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PHARMACEUTICAL  
COMPLIANCE CONGRESS AND  
BEST PRACTICES FORUM

## MINI SUMMIT III

# **INNOVATION IN COMPLIANCE: ANALYTICS, TRENDS AND TECHNOLOGY PART I: SAMPLES, GRANTS, DONATIONS AND SOCIAL MEDIA**

Manilla, August 2015



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## MODERATOR

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## Mini Summit Overview

- TWO Mini-summits interconnected
- Interactive cases discussions
- In depth review of best practices
- Sharing perspectives

Your participation is key!

A close-up, black and white photograph of a document page. The page is filled with horizontal lines, some of which are thick and dark, while others are thin and light. In the lower right quadrant, there are several circular patterns, possibly representing data points or decorative elements. The overall image has a textured, slightly grainy appearance.

# **Samples Management**

**Chi Chen, EY (China) Advisory  
Limited, China**

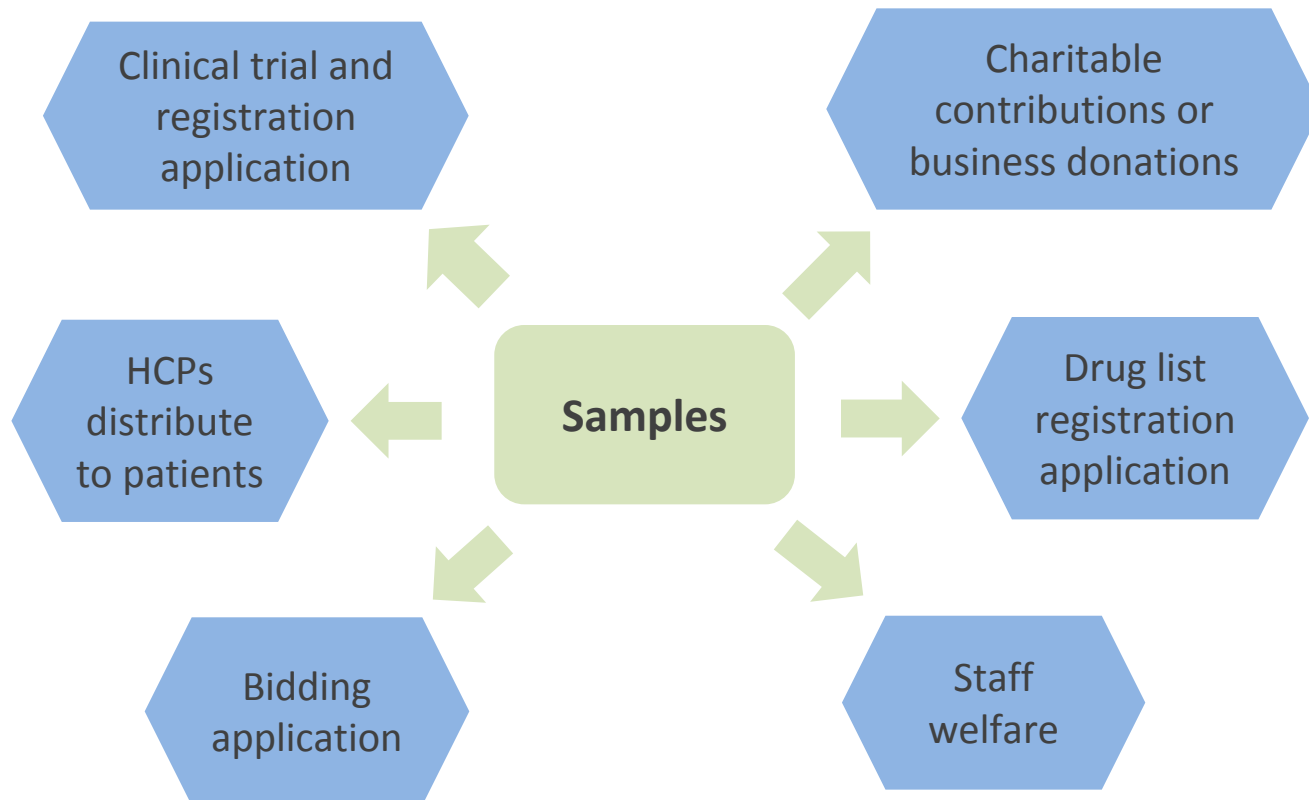
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## Pharma Companies provide samples to HCOs and HCPs

- ✓ Pharma companies sometimes will provide samples of companies' prescription products to hospitals and institutions(HCOs) or HCPs for distribution to patients.

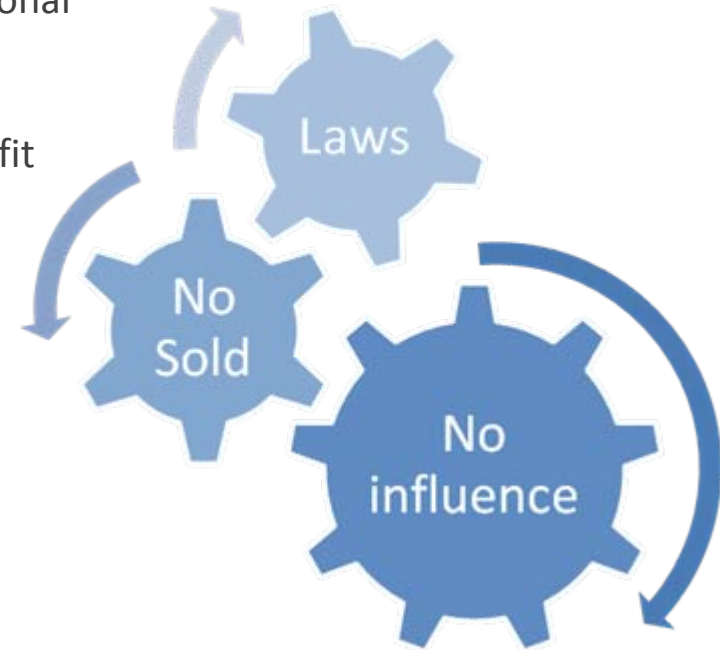




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## Regulations, Risks and Challenges of Samples

- ✓ Comply with relevant Local Restrictions and Laws
- ✓ Samples may not be sold, purchased, traded or offered for sale, purchase or trade
- ✓ Samples may not be used as gifts
- ✓ Samples shall be identified as 'Samples' on the package
- ✓ Samples shall be tracked and ensure accurate records
- ✓ Samples may not be provided to HCPs for their own personal use
- ✓ Must never create an appearance of impropriety
- ✓ Must never be offered to influence the outcome or benefit business activities





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## Case Study

- A HCP requests Samples with high volume for more than 1 year. The application volume exceeds reasonability.
  - a) Pharma company should verify the HCP's applications of the Samples are based on proper reasons.
  - b) Pharma company also needs to track and record the Samples delivered to HCPs.
  - c) Pharma company must make sure the Samples don't influence HCPs and HCOs.
  - d) Pharma company should perform analysis and monitoring on Samples for HCPs and HCOs for misuse.
  
- One pharma company's Samples are found being sold out in one pharmacy.
  - a) Samples should be marked as 'Samples' on the package.
  - b) Samples must not be sold.
  - c) Pharma company should perform audit on storage/delivery.
  - d) Receipts of Samples from HCOs and HCPs should be well archived and audited.



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## Case Study (Cont.)

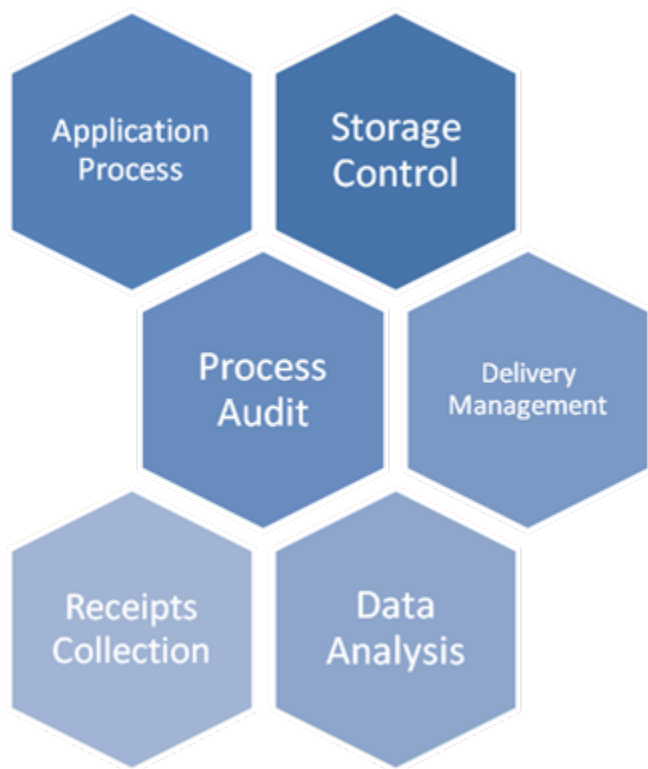
- Delivery and Storage of Samples of one Pharma Company is not well recorded and audited. During the Samples stock take audit, the Samples balance is not matched the application/delivery/storage volume recorded.
  - a) Pharma company also needs to track and record the Samples delivered to HCPs.
  - b) Pharma company should well record the Samples application, Samples Storage and Samples Delivery.
  - c) Pharma company should perform process audit and control.
  
- One sales force colleague's Samples application volume is very high in past several months.
  - a) Pharma company should well record the Samples application of employees.
  - b) Pharma company should perform analysis and monitoring on Samples for internal and external recipients for misuse.





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## Controls address these challenges



- ✓ Ensure all Samples are tracked and all records regarding the tracking of Samples are maintained
- ✓ Perform control and audit on Samples process
- ✓ Perform data analysis on Samples application volume and frequency regarding the reasonability



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# Grants & Donations

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## Case Study

- Dr John Doe, a radiologist, is the vice president of an HCPs association
  - Dr Doe asks a sales representative of MyDrug Pharma company for a grant
  - The association is registered in the radiology center owned by Dr Doe
  - In the statutes of this association, its goal is to represent the interests of radiologists
  - The last version of the statutes is not available
- => the grant is used to finance a training



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# The game of 7 mistakes !

Location of the  
Association

Origin of the grant  
request

Is the association  
authorized?

Proof of the  
request

Is the association  
authorized to  
receive this grant?

Use of the grant?

Goal of the  
Association



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# The risks

- Risk of abusing corporate assets
- Risk of conflicts of interests
- Fiscal risk
- Risk according to local regulations (i.e France)
  - Funding an HCP association
  - Creating a financial relationships between sales representatives and HCPs





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# Challenges

An End to End  
approval workflow

An up to date  
repository of  
associations/ HCO

A real time  
assessment of the  
total amount of  
grants

Anticipating conflicts of interest

Grant of an HCO or Transfer of Value to an HCP?



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# Social Media

## Opportunities & Risks for Pharma

**Mohit Grover**, Deloitte Southeast Asia  
August 2015





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## Pharma companies are becoming more “Social”

473 Tweets per week  
by big 14 pharma  
companies, increased  
by 530%



1,300,000 Facebook  
followers for big 14  
pharma companies,  
increased by 44%



28,000 YouTube  
subscribers for big 14  
pharma companies,  
increased by 133%



J&J, leading social media activity,  
runs corporate FB page and FB  
community page for engagement,  
Twitter for the press, YouTube for  
corporate branding.



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# Social Media Guidance issued by Regulatory Bodies

- ✓ Inherent nature of **Social Media** means that the **stated guidelines** from regulatory authorities does not **clearly state the dos and don'ts**.
- ✓ Pharma companies need to start with defining their **own Social Media guidance** for **self-regulation**.

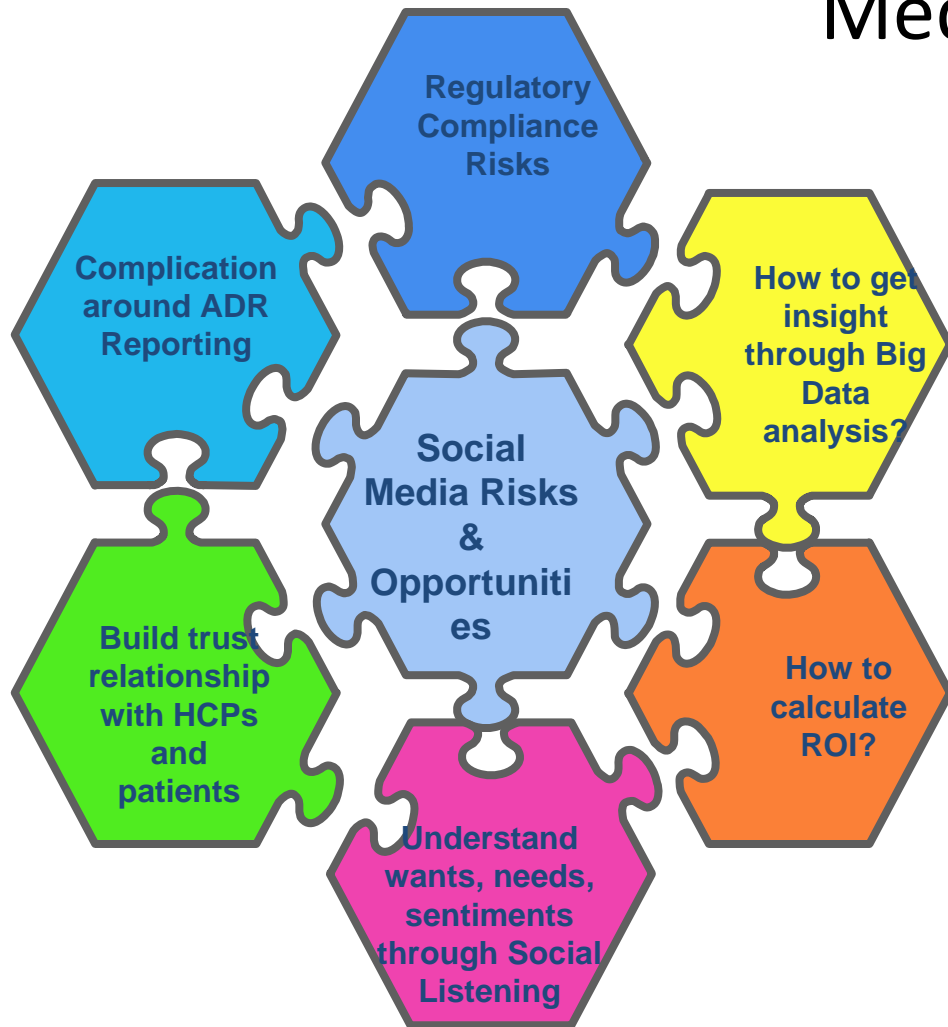


FDA Draft Guidance Title	URL
<b>Guidance for Industry</b> Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices	<a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf</a>
<b>Guidance for Industry</b> Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices	<a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf</a>



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# Risks, Challenges and Opportunities of Social Media



## Risks

FDA issued warning letters in relation of Social media activities:

- “Liked” a consumer’s comment on its FB page
- Did not provide adequate risk information on its Facebook Share widget

If a company is actively monitoring Social media, they must take action on reported adverse events

## Opportunities

Social media listening can enable a pharma company to:

- Understand patients wants and needs, sentiments and trends
- Identify Key opinion leaders leading dialogues
- Improve targeting and brand message





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## Risks, Challenges and Opportunities of Social Media (contd)

- Limited guidance from Regulators worldwide
- Evolving medium
- Risk of perception of Direct to Consumer /Advertising
- Navigate do's and don't's of communication with Patient groups (versus Healthcare Professionals) e.g. potential for patient backlash
- Once published, the information remains "out there"
- Pharma versus OTC versus wellness/beauty
- However, important medium that cannot be ignored



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# Social Media Expectations

**Divina Ilas-Panganiban,** Quisumbing Torres, A member firm of Baker & McKenzie International  
August 2015



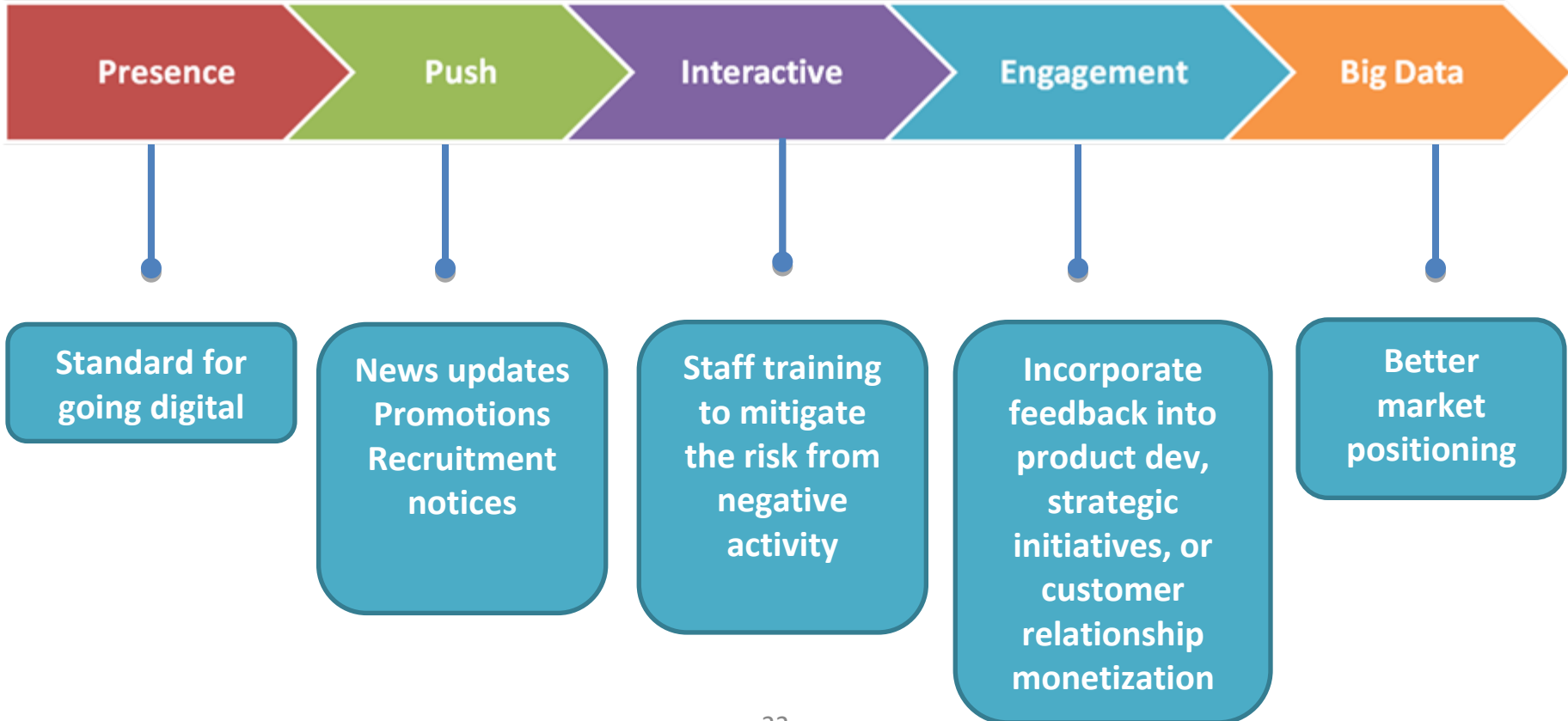
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- It is rapidly becoming a **basic business expectation** to have some sort of social media presence.
- Social media has dramatically sped up the impact of corporate disclosure.
- For more than 50% of Asians who use social networks, there is a direct correlation between positive social media sentiment and actual purchase.



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# 5 Phases of Engagement



## Set your targets

Potential benefits increase exponentially due to amplification – but so does potential risk

## Prepare for the unexpected

Constant vigilance and effort is required for social media success – and the effort *and investment* required increases as a company progresses through the phases.



## You can't afford *not* to invest

Facebook, Twitter, Google or LinkedIn will not suffice. To be successful in Southeast Asia, corporate social media users *must* move beyond the four global platforms and onto the local leaders.

## Common sense is neither common nor sensible as a policy

Although freedom of speech is a constitutional right, not all speech is protected.





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# Diversity - Regulatory Landscape and Crossing Borders

**Seck Yee Chung**, Partner, Baker & McKenzie (Vietnam) Ltd

August, 2015

# A. SOCIAL MEDIA

What is social media? An IT-enabled cultural phenomena of see and be seen





## Social media features

- beyond email
- online/mobile platform
- networking effect
- social interaction and scaleable technology
- broadcast monologues (one to many) become social dialogues (many to many); sharing
- content consumers become content producers
- impacts cultural mindset & behavior; grows communities
- real time



# Opportunities...

- Audience
- Reach
- Feedback
- Scalable
- Cost efficiencies
- Rapid spread
- Personalisation / targeting
- Viral effect
- Collaboration
- Dynamic and evolving



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## ...and risks

- Cross-border
- Regulation
- Dependence on platform provider
- Reputation
- Loss of control
- User Generated Content
- No credentials / verification
- Anonymity

**What's *not* different:**

***You're responsible for content you put out there***

**What *is* different:**

***You are not in control of the content users put out there***

***In short: the only behavior you can control is your own.***

## B. REGULATORY LANDSCAPE

- Diverse policy and regulatory landscape – open vs restrictive
- Advertising / Content – drugs / alcohol / politics / religion / abortion clinics / sex toys
- Licensing and approvals – is HQ- managed website sensitive to local formalities?
- Competition laws – unfair competition – stealth marketing
- Industry specific rules – pharma – off-label use, restrictions on advertising, adverse effect reporting



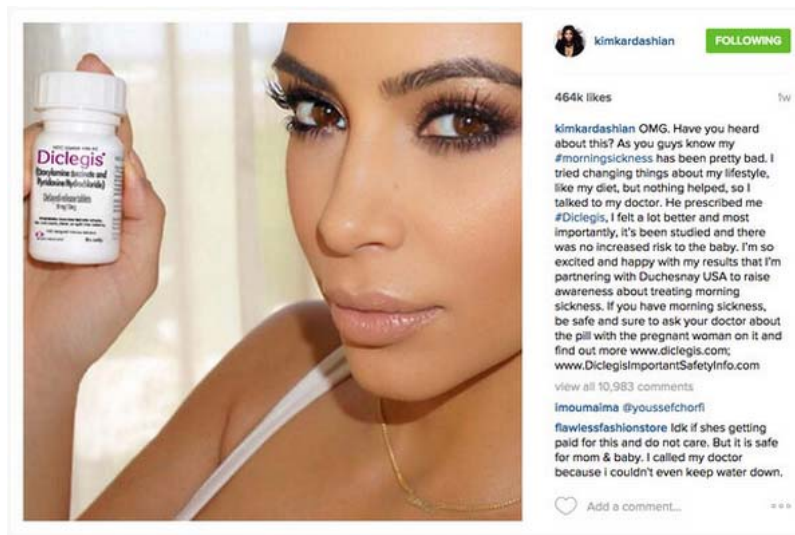


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## Examples

Duchesnay Inc. and Kardashian:

- Duchesnay Inc. got warned by FDA for Kim Kardashian's Instagram post about their morning-sickness drug, Diclegis, to immediately cease misbranding.
- The post failed to give information about the drug's risks.





# Examples

## ACCC v Allergy Pathway

- In 2009, Allergy Pathway had provided an undertaking to the Federal Court that it would not "make or publish or cause to be made or published in any internet website", prohibited statements such as: "representations that Allergy Pathway could cure or eliminate, or successfully treat, any allergies or any allergic reactions, and that after its treatment it was safe for that person to have contact with the allergen to which the person had an allergic reaction. ”.
- However, in 2011, Allergy Pathway was liable for misleading and deceptive statements which had been posted on its website, and its Facebook and Twitter pages, by its customers.



## C. DATA PRIVACY

- Collection, processing, use and transfer
- Consent
- Sensitive data
- BYOD

# Asia Pacific Overview

NPC: National People Congress  
PDPA: Personal Data Protection Act

**South Korea:** Personal Information Protection Act 2011

**Thailand:** Draft law sent to Parliament in 2012

**Japan:** Act on the Protection of Personal Information 2003

**India:** The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011

**China:** Provisions regulating Internet Information Services/ NPC Decision on strengthening the protection of internet information

**Hong Kong:** Personal Data (Privacy) Amendment Ordinance (amendments in full effect on 1/4/2013)

**Taiwan:** PDPA 2010 in effect from 1 October 2012

**Malaysia:** PDPA 2010 in effect from 15 November 2013

**Philippines:** Data Privacy Act (August 2012)  
Cybercrime Prevention Act (September 2012)

**Singapore:** PDPA passed 15 October 2012; phase-in period until 2/1/14 and 2/7/14

**Vietnam:** Provisions spread across the Civil Code, IT Law, Consumer Protection Law, Penal Code, Telecommunications Law and their implementing regulations

**Australia:** Privacy Amendments Enhancing Privacy Protection Act come into effect in March 2014

**Indonesia:** Electronic Information and Transaction Law 2008; Regulation 82 Provision of Electronic System and Transaction





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## Where we are now?

	Australia	China	Hong Kong	India	Indonesia	Japan	Malaysia	Philippines	Singapore	South Korea	Taiwan	Thailand	Vietnam
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Mandatory breach notification				✓ (if so required)	✓	✓		✓		✓	✓	✓ (certain industries)	✓
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Cross-border data transfer specifically regulated	✓	✓	✓^	✓	✓	✓	✓ (to jurisdictions specified by the Minister only)	✓	✓^	✓	✓	✓ (certain industries)	✓ (banking sector)
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Data Protection Officer required				✓		✓ (if so required)		✓	✓^	✓		✓ (public institutions)	
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^ Provision has been enacted but is not yet in force

# Enforcement and Penalties

<b>Australia</b>	Civil penalties range from AU\$340,000 for individuals or AU\$1.7 million for corporations
<b>China</b>	No central law but penalties available depending on field (eg banking). Infringement of privacy right can give rise to injunctive relief + compensatory damages under tortious liability law. Administrative penalties may be imposed for violating NPC Decision.
<b>HK</b>	Civil and criminal penalties up to HK1 million for personal data for direct marketing + 5 years imprisonment
<b>Indonesia</b>	No sanctions under EIT law and Regulation 82
<b>India</b>	Damages for breach of IT Act. No limit on amount recoverable
<b>Japan</b>	Statutory penalty – imprisonment up to 3 years and/or fine up to JPY500,000
<b>Malaysia</b>	Up to RM500,000 fine and/or imprisonment of up to 3 years
<b>Philippines</b>	Up to Php1,000,000 + imprisonment of up to 5 years (upon passing of rules and regulations)
<b>Singapore</b>	Civil fines up to \$1million; Criminal max fine of S100,000 and/or imprisonment of up 12 months for obstruction or making of false statements to mislead.
<b>Korea</b>	Fine up to KRW 50 million / imprisonment for up to 5 years
<b>Taiwan</b>	Up to NT200,000
<b>Thailand</b>	Fine of suspension / revocation of telecoms licence Criminal penalties under Credit Bureau Act + draft Privacy law
<b>Vietnam</b>	Civil awards, administrative and criminal sanctions apply - including fines up to US\$2,000 and / or two years of imprisonment.





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# Data Breach Notification Obligations

	Australia	China	Hong Kong	India	Indonesia	Japan	Malaysia	Philippines	Singapore	South Korea	Taiwan	Thailand	Vietnam
Statutory obligation to notify data subject		5						✓		✓	✓	✓ <sub>3</sub>	
Statutory obligation to notify regulator													✓
Sector specific obligation to notify									✓ <sub>2</sub>				✓
Non-binding Guidelines	✓		✓			✓ <sub>1</sub>	✓						✓ <sub>4</sub>

- 1 Sector specific guidelines for financial services and banking industries create strong incentive to notify government authorities
- 2 Monetary Authority of Singapore regulations require notification
- 3 Telecommunications Business Act relating to subscriber's right
- 4 Credit Information Protection Committee
- 5 No. However in context of consumer transaction consumers and authorities must be informed