

# Country Compliance Updates

Malaysia and Indochina, including Cambodia, Laos,  
Thailand and Vietnam

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# Agenda

- Overview on Legal & Compliance Landscape
- Country discussion
  - Risk arising from hospitality/promotional activities
  - Industry Codes & Guidelines
  - Government Regulation and Enforcement
  - Recent Developments and Updates

# Overview

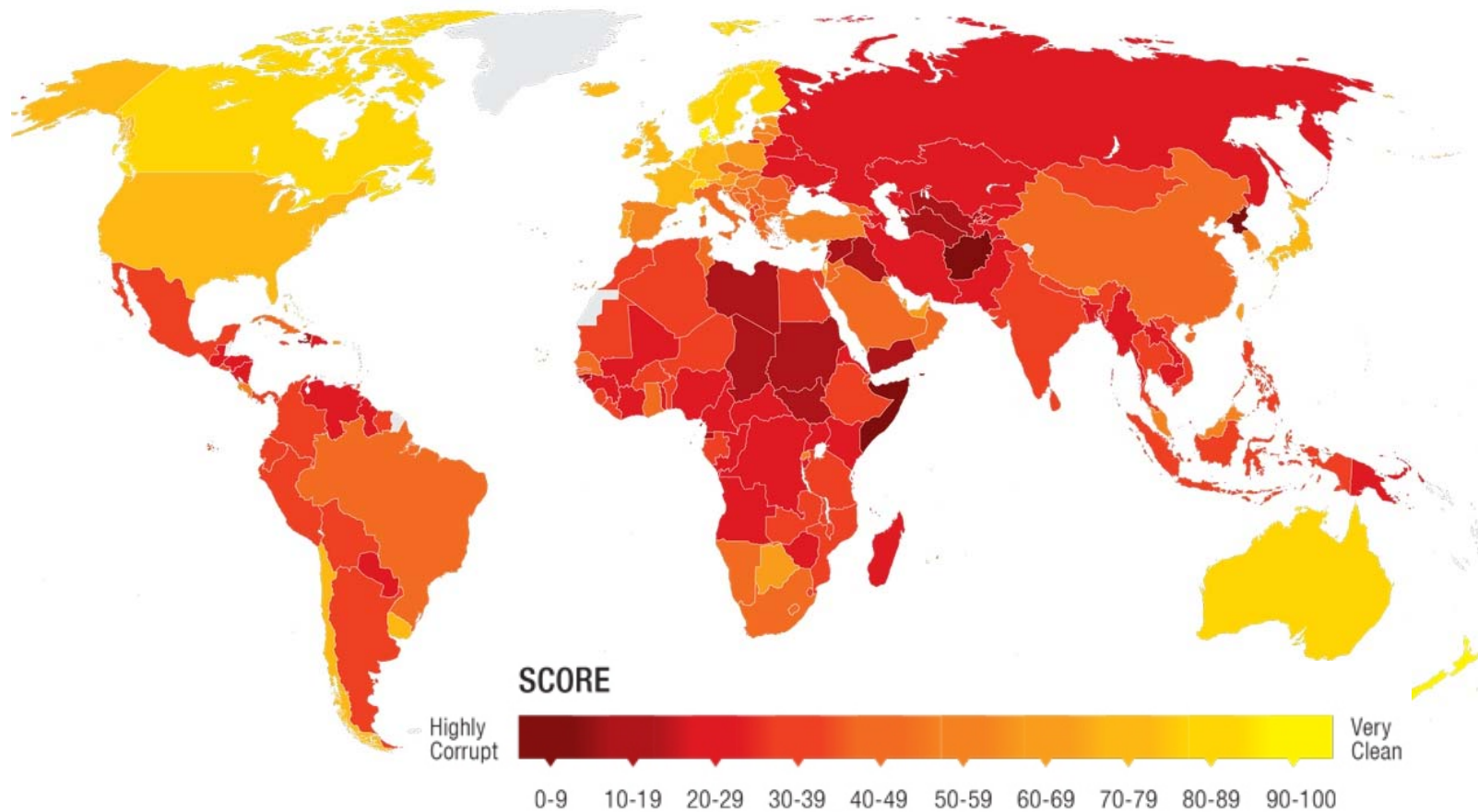




# Overview

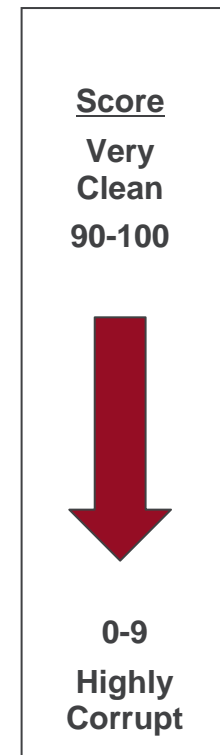
- Cambodia, Laos, Malaysia, Thailand and Vietnam Updates

# Transparency International Corruption Perceptions Index 2013



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Rank	Regional (Asia Pac) Rank	Country/ Territory	CPI 2013 Score
1	1	New Zealand	91
5	2	Singapore	86
15	4	Hong Kong	75
18	5	Japan	74
53	10	Malaysia	49
80	11	China	40
94	14	India	36
94	14	Philippines	34
102	16	Thailand	37
114	17	Indonesia	32
116	19	Vietnam	31
140	23	Laos	26
157	25	Myanmar	21
160	26	Cambodia	20



# APAC Local Laws

Country	Public Sector	Private Sector	Foreign Public Official	Bribe Recipient	Bribe Giver	Ectra-territorial
Cambodia	✓		✓	✓	✓	
China	✓	✓	✓	✓	✓	✓
Hong Kong	✓	✓	✓	✓	✓	✓
India	✓	Proposed	Proposed	✓	Abettor	✓
Indonesia	✓			✓	✓	✓
Laos	✓			✓	✓	✓
Malaysia	✓	✓	✓	✓	✓	✓
Philippines	✓			✓	✓	✓
Singapore	✓	✓		✓	✓	✓
South Korea	✓	✓	✓	✓	✓	✓
Taiwan	✓		✓	✓	✓	✓
Thailand	✓			✓	✓	✓
Vietnam	✓			✓	✓	✓

# Country Discussion





# Question

1

Whether hospitality / promotional activities give rise to corruption risks:

- sponsorship for individuals to attend events organized by a pharmaceutical company
- entertainment/monetary thresholds for F&B
- remuneration for speakers
- gifts/giveaways for personal benefit

# General

- Key concerns are around whether hospitality / promotional activities give rise to corruption risks
  - sponsorship for individuals to attend seminars (classes of air travel; location of seminars; types of accommodation)
  - acceptable entertainment and monetary thresholds for F&B
  - remuneration for speakers
  - gifts for personal benefit

# Cambodia

- Cambodia is unique in that the currency in Cambodia is in US dollars, so all companies not only fall under the laws of Cambodia but the FCPA.
- There are no laws that specifically address Pharma issues in Cambodia.
- Under the Anti-Corruption Law, no gifts are allowed except for traditional gifts; for example wedding. Most HCP are government officials therefore under the current law all of the abovementioned issues would create a risk.

# Laos

- Giveaways or other gimmicks are not prohibited or regulated by any specific Lao law. Therefore, there is also no specific threshold regulated by law for giveaways.
- However, such giveaways or other gimmicks received by HCPs deemed to be government officials should not influence them from acting or omitting to act in a manner contrary to their duty because it is prohibited for them to accept money, material items or other benefits from any individual or organization in relation to their functions, which may cause damage to the interests of the State and society, or the rights and interests of Lao citizens.

# Malaysia

- Public servant v private employee distinction for doctors and other HCPs not as relevant
- Public servant generally prohibited from receiving any form of gifts or entertainment unless approved by head of department or in an awkward position to decline such gifts;
- Industry guideline and code sets out best practices when engaging with HCPs who are public servants and private employees

# Thailand

- Approval of on-duty travel of officials is required under the Regulations of the Office of the Prime Minister on Approval of On Duty-Travel and Organizing Official Meetings B.E. 2524 (1981) as amended (the “**Travel Regulations**”).
- A State official may not receive any property or other benefits, on a single occasion, from a person who is not related, with a value in excess of Baht 3,000 (approximately USD 95).

# Vietnam

- Interactions with HCPs, including gift giving, payment of commission / rebates and hospitality
- Sponsorships of HCPs to attend local and overseas conferences
- Service agreements with HCPs
- Third party local distributor/tender

# Question

2

Does the Pharma Industry in Cambodia, Laos, Malaysia, Thailand and Vietnam have Codes/Guidelines which may assist to minimize corruption risks?



# Cambodia

- The Anti-Corruption Law which became effective in August 2011. This law defines benefits and gifts in relationship to government officials.
- The Criminal Code, 2007 which states the crimes and penalties - this law must be read in conjunction with the Anti- corruption law.
- Sub decree No 61 August 28, 2003 “The Physician Code of Ethic.” This Sub decree provides that HCP cannot enter into service contracts in returns for gifts.
- There is no specific Pharma law in Cambodia.

# Laos

- **Law on Anti-Corruption 2005 & Law on Drugs and Medical Products 2011**

“Not influence HCPs from acting or omitting to act in a manner contrary to their duty because it is prohibited to accept money, material items or other benefits from any individual or organization in relation to their functions, which may cause damage to the interests of the State and society, or the rights and interests of Lao citizens.”

# Malaysia

- Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products issued by the Pharmaceutical Association of Malaysia ("**PHAMA Code**") generally provides that inappropriate financial or material benefit should not be offered to HCPs to influence prescription of pharmaceutical products
- PHAMA Code specifically disallows providing gifts to HCPs for their personal benefit. Exemptions for inexpensive gifts of cultural courtesy of no more than RM100 given in acknowledgement of a significant festive occasion and limited to maximum of twice a year.
- Compliance with the PHAMA Code is on a self-regulatory basis, and while breaches of which will attract a fine of up to RM25,000 for a one-off breach or RM50,000 for a repeated breach, there is no corresponding mechanism to enforce the fine

# Malaysia

## Summary of Phama Code

Events involving Foreign Travel	<ul style="list-style-type: none"><li>• No, if majority of attendees are Malaysians.</li><li>• Permissible if participants are from different countries</li></ul>
Appropriate Venue	<ul style="list-style-type: none"><li>• Conducive to scientific or educational objectives</li><li>• Avoid renowned or extravagant venues, such as venues with leisure activities (e.g., spa, ski, golf, gambling, cruise ships)</li></ul>
Meals/ Refreshments	<ul style="list-style-type: none"><li>• Meals/refreshment incidental to the main purpose of the Events allowed</li><li>• Exclusively to participants of the Events</li></ul>
Entertainment	<ul style="list-style-type: none"><li>• Modest and secondary to main purpose. At least 75% of time should be dedicated to scientific and educational purpose</li></ul>
Sponsorship	<ul style="list-style-type: none"><li>• Limited to the payment of travel, meals, accommodation and registration fees</li><li>• No compensation for time spent</li><li>• No payment for companions (e.g., spouses and/or children)</li></ul>
Gifts	<ul style="list-style-type: none"><li>• No cash or cash equivalent</li><li>• Cultural courtesy gifts (subject to a maximum of RM 100/twice a year)</li></ul>

# Thailand

- Code of Practice 9<sup>th</sup> Edition 2012 of the Pharmaceutical Research and Manufacturers Association (“**PReMA Code**”) is broadly similar to other codes.
- The PReMA Code specifically disallows providing gifts to HCPs for their personal benefit. Exemptions for gifts for customary and acceptable local occasions of no more than Baht 3,000 per HCP per occasion.
- Non-compliance can attract a fine: Baht 100,000 for first offense.

# Vietnam

- European Chamber of Commerce Pharmaceutical Group Code of Pharmaceutical Marketing Practices
  - Sets out standards for ethical promotion of medicines to HCPs and interactions with HCPs
  - Prohibits offering or providing financial benefits to inappropriately influence HCP in prescribing, recommending, purchasing, supplying or administering medicines
  - Regulates activities directed at HCPs to promote the prescription, recommendation, supply and administration of medicines (e.g. giving of samples, gifts / give-aways, sponsorships and hospitality, honorariums for services provided)

# Question

**3**

How is the enforcement regime in Cambodia, Laos Malaysia, Thailand and Vietnam?

# Cambodia

- Cambodia has an Anti- Corruption Unit but this is in relationship to government officials. There has been no cases involving HCP and Pharma companies.
- As there are no Pharma laws in Cambodia there has been no enforcement on this issue.



# Laos

- The counter-corruption organization is a State organization that has the role to prevent and counter corruption within the country.
- The causes that result in the conduct of an inspection by the counter-corruption organization are as follows:
  - Evidence that an act constituting corruption has been committed are found;
  - Notification, submission, proposal, report, claim regarding corruption;
  - When any government staff appears to be unusually rich.

# Malaysia

- The Malaysian Anti-Corruption Commission is the main legislative body to combat anti-corruption in Malaysia (“MACC”).
- Principal offence is the offering, giving or soliciting “gratification” to do or forbear to do something. Presumption that “gratification” is with corrupt intent;
- Powers are derived from the Malaysian Anti-Corruption Commission Act 2009. Very wide powers and any “person” including a body corporate can commit an offence;
- MACC usually commence investigation based on tip-off or complaints received;
- MACC will invite “suspects” for interview or may conduct dawn raid at premises

# Thailand

- The National Anti-Corruption Commission (“NACC”) is the main authority to enforce the anti-corruption law in Thailand.
- It is an offense for a person either to offer or to receive property or other benefits as an inducement for performing, not performing or delaying of any act within the area of an official’s responsibility, regardless of whether such performance or non-performance is itself wrongful.
- Thailand has no concept of facilitating payment.
- NACC usually commences investigations based on complaints received.
- NACC will normally invite “suspects” for interview.

# Vietnam

- Healthcare facilities
- Ethical standards of doctors
- On-going investigations and sentencing

# Question

4

What are the recent developments and updates in Cambodia, Laos, Malaysia, Thailand and Vietnam?

# Cambodia

- The Anti-Corruption Unit, empowered to implement the Anti-Corruption Law, continues to be active and makes arrests on a regular basis. However, we are not aware of any enforcement actions relating to the health or pharmaceutical industry.
- Since the 2013 national elections, the Royal Government of Cambodia has been actively promoting a reform agenda, and many ministries are drafting and enacting new laws, sub-degrees and regulations. However, we are not aware of any being implemented by the Ministry of Health.

# Laos

- Property Declaration
- Before or after receiving position, power, or duty, the person who has position, power, and duty must declare his or her own property and debts.
- Procedure Development
  1. Examine the notification report, or claim;
  2. Inspect all documents and assets of concerned individuals or organizations.
  3. Invite the representative to come to give explanations and clarification.
  4. Summarize, evaluate, and decide on the result of the inspection.

# Malaysia

- Proposed amendments to the Malaysian Anti-Corruption Commission Act 2009. Introduction of Corporate Liability
- So far, only prosecution of natural persons.
- Attorney General Chambers not confident of being successfully able to prosecute body corporates
- Proposed amendment to the MACC to extend liability to body corporates
- Relevant bill for amendment expected to be tabled in the Malaysian Parliament within this year
- No draft available as yet



# Thailand

- The term “official” has not been defined in the Penal Code.
- Thailand is going to have a Penal Code amendment defining the term “official” based on the Supreme Court rulings.
- An “official” shall mean “a person who performs governmental duties and is appointed in accordance with law”.

# Vietnam

- Monetary reward for corruption of whistle-blowers?

# THANK YOU

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