

Pharmaceuticals in Myanmar – Law and Procedure

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This article considers the National Drug Law, 1992, of Myanmar or Burma. This legislation, which is the main law governing pharmaceuticals in Myanmar, systematically regulates the manufacture, import, export, storage, distribution and sale of drugs in the country. The authors take the reader through the intricacies of the Act and the institutions and regulatory regimes it creates, describing their operations and problems.

I. INTRODUCTION

THE Myanmar (Burma) government enacted the National Drug Law ('the ND Law') in 1992. The basic purpose of the ND Law is to control and systematically regulate the manufacture, import, export, storage, distribution and sale of drugs.

The ND Law is administered by the Ministry of Health ('the MOH'). The MOH is composed of a total of 14 departments and institutes. They are: Office of the MOH, Institute of Dental Medicine, Department of Health ('DOH'), Malaria Institute of Myanmar, Department of Health Manpower, Department of Health Planning, Department of Traditional Medicine, Department of Medical Research, Department of Medical Service, Institute of Medicine 1, Institute of Medicine 2, Institute of Community Health, Institute of Nursing and Institute of Pharmacy. The state-owned hospitals are also supervised by the MOH.

Under section 4 of the ND Law, the Myanmar Food and Drug Board of Authority ('the Board') was formed. The chairman of the Board is the Minister of Health. The Board consists of 19 members from various ministries. Section 5 of the ND Law gives the Board wide-ranging authorities and responsibilities.¹ Section 6 of the ND Law confers on the Board the power to delegate to any organization or any person its functions and duties.

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¹ The functions and duties of the Board are laying down the national policies relating to registration of drugs; determination of an essential drug within the meaning of the ND Law; the utilization of drugs; determining the qualifications of persons entitled to apply for licences and the terms and conditions for the

When the ND Law was implemented in 1992, Central Food and Drug Supervisory Committee and Food and Drug Supervisory Committees ('the Supervisory Committees') in every Myanmar State, Division, District and Township were formed. Also, in accordance with section 29 of the ND Law, the Food and Drug Administration ('the FDA') was formed under the DOH to administer all food and drug matters. The FDA plays a major role in monitoring food and drug registration.

II. THE MYANMAR LEGAL SYSTEM

The Myanmar legal system is descended from that of England and is a common law system in which the principle of *stare decisis* is applicable. The laws which have been enacted in the Union of Myanmar can be divided into six main categories according to the period in which they have been enacted: (i) the Colonial Period Laws (before 1948); (ii) the Parliamentary Laws (1948-1962); (iii) the Revolutionary Council Laws (1962-1974); (iv) the Pyithu Hluttaw Laws (1974-1988) (the legal system which was exercised during this period is called the Socialist legal system); (v) the State Law and Order Restoration Council Laws (18 September 1988 to 14 November 1997); (vi) the State Peace and Development Council Laws (15 November 1997 to the present day). As Myanmar was once part of India, present-day Indian law is considered secondary authority in Myanmar.

In large part because of the common law tradition, enforcement of statutory law such as the ND Law is vigorous and exacting. This article will concentrate on the regulatory steps faced by foreign companies wishing to register and sell their pharmaceutical products in Myanmar.

manufacture, storage, distribution and sale of pharmaceutical raw materials or registered drugs; stipulating terms and conditions for the manufacture, import, export, storage, distribution and sale of pharmaceutical raw materials or registered drugs; determining good practices for assurance of quality in respect of manufacture, clinical tests and laboratory analyses of pharmaceutical raw materials or registered drugs and all matters relating to drugs; permitting, refusing, temporary revocation and cancellation of registration of drug; granting, refusing, temporary revocation and cancellation of a license; stipulating terms and conditions relating to labeling of drugs, and advertising; determining and canceling any type of substance as a drug; forming committees in respect of matters relating to expertise and determining the functions and duties of such committees; forming Food and Drug Supervisory Committees in the States, Divisions, Districts and Townships in order to supervise matters relating to food and drugs; determining the functions and duties of such committees; prescribing primary laboratories and appellate laboratories and stipulating terms and conditions relating to food.

III. REGISTRATION

A drug is defined by section 2(b) of the ND Law as a substance for use, whether internal or external, in the diagnosis, prevention and treatment of disease, birth control or for any beneficial effect in human beings and animals. Also included in the legal definition of a drug is any substance determined by notification to be a drug by the MOH.

The FDA concerns itself only with drug registrations and is not involved with the registration of the other items such as personal goods, household goods and cosmetics. It is unnecessary, at present, to register these items with any other regulatory authority in the country in order to sell or import them. Medicated shampoos and medicated soaps can, however, be registered with the FDA. The authors have, moreover, been told that the FDA will commence registration of cosmetics in near future.²

Those who wish to manufacture, import, export, store, distribute and sell pharmaceutical raw materials or drugs must register the relevant these with the FDA in the manner mentioned below.³ An applicant must be a resident of Myanmar. If the producer is a foreign company, the applicant must be a resident representative of the foreign company.⁴ An authorization letter must be given by the foreign manufacturer to the local party. If such a letter is granted to a local company, rather than an individual, an employee of the company who is authorized to serve as a contact person must also be designated in the letter of appointment.

Drug registration must be initiated by entering a list of drugs that the applicant wishes to register in a registry book at Drug Control Section 1 ('DCS1'), part of the FDA. The DCS1 will then issue a letter of intimation for remittance of assessment fees, which amount to US \$100 plus fees in kyats for laboratory analysis, depending on the category of the drug.⁵ After obtaining such letter, the applicant must

² Personal goods, household goods and cosmetics fall under the Public Health Law of 1972 ('the PH Law'). According to the PH Law, these items must be in conformity with standard specifications as prescribed by the government from time to time. Under the PH Law a regulatory authority to be formed has the power to seize harmful personal goods, household goods and cosmetics from the market and destroy them. At present, however, neither such standard specifications for these goods nor no such regulatory authority have been promulgated.

³ *Ibid*, s 7 of the ND Law and Notification No 3/93 issued by the MOH.

⁴ Notification No 3/93 issued by the MOH.

⁵ The maximum fee for laboratory analysis is 5000 kyats.

remit the assessment fees to account No 91892 at Myanmar Foreign Trade Bank ('MFTB').

The next step⁶ in the approval process is to get the approval of the FDA for importation of samples of the items entered in the registry mentioned above. This step must be followed within 6 months of the remittance of the assessment fees. To obtain this approval, one original and two photocopies of the credit advice issued by MFTB, a letter from the MFTB informing FDA that payment for the fees had been made and a list of the samples in prescribed form⁷ must be submitted to DCS1. If the samples are already at the port of entry, in addition to the above requirements, the airway bill, a signed invoice and packing list of samples must be submitted. The DCS1 will then issue an approval for importation of samples. The samples may then be imported in accordance with the regulations of Directorate of Trade ('DOT') under the Ministry of Commerce ('the MOC') and Customs Department under the Ministry of Finance and Revenue ('the MOFR') and the conditions as specified in the approval. The samples are normally required for three purposes: clinical trial on sixty patients,⁸ for laboratory analysis and for retention. The total numbers of samples submitted must be in conformity with the FDA circular 1/97, which specifies the required quantities of samples. The samples must be submitted within two days of the date of clearance from the port of entry. At the stage of submission of the samples, an original approval of importation and photocopied airway bill, signed invoice, packing list of the sample drug and the analytical report⁹ must accompany such samples. Thereafter, a receipt for the samples will be issued by the DCS1.

On the completion of the above steps, the applicant must type out an additional form and submit it to the DCS1. Such form must be accompanied with administrative documents, pharmaceutical documents and pharmacological and clinical documents¹⁰ as defined below.

⁶ This step must be skipped if the application is for registration of drugs manufactured in Myanmar.

⁷ This form specifies: name of drug, including trade name, generic name, dosage form, presentations, contents of each unit dose, pack size and quantities.

⁸ For certain rare diseases fewer numbers of samples may be acceptable.

⁹ *I.e.*, the certificate of analysis. The name and designation of an official who signs the report must be stated. A photo-copy of report is not acceptable.

¹⁰ For common, established 'me-too' drugs, the pharmacological and clinical data may be left out, unless there are findings in them differing significantly from those of the earlier registered products.

These documents must be submitted in person or by an authorized representative of the owner of the drug.¹¹

Administrative documents as mentioned above mean a letter of authorization of the representative of the owner of the drug issued to an applicant, a company profile,¹² the certificate of pharmaceutical products in a format adopted by WHO for its certification scheme on the quality of pharmaceutical products moving in international commerce,¹³ GMP certificate,¹⁴ properly endorsed photo-copy of manufacturing licence, proforma statement and summary drug information sheet.

Pharmaceutical documents as mentioned above mean those stating the following: the name of drug including brand name and generic name; formula and composition with necessary reference to its justification; the pharmacopoeia¹⁵ to which active substance and excipients conform;¹⁶ data on physical and chemical properties, structural and empirical formula of active substances and excipients; analytical methods for active substances and excipients; documents relating to quality control of raw material;¹⁷ manufacturing process; standard procedure

¹¹ *I.e.*, the product licence holder at country of origin.

¹² Company profiles are required only for companies whose products have not been previously registered in Myanmar.

¹³ (a) An original certificate must be submitted. The up-dated format should always be used.

(b) If a validity period is not stated on the certificate, the certificate shall not be older than one year at time of submission.

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¹⁵ Preparations being listed in either BP, USP or Eu Phr, must conform to BP, USP or Eu Phr standards. As to preparations not being listed in above pharmacopoeias, standards of the pharmacopoeia other than BP, USP or Eu Phr may be accepted.

¹⁶ If it is a new chemical entity, relevant references must be provided.

¹⁷ The documents relating to quality control of raw material are as follows:

(a) Standard control procedure (control on supplier, accept/reject system, quarantine/release system, sampling procedure, test parameters and testing methods reporting and record keeping system *etc.*)

(b) Raw material specifications.

(c) Specimen QC report on raw material.

(d) Attestation to above particulars by a responsible person not lower than QC manager. The signature, name and designation of such person should be printed on the attestation.

for in-process quality control;¹⁸ finished product specifications;¹⁹ packaging specifications.²⁰

Pharmacological and clinical documents contain data on basic pharmacological and microbiological studies²¹ and data on clinical studies.²²

Two full sets of the above documents must be submitted to the DCS1 in files marked 'Documents Required for Registration of Drugs'. A list of documents submitted must also be shown on the first sheet

¹⁸ They are accept/reject system, sampling procedure, test parameters and testing methods, reporting and record keeping system, specimen in-process QC report and attestation to above particulars by a responsible person not lower than QC manager. The signature, name and designation of such person should be printed on the attestation.

¹⁹ Documents relating to finished product are:

- (a) Specifications, including detailed description of physical characteristics.
- (b) Detailed composition of capsule shell, tablet coating.
- (c) Disintegration and dissolution profile.
- (d) Analytical methods and its parameters tested; the pharmacopoeia to which it conforms.
- (e) A sample copy of certificate of analysis.
- (f) Stability test report (testing method, test parameters, testing condition including temperatures, humidity, type of packing)
 - (i) Testing condition which is similar to climatic condition of tropical countries is preferred.
 - (ii) Test done on drugs in its original packing(s) for which the application is made, is required.
 - (iii) Test reports on at least three different batches have to be submitted.
- (g) Recommended shelf life and storage condition citing relevant data for making such claim.

²⁰ The following are required to be submitted for all types of packaging that are applied for registration. (Lack of any of such items in the submitted dossier will result in non-consideration for approval of the packaging.)

- (a) type of package, its shape, size, color.
- (b) nature of packaging material.
- (c) package size.
- (d) specimen package.
- (e) specimen label.
- (f) specimen package insert.
- (g) quality control procedure on label and packaging, and its specimen QC report.

²¹ Such data are:

- (a) Toxicity data (acute toxicity, sub-acute toxicity, chronic toxicity)
- (b) Teratogenicity data.
- (c) Mutagenicity data.
- (d) Data on efficacy and general pharmacology.
- (e) Data on pharmacokinetics.

²² These are clinical pharmacokinetics, bio-availability and drug interactions.

of each file. Separate applications have to be made for pharmaceutical preparations of different strengths or dosages or package sizes.

The DCS1 may return non-conforming dossiers. When the DCS1 accepts conforming dossiers, it will issue an acknowledgement of receipt of the forms and registration files. After previewing the documentation, if the information provided is inadequate, the DCS1 will require further information. If all documentation is in order, the evaluation process of registration will proceed at the primary laboratory of the FDA.

When and if the primary laboratory analysis results are in favour of registration, the FDA announces its approval²³ and the General Affairs Section ('GAS') of the FDA issues a letter of intimation to remit registration fees of US\$200 for each drug approved. The applicant must remit these registration fees through the MFTB as mentioned above within 90 days from the date of the intimation letter. If the applicant fails to remit the registration fees within such period, the application is deemed to have been abandoned. In such case, neither will the registration assessment fees be refunded nor the registration documents and samples be returned. When the MFTB issues the credit advice in connection with the payment of the registration fees, a forwarding letter accompanied with the credit advice must be submitted to GAS. GAS will acknowledge the receipt of the credit advice. Finally, the drug registration certificate²⁴ ('the Registration Certificate') will be issued approximately one week following the date of the receipt of the credit advice.

When the primary laboratory analysis results are not in favor of registration, the FDA will refuse registration. If the applicant is dissatisfied, he or she may file an appeal to the Board within 60 days from the date of the refusal. The Board will then require an appellate laboratory to reanalyze the samples.²⁵

The holder of the registration certificate must guarantee the drug's quality, efficacy and safety. The manner in which it is manufactured, imported, exported, stored or distributed and sold must be set forth

²³ Generally, it takes the FDA 3 months to approve the registration of common drugs, 6 months for less common drugs and 12 months for new chemical entities.

²⁴ The registration certificate will be delivered only to an authorized representative of the owner of a drug. If such representative is a local company, the person receiving the certificate must be an employee of the company designated in writing as a contact person and whose specimen signatures have been provided to the FDA by the company. Certificates are issued only on Fridays during office hours.

²⁵ Ss 13 and 14 of the ND Law.

in the application. If there are any subsequent alterations with respect to these particulars, prior approval must be obtained from the FDA. When harmful effects are observed by the registrant after the registration, the holder of the registration certificate must immediately inform the FDA and submit a complete description of such effect.²⁶ If the FDA or the holder of the registration certificate notices that a batch of the drug does not comply with the specifications in the application, the import, export, storage or distribution and sales of that batch must be suspended immediately. Any of that particular batch that has been distributed for sale must be recalled.²⁷

If the holder of the registration certificate wishes to cancel the registration of a drug, an application must be lodged with the FDA stating the reasons. The drug registration certificate must be returned to the FDA within 7 days from the revocation or cancellation date. The period of the registration is 5 years unless it is revoked temporarily or cancelled by the Board as a result of contravention of the rules and regulations of the ND Law.²⁸

a. *Renewal of registration*

The registration must be renewed 90 days prior to its expiry. Failure to apply for renewal of registration will result in invalidation of registration with effect from the date of expiry of the certificate. The procedure for renewal is similar to that of the registration mentioned above. For renewal, samples for clinical trials are normally not required unless the situation warrants a repeat clinical trial. The samples for laboratory analysis and for retention, however, are required for renewal for registration. Moreover, the documentation required is the same as that of an initial application. The information provided in the renewal application must be updated and any new findings have to be submitted.

Registration Assessment fees of US\$100 plus additional small fees in kyats for laboratory analysis depending on the category of the drugs must have been remitted to account No 91892 mentioned above at the time of the application of renewal of registration. When the FDA approves the renewal, US\$200 in registration fees must be remitted. On the approval of renewal, a new registration number will be designated and the old one considered void.²⁹

²⁶ The procedure for informing the FDA is described below.

²⁷ Notification No 3/93 issued by the MOH.

²⁸ *Ibid.*

²⁹ *Ibid.*

b. *Updating Changes to Registered Drugs*

The holder of the registration certificate may update the certificate, for example, to amend scientific findings after the date of registration. To do so, the holder must lodge an application for variation of registration with the FDA. In the application, the reasons for the changes, relevant data or findings from studies on which the changes are based and the significant effects of the changes to the specifications of drug must be stated. A photocopy of the original registration certificate of the drug and an attestation of the home country's drug regulatory authority approving such changes must accompany the application. If the holder of the registration certificate cannot provide such an attestation, an explanatory letter must be provided.

When and if the FDA approves the changes, a US\$100 variation fee will be levied on the applicant. The Drug Advisory Committee may waive this fee if it believes that the change is of benefit to the public quality, safety or the efficacy of the drug. The original registration certificate must then be submitted. The approved amendments are made on this certificate.³⁰

c. *Registration of Active Pharmaceutical Raw Materials*

Application for registration of active pharmaceutical raw materials must be made in the same manner as that of finished products discussed above. Approval of the FDA for importation of sample raw material is also required. A sample weighing 20 gm must be submitted together with the files mentioned above. The sample must be packed and labeled properly. Assessment fees, registration fees and variation fees are the same as for finished products.

Unlike finished drug registrations, the applicant for active raw materials must be a registered business representative. 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 representative³¹ in the country.

³⁰ *Ibid.*

³¹ A Business Representative is defined by the business representatives order as an agent engaged in accepting indents 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 dealings with a third person. This definition includes economic organizations and the following:—

- technical assistants and business consultants employed by a foreign manufacturer or exporter;

The documentary requirements for registration of raw material can be categorized as administrative documents and pharmaceutical documents. Administrative documents include a certificate issued by the regulatory authority of the home country to the effect that the product is authorized to be sold in the country of origin, a properly endorsed photo-copy of a valid manufacturing licence, a GMP certificate of the manufacturing plant, a letter of authorization for legal representation of the manufacturer or owner of the product in Myanmar and a business registration certificate of the local representative. Pharmaceutical documentation includes generic name, chemical name, empirical and structural chemical formula, pharmacopoeia to which the product conforms, pharmaceutical specifications,³² method of analysis, manufacturing process, quality assurance system,³³ certificate of analysis, stability test report of at least three different batches, recommended shelf-life, recommended storage conditions and packaging specifications.

IV. LABELING

Every drug registered in Myanmar must be labeled. Every drug to be used only under the direction of a doctor must have a separate written instruction for use. Labels and directions for use may be written in Myanmar or in English or in both Myanmar and English. Also the brand name, generic name, standard, name of active ingredients and amount, batch number, date of manufacture, expiry date, quantity or volume and name and address of manufacturer must be indicated on containers of a drug, such as bottle, package, strip, box, packaging material and injection vial or ampule. In addition to the above mentioned particulars, the Myanmar drug registration number, method of administration and storage conditions must be stated thereon. Drugs to be used only under

- products specialists, buying agents, technicians and business consultants employed by foreign buyers who purchase Myanmar export products;
- individuals who represent a foreigner in foreign trade and who render services for the benefit of such foreigner;
- individuals having an established office in the Union of Myanmar and representing a foreign company or organization or an entrepreneur to act as business representative or to engage in consultancy services or employee recruitment but not registered because they are not governed and registered under any other existing law.

³² This includes physical characteristics, solubility, identification, loss on drying, sulphated ash, heavy metal, purity, assay.

³³ This includes control of starting material, in-process control, finished raw material control, packaging control.

the direction of a doctor must be labeled with the words 'Drug only with prescription'. Drugs for veterinary use must be labeled with the words 'For Veterinary Use Only' and precautions must be indicated thereon.³⁴

With respect to the separate written direction sheet, the brand name, generic name, names and amount of active ingredients, pharmacological actions (references cited), indications, adverse reactions, contraindications, drug interactions, precautions, dosage, storage conditions, Myanmar drug registration number and name and address of the manufacturer must be stated.³⁵

V. ADVERTISING

Drugs that have been registered as discussed above can be advertised in Myanmar. Advertising of registered drugs for which a prescription is required can be made to doctors, dental surgeons, veterinary surgeons, nurses, pharmacists, paramedics. Advertisement to the public can be made only for registered drugs which do not require a prescription from a doctor.³⁶

In advertising to the public, all the particulars mentioned in relation to the drug must be true and not be made as misleading claims. Technical terms not understandable to laymen or those that can be misinterpreted by laymen, must not be used in any advertisement. An advertisement tending to cause the drug to be used wrongly will not be permissible. Advertisement of comparisons with other drugs, displaying pictures of patients recommending drugs are, likewise, not permitted. Comparison of conditions before and after treatment must not be displayed in any form in any advertisement. Advertisements by mentioning or by referring to recommendations from a doctor and advertisement by misleading references in connection with educational instruction and sports activities are not acceptable. Advertisement offering samples of the drug, advertisement incorporating the national emblem or seal and advertisement by offers of money or gifts are also forbidden.³⁷ Furthermore, the registration certificate for a drug is not allowed to be used for advertising purposes.³⁸

³⁴ Notification No 7/93 issued by the MOH.

³⁵ *Ibid.*

³⁶ *Ibid.*

³⁷ *Ibid.*

³⁸ Notification No 3/93 issued by the MOH.

VI. IMPORTATION

The procedures relating to drug importation are set forth in Notification No 5/93 issued by the MOH. Registered drugs may be imported only by a Myanmar person or a corporation that is a general registered importer. In addition to this, the person or the corporation must have a special registration certificate for pharmaceuticals known as a drug importation approval certificate ('the importation certificate').³⁹ Each shipment must also have a separate licence, issued by the MOC.⁴⁰ The specifications of the manufacturer, country of origin and other relevant particulars of the imported drug must be in conformity with the facts mentioned in the drug registration certificate.

a. General Registration for all Importers

A person or company wishing to import pharmaceuticals on a regular basis must first register with the DOT as an importer. The registration fee or extension fee for one year for such registration is kyat 15,000, two years for kyat 20,000 and three years for kyat 30,000.⁴¹ 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. The minimum licence fee payable for one shipment is 250 kyat and the maximum fee is 50,000 kyat depending on the landed cost of the import goods.⁴²

b. Certificate Procedure Specific to Importers of Pharmaceuticals

Those who wish to import pharmaceuticals on a regular basis must submit, in addition to the above, an application to the Township Supervisory Committee ('the TSC'). The TSC then forwards the application to the FDA. After scrutinizing the application, the FDA submits it to the Board with its recommendation. The TSC where the importer resides or, in case of a company, where the company has its registered office, then grants a certificate to the importer. The applicant must be a resident of the Myanmar. The minimum age for an applicant is 20. If the applicant is an employee of a foreign company, the applicant

³⁹ The procedures are explained and discussed below.

⁴⁰ Letter No 14-Za 89 (oo\sa) Dated October 5, 89 issued by the MOC.

⁴¹ Directorate of Trade, Press release No 3/99, Dated March 25, 99.

⁴² Medicines and 36 kinds of pharmaceutical raw materials used in the manufacture of drugs and medicines that are imported by the state-owned economic enterprise or registered private exporters/importers for the purpose of supporting 'the improvement of public health and the welfare of the people in receiving medical treatment' are exempt from import licence fees.

must have been designated by a letter as the company's representative. A person who has been convicted under the ND Law or the Narcotic Drug and Psychotropic Substances Law ('the NDPS Law') may not apply for an importer certificate.⁴³ Drug importation is considered doing business and consequently, a local person engaging this transaction must also be a registered business representative of the foreign company as explained above.

The applicant must fill out a form and submit it with the other documentation to the Board through the FDA and the relevant TSC. Additional documentation, including layout of the building and premises, a list of machinery and equipment, a list of supervisors and their educational qualifications and the functions, a list of employees and their educational qualifications and functions, supporting documents showing that the prescribed fee⁴⁴ has been paid must be annexed to the application. Separate applications for such certificates and separate fees must be submitted for each premise if the applicant desirous of carrying out the business at more than one location.

Following the above, if the Board decides to grant the importation certificate it does so. Only the drugs mentioned and permitted in the importation certificate can be imported. The validity of the importation certificate is 3 years commencing from the date of issuance. Importation cannot be made on the expiry of registration. Renewal must be made 90 days prior to the expiry of the importation certificate, otherwise it is considered invalid.

The premises where the importer stores the products must be in good condition⁴⁵ for storage, ensuring the quality and efficacy of drug will not deteriorate. The premises must not be used for other purposes, especially as a rest or recreation room for the employees. Separate rooms for resting, dining, washing and changing for the employees must be provided.

A supervisor of the drug importation business must possess experience and the qualifications prescribed by the Board and not have been convicted of using narcotic drugs or psychotropic substances or on other grounds under the NDPS Law.

⁴³ Notification No 5/93 issue by the MOH.

⁴⁴ The fees amount to 10,000 kyats.

⁴⁵ The area for receiving, inspection, storage and issuing of drugs must have appropriate space. Such areas must be especially neat and clean and must also permit easy cleaning. There must have adequate lighting and good ventilation, appropriate temperature and relative humidity.

The receiving, storing and distribution systems described in the application must ensure the efficacy of the drug quality and the prevention of erroneous distribution. Drugs for human use and drugs for veterinary use must be stored separately. The system must provide that imported drugs must be labeled in accordance with the requirements discussed above. Imported drugs that are not yet ready for use or pharmaceutical raw materials must be labeled with their chemical names, name of drug, referred pharmacopoeia, the name of the manufacturer, the name of the distributor, batch number, expiry date, storage system and other special instructions.

Any change in the specifications, manufacturer, country of origin and other relevant particulars of the imported drug or the name of the business, address, name of owner or supervisor, machines and equipment as mentioned in the certificate must be made only after obtaining prior approval from the Board. If as a result of such changes new chemical analysis is deemed necessary by the Board, the cost thereof must be paid by the holder of the certificate.

The holder of the certificate must inform the Board, the manufacturer and sellers if the holder notices that the imported drug or pharmaceutical raw material are harmful or not in conformity with the specifications in the certificate. The importation or distribution of such drug or pharmaceutical raw material must in this case be suspended immediately. Such drugs or pharmaceutical raw materials must also be recalled from the market.⁴⁶

The holder of the importation certificate must keep documents and records⁴⁷ relating to imported drugs and pharmaceutical raw materials for two years commencing from the date of importation. Any person authorized by the Board may inspect these documents.

At the stage of getting approval for importation, the holder of the importation certificate must show the importation certificate, drug wholesaler or retailer licence and drug registration certificate to the DOT.⁴⁸

⁴⁶ Notification No 5/93 issued by the MOH.

⁴⁷ They are 1) name of imported drug or pharmaceutical raw material, drug form, (eg, tablet, capsule, syrup) composition, batch number, name and address of manufacturer, name and address of distributor, Myanmar drug registration number; 2) Certificate of analysis of the imported drug; 3) Amount imported; 4) Name of persons to whom drugs are distributed, amount distributed and date of distribution.

⁴⁸ Para 70 of the Myanmar Export/Import Rules and Regulations.

c. Import and Export Procedures

Government control of imports, exports and foreign currency is a complex issue, especially due to the chronic shortage of foreign exchange. In exercise of the power conferred by section 3 of the Control of Imports and Exports (Temporary) Act of 1947, the MOC has designated imports as priority items (known as 'A' items) by Order No 4/98 on March 23, 1998. This order provides that if an importer wishes to import items on the B list, the importer must simultaneously import items on A list in a ratio of 80% from list A and 20% from list B.

Medicines, medical equipment and some raw materials for the pharmaceutical industry are on the A list. Consequently, these items can be imported without regard to the limitations mentioned above. The significance of these categories for the pharmaceutical industry however is discussed below.

Paragraph 79 of the Myanmar Export/Import Rules and Regulations creates four categories of foreign exchange which may be used to purchase imports. They are a) foreign exchange income earned on the export of local purchases; b) foreign exchange income earned as a result of providing services such as house rent, motor car rental, salaries and other services charges; c) foreign capital brought into Myanmar by a company;⁴⁹ d) foreign currency sent into Myanmar either by a foreign company or a person abroad to a company/person in Myanmar for business purposes. Imports are allowed with funds in this category only after a 10% tax is paid. No foreign exchange other than the foregoing categories may be used to import goods legally.

If a party possesses foreign exchange in one of the above categories, he or she can receive what is known as 100 per cent export retention. This means he or she may import, using these earnings, priority items (A) and (B) in the ratio of 80% and 20%, respectively. Since, as mentioned above, pharmaceuticals are on list A, companies importing pharmaceuticals also have the right to import 20% of their total imports of items on the B list. It is possible, therefore, for pharmaceutical importers to import some products on the B list on behalf of other importers wishing to do so. In addition, parties having the above export earnings can swap such earnings for the local currency of importers (such as that of pharmaceutical importers who sells their products in kyat) lacking such export earnings. Thus, depending on the position of the

⁴⁹ Not more than 75 percent of the total foreign capital brought into Myanmar by a company may be used to purchase imports.

pharmaceutical importer with respect to export earning, hard currency may be earned in the above manner to enable the importer to import further shipments.

VII. SALE

In exercise of the powers conferred under section 32, sub-section (b) of the ND Law, the MOH issued the notification No 6/93 dated August 5, 1993, containing the procedure for the sale of pharmaceuticals. According to this notification, a person desirous of obtaining a drug wholesaler's licence or drug retailer's licence ('the seller's licence') must apply to the relevant TSC.

The requirement for qualification of an applicant for the seller's licence is similar to those for drug importation. Likewise, the documents necessary to be annexed to the application for the seller's licence are similar to those required for drug importation. As with importation, separate applications for licences must also be submitted for each separate location. The fee payable for the wholesaler's licence is 3000 kyat and 2000 kyat for the retailer's licence.

The seller's licence, issued by the TSC, is subject to the confirmation by the District Supervisory Committee ('the DSC'). In case of refusal by the DSC, the applicant may apply again after complying with additional written requirements. The validity period of the licence is 3 years commencing from the date of issuance. If a person wishes to renew the licence he must apply 90 days prior to its expiry. If the seller does not renew, the seller's licence will be considered invalid on the date of expiry.

As with importers, mentioned above, the premises for the sale of pharmaceuticals must have adequate lighting, good ventilation and appropriate space. Moreover the premises must be especially neat and clean. It must permit easy cleaning. In addition, necessary arrangements must be made in the building and land so as to prevent the entry of rodents and insects. The area for receiving, inspection, storage and issuing of pharmaceuticals must have appropriate space. The building and land for drug storage must not be used for additional other purposes. It must not be used as a leisure room for employees. Separate rooms for resting, dining, washing and changing must be provided for employees. The vendor must guarantee that the quality and efficacy of the drugs must not deteriorate due to the premises and equipment used.⁵⁰

⁵⁰ Notification No 6/93 issued by the MOH.

With respect to qualifications of the employees, at the sale premises supervisors must have proper experience. A user of narcotic drugs and psychotropic substances or a person convicted under the NDPS Law is not qualified to be a supervisor.⁵¹

In receiving, storing and distributing of drugs, the operational system of the seller must ensure the efficacy and quality of the drug and the prevention of erroneous distribution. The environment of the seller's premises must have the required temperature and relative humidity. Drugs for human use and drugs for veterinary use must be stored separately at the place of storage or sale. Controlled drugs, narcotic drugs and psychotropic substances must be kept specially in a separate room so as to prevent theft and misuse.⁵²

Prescription drugs must not be sold to anyone except by prescription given by any registered physician, dental surgeon or veterinary surgeon. In such prescription, the name and signature of the physician, dental surgeon or veterinary surgeon; the registration number; name, age and address of the patient must be mentioned. If the drug supplied is for veterinary use, the name and address of the owner of the animal; diagnosis and the name of the drug, dosage and quantity must be included.⁵³

The holder of the drug retailer's licence must, on sale of controlled drugs, record the following particulars: name, national identity card number or national registration certificate number and address of the purchaser; the name and registration number of the physician, dental surgeon or veterinary surgeon who gave the prescription; the name, age, diagnosis and address of the patient; if the drug supplied is for veterinary use, the name and address of the owner of the animal; the name of the drug, dosage and quantity. The holder of a drug wholesaler's licence must, on sale of controlled drugs, record the following particulars: date of sale; the name, national identity card number or national registration certificate number of the purchaser; the name of drug, dosage and quantity.⁵⁴

In connection with the sale of the narcotic drugs and psychotropic substances, the seller must not display or advertise them.⁵⁵ The wholesaler of drugs for ready use must sell the same only to licenced retailers

⁵¹ *Ibid.*

⁵² *Ibid.*

⁵³ *Ibid.*

⁵⁴ *Ibid.*

⁵⁵ The seller of the narcotic drugs and psychotropic substances must have a specific licence, as fully explained below.

and to physicians, dental surgeons and veterinary surgeons who are allowed to prescribe such drugs. The wholesaler of a drug which is not yet ready for use,⁵⁶ may sell the same to the manufacturer or the purchaser who will supply it to the manufacturer. If it is a sale of drug for ready use, it must be labeled as specified. If it is a sale of drug which is not yet ready for use, it must be labeled indicating chemical name, name of drug, pharmaceutical referred, name of manufacturer and distributor, batch number, expiry date, storage system and other special instructions as are required.⁵⁷

The holder of the seller's licence must obtain the approval of the TSC prior to any alteration of the particulars of the licence. Any documents and records relating to business mentioned in the licence and documents and records directed to be kept by the TSC from time to time must be kept systematically. The documents and records must not be destroyed during a period of two years following their preparation without the consent of the licensing department. Such documents and records must be open to the inspection of any person authorized by the TSC.⁵⁸

The holder of the seller's licence must inform the TSC immediately if the drugs have been noticed by such holder to be harmful or not in conformity with their specifications. He or she must then immediately suspend the sale and distribution or recall the drug from the market.⁵⁹

VIII. MANUFACTURING

The procedure relating to the application for a drug manufacturer's licence is set forth in Notification No 4/93 dated August 5, 1993, issued by the MOH. According to this notification, when a person wants to obtain drug a manufacturer's licence ('the manufacturer's licence') he or she must apply to the Board through the FDA and the relevant TSC. At present, the issuance of all manufacturers' licences by the Board has ceased temporarily. The basic qualifications for the applicant are the same for those for drug importation and selling licences, discussed above.

To obtain a licence the applicant must complete a form and submit it together with a layout of the building and premises of the facility; a list of machinery and equipment and other relevant facts; a list of supervisors, their educational qualifications, functions and duties;

⁵⁶ *Ie*, must be further processed or packaged before sale to the consumer.

⁵⁷ Notification No 6/93 issued by the MOH.

⁵⁸ *Ibid*.

⁵⁹ *Ibid*.

a list of employees, their educational qualifications and functions and supporting document showing that the required fee has been paid. The fee payable for the manufacturer's licence is 10,000 kyat.⁶⁰

Following the above steps, the Board may issue the manufacturer's licence. An applicant refused may apply again for the licence after complying with the requirements explained by the Board in the refusal letter. After the resubmission, if the application for a licence is refused again, 50% of the licence fee paid on application will be refunded.⁶¹

The validity of the manufacturer's licence is 3 years from the date of issuance. On expiry of the licence a person wishing to renew licence must apply 90 days prior to the expiry, otherwise the licence is deemed invalid on the date of expiry of the licence.⁶²

The aforesaid notification requires that separate applications must be submitted for each new location, if the manufacturer desires to manufacture at a place other than the address mentioned in the original application.

According to Notification No 4/93, mentioned above, drugs must be manufactured in conformity with proper manufacturing practices. The premises for drug manufacturing must have adequate lighting, ventilation, required temperature and relative humidity so as to prevent the deterioration of the quality and efficacy of drugs and impairment of machines and equipment. Moreover, there must be systematic storage of machinery and equipment so as to minimize the risk of confusing different drugs or their components, control the possibility of cross-contamination of drugs or substances and minimize the risk of omission of any processing or control step. Buildings and rooms must be designed and constructed as to prevent the entry of rodents and insects. Interior surfaces such as walls, floors and ceiling must be neat and clean, smooth and free from cracks. The interior must not shed particulate matter and must permit easy cleaning and, if necessary, disinfecting. The manufacturer must provide separate rooms for resting, dining, washing and changing for employees.⁶³

With respect to the place for manufacture of sterile drugs, it must be in conformity with the stipulations prescribed in the manufacturer's licence for such manufacturing. The required apparatus and equipment must also be installed for undertaking sterilization procedures. In addition, storage areas must also have adequate lighting, ventilation, and also appropriate space for storage of quarantined products,

⁶⁰ Notification No 4/93 issued by the MOH.

⁶¹ *Ibid.*

⁶² *Ibid.*

⁶³ *Ibid.*

inflammable drugs presenting special risks of fire, narcotic drugs and psychotropic substances, rejected drugs and recalled drugs. Any person authorized by the licencing department may inspect, from time to time, premises, rooms, staff, equipment, drugs, pharmaceutical raw materials and documents related to manufacture of drugs.⁶⁴

In connection with the qualifications of the employees, a supervisor of the manufacture and the quality controller must have professional qualifications concerning manufacture and quality control of drugs. Likewise, they must have practical experience, not be convicted users of narcotic drugs and not have been previously convicted under the NDPS Law. With respect to machinery and equipment, these must be suitable for their intended use and thoroughly clean. They must be able to prevent any contamination of drugs and other substances during manufacture and the omission of a processing step.⁶⁵

In examining the quality of the product, the quality of the pharmaceutical raw material or the process of drug manufacturing or manufactured drug must be examined internally to ensure its quality, efficacy and safety. Importantly, the quality control supervisor and production supervisor must not be the same person.⁶⁶

There are some additional conditions to which the holder of the manufacturer's licence must abide. The holder of the manufacturer's licence must obtain the approval of the FDA prior to any alteration in the particulars mentioned in the licence. In case of manufacturing of drug commencing not from the pharmaceutical raw materials but from any intermediate stage of the process, the name of the original manufacturer or the importer must be submitted to the FDA. Any alteration of the name and address of the licence holder must be submitted thereto. Finally, the holder of the manufacturer's licence must take responsibility that the quality and efficacy of the manufactured drug conforms to the specifications as mentioned in the licence.⁶⁷

The holder of the manufacturer's licence has the right to sell the drugs manufactured. The holder of the manufacturer's licence must compile and keep the records in the form required by the FDA for two years. If the drug manufactured by the licensee is found the licensee to harmful, he or she must immediately inform the FDA, exporters and distributors, immediately suspend the transportation of the same to distributors and recall them from the market.⁶⁸

⁶⁴ *Ibid.*

⁶⁵ *Ibid.*

⁶⁶ *Ibid.*

⁶⁷ *Ibid.*

⁶⁸ *Ibid.*

IX. NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In order to protect the public against the dangers of narcotic drugs and psychotropic substances⁶⁹ the NDPS Law prohibits, *inter alia*, cultivation of narcotic drug plants, possession, transportation, distribution and sale without permission under the NDPS Law of materials, implements and chemicals which the MOH has, by notification, declared to be materials used in the production of a narcotic drug or psychotropic substance, possession, transportation, transmission and transfer of narcotic drugs and psychotropic substances, offering for sale, agreeing thereto or communicating to market a narcotic drug or psychotropic substance; production, distribution and sale of a narcotic drug or psychotropic substance; importing and exporting a narcotic drug or psychotropic substance and contacting⁷⁰ to effect such import and export.⁷¹

The NDPS Law exempts some activities accomplished with the consent of the MOH such as i) the production of narcotic drug or psychotropic substance and carrying out works of research thereupon; ii) use, possession, transportation, transmission, transfer, sale, import, export and external dealing with respect to narcotic drugs or psychotropic substances in the manner prescribed for the purpose of production, work of research or medical treatment; iii) use, possession and transportation of narcotic drugs or psychotropic substances permitted by the MOH under the direction of any registered medical practitioner, in accordance with the requirements of the NDPS Law.⁷²

a. *Production of and Research on Narcotic Drugs and Psychotropic Substances*

Any enterprise, department, organization or person having a registration certificate and manufacturer's licence under the ND Law wishing to produce narcotic drugs and psychotropic substances or any enterprise, department, organization and person wishing to do

⁶⁹ S 2(a) of the NDPS Law defines narcotic drug as poppy plants, coca plants, cannabis plants or any kind of plant which the MOH has, by notification, declared to be a narcotic drug, substances and drugs derived or extracted from any such plants and drugs which the MOH has, by notification, declared to be narcotic drugs, and substances containing any type of such drug. Psychotropic substance is defined by s 2(b) of the NDPS Law as drugs which the MOH has, by notification, declared to be a psychotropic substance.

⁷⁰ *Ie*, conspiring.

⁷¹ Ss 16, 19 and 20 of the NDPS Law.

⁷² *Ibid*, s 28.

research for the purpose of preparing narcotic drugs and psychotropic substance or giving medical treatment in connection therewith must apply for permission to do so from the MOH.⁷³ The MOH may issue a permit for production of narcotic drugs and psychotropic substances ('the permit for production') or a permit for research for the purpose of preparing of narcotic drugs and psychotropic substances ('the permit for research'). These permits must set forth the type, quality, quantity and weight of the narcotic drugs and psychotropic substances which the licensee is entitled to produce or to do research upon. The permit will provide conditions with which the licensee must comply.⁷⁴

The holder of the permit for production or the permit for research must compile a list of the type, quality, quantity and weight of pharmaceutical raw materials it needs. This must be directed by letter to the Administrative Committee for Disposal of Narcotic Drugs and Psychotropic Substances Seized ('the Administrative Committee'), at least 6 months before the end of the fiscal year. The purpose for which the pharmaceutical raw materials are required and the manner in which they are to be used must be mentioned in detail in the information letter.⁷⁵

The Administrative Committee may then arrange and carry out suitable measures to enable the required type, quality, quantity and weight of pharmaceutical raw materials to be obtained by the permit holder within the required year. If the proposed pharmaceutical raw material is crude opium which can be obtained locally, the Administrative Committee may allow purchase of the same after coordinating with the relevant departments and organizations. If it is a pharmaceutical raw material that has to be purchased from abroad, the Administrative Committee may allow importation of the same after coordinating with the relevant departments and organizations.⁷⁶

The holder of the permit for production or the permit for research must, after receiving of the narcotic drugs or psychotropic substances, inventory them systematically and store and maintain them safely. Moreover, the holder of the permit for production must establish a programme of supervision for research and production and carry this out. The holder of the permit for production or the permit for research must carry out the maintenance and distribution of the drug properly. In addition, the holder of the permit must monthly complete a form

⁷³ Rule 44 of the Rules Relating Narcotic Drugs and Psychotropic Substances.

⁷⁴ *Ibid.*

⁷⁵ *Ibid.*, rule 45.

⁷⁶ *Ibid.*, rule 46.

containing a list of the pharmaceutical raw materials in connection with the research that has been done or drugs which have been produced, drugs distributed and the remaining pharmaceutical raw materials and drugs and send the form to the Administrative Committee.⁷⁷

With the exception of the drugs prohibited under special notification issued by the MOH, the following are the enterprises, departments, organizations and persons that have the right to use and possess narcotic drugs and psychotropic substances and the drugs and the substances which have been prepared with such drugs in accordance with the directives prescribed, as set forth above:⁷⁸

- (a) medical corps, hospitals and dispensaries under the Director of Medical Services of the Ministry of Defence;
- (b) hospitals and dispensaries under the MOH;
- (c) institutes of medicine, institutes of paramedical science and institutes of livestock breeding and veterinary science;
- (d) the Medical Research Centre and other departments relating to works of research recognized by the Government;
- (e) the Myanmar Pharmaceutical Industries, the Ministry of Industry 1;
- (f) pharmacies under the Ministry of Commerce;
- (g) private medical centres registered under the relevant law;
- (h) medical practitioners registered under the relevant laws and rules;
- (i) medical patients and owners of animals, who have been given prescriptions by the registered medical practitioners to use for any disease;
- (j) veterinary surgeons who have graduated from the Institute of Veterinary Science hospital, medical centres, the Institute of livestock Breeding and Veterinary Science or similar institutes and the Institute of Veterinary Science recognized by the Government;
- (k) enterprises, departments, organizations and persons who or which have obtained permission for production and research under Rule 44, explained above;

⁷⁷ *Ibid*, rule 47.

⁷⁸ *Ibid*, rule 48.

- (l) persons from the departments and organizations who or which have to take action under the Law;
- (m) enterprises, departments, organizations and persons who or which have been permitted under notifications issued from time to time by the MOH.

Possession and usage of the type, quality, quantity and weight of narcotic drugs and psychotropic substances by the aforesaid enterprises, departments, organizations and persons must be in conformity with the requirements of the MOH.⁷⁹

The above enterprises, departments, organizations and persons having the right to use and possess narcotic drugs and psychotropic substances have the right to use and possess only the type, quality, quantity and weight of such drugs not exceeding the amount determined by the MOH from time to time. They must keep said drugs separately and safely in accordance with the requirements of the MOH. They must also keep a register of the receipt and issue of the type, quality, quantity and weight of the narcotic drugs and psychotropic substances. They must not give their patients or owners of animals more than two-week supplies of narcotic drugs and psychotropic substances.⁸⁰

b. Storage and Sale of Narcotic Drugs and Psychotropic Substances

Any enterprise, department, organization and person holding the drug registration certificate and seller's licence under the ND Law that wishes to store or sell narcotic drugs and psychotropic substances must apply for permission from the MOH. The MOH may then issue a permit for storage or sale of narcotic drugs and psychotropic substances ('the permit for storage or sale'). The type, quality, quantity and weight of drugs, which are to be stored or sold must be set forth in the permit. The conditions of storage or sale will also be set forth in the permission.⁸¹

The holder of a permit for storage or sale has the right to store the type of drug, quantity and weight thereof allowed in the permit and to sell to the departments, organizations and persons entitled to use and possess mentioned above. In general, the holder of a permit for storage or sale may sell to registered medical practitioners, registered dental surgeons and veterinary surgeons recognized by the

⁷⁹ *Ibid*, 49.

⁸⁰ *Ibid*, 50.

⁸¹ *Ibid*, 51.

government after causing them to show their registration cards or certificates. Moreover, such permit holders have the right to sell to patients if patients show a doctor's prescription. The holder of a permit for storage and sale must keep systematic records containing registration card numbers and addresses of the persons to whom and in what amount and the type of drugs have been sold together with the dates of such sales. Such register and records must be shown if they are demanded for inspection to any person who has been assigned the duty of inspection by the relevant Ministry.⁸²

The holder of a permit for storage and sale may transport the product within Myanmar in accordance with the conditions stated in the licence. Generally, the holder of permit for storage and sale may transmit and transfer to the enterprises, departments, organizations and persons entitled to use and possess under Rule 48 discussed above. In carrying out such transmission and transfer, the holder of a permit for storage and sale must maintain records as to whom transmission or transfer took place and on which date and for what purpose. The records must include the type, quality, quantity and weight of drugs transferred. There must be receipt signed by both parties for transmission, transfer and acceptance.⁸³

c. Importation and Exportation of Narcotic Drugs and Psychotropic Substances

Any enterprise, department, organization and person having a certificate of drug importing or exporting under the ND Law and desirous of importing or exporting narcotic drugs and psychotropic substances must apply for permission to the MOH. When the MOH issues a permit for importing or exporting of narcotic drugs and psychotropic substances ('the permit for importing or exporting'), it will include the type, quality, quantity and weight of drug which are allowed to be imported or exported.⁸⁴

The Director General of the Customs Department must, with the approval of the Law Enforcement Supervisory Committee, determine the airport, port or centres and office of the border trade to which the permitted drugs are to be transported by the holder of permit for importing and exporting.⁸⁵

⁸² *Ibid*, 52.

⁸³ *Ibid*, 53.

⁸⁴ *Ibid*, 54.

⁸⁵ *Ibid*, 55.

The holder of a permit for importing and exporting must obtain an export and import licence issued by the MOC, after obtaining the permission of the MOH. The holder of a permit for importing and exporting must pack the permitted drugs systematically and safely. Some particulars⁸⁶ must be noted in a conspicuous place on the package.

The above particulars must also be mentioned in the bill of lading and the importer must arrange to show such permit and the export and import business licence to the customs authorities when they request it. The holder of permit for importing and exporting must describe the drugs to be imported specifically in the invoice form prescribed by the Customs Department and submit this to Myanmar custom together with 1) the permit to export from the exporting country and 2) a declaration form to the Customs Department. The declaration form will be scrutinized by customs to determine whether it conforms with international transportation restrictions.

The Central Committee for Drug Abuse Control ('the CCDAC') has, by official notification, published a list of narcotic drugs, psychotropic substances and chemical precursors. According to the CCDAC's notifications there are 126 narcotic drugs, 41 psychotropic substances and 8 chemical precursors. These narcotic drugs, psychotropic substances and chemical precursor can be imported only after, in addition to the above restrictions, receiving a certificate from the CCDAC. In carrying out the importation or distribution, the importer must also strictly follow special instructions from the CCDAC.

X. OFFENCES AND PENALTIES

a. *Under the ND Law*

Section 15 of the ND 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;

⁸⁶ Such as the route (by way of air, waterway or road) by which such drugs must be imported or exported, the journey and places to be stopped at, duration of time within which to carry out the work; the type, quality, quantity and weight of drug; the names and addresses of the holder of permit; the purpose for which it is to be used; a photocopy of the permit of the MOH a photocopy of the export and import business licence issued by the MOC.

- fake drug,⁸⁷ drug differing from standards,⁸⁸ deteriorated drug,⁸⁹ adulterated drug;⁹⁰
- 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.

Section 18 of the ND Law mandates the penalties for contravention of section 15. It states that whoever violates any provision of section 15 shall, on conviction, be punished with fine from a minimum of kyats 5000 to a maximum of kyats 50,000 or with imprisonment for a term which may extend to 7 years, or with both. In addition, the exhibits involved in the offence shall also be liable to be confiscated.

Section 16 of the ND Law prohibits the manufacture, storing, distribution or sale of a pharmaceutical raw material or drug without a licence. Section 17 of said Law prescribes the penalties for an offence under the section 16, namely a) if it is an offence relating to an unregistered drug, those convicted will be punished with fine from a minimum of kyats 5000 to a maximum of kyats 50,000 or with imprisonment for a term which may extend to 7 years, or with both; b) if it is an offence relating to a registered drug, a fine from a minimum of kyats 1000 to a maximum of kyats 10,000 or with imprisonment for a term which may extend to 2 years, or with both; c) the exhibits involved in the offence shall also be liable to be confiscated.

Section 17 of the ND Law provides that a person who has obtained a licence as discussed above must abide by any condition of the licence and must abide by the orders and directives issued by the MOH or by the Board. If such person violates this provision, he or she shall be punished with fine from a minimum of kyats 500 to a maximum

⁸⁷ Fake Drug is defined by s 2(d) of the ND Law as a drug the whole or part of the label of which is an imitation or resemblance by various means or is written similarly to that of a licenced drug, as a drug with respect to which the expiration date or manufacturer or distributor or place of manufacture or country of manufacture is fraudulently shown a registered drug with respect to which 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.

⁸⁸ S 2 of the ND 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.

⁸⁹ Deteriorated is defined by s 2(g) of the ND 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.

⁹⁰ Adulterated Drug is defined by s 2(h) of the ND Law as a drug which contains, wholly or partly, a deteriorated drug, other drugs or substances.

of kyats 5000 or with imprisonment for a term which may extend to 1 year, or with both.

In instituting legal proceedings under the ND Law, prior approval of the MOH or the organization or person delegated with powers for this purpose must be obtained by the prosecutor.

The ND Law provides two exemptions to its penalties. The MOH may exempt any governmental department or organization from compliance with any provision of the ND Law.⁹¹ In addition to this, the ND Law does not apply to drugs brought by an individual from abroad for personal use.⁹²

b. *Under the Penal Code*

Section 274⁹³ of the Penal Code was enacted to preserve the purity of drugs for medical purposes. Under section 274 a substance falls within the meaning of adulterated drug if the efficacy of a drug is lessened; it need not necessarily become absolutely useless. The offence under section 275⁹⁴ of the Penal Code consists in selling, or offering, or exposing for sale, or issuing from any dispensary, an adulterated drug as unadulterated. This section not only prohibits the sale of an adulterated drug but also its issue from any dispensary. The offence contained in section 276⁹⁵ prohibits substitutions of one medicine for another. Section 276 is not concerned with adulteration or inferiority. It is concerned only with substituted medicines.

⁹¹ S 22 of the ND Law.

⁹² *Ibid*, S 23.

⁹³ S 274 of the Penal Code states 'whoever adulterates any drug or medical preparation in such a manner as to lessen the efficacy or change the operation of such drug or medical preparation, or to make it noxious, intending that it shall be sold or used for, or knowing it to be likely that it will be sold or used for, any medicinal purpose as if it had not undergone such adulteration, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand kyats, or with both.'

⁹⁴ S 275 of the Penal Code states 'whoever, knowing any drug or medical preparation to have been adulterated in such a manner as to lessen its efficacy, to change its operation, or to render it noxious, sells the same, or offers or exposes it for sale, or issues it from any dispensary for medicinal purposes as unadulterated, or causes it to be used for medicinal purposes by any person not knowing of the adulteration, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand kyats, or with both.'

⁹⁵ S 276 of the Penal Code states 'whoever knowingly sells, or offers or exposes for sale, or issues from a dispensary for medicinal purposes, any drug or medical preparation as a different drug or medical preparation shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both.'

c. *Under the NDPS Law*

Section 16 of the NDPS Law provides:

whoever is guilty of any of the following acts, such as cultivation of narcotic drug plants, possession, transportation, distribution, sale, possession, transportation, transmission and transfer of narcotic drugs and psychotropic substances, offering for sale, agreeing thereto or communicating to market a narcotic drug or psychotropic substance; production, distribution and sale of a narcotic drug or psychotropic substance; importing and exporting a narcotic drug or psychotropic substance; communicating⁹⁶ to effect such import and export [without all of the approvals discussed above] shall, on conviction, be punished with imprisonment for a term which may extend from a minimum of 5 years to a maximum of 10 years and may also be liable to a fine.

Section 19 provides:

whoever is guilty of any of the following acts such as possessing, transporting, transmitting and transferring a narcotic drug or psychotropic substance for the purpose of sale; offering for sale, agreeing thereto or communicating to market a narcotic drug or psychotropic substance; concealing and causing to disappear money, property and benefits derived from the commission of any offence contained in this Law, so that action may not be taken; transferring and converting money, property and benefits involved in an offence, so that it may appear to have been acquired from a legitimate source shall, on conviction, be punished with imprisonment for a term which may extend from a minimum of 10 years to a maximum of an unlimited period.

Section 20 mandates:

whoever is guilty of production, distribution and sale of a narcotic drug or psychotropic substance; importing and exporting a narcotic drug or psychotropic substance; communicating to effect such import and export [without all of the approvals discussed above] shall, on conviction, be punished with imprisonment for a term which may extend from a minimum of 15 years to a maximum of an unlimited period or with death.

Section 16 is concerned with, among other things, offences for possession of the materials used in production of a narcotic drug or psychotropic substances, transportation, distribution and sale of the same. Whereas an act of mere possession, mere transportation, mere transmission or mere transfer of a narcotic drug or psychotropic substance fall within section 16, those acts for the purpose of sale⁹⁷

⁹⁶ *I.e.*, conspiring.

⁹⁷ S 26 of the NDPS provides a list of weights for each drug to be deemed as possessed, transported, transmitted or transferred for the purpose of sale.

are considered as offences under section 19. Sale of a narcotic drug or psychotropic substances is an offence under section 20. Thus, section 16 is intended to apply to drug users, section 19 is intended to apply to drug transporters and brokers and section 20 is intended to apply to drug dealers and manufacturers.

XI. COMMERCIAL TAX AND CUSTOM DUTIES

Under the Commercial Tax Law ('the CT Law') a commercial tax is charged on all goods produced within the county or imported.⁹⁸ The commercial tax payable is liable to be paid by the manufacturer or the importer.⁹⁹ The government may grant exemption from tax with respect to any kinds of goods.¹⁰⁰

The Sea Customs Act ('the SC Act') provides that the government may fix duties and tariff-values of any goods exported or imported on which customs duties are imposed.¹⁰¹ The government may also exempt any goods imported into, or exported from, the country from the whole or any part of the custom-duties leviable on such goods.¹⁰²

In exercise of power conferred by the CT Law and the SC Act, the Ministry of Finance and Revenue has issued notification No. 1/93, in which 36 kinds of medicine are exempted from custom duty and commercial tax. The commercial tax payable on other medicines is 5% on the landed cost for imported goods or the sale receipt for that manufactured in the country. The custom duties payable on the other medicines is at rates ranging from 0% to 1.5% on tariff values.

XII. TRADEMARK LAW

Pharmaceuticals may be trademarked in Myanmar. Officially, moreover, drugs must be registered as discussed above before being trademarked.

There is no comprehensive trademark statutory scheme in Myanmar. The case law is clear on this point:

In Myanmar there is no system of registration of trademarks, nor for a statutory title to a trademark. So the rights of parties setting up rival claims of ownership of a trademark must be determined in accordance with the principles of Common Law.¹⁰³

⁹⁸ S 4 of the Commercial Tax Law.

⁹⁹ *Ibid*, s 5.

¹⁰⁰ *Ibid*, s 8.

¹⁰¹ S 22 of the Sea Customs Act.

¹⁰² *Ibid*, s 23.

¹⁰³ *The Tajmahal Stationery Mart v KE Mohamed Ebrahim VS Aliar & Co* (1950) BLR 41 (HC).

The foregoing has been confirmed by a line of cases which hold that not only is there no official registration authority for trademarks, but that there is no law establishing a right to a particular trademark. Rights to trademarks in Myanmar are thus dependent on general principles of commercial law. Despite all of the formalities mentioned below, it should be borne in mind that they are merely evidentiary of ownership. In the event of a dispute the formalities are simply a factor considered by the finder of fact.

Notwithstanding the vacuum created by the lack of a trademark law, a strong traditional practice has developed for the evidentiary assertion of the rights of ownership in a trademark. A mark is first registered at the Office of the Registration of Deeds. The underlying statutory authority for doing so is contained in Section 18(f) of the Myanmar Registration Act, which provides that documents not required by law to be registered may also be registered with the Office of Registration of Deeds. Direction 13 of the Registration Act explicitly provides that trademarks may be registered by means of a declaration of ownership. A trademark can be registered if it is distinguishable from other registered marks. As a matter of practice, however, mere words or names, printed without accompanying devices or logos can be registered only after obtaining pre-approval of the Registrar. The particulars of the registration process are as follows:

- Each application for registration should relate to one class only and should be accompanied by a list of goods and services for which the mark will be used.
- A foreign applicant must submit the application through a licenced agent or a lawyer. A power of attorney from the applicant to the agent must be filed with the application. The power must contain the name of the owner, the country of origin of the mark, the address of the owner and the signature of the owner or the corporate officer granting the power. The power of attorney must be notarized and legalized at the Myanmar embassy or consulate in the country of registration and/or citizenship of the owner of the mark.
- The declaration of ownership must include the full name of the applicant, its registered address, dates and places of incorporation, if applicable, and a description of the goods and/or services covered by the mark. The declaration of ownership must be signed by the same person who signed the power of attorney and it only needs to be notarized in the country of origin, not legalized at a Myanmar embassy or consulate. A separate declaration must be executed for each

mark and class to be registered. The declaration must include the requisite 25-kyat stamp duty.

- The application must be accompanied with a copy of the registered certificate of trademark in the country of origin. If this certificate is not in English it must be accompanied by a certified English translation.
- A specimen of the trademark must be filed with the applicant. There is no specific legal requirement as to the numbers, forms of presentation or sizes, which are required. In practise, however, at least 10 copies of specimen mark and logo or device, which must be 2" x 2" in size are required.
- A fee of 300 kyat charged for each prescribed application form. Registration fee payable is 6 kyat per class.

After registration, it is customary to place a 'cautionary notice' in a local newspaper of wide circulation. The notice should include the name of the trademark, its owner, the registration number which has been assigned to the goods and services covered by the mark and a warning stating that fraudulent imitation or unauthorized use will be dealt with in accordance with the law.

There is no legal provision regarding period of validity period of trademark registrations. In practice, however, registration is renewed every two years.

In the event of infringement there are two remedies, which are usually sought simultaneously: instituting criminal proceedings against the infringer under the penal code and bringing a civil action for damages and an injunction against the infringer.

XIII. THE PHARMACEUTICALS INDUSTRY IN MYANMAR

In general, a foreign entrepreneur may make an investment in the pharmaceutical sector in Myanmar by appointing a business representative, by establishing a branch office, by incorporating a 100% foreign-owned local subsidiary or by forming a joint venture company. Furthermore, manufacturing and marketing of pharmaceuticals are allowed to take place under the Myanmar Foreign Investment Law ('the MFIL'), which provides a three-year tax holiday and guarantees against nationalization.

In Myanmar there is one government pharmaceutical factory, namely the Myanma Pharmaceutical Factory ('the MPF') established under Myanma Pharmaceutical Industries ('the MPI') of the Ministry of Industry (1). The MPF produces pharmaceuticals and related products, which include powders, liquids, ointments, tablets, capsules, injections and biological products, including anti-snake venoms. The MPI seeks

investment for new pharmaceutical factories on a joint venture basis, renovation and development of its existing pharmaceutical factory and mutual cooperation in the field of manufacturing pharmaceuticals and health care products. The MPI is interested in various additional collaborations with foreign entrepreneurs. There are three methods of such collaborations that would be, according to MPI officials, especially attractive to the MPI. These are joint ventures, buy-back arrangements and production on a consignment basis.

In the private sector, at least 22 pharmaceutical companies, including foreign companies, have been established. Whereas some of these companies only engage in trading, some are carrying out production of medicines with the MPI on a consignment basis.