



# **The First Asia Pacific Pharmaceutical Compliance Congress & Best Practices Forum**

**Overview of Asia Pacific Pharma & Device Compliance Trends – Sabina Sudan**

**Sept 2011**

**The Ritz-Carlton, Millenia Singapore**



# What does it say?

**A little more civic-minded, to a little more  
harmonious & graceful community;  
A little more \*selflessness for lesser disputes  
& unpleasantness in the community**

*\*Technically the translation from the previous picture is not wrong, the word 私心 meant selfishness*

# Oversight

## **o-ver-sight**

- /oʊ vərsaɪt/ Show Spelled[**oh-ver-sahyt**] **–noun**
- **1.** an omission or error due to carelessness: *My bank statement is full of oversights.*
- **2.** unintentional failure to notice or consider; lack of proper attention: *Owing to my oversight, the letter was sent unsigned.*
- **3.** supervision; watchful care: *a person responsible for the oversight of the organization.*



# Some Highlights

- **Australia** has alleged that Securrency, the Reserve Bank's currency maker bribed Vietnamese official to gain contracts by paying for son's education in the UK through middlemen's offshore accounts. 2 executives have been sentenced to prison in ongoing investigation.
- **China** - on May 1, 2011, added a new clause to the commercial bribery provision of Article 164 to include non-commercial entities such as NGOs.
- **India**
  - In September 2011, the Department of Pharmaceuticals is set to publish its final code of conduct for drug marketing. The code applies to foreign and local companies.
  - In March 2011, India introduced a bill to criminalize foreign bribery
  - In 2010, in “Iridium India Telecom Ltd v Motorola Incorporated & Ors”, the Supreme Court held that a company can possess the requisite intent to commit a crime.

# Some Highlights (Continued)

- **Indonesia** - in April 2011, extended the bribery laws to
  - (a) the private sector ;
  - (b) foreign officials and;
  - (c) to the taking or receiving bribes by a foreign official.
- **Korea** - in May 2011, enforced its foreign bribery act against 2 individuals with respect to bribery of a foreign public official in Korea.

# The ever changing landscape

- As “Payers” start to feel the slow down of the economy, they are reaching out to Industry.
- Trends will have a ripple effect across the Region.
- These efforts at “collaboration” are being driven by Regulators, industry associations, and Ministries of Health.

# Collaboration between Regulators & Industry - Korea

The challenges to strengthen pharmacovigilance (both pre and post-marketing), with the introduction of Risk Evaluation & Mitigation Strategy (REMS) were presented by many Asian regulatory authorities at a recent meeting. Korean authorities will found a Korea Drug Safety Management Center, introduce REMS system within 2011, and establish life-cycle drug approval and pharmacovigilance system by 2020. The participants all emphasized the importance of close collaboration between (a) regulatory authorities and (b) between regulatory authorities and industry to facilitate exchange of safety information to protect patient health.

Overall, harmonization, standardization, collaboration between regulatory authorities and between industry and regulatory authorities, more and better communication are key to improve availability and access to safe and effective innovative medicines to patients in Asia and beyond Asia.



# Park Doctrine

- As of April 2011, drug makers are in discussion with the US FDA for a new pilot program to improve the drug-review process.
- The US FDA and healthcare industry have moved one step closer to deciding on the framework for a new pilot program to enhance the FDA's drug-review process.
- The agency has asked for increased user fees from the drug makers to hire additional staff and regularly update the FDA's tracking system.

# Association of British Pharmaceutical Industries (ABPI) CODE OF PRACTICE for the PHARMACEUTICAL INDUSTRY 2011 Edition

## **Clause 1.1 Joint Working**

*Joint working with health authorities and trusts and the like is permitted if carried out in a manner compatible with the Code. Joint working is where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. The Department of Health has issued to the NHS Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations. A toolkit, Moving beyond sponsorship: joint working between the NHS and the pharmaceutical industry has been issued by the Department of Health and the ABPI. The ABPI has produced guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients. The conduct of joint working is dealt with in Clause 18.5 and its supplementary information.*

## **18.5 Joint working between one or more pharmaceutical**

Companies and health authorities and trusts and the like is acceptable provided that this is carried out in a manner compatible with the Code. Joint working must always benefit patients. A formal written agreement must be in place and an executive summary of the joint working agreement must be made publicly available before arrangements are implemented.

# Conflict of Laws?

- In September 2010, a pharmaceutical company was found liable for violating Russian anti-monopoly laws by Russia's Federal Anti-Monopoly Service("FAS".)
- In January 2011, the FAS confirmed the verdict "for unlawfully evading contracts" with properly licensed distributors that, among other things, failed anti-corruption screening based on company-mandated compliance standards. FAS held that, by arbitrarily reducing its distributor ranks, the company used its industry dominance improperly to alter the price of its medicines.
- FAS fined the company more than 85 million Rubles (approximately US\$3 million).

# Anti-Bribery Compliance in Russia: One Step Forward, Two Steps Back?

- As a further remedy, FAS issued a Directive which, among other things, directed the company to remove from distributor contracts all requirements with respect to:
  - (1) the conduct of anti-corruption audits, and,
  - (2) the implementation of extensive compliance procedures, to the extent those procedures are not required by Russian law.
- The Company has appealed the FAS decision to the Moscow Arbitrazh Court
- FAS said that the Company's compliance requirement in their policies were not required by Russian law.
- Can any anti-corruption compliance standards be used to exclude a distributor without running afoul of the Russian anti-monopoly laws?

*Cont...*

## Anti-Bribery Compliance in Russia: One Step Forward, Two Steps Back?

- The FAS also recognised the Russian problem of “black PR” – where a company buys media articles that disparage its competitors in various ways, including by making unfounded corruption allegations that can cause a company to fail a reputational risk assessment.
- One view is that unless a company has actually been convicted of bribery in Russia, one cannot refuse to do business with it. Will a company that follows the Russia decision be protected from other anti corruption laws e.g. the US FCPA enforcement, UK Anti Bribery laws or other anti corruption laws etc?



Questions???????