

Asia Pac Hot Compliance Markets Updates

- Update from VIETNAM -

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DISCLAIMER

The views and comments I will present are of my own and do not reflect the views or comments of my employer Sanofi or any other Company/ Association.

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A milestone achievement in healthcare in Vietnam;

Enforcement upon Multinational Pharmaceutical Companies in Vietnam;

➤ Business Operational Model

- Restructuring of business operational model by setting up commercial legal entities (subsidiary companies instead of Representative Office model);

➤ Distribution & Supply Chain

- FDI companies are unable to engage in distribution sector for pharmaceuticals;
- Pharmaceutical companies have to find new local distributors (*100% local investment*) and “restructure” the supply chain channels;
- Pharmaceutical companies must work directly with qualified local distributors in distribution;

➤ The Practicing License of Medical/ Sale Representative

- In order have the “practicing license” (called Medical/ Sale Representative Card), the Medical/ Sale Representative must have a college degree or higher in medicine or pharmacy.

Legal Regimes on Anti-Corruption

2015 Penal Code

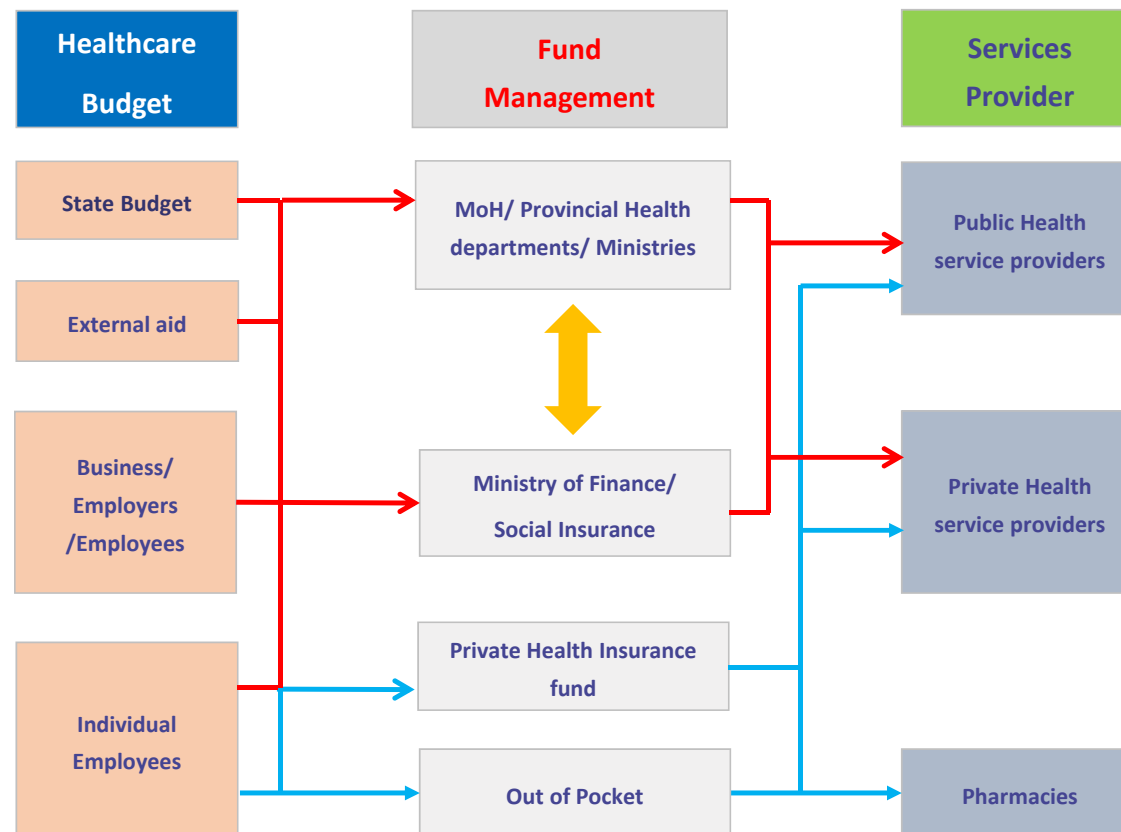
- **Corporate liability**
 - ❑ Commercial legal entities may be subject to criminal liable for some key offenses
- **Corruption-related offenses being extended to the Private Sector**
 - ❑ The act of directly giving bribes or acting as an intermediary in giving bribes to either public or private officials shall be subject to criminal liability

Draft Law on Anti-Corruption

- **Proposed provisions relating to Business Integrity**
 - ❑ Strengthening regulations on integrity of public officials;
 - ❑ Introducing control of conflicts of interest;
 - ❑ Promoting a non-corrupt culture;
 - ❑ Applying requirements for preventive measures
- **New Obligations for Private Sector**
 - ❑ Code of conduct
 - ❑ Internal control duty
 - ❑ Duty to report corrupt acts
- **Additional rules for public companies and credit institutions**
 - ❑ Code of conduct
 - ❑ Internal control duty
 - ❑ Duty to report corrupt acts
 - ❑ Operational transparency
 - ❑ Managers' assets transparency

BACK UP – For Reference

The Healthcare System in Vietnam is complex with many stakeholders



Private Public

Source: MOH, IMS Market Prognosis