



Myanmar Market Access & Compliance Update
Fourth Asian Pharmaceutical Compliance Congress
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BANGLADESH | CAMBODIA | INDONESIA | LAO PDR | MYANMAR | SINGAPORE | THAILAND | VIETNAM

I. Introduction

II. Sanctions, update and reputation risk issues.

III. New Anti-corruption Law, Treaties

IV. Legal framework of Pharmaceutical Industry and where compliance issues are

a. Regulatory authorities

b. Illegal imports

c. May a foreign company import pharmaceuticals to Myanmar

d. Local agents and business representatives

e. Termination of agents and reps

f. Practical alternatives to local agents and reps

g. Penalties Specific to Pharma Laws [If time allows}

1. Three years ago—all developed countries had sanctions on Myanmar with respect to 1. movement of funds, 2 investment, exports to the developed countries.
2. Virtually all sanctions have been suspended except: SDN-- Specially Designated Nationals list US and Canada.
3. “SDN” —OFAC regulations issued by US Treasury Department.
4. Now the SDN issue is a real issue for “American Persons” but a major reputational risk for all others doing business in US.
5. Regs prevent “dealing with,” including with third parties
6. Problem: all companies in Myanmar are interlocking with relatives holding shares for relatives.

1. Due diligence. How do you do this?
2. Two theories: a. anecdotal and b. representations from parties.
3. Representations from the parties. Not enough for OFAC on the face of the regs, but better than nothing using due diligence concept.
4. Finding out. No central registry. Example—"calls"

Key Anti-Corruption Laws

The key law relating to anti-bribery in Myanmar is the Anti-Corruption Law of 2013 (the “**Anti-Corruption Law**”). The implementing regulations for the Anti-Corruption Law have not been promulgated, however.

Gratification issue.

Extraterritorial Application

The Anti-Corruption Law applies to all offences committed by any person within Myanmar, and to citizens and permanent residents of Myanmar outside as well as within Myanmar.

Gratification concept.

The Anti-Corruption Law make no mention of a minimum level below which gifts are acceptable. Any gift or economic benefit could potentially constitute a bribe depending upon the context in which it is given. The Union Government has their own codes of conduct which impose limits on the cost of gifts or entertainment that can be given. The cost of gifts or entertainment is specifically limited to USD 300.

Under section 5(4) of the Interpretation of Expressions Laws of 1973, the general offences can be committed by both individuals and companies. There is no explicit legal authority for whether legal persons can be liable to prosecution for corruption. However, Indian case law, which is considered to be a secondary authority in Myanmar, provides that a company cannot be prosecuted in respect of an offence involving the element of *mens rea* (the guilty state of mind). This would exclude corruption and other offences such as treason, felony and perjury. Under the Anti-Corruption Law it does not appear that a legal person could be deemed to commit offences (as such offences are punishable with imprisonment). Therefore, not definite.

The penalties for the offence of bribery differ according to the status of person who commits the offence. In general, there are three categories of status.

- Any person holding a political office is found guilty of an offence under the Anti-Corruption Law shall be liable to imprisonment for a term not exceeding 15 years and may also be liable to a fine.
- Any person in a position of authority other than a person holding a political office is found guilty of an offence under the Anti-Corruption Law shall be liable to imprisonment for a term not exceeding 12 years and may also be liable to a fine.
- Any person other than a person in a position of authority is found guilty of an offence under the Anti-Corruption Law shall be liable to imprisonment for a term not exceeding 7 years and may also be liable to a fine.

The court may make an order as it thinks fit for the disposal of any property which an offence under the Anti-Corruption Law appears to have been committed.

The same penalties apply to those committing a conspiracy or abetment offence.

Transparency International (TI) Rankings

- Ranking on TI's Corruption Perceptions Index (2013)

Myanmar is ranked 157 of 175 on the TI Corruption Perceptions Index. Moving up from 2 years ago

International anti-corruption conventions and inter-governmental organisations

Myanmar has ratified the UNCAC and UNCTOC. Myanmar is a member of Asia / Pacific Group On Money Laundering. Myanmar is not is a member of ADB/OECD Asia Pacific Anti-Corruption Initiative and the FATF.
No treaty implemented.

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.

a. Regulatory Authorities

- 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

- 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.

- 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 Department 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.

- It costs around USD 2,000 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

- 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.

- In the mean time, (before trading allowed) a foreign pharmaceutical company will need to appoint a local business representative to facilitate registration of pharmaceutical products and bringing the products into Myanmar.
- This local business representative is an agent, not a distributor.
- All problems of handling agents, who are not even employees, drug registered in name of agent so agent has much control. In theory, agents can be terminated at will, in practice, problems.



- 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. Contract May provide for reasons to terminate.
- Termination of captive local importer relationships are also conducted pursuant to the import contract.
- If a foreign pharmaceutical company is to terminate the engagement of its local business representative, it must inform the Board and the Board will cancel the registrations the local business representative holds. Then have a new registration with a new rep. In practice, has been difficult to cancel in past, hence practical solution with captive company.

- Practical solution is to engage a captive Myanmar company with service contracts to act as an agent by importing the pharmaceuticals. Often with a reputable foreign holding company.
- 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.

Procedure for registering to begin pharmaceutical manufacturing business



- Manufacturing is an alternative to having an agent
- Foreigner: must be under the under FIL. Part of the application will be the above application.



Benefits available to foreign investors that receive the approval of the Myanmar Investment Commission include:

- Opportunity to take a long-lease (50yr+) on land
- Guarantee that investment will not be nationalized
- Exemption from corporate income tax for the first five years of operation
- Right to accelerate the depreciation rate for the machinery, equipment, building or other working capital and to claim the same as a deductible expense
- Expenses for research and development may be deducted from income

- 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.

- 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.

- 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.

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.

In the National Drug Law

- Manufacturing, storing, distributing or selling an unregistered drug – including one illegally imported 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.

Thank you



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Excellence · Creativity · Trust

Legal framework of Pharmaceutical
Industry and where compliance issues are

Since 1994

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- 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. K300,000 fee for application [Prior to form 1, next slide.] Trials may be waived in some cases, but samples required.
- Initial application for registration submitted in person by authorised representative who is a Myanmar resident
- Registration certificates valid for 5 years

- 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

- 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.

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- 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

Renewing registration of a drug

- 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.

Renewing approval/licence eg for manufacturing

- An application to renew must be lodged with the initial application authority at least 90 days before the expiration of any approval certificate.

The Foreign Investment Law notification No. 49/2014 stipulates which activities require the approval of the Myanmar Investment Commission, and require a joint venture with a Myanmar citizen/company.

- Manufacturing of raw materials for drugs;
- Manufacturing of pharmaceuticals used in medical treatment, blended with any kind of controlled chemicals (also requires approval from Ministry of Industry);
- Private pharmaceutical production (also requires approval from Ministry of Health)

- 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.
- Can a company commit bribery? New Anti-Corruption Law looks chiefly at individuals.

- 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.

- 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
- Like 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.

- Registered business representative:
 - shall be a citizen and resident of Myanmar.
 - if it is the foreign company, the applicant shall be an authorized representative who lives locally.
 - Different issue discussed earlier about manufacture, not import. if it is the registration for the drug manufactured locally, it shall be applied in person by the manufacturer.