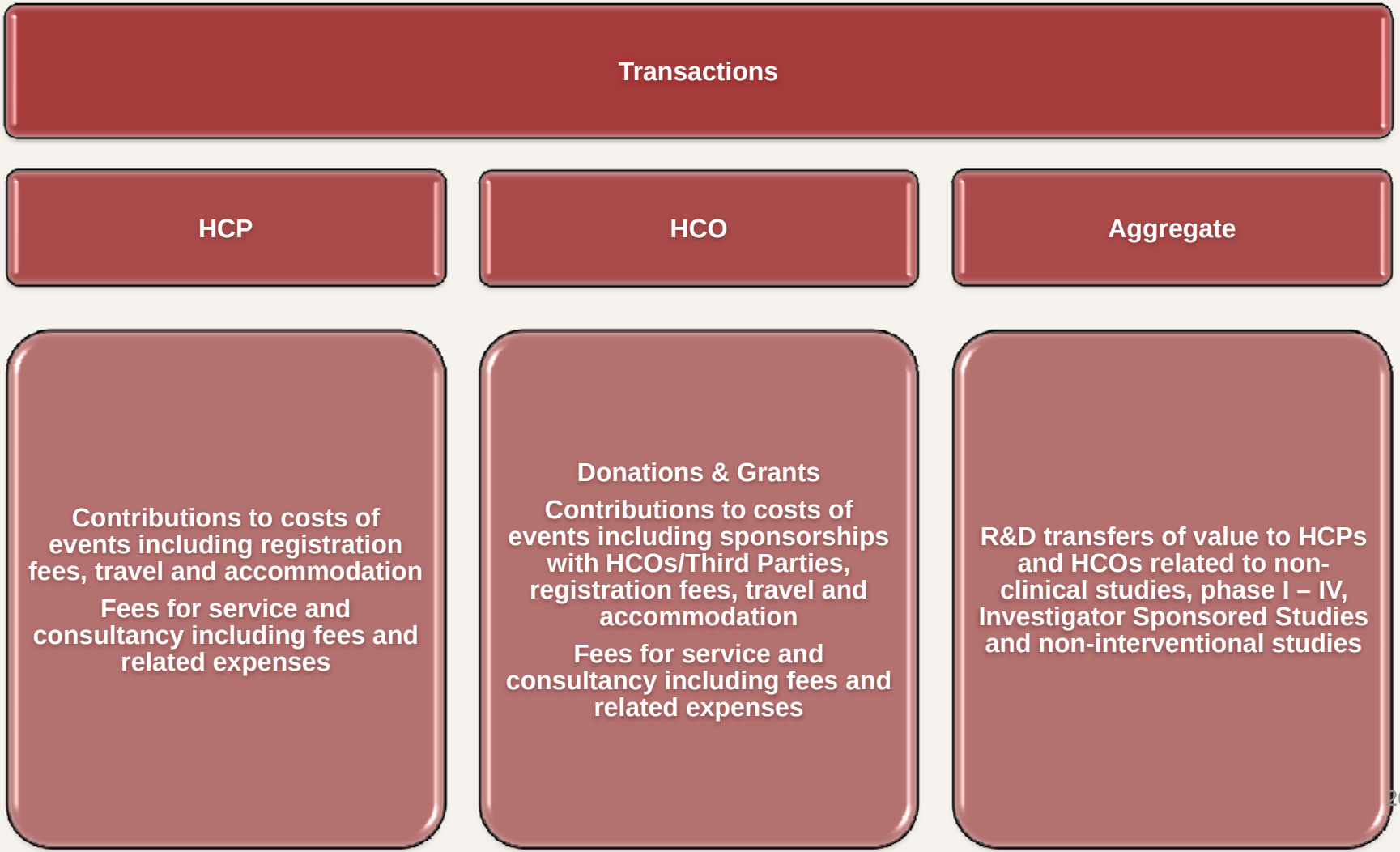
  Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

- Code require that the information is captured and disclosed:
  - Whether the payment made by manufacturer or through a Third Party on behalf of the manufacturer
- EFPIA requires that the Disclosure Code is transposed into local National Codes
- Data must be posted on a public platform (company's or public website)
- Extra-territorial...code follows the HCP
- **Requirement to obtain consent from HCPs and certain country HCOs to disclose data at an individual level**

EFPIA Disclosure Code Requirements: Covered Recipients



EFPIA Disclosure Code Requirements: Transactions



EFPIA Disclosure Code: Disclosure Template

Schedule 2 - TEMPLATE

Article 2 - Section 2.03

		Full Name	**HCPs:** City of Principal Practice **HCOs:** city where registered	Country of Principal Practice	Principal Practice Address	Unique country local identifyer *OPTIONAL*	Donations and Grants to HCOs *(Art. 3.01.1.a)*	Contribution to costs of Events *(Art. 3.01.1.b & 3.01.2.a)*			Fee for service and consultancy *(Art. 3.01.1.c & 3.01.2.c)*		Transfers of Value re Research & Development as defined *(Art. 3.04)*	**TOTAL** *OPTIONAL*
		(Art. 1.01)	*(Art. 3)*	*(Schedule 1)*	*(Art. 3)*	*(Art. 3)*		Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accomodation	Fees	Related expenses agreed in the fee for service or consultancy contract		
INDIVIDUAL	HCPs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCP*** *(i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
		Dr A					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		Dr B					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
		Aggregate amount attributable to transfers of value to such Recipients *- Art. 3.2*					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	N/A	*Optional*
		Number of Recipients *(named list, where appropriate) - Art. 3.2*					N/A	N/A	*number*	*number*	*number*	*number*	N/A	*Optional*
		% of total transfers of value to individual HCPs *- Art. 3.2*					N/A	N/A	%	%	%	%	N/A	N/A
	HCOs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCO*** *(i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
		HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
		Aggregate amount attributable to transfers of value to such Recipients *- Art. 3.2*					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	N/A	*Optional*
		Number of Recipients *(named list, where appropriate) - Art. 3.2*					*number*	*number*	*number*	*number*	*number*	*number*	N/A	*Optional*
		% of total transfers of value to individual HCOs *- Art. 3.2*					%	%	%	%	%	%	N/A	N/A
AGGREGATE		***AGGREGATE DISCLOSURE***												
		N/A	N/A	N/A	N/A	N/A	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*TOTAL AMOUNT*	*OPTIONAL*

National Disclosure Codes (Examples)

National Code Requirements: Germany

Current Status:

•EFPIA code has been transposed into the local code (FSA-Kodex)

- ✓ Approved by EFPIA
- ✓ Approved by the Federal Cartel Office (Bundeskartellamt)
- ✓ Effective by 1st of January 2015
- ✓ Disclosure in June 2016

•Platform to be used for disclosure, will be decided upon by end of 2014.

•Expected to be an Association platform, with links to the membership company platforms

•Languages must be in German and it is recommended to make it available in English

•Covered Receipients: Phycisian's and pharmacists, and other government officials who prescribe medicines for human use

National Code Requirements: Slovenia

FORUM OF INTERNATIONAL RESEARCH & DEVELOPMENT PHARMACEUTICAL COMPANIES, EIG

Current Status:

- EFPIA disclosure code has been transposed into the local disclosure code
  - ✓ Effective from 1st January 2015
  - ✓ Approved by EFPIA
- Slovenia implementation mirrors the EFPIA Disclosure Code
- Disclosure will be on the company's website in Slovenian language and also encouraged to disclose in English
- Covered Receipients: Physicians, pharmacists and nurses, who may prescribe, administer, purchase or supply medicines for human use (excluding wholesalers and distributers)

National Code Requirements: Switzerland

Current Status:

- Swiss code was updated by the 1st of May 2014
  - ✓ Effective as of January 2015
  - ✓ Approved by EFPIA
- Swiss implementation is very similar to the EFPIA code
- Disclosure to be made available on the company's Swiss or International internet web-site
- In principle, disclosure must be made in the English and whenever possible in the German, French and Italian languages
- Where a pecuniary benefit for a healthcare professional which must be disclosed is provided indirectly via a healthcare organization, it need only be disclosed once, but if at all possible individually

National Code Requirements: Italy

Current Status:

- Italian code was updated by the 11th of December 2013
  - ✓ Effective as of January 1, 2015
  - ✓ Approved by EFPIA
- Italian implementation mirrors the EFPIA Disclosure Code
- No central platform is foreseen – disclosure by individual member company
- Pharmaceutical companies shall do the utmost possible to obtain consensus from the Healthcare Professionals.
- IIT's to be disclosed as aggregate spend under "Research"
- In the case a transfer of value has been made to an individual Healthcare Professional indirectly via a Healthcare structure or third party, this data shall be disclosed on an individual basis where possible, and only once

National Code Requirements: UK

Current Status:

- EFPIA code has been transposed by ABPI
  - ✓ Effective 1st of January 2015
  - ✓ Approved by EFPIA
- Multiple differences from EFPIA Disclosure Code
- A template which can be used is available to download from the Authority's website (www.pmcpa.org.uk)
  - ✓ Requires additional information to the demographic information for HCP or HCO recipients
  - ✓ Requires the listing of each individual payments to HCOs (rather than allowing aggregation by reporting category)
  - ✓ Requires the company to attest to whether the company has a joint working agreement with recipient entity
- Disclosure will be on a central platform for disclosure
- Covered Receipients: Phycisian's and pharmacists, and other government officials who prescribe medicines for human use

Other Pending Requirements

- Columbia Disclosure Resolution in DRAFT
- India, Brazil, Canada...

- We can conclude that...we are moving to a world of more transparency vs. less...

Future State: Beyond External Reporting

What about other countries / regions?

Future state of External Reporting given the lessons from Open Payments and preparation for efpia reporting.

Once the data is out there

Data Analytics

Compliance Program enhancements

- *Policy / Training / Disputes*

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EFPIA Transparency Requirements: Operationalizing compliance components

October 2014

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Agenda

- *Defining strategies to address the following components of EFPIA requirements:*
  - *Consent Management*
  - *Data Privacy*
  - *Cross Border*
  - *Data Management*
- *Conclusion*

Defining strategies to address components of EFPIA requirements

Operational components of a global transparency program

1. Consent Management
2. Data Privacy
3. Cross Border
4. Data Management

Operational components of a global transparency program

1. **Consent Management**
2. **Data Privacy**
3. **Cross Border**
4. **Data Management**

Consent Management

Important component to ensure that EFPIA's self regulatory Disclosure Code does not violate local laws

1. What are the consent considerations for EFPIA member countries?
2. How should consent be streamlined across member countries?
3. How will companies manage refusal or revocation of consent?
4. How will companies address additional compliance and business considerations related to consent?

Consent in EFPIA Disclosure

EFPIA Requirements

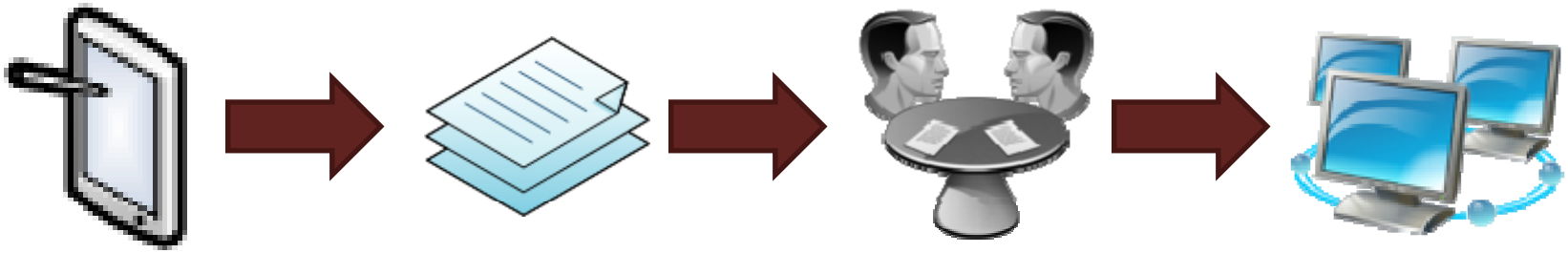
- Companies are encouraged to include consent provisions in written contracts with HCPs/HCOs relating to the recipients' consent to disclose Transfers of Value in accordance with the provisions of the Disclosure Code (including renegotiating existing contracts)
- They also recommend that all existing agreements be redone to include a consent provision.
- EFPIA recommends that all agreements between companies and HCPs and HCOs include a waiver of the privacy privilege.

Challenges

- National industry associations may interpret consent differently
- Data privacy regulations differ across country codes
- Manage consent data centrally at the individual HCP level -
- Track across languages and countries and keeping it available at global level
- Difficult to reconcile individual contracts with event/meeting information

Operationalizing Consent

Legal and Compliance		Business	Compliance and IT
Create streamlined consent language and include in standard contract templates	Determine if standard language can be utilized across all country affiliates according to local codes and regulations	Renegotiate all existing contracts for vendors, distributors, customers with updated consent language	Determine centralized location for data capture of consent indicator at the HCP profile level



Refusal and Revocation of Consent

- EFPIA states that any individual can refuse or revoke consent to disclose spend information.
- Some Member Association codes also explicitly recognize healthcare professionals' rights to refuse or revoke consent as well.
- Country specific consent nuances:

Under the Germany code of conduct, if an HCP does not consent, data will be published in aggregate

Under the Greece code of conduct, companies cannot provide benefits to HCP/O if they have not consented to publish data

Under the Slovenia code of conduct HCPs who revoke consent must return benefit under contract

Strategies for Refusal and Revocation of Consent

- Take reasonable steps to obtain consent and report spend data in aggregate
- Establish grounds for fair processing in order to collect, remediate, and aggregate

Require that consent be obtained prior to working with the HCP

OR

Require that consent be obtained prior to providing payment or benefit to HCP

Consent: Additional Considerations

- Capture consent for indirect payments made to HCPs by a third party on behalf of the company
  - Utilize standard contract templates which already includes consent language
  - Utilize separate template for HCP consent only
    - Will require training of third party vendors to ensure that consent is obtained
- Effectively manage customer relationships and expectations while ensuring consent is gathered

Operational components of a global transparency program

1 Consent Management

2 Data Privacy

3 Cross Border

4 Data Management

Data Privacy

EFPIA Requirements

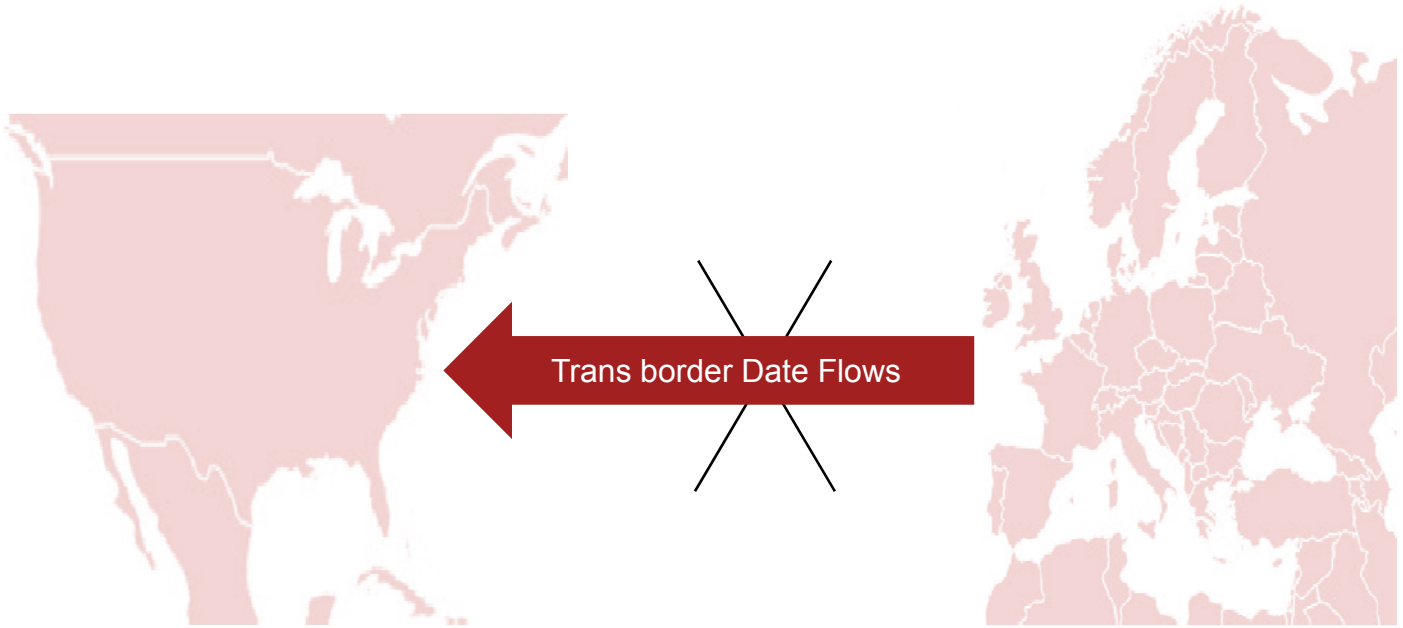
- EFPIA states that companies must comply with applicable data protection and other laws, which may limit their ability to disclose on an individual basis
- Data privacy requirements must be checked at the country level (i.e., the jurisdiction of the HCP/HCO receiving payment or transfer of value) by the member company prior to any disclosure

Challenges

- Ensure that all HCP/HCO are aware of data privacy laws and considerations
  - Obtain consent from HCP/HCO prior to disclosure
- Limits ability to standardize program and process for data collection
- Enhanced complexity to share information across borders
  - Difficult to maintain unique HCP identifier and profile information

Data privacy considerations: EU-US data transfer restrictions example

The Issue: The EU Data Protection Directive prevents the transfer and access of EEA-related business and employee data to countries that are deemed “inadequate” such as the US.



- For EFPIA reporting ensure that data collection is centralized and stored in Europe
- For Non-EU members retain data in country and collect, remediate, and aggregate locally(e.g., Russia)

Operationalizing Data Privacy

Business Process

Confirm standardized contract language with country Data Privacy Officer where event is held

HCP signs contract with consent and data privacy language prior to event

HCP conducts activity and spend transaction occurs in country

Data Process

Minimum required data is sent to secure central location

Data is remediated and aggregated in central location

Aggregated data is sent back to HCP's country of principal practice for disclosure

Operational components of a global transparency program

1. Consent Management
2. Data Privacy
3. **Cross Border**
4. Data Management

Cross Border

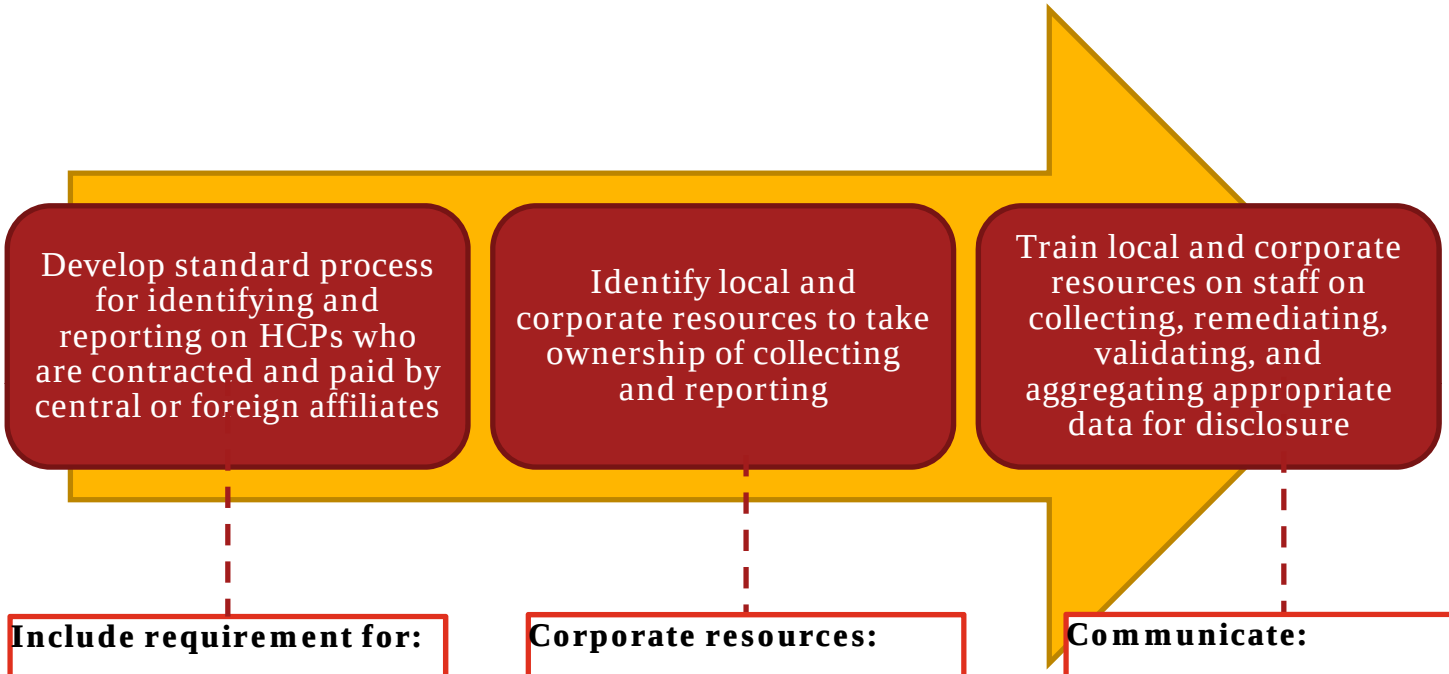
EFPIA Requirements

- EFPIA requires that companies disclosure payments made to HCPs/Os based within their borders even if those payments originate within a foreign country
    - For example, "if an Italian affiliate of an EFPIA Member Company engages with a HCP whose practice is in Spain for an activity in Germany, this Transfer of Value will have to be disclosed under the name of the recipient HCP in Spain (following the applicable laws, regulations and the national code in Spain).

Challenges

- Obtain consent from all HCPs to ensure that HCPs are contracted in line with cross border and data privacy requirements
- Managing spend cap and meal limits cross border
- Engage with Compliance and Legal to ensure that disclosure reporting requirements are met
    - Additional considerations: Foreign Corrupt Practices Act and UK Bribery, anti-bribery and anticorruption regulations

Operationalizing Cross Border



Include requirement for:

- Notifying HCPs country of principal practice
- Approval for use and payment by country of principal practice

Corporate resources:

- Remediate and aggregate data in central location

Local resources:

- Collect data and validate data for disclosure
- Assist with data remediation questions

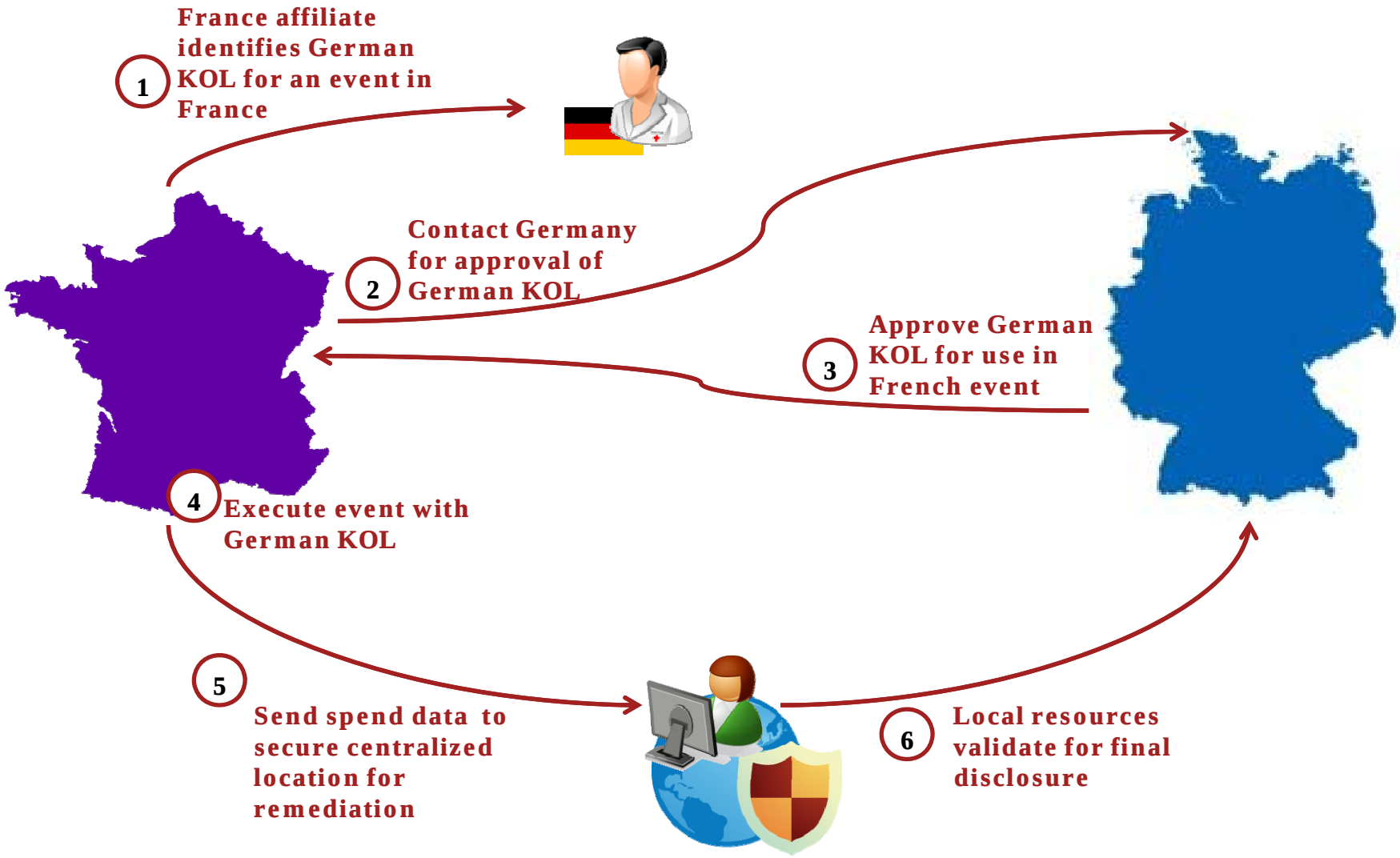
Communicate:

- Global policy and procedure on engaging HCPs cross border

Training:

- Ensure that data is accurately and completely captured for appropriate disclosure

Cross Border Considerations



Operational components of a global transparency program

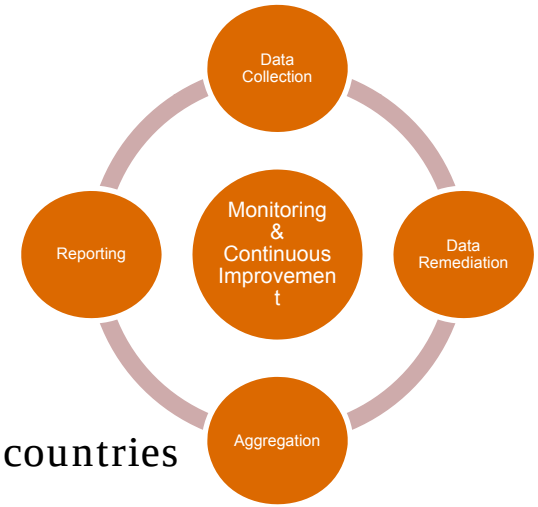
1. Consent Management
2. Data Privacy
3. Cross Border
4. Data Management

HCP/O Data Management Strategies

EFPIA Requirements

Strategies to develop at each stage of data management cycle to ensure that disclosure report is complete and accurate:

- Collection
- Remediation and Validation
- Aggregation and Consolidation
- Reporting



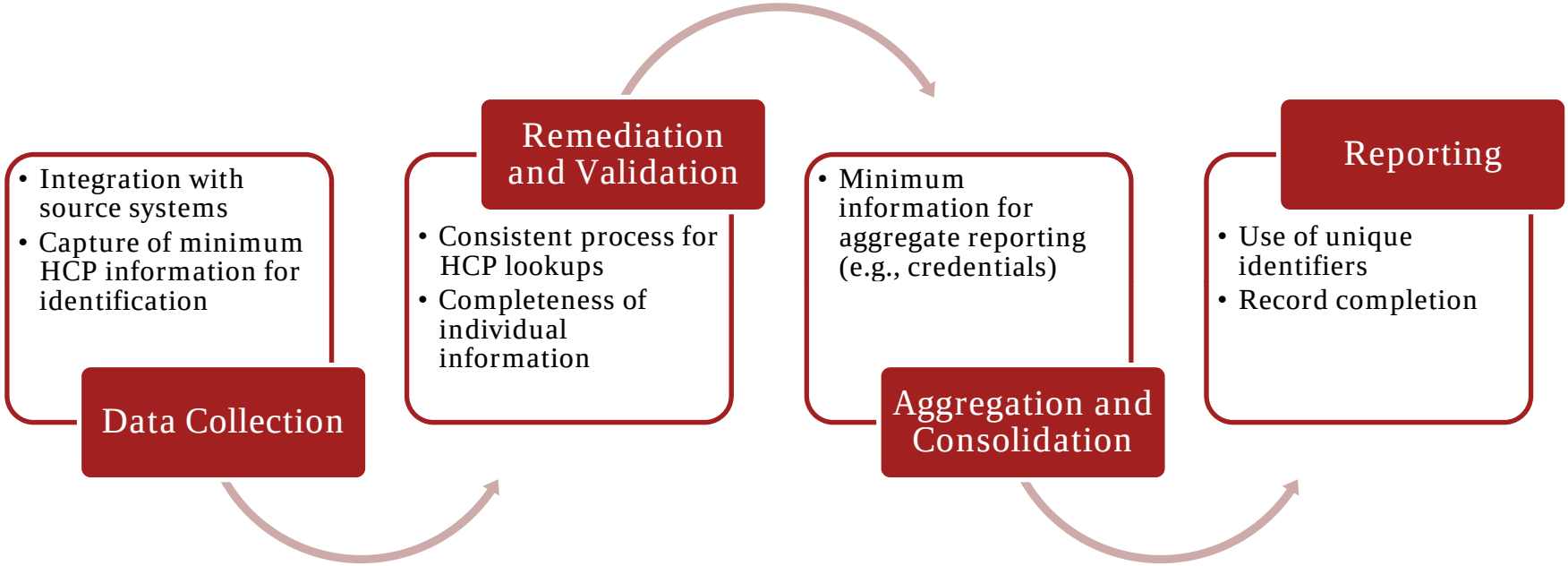
Challenges

- Identifying a single, unique ID for an HCP/O across all countries
- Managing HCP/O data and requirements across multiple countries
- Validating unique customers across different country HCP lists

EFPIA HCP/O Data Required

Code of Conduct	HCP	HCO
EFPIA Disclosure Code	Full Name	Full Name
	City of Principal Practice	City where registered
	Country of Principal Practice	Country of Principal Practice
	Principal Practice Address	Principal Practice Address
	Unique Country local identifier	Unique Country local identifier
ABPI	Title	
	Specialty	
	Role	
	Institution Name	
	Email	
	Local Register ID or Third Party Database ID	
France Sunshine	RPPS Unique Country Identifier	

HCP/O Data Management Strategies



Conclusion

Questions?