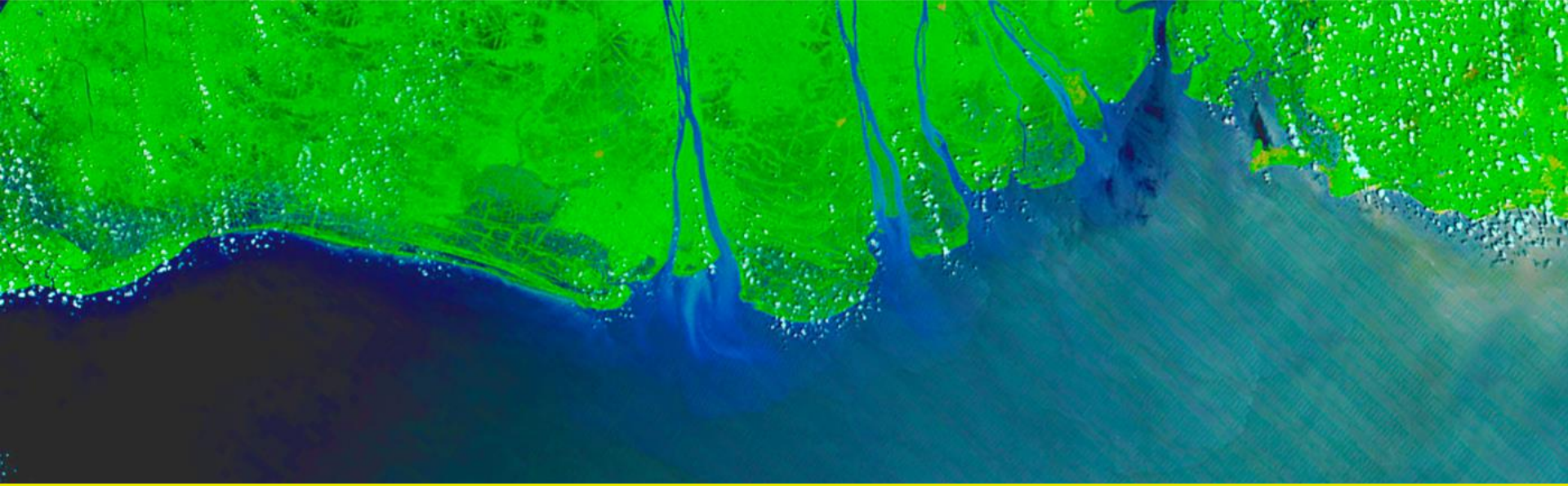


DFDL

# Myanmar Market Access & Compliance Update
# Fourth Asian Pharmaceutical Compliance Congress

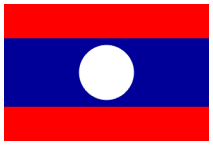
James Finch, Partner

Shanghai, China: September, 2014

BANGLADESH | CAMBODIA | INDONESIA | LAO PDR | MYANMAR | SINGAPORE | THAILAND | VIETNAM

# What makes us unique?

## “We are pioneers in emerging markets”

| 1994 | 1995 | 2005 | 2006 | 2010 | 2011 |
|---|---|---|---|---|---|
|  |  |  |  |  |  |
| Lao PDR | Cambodia | Thailand | Vietnam | Singapore | Bangladesh |
| |  | | | |  |
| | Myanmar | | | | Indonesia |

Our Strategy

Not “Go Where our Clients Go”, BUT “Go BEFORE you Go”.

# Introduction to Myanmar

- Population of 51.4 million
- Estimates of average annual income vary widely, average around USD 894
- Quickly evolving legal landscape

# Pharmaceuticals in Myanmar

- Cultural familiarity with pharmaceuticals – pharmacists often primary healthcare professional consumers interact with
- Increasing opportunities for foreign investors
  - Upcoming changes to legislation that will allow foreigners to participate directly in trading activities; *[Trading will be discussed later]*
  - Upcoming changes to the foreign investment and Myanmar citizen investment laws;
  - Upcoming changes to the banking and financial services landscape

# Relevant Laws

Quite a simple legal scheme:

- The National Drug Law of 1992 (the "National Drug Law"): Main Law
- The Control of Imports and Exports (Temporary) Act of 1947 (the "Control of Imports and Exports Act") – *changes to trading expected in the next year*
- The Public Health Law of 1972 (the "Public Health Law")
- The Penal Code of 1861 (the "Penal Code")
- The Narcotic Drug and Psychotropic Substances Law of 1993 (the "Narcotic Drug and Psychotropic Substances Law ")
- New Anti Corruption Law of 2013
- UN Convention Against Corruption 2003, ratified by Myanmar in 2012.

# Regulatory Authority

- The Myanmar Food and Drug Board of Authority ("the Board") was formed under the National Drug Law.
- The chairman of the Board is the Minister for Health.

*FDA Myanmar - Department of Health*

# Regulatory Authority *cont'd*

- The Board has wide-ranging authorities and responsibilities:
  - Policy making;
  - Issuing licences;
  - Stipulating terms and conditions for import, manufacture and sale of pharmaceuticals;
  - Disciplinary action.
- The Board has the power to delegate to any organization or any person its functions and duties.

# Regulatory Authority *cont'd*

- Central Food and Drug Supervisory Committee and Food and Drug Supervisory Committees ("the Supervisory Committees") in every Myanmar State, Region, District and Township were formed.
- The Food and Drug Administration ("FDA") was formed under the Depart of Health ("DOH") under the MOH to administer all food and drug matters.
- FDA plays a major role in monitoring food and drug registration.
- Those who wish to manufacture, import, export, store, distribute and sell pharmaceutical raw materials or drugs must register the relevant these with the FDA.

# Illegal imports

- It costs around USD 1,000 to register a drug with the FDA,
- There are about 17,000 drugs registered with the FDA
- About 20% of drugs offered for sale in have been illegally Imported into the country and are being sold illegally
- Illegal medicines counterfeit and poor quality
- Government spending on health care increasing significantly – expected to see pharmaceutical market growth of 10 to 15% year on year

# May a foreign company import pharmaceuticals?

- In Myanmar “trading” activities – which includes export and import – is a restricted activity.
- Only Myanmar citizens or companies can engage in “trading”.
- However, the government has signaled an intention to loosen this restriction sector by sector.
- Change could come as early as the end of 2014.

# Local Business Representative

- In the mean time, a foreign pharmaceutical company will need to appoint a local business representative to import products to Myanmar.
- This local business representative is an agent, not a distributor.

# Local Business Representative *cont'd*

- Only a person who has been granted registration under the Registration of Business Representatives Order No 2/89 issued by the MOC can carry on business as a business representative in the country.
- A business representative is defined by the Registration of Business Representatives Order as an agent engaged in accepting incidents and placing orders for goods from the suppliers abroad on a commission basis or any business representative employed to do any business transaction for any individual or organization abroad or to represent another person in dealing with a third person.

# Local Business Representative *cont'd*

- Must be an authorised representative of the foreign company – a letter of authorisation must be given by the foreign company to the local business representative individual or company
- Local representatives,  such as sales reps must be registered
- Unlike finished drug registrations, the applicant for active raw materials must be a registered business representative.
- Only a person who has been granted registration can carry on business as a business representative in the country. Simple procedure,  submit contract.

# Local Business Representative *cont'd*

- Registered business representative:
  - shall be a resident of Myanmar.
  - if it is the foreign company, the applicant shall be an authorized representative who lives locally.
  - if it is the registration for the drug manufactured locally, it shall be applied in person by the manufacturer.

# Local importer

- Practical solution is to engage a captive Myanmar company with service contracts to act ass an unregistered agent by importing the pharmaceuticals.
- A local importer can merely import from a foreign supplier. Local importer responsible for all registration and importation applications and approvals.
- In different contracts, the local importer may also act as distributor and take responsibility for sales into local markets.
- However, this gives rise to anti corruption issues.

# Disputes/contract termination

- If a pharmaceutical company wants/needs to terminate the local business representative, in practice this is done pursuant to the agency contract between the two parties.
- Termination of captive local importer relationships are also conducted pursuant to the import contract.

Can the contract be made terminable pursuant to its terms?

Does the above mean one can't terminate the business representative at will but the practical solution is to use a foreign company that has a captive local company that will release the foreign company when the foreign company wants it?

# Procedure for registering pharmaceuticals

- Must be the local business representative who completes the registration as agent for the foreign company
- First local business representative to apply for approval from the FDA to bring in drug sample for trial. MMR 300,000 fee for application
- Initial application for registration submitted in person by authorised representative who is a Myanmar resident
- Registration certificates valid for 5 years

# Registration - documentation

- Submit Form 1, two sets of documents that detail:
  - Complete information of drugs including original analytical reports
  - FDA approval to bring in samples
  - Samples for laboratory analysis, retention and clinical trial
  - Particulars relating to drug manufacturing enterprise such as investment amount, manpower and machine power
- Food supplements, vaccines have different document requirements.
- For foreign companies, the documents should also detail the authorized business representative of the relevant drug company

# Procedure for importing registered pharmaceuticals

- A person or company wishing to import pharmaceuticals on a regular basis must first register with Directorate of Trade under the Ministry of Commerce, then apply to Myanmar Food and Drug Authority Board.
- Documents required must detail the intended storage facility in Myanmar.
- The validity period of an import licence for a particular shipment is normally six months from the date of payment of the import licence fee.
- Only registered drug shall be imported
- Each shipment must also have a separate licence
- The specifications of the manufacture, country of origin and other relevant particulars of the imported drug must be in conformity with the facts mentioned in the drug registration certificate.

# Procedure for registering to begin pharmaceutical manufacturing business

- A person desirous of drug manufacturing licence shall apply to Myanmar Food and Drug Authority Board or Food and Drug Supervisory Committee assigned the duty by the Authority Board
- Similarly, applicant for a foreign company must be “local business representative”.

# Manufacturing application - documentation

- Submit documents detailing:
  - the layout of the building and premises of the proposed manufacturing facility
  - a list of machinery and equipment and other relevant infrastructure details
  - a list of supervisors, their educational qualifications, functions and duties
  - a list of employees, their educational qualifications and functions
  - supporting documents showing that the specified licence fee has been paid

# Renewal process

- For renewing registration – same documents required as when applying for registration. However, no samples of clinical trials required unless there has been changes to the drug fees payable for lodging renewal application and for receiving renewed registration. Renewed registration replaces the previous registration.
- For renewing each approval - an application to renew must be lodged with the initial application authority at least 90 days before the expiration of any approval certificate.

# Penalties specific to Drug laws

- None related to corruption but foreign compliance specialists often ask about these.
- The National Drug Law prohibits the manufacture, importation, exportation, storing, distribution or sale of the following:
  - a drug which has not been registered;
  - a drug whose registration has been revoked temporarily or cancelled;
  - fake drug, drug differing from standards, deteriorated drug, adulterated drug;
  - a drug which has been manufactured with harmful substances;
  - a dangerous drug which is determined by notification as not fit for utilization by the MOH.

# Penalties Specific to Drug Laws *cont'd*

- The National Drug Law prohibits the manufacture, storing, distribution or sale of a pharmaceutical raw material or drug without a license.
- In instituting legal proceedings under the National Drug Law, prior approval of the MOH or the organization or person delegated with powers for this purpose must be obtained by the prosecutor.

# Particular Criminal Penalties Under ND Law

- Fake Drug is defined by section 2 (d) of the National Drug Law as an imitation or resemblance or it is fraudulently claimed that the drug was manufactured according to the formula mentioned at the time of registration of the drug when this is not the case.
- Section 2 of the National Drug Law defines a Drug Differing from Standards as a drug which is not in conformity with the specifications of a relevant drug or a drug which is lower or higher than the minimum or maximum standards prescribed by the Board of Authority in respect of the standard of drugs.
- Deteriorated is defined by section 2 (g) of the National Drug Law as a drug the expiration date of which has been reached or is past or a drug which has so denatured in any manner that it has become a drug differing from required standards.

# Penalties

## In the Penal Code

- Adulterating a medicinal drug so as to lessen efficacy or change character of the drug – maximum six month prison sentence and MMK 1,000 fine.
- Knowingly selling adulterated drugs – maximum six month prison sentence and MMK 1,000 fine.
- Knowing selling different drugs to those requested – maximum six month prison sentence and MMK 1,000 fine.

# Penalties *cont'd*

## In the National Drug Law

- Manufacturing, storing, distributing or selling an unregistered drug – maximum fine of MMK 500,000 and/or a maximum prison term of 7 years.
- Manufacturing, storing, distributing or selling a registered drug, but without a licence – maximum fine of MMK 100,000 and/or maximum prison term of 2 years.

# Bribery definitions and basic law

- Sections 161 to 165 of the Penal Code and Chapter 10 of the Anti-Corruption Act provide for an offence of receiving bribes by a public servant. These provisions focus on the receipt of such advantages by government officials and the penalties that would be imposed on such government officials if undue advantages are granted.
- A party granting a gratification determined to be illegal under these provisions would also be guilty of a crime pursuant to ss. 109 and 116 of the Penal Code.
- An offer to make an illegal payment to a public official is an offence even if the public official refuses to take it.
- Private person or company—no crime to bribe unless public function.
- Can a company commit bribery? New Anti-Corruption Law looks chiefly at individuals.

# Thank you

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