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Seventh Asia Pacific Pharmaceutical and Medical Device Compliance Congress

Mini Summit VI: Transparency Reporting to Prevent Corruption Risk

Time: 13.00 – 14.15 pm
Date: September 14, 2017

Introducing the panel

Myung Soon Chung, Esq.
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Director, Compliance Rules & Management, Japan Pharma Business Unit, Takeda Pharmaceuticals; Member, Code Compliance Committee, Japan Pharmaceutical Manufacturers Association; Member, IFPMA Ethics & Business Integrity Committee (eBIC), Tokyo, Japan

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China Head, Global Ethics & Business Integrity, Sanofi Group; Former Associate Compliance, Director, Eli Lilly China, Shanghai, China

Mike Zhao, MBA
Ethics and Compliance Lead, China, UCB; Former Compliance Manager, Johnson & Johnson, Shanghai, China

Joyce Wong
Managing Director, Polaris Asia-Pacific; Former General Manager, Eli Lilly Asia Inc., Hong Kong (Moderator)

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Discussion Topics

1. Overview on the latest transparency reporting requirements in Asia Pacific
2. Transfer of value in Life Science Industry? Where are the risk areas?
3. How transparency reporting can prevent corruption risk?
4. Key consideration in preparing the transparency reporting?
5. Common challenges before spend is aggregated or a report is created?
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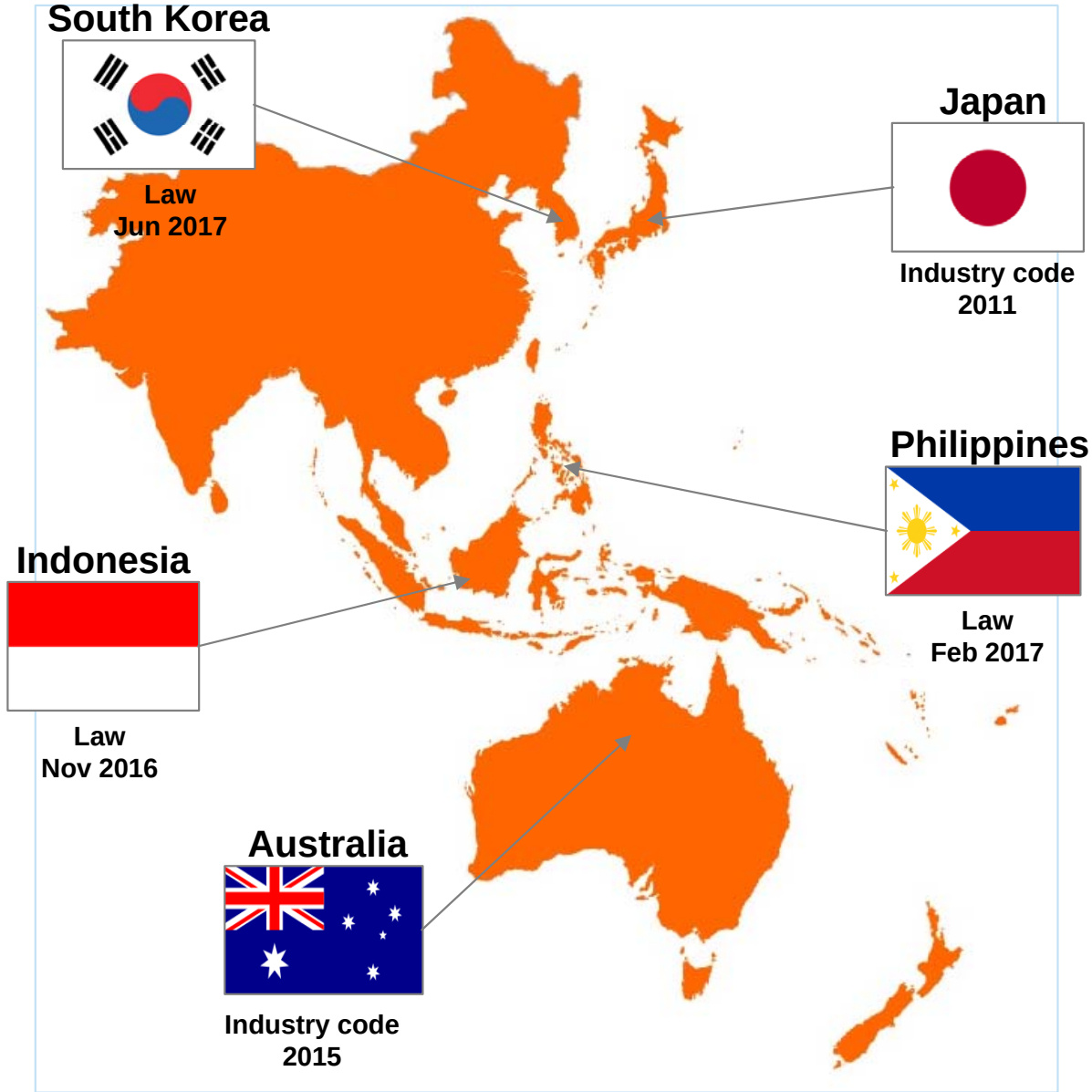
APAC Countries with Transparency Reporting Requirements

There are currently five countries within the APAC region requiring transparency reporting either by law or through an industry code.



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Korea: Transparency Reporting

Topic	KRPIA/KMDIA Fair Competition Code	Pharmaceutical Affairs Act (PAA)/ Medical Device Act (MDA)
Governing Body	KRPIA/KMDIA	Ministry of Health & Welfare
Industry	Pharma and MedDevices	Pharma and MedDevices
Reportable Recipients	HCPs and HCOs	HCPs
Reportable Activities	Donations, sponsorships for hosting academic conferences, sponsorships for attending academic conferences, product presentations (single, multiple institutions), market surveys, booth and print advertising fees, lecture and consulting (MedDevices)	Provision of product samples Support for clinical trials Compensation for post-marketing studies Benefits provided to attendees of company-hosted product presentations (includes training/education under MDA) Sponsorship to attend academic conferences Purchase price discounts
Disclosure Date Disclosed Items	No Disclosure Obligation*	No Disclosure Obligation
Consent/Pre-publication	No	No

*However, in case of sponsorships to attend academic conferences, title of academic conference, organizer of academic conference, name of sponsor, amount of sponsorship, number of participants and affiliated medical institution disclosed on each industry association's website

Korea's New Requirement – Expenditure Reports

- Pharma/medical device companies must prepare expenditure reports on value transfers made to HCPs and retain such reports and supporting materials for 5 years
- For value transfers starting on January 1, 2018
- No automatic submission requirement; companies to submit if MOHW so requests
- No disclosure requirement but information in the reports may become public
- Failure to prepare, retain or submit reports or provision of false information can result in criminal fine of up to KRW 2 million (roughly USD 2,000); may also trigger investigation

RENEWED DISCLOSURE RULES IN JPMA

	JPMA Transparency Guidelines
A. R&D expenses	
1.Joint research, 2.Research commissioning (Clinical)	(Recipient name and amount) ABC University: xx contracts, total xx Yen
3.Joint research, 4.Research commissioning (Non-clinical)	(Recipient name list / Company total) ABC University / Company total: xx contracts, xx Yen
5.Clinical study, 6.Post-marketing clinical study, 7. ADR/infection case reporting, 8.PMS	(Company annual total / Detail of each recipients) ABC University: xx contracts, total xx Yen
B. Academic research support expenses	
1.Scholarship, 2.General donation	(Recipient name and amount) ABC University: xx contracts, total xx Yen
3.Donation to / 4.Co-sponsoring with academic societies,	(Recipient name and amount) xxth Society of XYZ: xx cases, total xx Yen
C. Manuscript / Writing fee, etc	
1.Fee for speaking 2.writing 3.consulting, etc.	(Recipient name and amount) ABC University, XYZ department, HCP's position, HCP's Name, xx contracts, total xx Yen
D. Information provision-related expenses	
1.Expense for Lecture mtgs, 2.Product explanation mtgs, 3.promotional items, literatures	(Company total) Number of events, Total xx Yen
E. Other expenses	
1. Hospitality, gifts, etc as social courtesy	(Company total) Total xx Yen

for each fiscal year

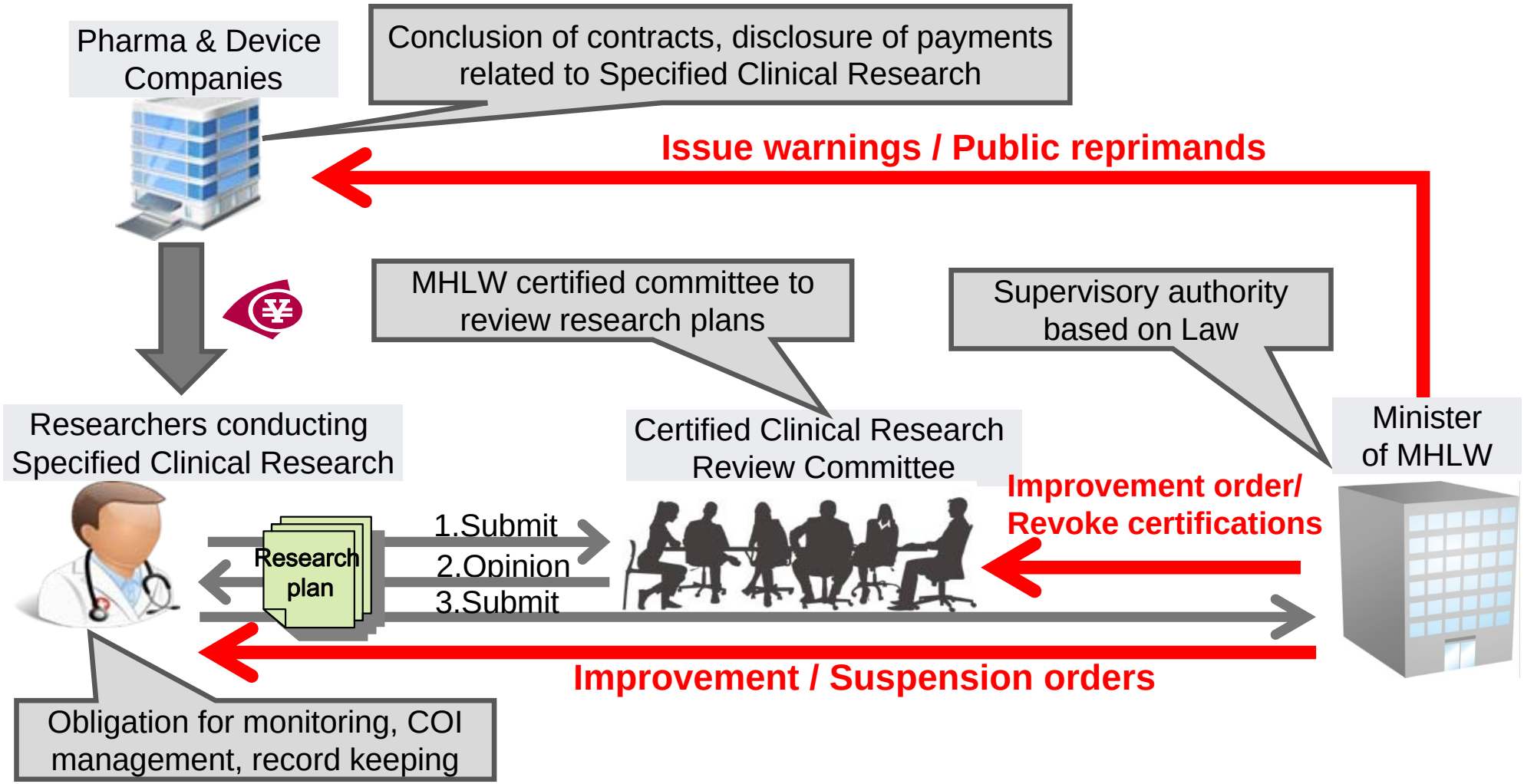
- Industry voluntary disclosure
- Detailed disclosure of R&D payments
- Payments made from FY2016 to be disclosed in FY2017
- Disclosed on each company websites

CLINICAL RESEARCH LAW

<table>
<tr><th colspan="4">Clinical Research on Medicines</th></tr>
<tr><td>Clinical Trials</td><td colspan="2">Specified Clinical Research</td><td rowspan="2">Other clinical research</td></tr>
<tr><td>Clinical research for approval</td><td>Clinical research of unapproved /off-label drugs</td><td>Clinical research on drugs funded by companies</td></tr>
<tr><td>Pharmaceuticals and Medical Devices Law</td><td colspan="3">Clinical Research Law</td></tr>
<tr><td>Mandatory abidance (GCP Ordinance)</td><td colspan="2">Mandatory abidance</td><td>Duty of best efforts</td></tr>
</table>

- Passed the Diet of Japan in April 2017
- To become effective by April 2018
- Includes mandatory disclosure clause for payments related to "Specified Clinical Research"

SUPERVISORY AUTHORITIES OF MHLW



SCOPE OF DISCLOSURE BY THE NEW CLINICAL RESEARCH LAW

	Transparency Guidelines	Clinical Research Law
A. R&D expenses		
1.Joint research, 2.Research commissioning (Clinical)	(Recipient name and amount) ABC University: xx contracts, total xx Yen	(Recipient name and amount) ABC University: xx contracts, total xx Yen
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Details to be decided by the MHLW

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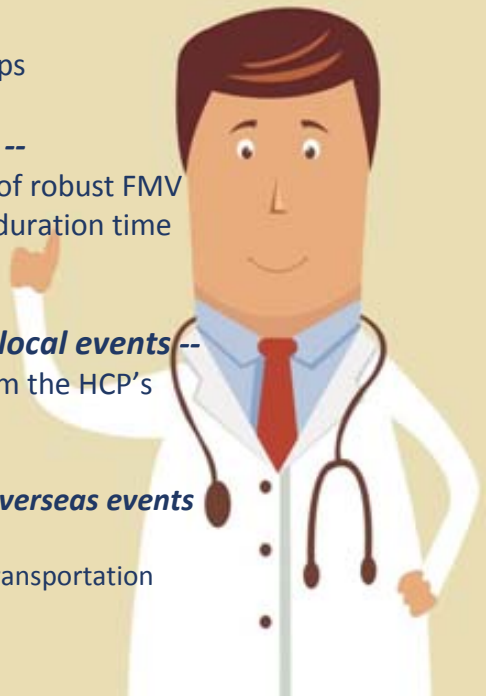
Transfer of value in Life Science Industry

Overall risks:

- **Missing contracts**
- **Incomplete/Inaccurate data entry**

- **Poor MDM management**
- **No or deficient background checks**

HCP



Hospitality -- caps

Fee for services -- Inconsistent Use of robust FMV rates – speakers duration time much less

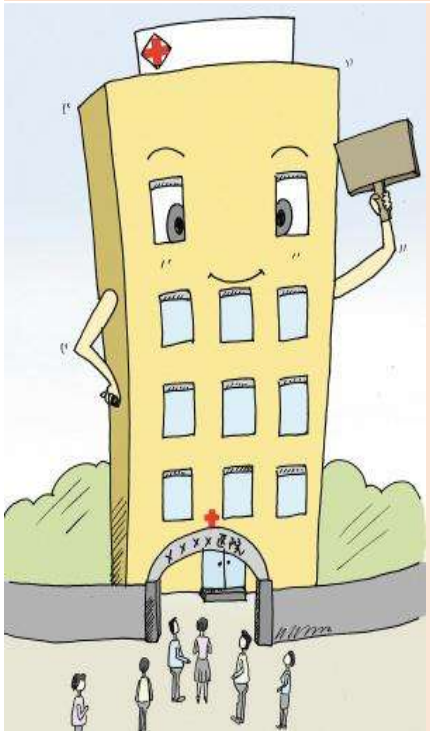
Sponsorship to local events -- endorsement from the HCP's employer

Sponsorship to Overseas events -- Daily Car Service Transportation

Other third parties

- Distributors
- Market Researchers
- Travel Agency
- Logistics Vendors

HCO/MSA



Contributions -- double dipping; Management Fees

Donations & Grants -- material benefits or not

SANOFI

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Who Needs to Prepare Expenditure Reports?

Suppliers of Pharmaceutical Products/Medical Devices

- Those holding product registrations
- Importers
- Wholesalers (pharmaceutical companies)/Distributors (medical device companies)
- Co-promoters (pharmaceutical companies)

Not subject to requirements

- CSOs
- CROs
- Overseas HQ, branches or affiliates

Value Transfers Covered – PAA/MDA

- Expenditure reports limited to economic benefits enumerated PAA Enforcement Regulations /MDA Attendant Regulations

- 6 Types:
  - Provision of product samples
  - Support for clinical trials
  - Compensation for post-marketing studies
  - Benefits provided to attendees of company-hosted product presentations (includes training/education under MDA)
  - Sponsorship to attend academic conferences
  - Purchase price discounts

- Lecture fees/consulting fees not subject to reports, but may be included in the future

When is the Effective Date?

- Need to record value transfers made starting on January 1, 2018
- Need to complete preparing expenditure reports within 3 months after the end of each company's fiscal year
- ***E.g., 1)*** Company's fiscal year starts from January 1, 2018
  - Must prepare expenditure reports for value transfers made from January 1, 2018 by March 31, 2019
- ***E.g., 2)*** Company's fiscal year starts from September 1, 2017
  - Must prepare expenditure reports for value transfers made from January 1, 2018 by November 30, 2018

What Must be Retained – Related Ledgers and Supporting Materials?

- In some cases, industry codes already provide for similar retention obligation

- According to MOHW:
  - "Related ledgers": Internal ledgers that include details on expense execution
  - "Supporting Materials": e.g., receipt for goods (provision of product samples); clinical trial agreement (support for clinical trials); sign-in sheets (benefits provided to attendees of company-hosted product presentations)

- "Electronic records" acceptable

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Common challenges in disclosure and aggregating reports in Japan

Understanding from HCPs

- Disclosure method
- Access to disclosed information

Capturing Correct Data

- Invalid input or selection by system user
- Misallocation of data
- Duplication (minus and plus)
- Capture of payments through vendors

Customer Master Management

- Consistency of disclosed information (institution, department, position, etc.)
- Insufficient update of master data

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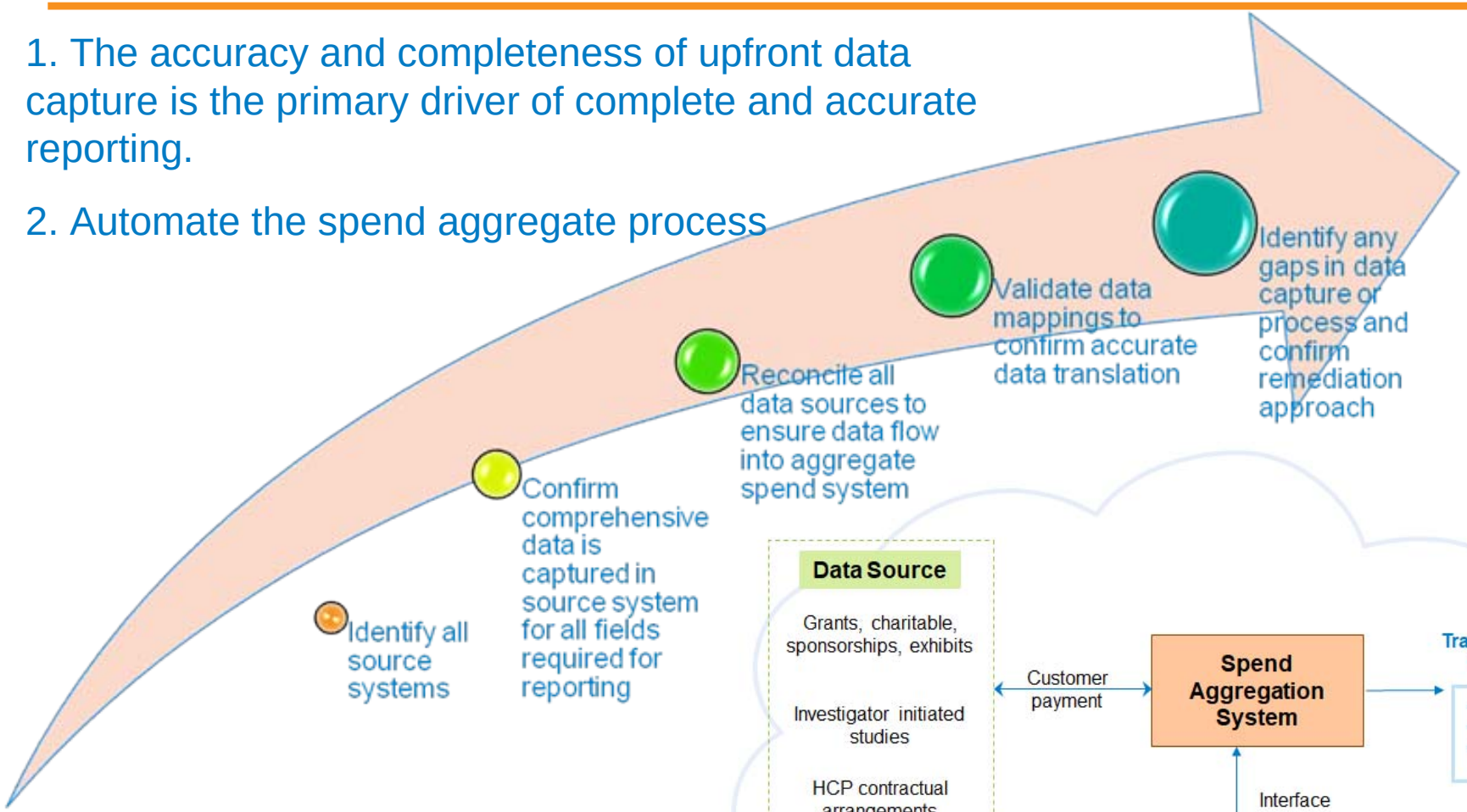
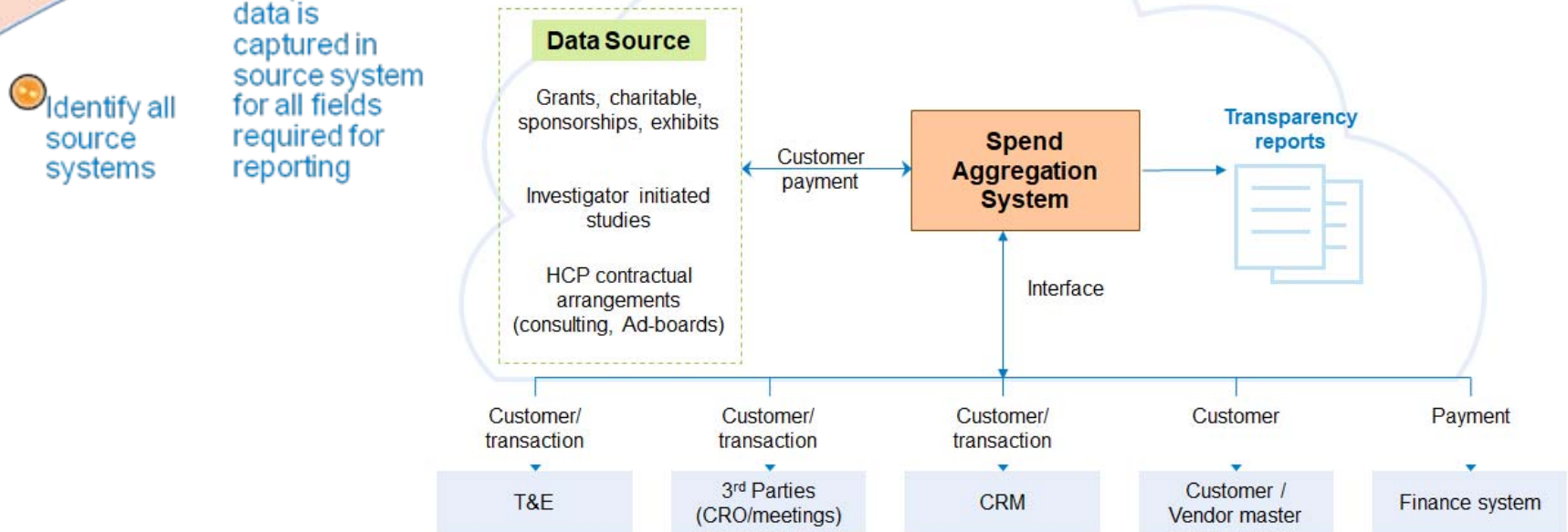
Transparency Reporting: Best Practice

1. The accuracy and completeness of upfront data capture is the primary driver of complete and accurate reporting.

2. Automate the spend aggregate process





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Benefits & Challenges of Voluntary Disclosure in the case of Japan

Benefits
- Maintain / restore industry reputation
- Can place industry in a strong position ever when unfavorable events occur
- More powerful than just setting rules
- Control

Challenges
- Agreement and alignment within membership
- Understanding from stakeholders (especially HCPs)
- Resource

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Transparency in the world

North America

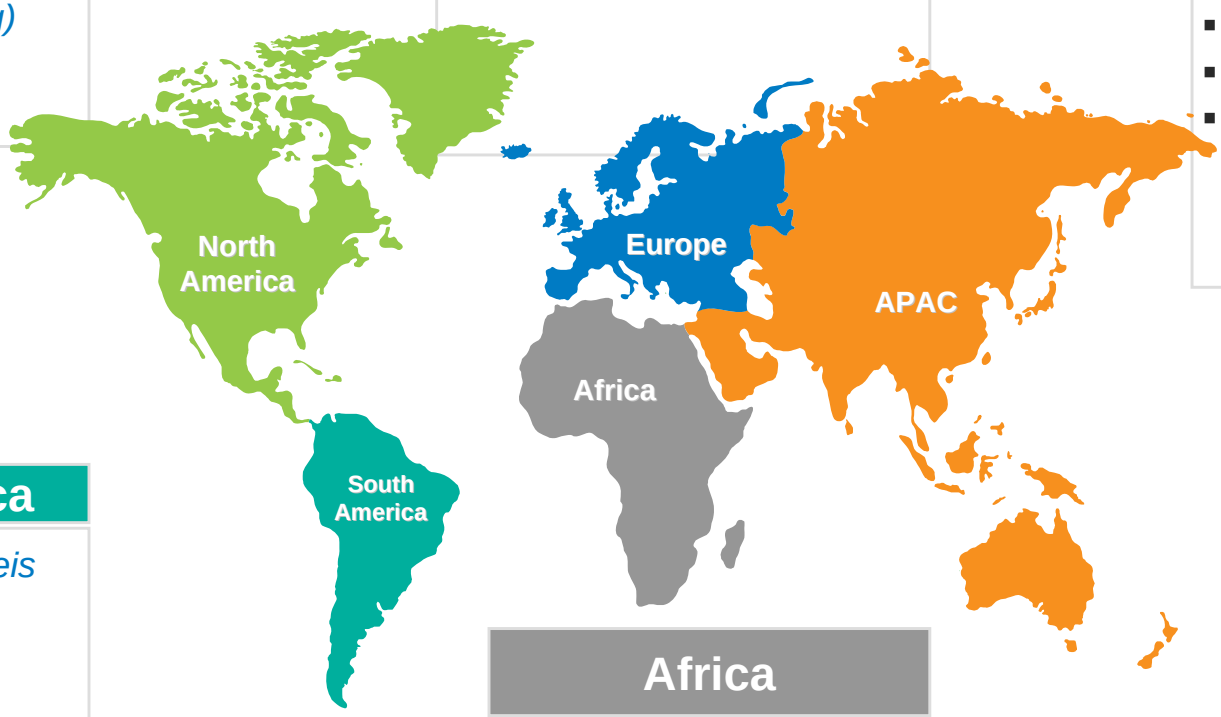
- USA (laws)
- *Canada (upcoming code)*
- *Mexico (upcoming)*

Europe

- EFPIA: 33 countries
- Not EFPIA members : 2
- *Medtech (upcoming code)*
- *Generic (upcoming code)*

APAC

- Japan (code)
- Australia (code)
- South Korea (Law)
- Philippines (Law)
- Indonesia (Law)
- *Saudi Arabia (upcoming law)*



South America

- *Brazil (Minas Gereis state law)*

Africa

- *Mecomed (MENA region upcoming code)*

More and more transparency regulations all over the world

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HISTORY OF DISCLOSURE OF PAYMENTS IN JAPAN

Fiscal year	Within JPMA	Other events
2009	·Started discussion on Disclosure	
2010		
2011	·Announced JPMA Transparency Guidelines	
2012	·Collection of Payment Data	
2013	·Started disclosure (excluding amount of honoraria)	·Discussion between JPMA, JMA, JAMS ·Misconduct in clinical research
2014	·2nd year of disclosure(full disclosure)	·Other associations follow JPMA disclosure ·JAMS request more disclosure in R&D
2015		
2016	·Decision to increase transparency in R&D related payments	
2017	·Start of detailed disclosure in R&D related payments	·Clinical Research Law passed the diet
2018		·Clinical Research Law to be implemented

JAMS: The Japanese Association of Medical Sciences

CLINICAL RESEARCH LAW

Items to be clarified

•Scope of recipient
•Timing of data collection and disclosure
•Method of disclosure
•Whether it is ok if we include legally required disclosure within our voluntary disclosure?
•Public access to transparency information. (Most companies currently require application for access.)
•Period of disclosure.

Details will be defined in the Clinical Research Standard, which will be published by the MHLW by April 2018.

Challenges

•Create database based on research and record related payments for donations to the institution and honoraria to the researcher
•Develop reliable system to comply with the law
•Voluntary disclosure and Legal disclosure will exist at the same time

Where Do Your Company Stand Currently for Transparency Reporting?

What is your current process?

1. Do you use a manual process?
   - Who owns your process?
   - Policy & SOP in place?
   - What buy-in have you had from different business functions?
2. Do you have automated controls/systems in place?

How confident are you in the accuracy of your spend data?

1. Do you audit spend information?
2. Are HCP/Os associated with spend validated?
3. Is spend information updated continually? Or collected and reviewed in time for filings?

How confident are you in the completeness of your spend data?

1. How many business areas report spend?
2. Does your company actively participate in the spend collection process?

Are your company ready if Transparency Reporting will be enforced in your country in the near future?

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