

Asia-Pac Anti-Corruption Update Roundtable

Panel discussion moderated by: Chris Fordham
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Panelists



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Key themes

- ▶ Anti-corruption compliance in China
- ▶ Key takeaways from South Korea
- ▶ An update from Thailand
- ▶ APAC overview
- ▶ Life sciences/ Pharma findings of EY's Asia-Pacific Fraud Survey 2017

Anti-corruption compliance in China



Medical Representative Regulations

Chronology

- Genesis: State Council “Opinion 13” (January 24, 2017)
 - Mandatory registration of MRs
 - No “drug sales responsibilities” for MRs
- CFDA “Circular 54” (May 11)
 - No “private contact” with physicians
- CFDA draft MR rule (July, 2017)
- Shanghai “Opinion 35” against drug kickbacks (August 15)
 - Designated time, location and personnel; with records
- Shanghai MR Registration Rules (draft) (August 22)

Shanghai MR Registration Rules (draft)

Key Requirements

- MRs must be “on behalf of” drug manufacturers
- Drug manufacturers must establish MR qualification requirements
- MRs must be registered to promote drugs
- MRs will be de-registered in case of bribery or other misconducts
- All MRs of drug manufacturers or MR “home companies” will be de-registered, if the companies have “bad records”
- Challenges and uncertainties

Other Compliance Hot Topics

- Two Invoice System: use of CSOs
- Secondary Price Negotiation (二次议价)
- “Pharmacy Trusteeship” (药房托管)
- SAIC’s enforcement on “equipment + consumable” bundling
- Removal of “direct sponsorship”
- NDRC’s antitrust enforcement on drug’s “excessive pricing”

Key takeaways from South Korea



Key Takeaways

- Vigorous enforcement of anti-corruption laws likely to continue with new administration's ambitious expansion in health insurance coverage
- New requirement to prepare/keep records of value transfers to HCPs takes effect January 1, 2018
- Investigation of MNC pharmaco highlights risk of multiple sanctions from different government agencies for same set of violations
- Enforcement of new Anti-Graft Act active, but cases are small
- Investigators rely on dawn raids and focus on seizing electronic documents

New Anti-Graft Act – Implications for Pharma/Device Companies

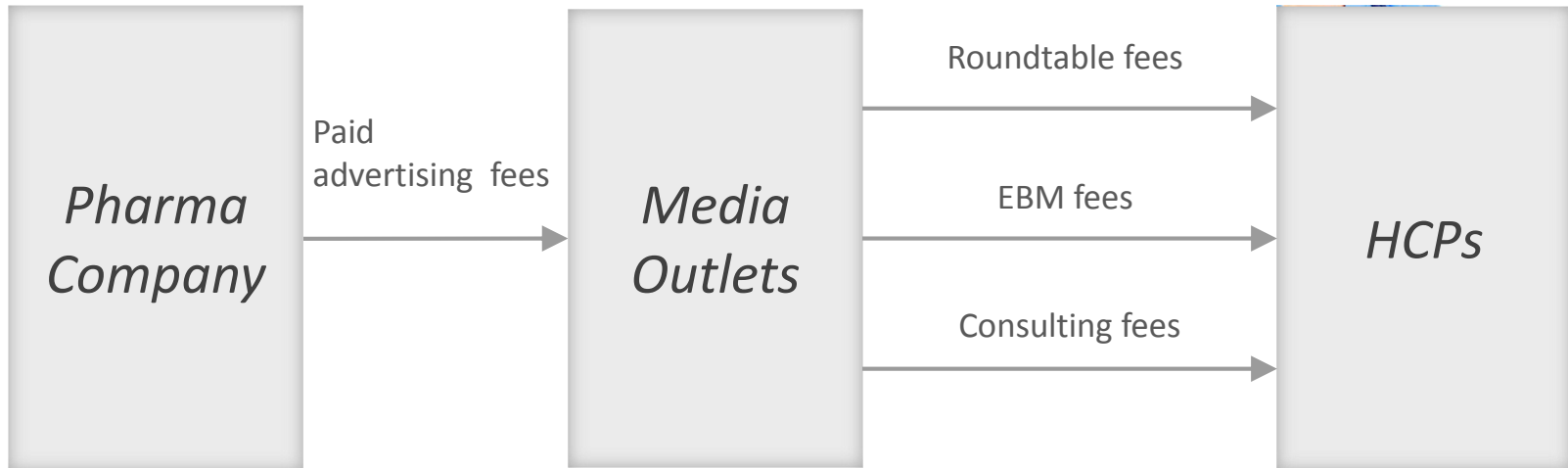
- “Public officials” include all HCPs who are university faculty (public & private) and journalists
- Companies should review policies for HCP engagement as speakers or other service providers, to comply with new caps under Anti-Graft Act
- Heightened scrutiny for benefits given under KRPIA/KMDIA Codes
 - Safe harbors under other laws are safe harbors under Anti-Graft Act, but industry codes do not have force of law, so value transfers permitted only under industry codes should be reviewed case by case

New Expenditure Reporting Requirement

- Prepare/keep (5 years) records on value transfers to HCPs
- Start keeping records from Jan 1, 2018; report should be completed within 3 months of fiscal year end
- Key value transfers covered:
 - Product samples
 - Payments for clinical trials and post-marketing studies
 - Support to attend academic conferences
 - Meals/gifts for company-hosted product presentations/training sessions
 - **Fees for services NOT included**
- No disclosure required, but MOHW may require companies to submit report
- Reports could be made public, once submitted to MOHW
- Failure to comply could trigger criminal fine (up to KRW 2 million) and invite investigation

Investigation Involving Media Outlets: Press Release (2016)

- 1 Prosecutors allege that improper benefits were provided through media outlets



An update from Thailand



Key Legislative Amendments

- **Corruption Act significantly amended in 2015**
 - Fighting corruption key priority for the current government
 - UN Convention against Corruption requires signatory countries to adhere to international standards
 - Specific 'Corruption Court' set up in 2016
- **Penal Code also amended to include a specific definition of an 'official', as any person:**
 - whom the law stipulates is a government official or
 - is appointed under the law to carry out governmental duties:
 - whether in a permanent or temporary position, and
 - whether they receive remuneration or not

Key Amendments to the Corruption Act

- Clear stipulation that it is an offence for:
 - any person to give bribes to officials (including Thai state officials, officials of foreign states and officials of international organizations), and for
 - such officials to accept bribes
- Corporation can be held explicitly liable for bribery offences that are:
 - committed by a person connected to the company and
 - where the act of bribery was undertaken for the benefit of the company unless
 - the company has in place the "appropriate internal control mechanisms" to prevent such offences

Appropriate Internal Control Mechanisms

- No specific guidelines yet on what may be deemed to be appropriate internal control mechanisms
- Likely in line with other internationally recognized standards
- Up to individual companies to consider their own specific circumstances (including but not limited to the industry in which it operates and the associated risks) in order to determine what is appropriate and sufficient

APAC overview



Asia Pacific Data

- Companies or individuals from Asia-Pacific make up 20% of US enforcement actions of the 199 enforcement actions concerning alleged bribery of foreign officials from 1977 – 2015
- In 2016, Asia-Pacific contributed the largest percentage of cases in numbers and penalties - 47 % of the DOJ cases, 65% of civil resolutions by the SEC
- **14** Healthcare & Pharmaceutical industry related reported FCPA investigations ongoing (as of 4 August 2017)
- Ongoing FCPA-related investigations per country (as of 8 August 2017)
 - **18** cases involving China (#2, #1 is Brazil with 35 cases)

Asia Pacific – the Changing Landscape

- Changes to local legislative and enforcement environments in the region reflect a determination to eradicate corruption
- Foreign regulators' increased presence
 - Pressure from law enforcement authorities (US, UK)
 - Increased resources (prosecutors, FBI agents) and new prosecution tools (UK: deferred prosecution agreements)
 - More aggressive cross-border cooperation (e.g. Switzerland, Hong Kong and Singapore are cooperating in investigating Malaysia's 1MDB)
- Rising costs
 - Investigations, penalties and settlement

Asia Pacific Enforcement Trends

- Increased global enforcement and cooperation
 - Sharing information
 - Joint prosecutions
 - More countries: UK, Canada, Australia, Russia, China, Brazil
- Expanded charges
 - Combining anti-corruption with mail and wire fraud, money laundering, and other criminal charges
- Aggressive expansion of FCPA jurisdiction to foreign affiliates

Asia Pacific Enforcement Trends (2)

- Greater awareness
 - Cooperating companies
 - Media report monitoring
 - Whistleblowers
- Higher expectations for compliance programs
 - Third party due diligence
 - M&A, JV due diligence
 - Investigations

Asia-Pacific Fraud Survey 2017 : Risks remain high



Setting the scene

Ethical conduct and value placed on the organization's compliance culture

93% of APAC and **96% of life sciences/ pharma** respondents say they want to work for a company with a strong compliance culture.

44% of APAC and **half of life sciences/ pharma (50%)** respondents say they would accept a lower salary if it meant working for an ethical employer.



Clarity and consistency

Changes you would make for a more understandable anti-bribery/anti-corruption policy

85% of APAC and 92% of life sciences/ pharma respondents say they want their companies to simplify and localize compliance policies to make them more understandable.



Millennials: “A wake-up call for businesses”?



Millennials

Justification of unethical behavior to help a business survive during economic downturn



46% of APAC and 38% of Life Sciences millennial respondents could justify offering entertainment.

43% of APAC and 44% of Life Sciences millennial respondents could justify offering personal gifts or services.



42% of APAC and 33% of Life Sciences millennial respondents could justify extending monthly reporting periods to meet financial targets.

Almost 40% of APAC and 33% of Life Sciences millennial respondents could justify offering cash payments.



Millennials

Unwilling to work for unethical businesses



Gen Y respondents would look for another job if their organization was involved in a major fraud, bribery or corruption case

A notable **four in five (83%) of Life Sciences millennial** respondents (25-34 years old) say they would look for a new job if their organization was involved in a major fraud, bribery or corruption case.

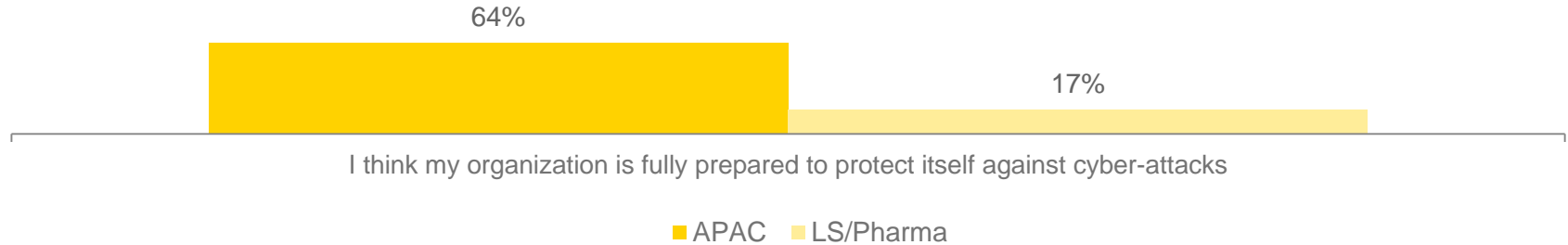
Cyber-risks: “Awash with naiveté”?



Cyber-risks

Organizations' preparedness against cyber attacks

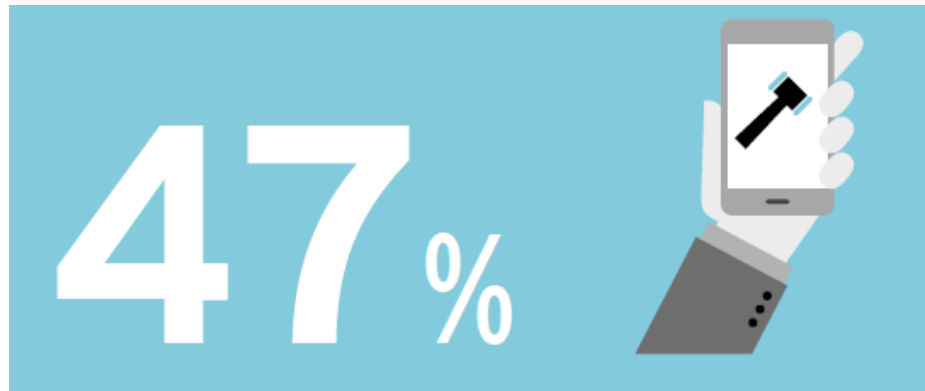
64% of APAC and 17% of life sciences/ pharma respondents think their organization is fully prepared against cyber attacks.



Cyber-risks

Devices provided for work-related activities

Almost half of APAC (47%) and life sciences/ pharma (49%) respondents say their organizations do not have any policies governing the use of personal devices for work-related activities.





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