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Mini Summit 6: Transparency Reporting Challenges and Approach: learning from Global

18th ASIA PACIFIC PHARMACEUTICAL AND MEDICAL DEVICE ETHICS AND COMPLIANCE CONGRESS

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Transparency Reporting Challenges and Approaches: Learning from Global Experience and Overview of the latest Transparency Reporting in Asia

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Speaker Bio

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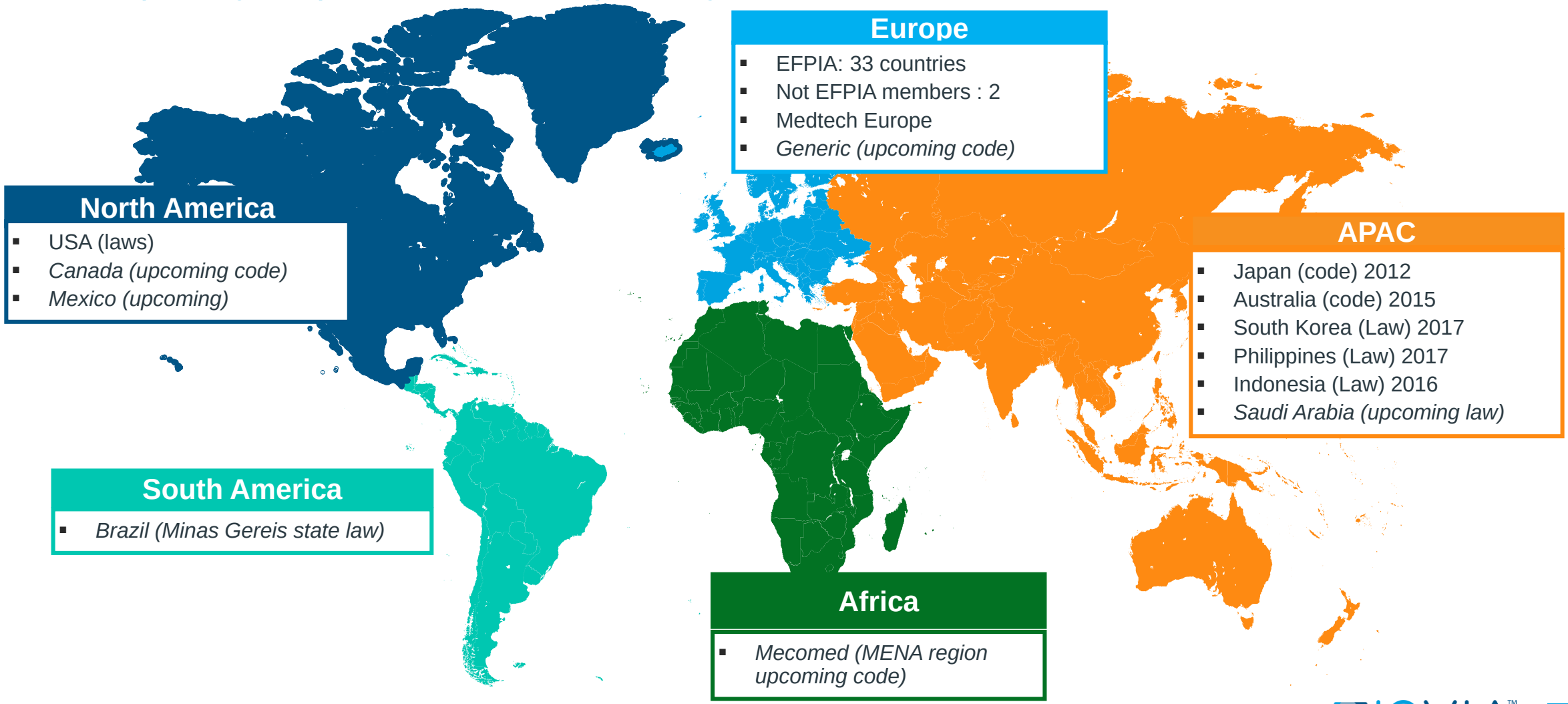
Currently 43 countries with transparency reporting requirements

Global Reporting Requirements are Expanding



North America

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

Europe

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

APAC

- Japan (code) 2012
- Australia (code) 2015
- South Korea (Law) 2017
- Philippines (Law) 2017
- Indonesia (Law) 2016
- *Saudi Arabia (upcoming law)*

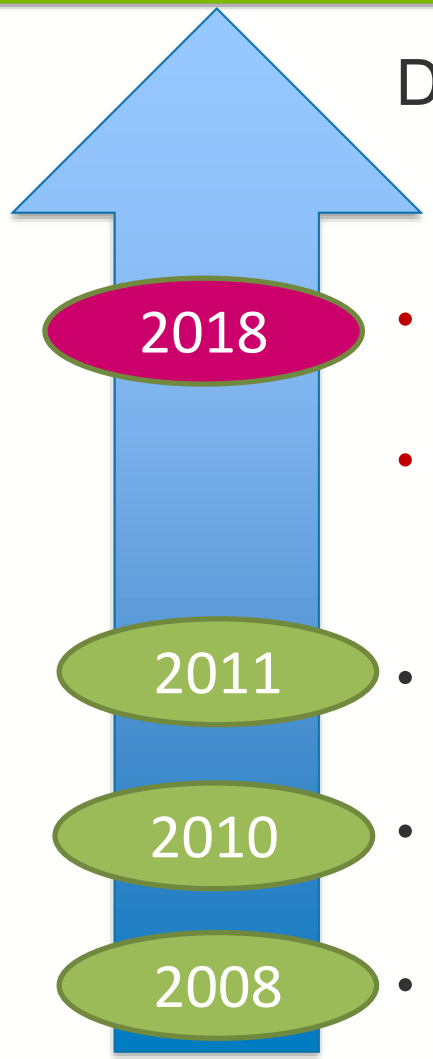
South America

- *Brazil (Minas Gereis state law)*

Africa

- *Mecomed (MENA region upcoming code)*

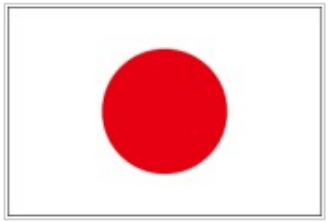
Transparency Reporting in APAC



Development in last 10 years…

- JAPAN The Clinical Trials Act and Transparency Guideline (August 2018)
- Amendment of Pharmaceutical Affairs Act & Medical Devices Act (K-Sunshine Act)
- JPMA Transparency Guidelines
- U.S. Sunshine Act
- Medicines Australia Cost for Educational Events

Overview of Transparency in Japan



- Expanding voluntary transparency guidelines.
  - Pharma for HCP/HCO (2011, revised 2015, planned 2018 Oct.), Pharma for Patients (2012), Device (2012), Generic (2012), Public medical institution (2014).
- Clinical Trials Act.
  - 7 April 2017 enacted. 1 April 2018 came into force.
  - Section 33 Transparency requirements.
  - MHLW Directive : Detailed disclosure requirements.

    e.g. Keep data for 5 years after the disclosure.
  - Penalty : Reminder by MHLW (Section 34.1)

    Disclose a company name by MHLW (Section 34.2)

Transparency Reporting - Japan

Transparency Guidelines was amended in April 2018

	Japan		US
Guideline Name	Transparency Guidelines	Clinical Trials Act	Sunshine Act
	Voluntarily	Mandatory	Mandatory
Scope	A. R&D B. Grants C. Honoraria D. Event E. Other	Clinical Study (including Grants, Honoraria)	Research activities, Grant, Honoraria, Consulting fees, Speaker fees, Education, Food and beverage, Travel and lodging, Gifts
Method	Home page of each company	Home page of each company	CMS.gov
The effective date	2011.3	**2018.4**	2010.3
Disclosure starting year	2013 (2012 payments)	2020 (2019 payments)	2014 (2013.8-12payments)
Penalty	none	Disclosure & Reminder	$ 1,000～10,000/ 1件

Transparency Reporting - Japan

Clinical Trials Act 2018.4

1. Obligation to execute contracts for Research Grants
2. Disclosure Obligation regarding Provision of Research Grants

- **Transparency Guideline Category A: as-is**

Category A	
A1.Collaborative research expenses	clinical research
	other than clinical research
A2.Contract research expenses	clinical research
	other than clinical research
A3.Clinical Trial	
A4.Clinical Trial (Phase4)	
A5.AE Report	
A6.PMS	
A7.Others	

- **To-be**

Category A
Specified Clinical Research
Research ethics on human participants
Other than clinical research
Clinical Trial
Clinical Trial (Phase4)
AE Report
PMS
Others

same

Required by law

Transparency Reporting - Japan

Sample Report of Category A under New Regulation

Specified Clinical Research

Clinical Research ID	Vendor (Pfizer payed to)	Institution conducting Clinical Research			# of Contract	Amount
		Institution Name	Department	Doctor Name		
xxxxxxx1	○○大学附属病院	○○大学附属病院	○○科	●● ●●	1	xxxxx円
xxxxxxx2	△△病院	△△病院	△△科	●● ●●	1	xxxxx円
Xxxxxxx3	▲▲大学	▲▲大学附属病院	▲▲科	●● ●●	1	xxxxx円
xxxxxxx4	NPO ◎◎	-	-		1	xxxxx円
		◇◇センター	◇◇部	●● ●●	-	(xxxxx円)
		□□クリニック	-	●● ●●	-	(xxxxx円)

Others of Category A

Vendor (Pfizer payed to)	Institution conducting Clinical Research	# of Contract	Amount
	Institution Name		
○○大学附属病院	○○大学附属病院	1	xxxxx円
△△病院	△△病院	1	xxxxx円
××大学	××大学附属病院	1	xxxxx円
▲▲大学	▲▲大学附属病院	1	xxxxx円

Transparency Reporting- Korea

K- Sunshine Act - Pharmaceutical Affairs Act (PAA) and Medical Devices Act (MDA)
From January 1, 2018, all pharmaceutical and medical device companies are required to prepare an expense report on transfer of value (economic benefits) provided to HCPs within three months after the termination of each fiscal year (Article 47-2 of KAA and Article 13-2 of MDA). Companies should retain and submit the expense report and supporting documents at the request of Minister of MOHW

- Scope of HCPs: pharmacists, oriental medicine pharmacists, medical personnel, medical institution founders, or persons working for a medical institution
- Retention Period: Expense report and support documents should be maintained for 5 years
- Expense Report Preparation Timeline: Within 3 months after end of a company's respective fiscal year
- Reporting Categories:(i) samples; (ii) clinical trials; (iii) post-market surveillances;(iv) product presentations to multiple medical institutions; (v) product presentation to a single medical institution; (vi) academic conferences; and (vii) price discounts based on payment conditions.

Transparency Reporting- Korea

1. Samples

① Number	Medical Institution		Product Information					⑧ Date
	② Name	③ Registration #	④ Name	⑤ Code	⑥ # of items in a package	⑦ # of package	⑧ Total #	
1	다나병원	123456789	리리카캡슐	987654321	10	1	10	2018-01-04

2. Product Presentation for multiple institutions

① Number	② Product	HCP Information		Transfer of Value				⑨ Venue	⑩ Time & Date
		③ Name	④ Institution	⑤ Transportation Cost	⑥ Brand Reminder	⑦ Accommodation	⑧ Meals & Bev.		
1	AAA정 25mg BBB정 50mg	나진료	다나병원	90,000	50,000	230,000	130,000	조은호텔	2018-07-15 19:00 ~ 2018-07-16 12:00

3. Product Presentation for single institutions

① Number	② Product	Medical Institution		HCP Information	⑥ Meal & Bev.	⑦ Venue	⑧ Time & Date
		③ Name	④ Registration #	⑤ Name			
1	AAA정 25mg BBB정 50mg	다나병원	123456789	나진료	90,000	다나병원 경복궁	2018-04-20 19:00

Transparency Reporting- Korea

4.Sponsorship for Participation in Academic Conference

① Number	Conference Information				⑥ Sponsoring Amount
	② Host Org.	③ Name	④ Country/city	⑤ Date	
1	Japan College of Abcdology, ADCD 학회	61stJ Japan College of Abcdology	일본 / 후쿠오카	2017-04-20 ~ 2017-04-22	1,025,240

5.Clinical Trials

① No.	Clinical Trial Information				Principal Investigator		C I		Transfer of Value			Contract Date
	② Study Name	③ Classification	④ Approval No.	⑤ Approval Date	⑥ Name	⑦ Institution	⑧ Name	⑨ Medical Institution	⑩ Amount	Product	# of product	
1	혈관세포의 KA1 enriched exosome 분비 기전과 특성 분석 연구	2	CMC-2017-05-213	2017-05-21	장아영	AA 병원	김민열	BA병원	35,000,000	RGH정	20,000	2017-01-25
							김은우	BB병원				
							이선미	BC병원				

6.Post Marketing Surveillance

① Number	Product Information	HCP Information			Transfer of Value	
	② Product	③ Subject to re-evaluation	④ Name	⑤ Institution	⑥ Payment/Case	⑦ # of cases
1	ZZZ 정	비대상	김민열	AA 병원	50,000	120

Pfizer integrity is...

Transparency Reporting - Background

Factors driving mandatory, government driven transparency reporting obligations:

- Issues involving improper transfer of value to HCPs or medical institutions
- Public/Media coverage calling for transparency in the industry
- Alignment with other government policies/direction

Transparency in Australia 

Since: effective from 1 October 2015 (superseding 2006 mandatory reporting HCP honoraria, sponsorships, meals)

Law / Code: Medicines Australia Code of Conduct (Pharmaceuticals)

First publication: 31 August 2016

Reporting obligation: every six months

Publication of payments: **HCPs**: each company's website; **HCOs**: website Medicines Australia

Amount / value in scope:

- Services by a healthcare professional (HCP)
- Sponsorship of HCP to attend medical education meeting (airfare, accommodation, registration fee)
- Sponsorships of HCOs

Information to be published:
HCP name and address, type of HCP, purpose of the payment, amount of value; same for HCO

Medicines Australia

Transparency in Australia 

Rationale for transparency obligations

Medicines Australia:
Companies support the education of healthcare professionals to develop knowledge and skills, which is important for patient care in a rapidly changing world. Companies also need advice from healthcare professionals, which leads to new and better medicines and treatments.

Greater transparency will increase confidence by patients that the working relationship between the industry and healthcare professionals is ethical and appropriate.

Self-regulation following public and political pressure to align with EU and US Transparency models; in case of no Medicines Australia code, a local law would be implemented.

Publication:
Patients were unaware of their doctors' competing interests but want to know of doctors' interactions with the pharmaceutical industry, indicating that disclosure of competing interests would improve their confidence in doctors' decisions.

Tattersall, M H N, Dimoska, A and Gan, K. (2009), 'Patients expect transparency in doctors' relationships with the pharmaceutical industry', Med J Aust 2009; 190 (2): 65-68

End of August 2018 the 5th report has been published!

Medicines Australia

Transparency Reporting in Southeast Asia & South Korea

Underlying regulation:

- Department of Health Administrative Order No. 2015-0053

Scope/purpose:

- Meetings/Symposia > 100 HCPs
- Sponsorship of HCPs involving Travel

Implementation:

- 10 February 2017

Reporting date & method:

- Notice of Symposia = 30 days before the event via FDA online portal
- Post Travel Report = within the calendar year of the sponsorship via FDA online portal or submission of excel sheet

Parties with Reporting Obligation:

- PPPMDs (Prescription Pharmaceutical Products and Medical Devices) companies for HCPs in the private sector
- HCPs (for those working in government)

Sanctions:

Administrative sanction: verbal warning, written warning, fine, up to license revocation.

Underlying regulation:

- Pharmaceutical Act Article 44
- KRPIA Code

Scope:

- MOHW Reporting for HCP Spend including samples, HCP sponsorships, clinical trials, hospitalities, gimmicks, post market surveillance
- MOHW reporting on distributor discounts
- KRPIA Reporting- Consulting & Lecture payments.

Implementation:

- 1 January 2018

Reporting date & method:

- MOHW reporting- after year end closing via online submission
- KRPIA Reporting – Quarterly online submission

Parties with Reporting Obligation:

- Pharmaceutical companies for MOHW HCP Spend & KRPIA Reporting
- Distributors for MOHW reporting on Distributor discounts

Sanctions:

Underlying regulation:

- Ministry of Health Regulation ("MoH") No.58 of 2016 concerning "Sponsorship for Health Professionals" ("Regulation") issued in November 2016
- MOH Circular Letter No.HK.02.01/MENKES/66/2017 concerning "Reporting Mechanism of Sponsorship" issued on Feb 10, 2017 as implementing guidance.

Scope/purpose:

- Sponsorship requirements for HCPs & HCOs
- Reporting to the Indonesian Corruption Eradication Commission ("KPK") after sponsorship is provided (by party providing and receiving sponsorship).

Implementation:

- Started the report to KPK and MoH in September 2017.

Reporting date & method:

- 10th of the moth, manual reporting via Excel Sheet

Parties with Reporting Obligation:

- Party **receiving** sponsorship (i.e. institution, profession organization, health facility service organization, health professional with individual practice)
- Party **granting** sponsorship (i.e. pharmaceutical, medical device, health laboratory equipment industry/company and/or other industry/company)

Sanctions:

Administrative sanction: verbal warning, written warning, up to license revocation.

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Discussing Questions

- What is your approach to prepare the South Korea Transparency Reporting? As the 1st report need to be ready by Mar 2019 for the full year of 2018
- As the Regional Compliance Officer, what is your approach to address additional country requirement? Or additional reporting requirement?
- What are the key learnings / best practice for Transparency Reporting management?

Global Payment Transparency (GPT) Overview 1/2

- Global Payment Transparency CoE created in 2016
- Discloses payments and transfers of value (ToV) to healthcare professionals (HCPs) and healthcare organizations (HCOs) covering 30+ markets
- Fulfil all existing and future transparency obligations while reducing the overall cost to the organization.
- Progressive plans are in place to expand reporting obligations

Global Payment Transparency (GPT) Overview 2/2

- Governance
- Data collection and stewardship
- Market level filing and analytics
- Quality assurance and control
- HCP/HCO dispute and inquiry management

Transparency reporting- on boarding new country

- Clarification of the reporting requirements
- Collaboration between GPT and local MC-early engagement of GPT
- Local lead and CFT with clear R&R (it is not a compliance project)

Integrating APAC solutions with systems in U.S. and Europe

Start

Excel

- Rudimentary start, e.g. Netherlands, France, Australia

Reports US/EU

- More and more requirements published, e.g. US, EFPIA, Japan

EFPIA approach

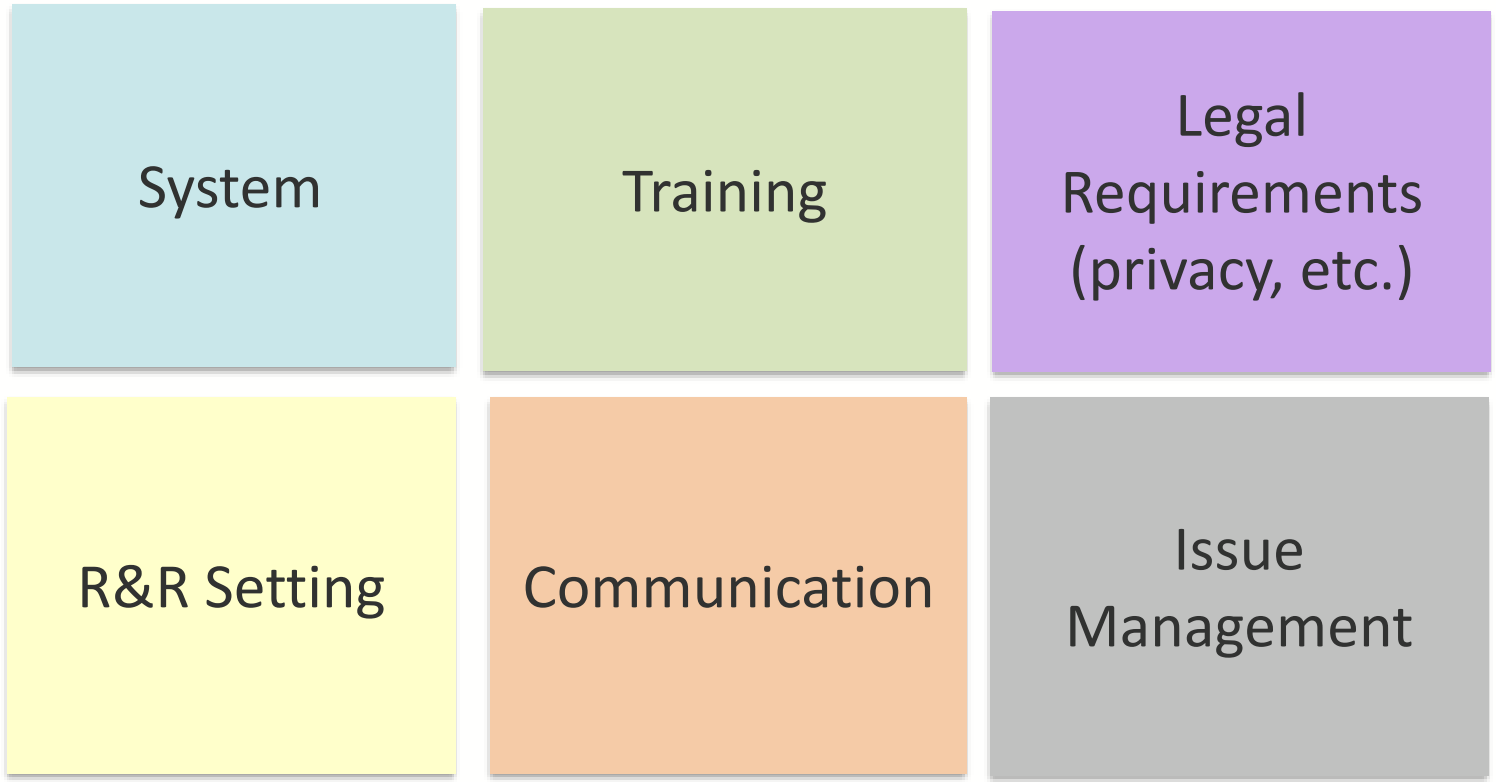
Clear

- Multinational (EU) companies develop or buy systems to automate preparation of disclosure reports (and forget APAC)

Global

- Global approach, opportunities to utilize the gathered data; disclosure reporting is one purpose, like monitoring activities; APAC more in scope and ‘easy’ to fit in (incl. Korea, Indonesia, Philippines).

Transparency Reporting - Company Perspective



Transparency Reporting – Experience Sharing

- How and whether government driven transparency requirements impacted the industry? HCP communities? Any changes in public perception?
- What are critical factors that Compliance function should consider when implementing transparency reporting system?
- What to expect in APAC region?

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Discussing Questions

- How you see the evolution of Transparency Reporting in your company?
- What value that Transparency Reporting can bring to the company, to HPC, to patient?

Patients and Financial Transparency
(quotes from literature)

Patients have a fundamental ‘Right to Know’

Patients want to know, but the information has no effect on the relationship

A patient is not always able to judge payments to physicians

the financial data are difficult to interpret

Transparency hands the problem over to the patient

Transparency has Limited effect

Is the general public really interested?

How many patients will discuss with their HCP?

Has transparency an added value?

Now, companies are creating business values through Transparency Reporting

Focus Full End to End Process to Reduce Risks

- Many companies are shifting their focus to the upstream processes ahead of data aggregation and report generation
- Covering the entire HCP / HCO engagement, including planning & budgeting and data capturing process
- The goal is to not only improve data accuracy, but to mitigate compliance risks and introduce business value to these core processes

Data Analytic to Support On-going Monitoring

- Generate reports seasonally for preview and use them to monitor compliance
- Using data for additional business or compliance insights, at a local / regional and global level
- Types of business insights obtained:
  - HCOs/HCPs for spend redistribution
  - Reallocate funds across sales / marketing activates
  - Measure business process effectiveness / efficiency
  - Monitor “waste” (e.g. non-consumed meals)

Global Compliance System to Enhance Efficiency

- Streamlining and standardizing of global process to improve operational efficiency
- Aggregate spend information from all data sources globally, allowing full overview and analysis to support better global decision-making
- Established a long term and scalable solution which can add additional report template and country into the process easily