Myanmar

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National Drug Law (Law No. 7/1992 of October 30, 1992)

The State Law and Order Restoration Council **The National Drug Law**

(The State Law and Order Restoration Council Law No. 7/92) The 5th Waning Day of Tazaungmon, 1354 M.E.

(30th October, 1992)

The State Law and Order Restoration Council hereby enacts the following Law:

Chapter I Title and Definition

1. This Law shall be called the National Drug Law.

2. The following expressions contained in this Law shall have the meanings given hereunder:

(a) Board of Authority means the Myanmar Food and Drug Board of Authority formed under this Law.

(b) Drug means 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. This expression also includes a substance determined as a drug by the relevant Ministry by notification from time to time;

(c) Essential Drug means a drug which is determined by the Board of Authority and which is essential for the health care of the majority of the people;

(d) Fake Drug means the following

(i) a drug the whole or part of the label of which is an imitation or a resemblance by various means or is written similarly:

(ii) a drug in respect of which the expiration date or manufacturer or distributor or place of manufacture or country of manufacture is fraudulently shown;

(iii) a drug in respect of which it is fraudulently shown that it is manufactured according to the formula mentioned at the time of registration of the drug;

(e) **Drug Differing from Standards** means 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;

(f) **Drug Specifications** mean a statement of complete specifications relating to such drug or complete specifications mentioned in the pharmacopoeias recognized by the Board of Authority.

(g) **Deteriorated Drug** means 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 standards;

(h) **Adulterated Drug** means a drug which contains wholly or partly, a deteriorated drug, other drugs or substances;

(i) **Expiration Date** means the date mentioned on the label of a drug to indicate that such drug no longer possesses the claimed efficacy, safety and quality;

(j) **Label** means the indication in manuscript or printed, which is displayed on the container, bottle, pack, outer package or any packing material in which the drug is contained;

(k) **Labelling** means the act of displaying labels on the container, bottle, pack, outer package or any packing material in which the drug is contained;

(l) **Pharmaceutical Raw Material** means the substance to be used in the manufacture of a drug and which is determined by the Board of Authority.

(m) **Drug Registration** means the registration of the drug with the Board of Authority for the purpose of manufacture, import, export, storage, distribution and sale of the drug;

(n) **Licence** means a permit granted for the manufacture, storage, distribution and sale of pharmaceutical raw material or drug;

(o) **Drug Manufacture** means the operations to be carried out in the manufacture of a drug. This expression also includes the performance of all operations carried out in processes commencing from the pharmaceutical raw material or performance of any stage of those processes. However, it does not include compounding of drugs according to medical practitioner's or dentist's or veterinarian's prescription for the relevant patient at a hospital, dispensary and drug retail shops;

(p) **Sale of Drug** means an offer, agreement, attempt, exhibition, storage, possession, distribution and sale for the purpose of selling the drug;

(q) **Storage of Drug** means systematic storage to preserve the efficacy of the drug;

(r) **Quality Assurance** means the warranty of the whole process including obtaining of pharmaceutical raw material, manufacture of the drug, packing, storage, distribution and sale, with the object of enabling every consumer of the drug to use genuine quality, safe and effective drug;

(s) **Advertising** means carrying out measures in a direct or indirect manner to inform the public in order to promote distribution and sale of the drug;

(t) **Primary Laboratory** means a laboratory prescribed by the Board of Authority by notification to analyse samples of the drug;

(u) **Appellate Laboratory** means a laboratory specified by the Board of Authority in order that a final and conclusive decision may be made in respect of analysis remarks of drugs from primary laboratories or when either party is dissatisfied and files an appeal.

Chapter II Aims

3. The Myanmar Food and Drug Board of Authority is formed with the following aims: -

(a) to enable the public to use genuine quality, safe and effective drugs;

(b) to register drugs systematically;

(c) to enable the public to consume genuine quality and safe food;

(d) to control and regulate systematically manufacture, import, export, storage, distribution and sale of food and drugs.

Chapter III Formation of the Myanmar Food and Drug Board of Authority

4. The Government shall form the Myanmar Food and Drug Board of Authority consisting of the following persons: - (a) Minister Chairman Ministry of Hearth

(b) Deputy Minister Vice-Chairman Ministry of Health

(c) Director-General Member Department of Health Ministry of Health

(d) Director of Medical Services Member Ministry of Defence

(e) Director-General Member General Administration Department Ministry of Home Affairs

(f) Director-General Member Livestock Breeding and Veterinary Department Ministry of Livestock Breeding and Fisheries

(g) Managing Director Member Medicines and Medical Equipment Trading Ministry of Trade

(h) Managing Director Member Myanmar Phamacecutical Industries Ministry of No 1 Industry

(i) Managing Director Member Myanmar Agriculture Service Ministry of Agriculture

(j) Managing Director Member Myanmar Foodstuff Industries Ministry of No 1 Industry

(k) An expert each relating Member to the following subjects: (1) Medicine (2) Pharmacology (3) Pharmacy (4) Veterinary Science (5) Chemistry (6) Pharmaceutical Industry

(l) A person assigned responsibility Secretary by the Chairman

Chapter IV Functions and Duties

5. The functions and duties of the Board of Authority are as follows: (a) laying down the policy relating to registration of drugs;

(b) laying down the policy relating to determination of an essential drug;

(c) laying down the policy relating to the utilization of drug;

(d) determining the qualifications of persons entitled to apply for licence and the terms and conditions thereof for the manufactures, storage, distribution and sale of pharmaceutical raw material or registered drug;

(f) determing good practices for assurance of quality in respect of manufacture, clinical tests and laboratory analyses of the phamaceutical raw material or registered drug and all matters relating to drugs;

(g) permitting, refusing, temporary revocation and cancellation of registration of drug;

(h) granting, refusing, temporary revocation and cancellation of a licence;

(i) stipulating terms and conditions relating to labelling of drugs, and advertising;

(j) determining and cancelling any type of substance as a drug;

(k) forming committees in respect of matters relating to expertise and determining the functions and duties of such committees

(l) forming Food and Drug Supervisory Committees in the States, Divisions, Districts and Townships in order to supervise matters relating to food and drug; determining the functions and duties of such committees;

(m) prescribing primary laboratories and appellate laboratories;

(n) stipulating terms and conditions relating to food.

6. The Board of Authority may delegate any organization or any person to carry out its functions and duties.

Chapter V Registration

7. A person desirous of manufacturing, importing, exporting, storing, distributing and selling phamaceutical raw material or drug shall register the relevant drug with the Board of Authority in the prescribed manner.

Chapter VI Application for Licence

8. A person desirous of manufacturing storing, distributing and selling pharmaceutical raw material or registered drug shall apply for a licence in the prescribed manner.

Chapter VII Quality Assurance

9. A person who has been granted the right to manufacture, import, export, store, distribute or sell pharmaceutical raw material or registered drug shall abide strictly by the order, directive and conditions issued by the Board of Authority in respect of quality assurance of the drug.

Chapter VIII Labelling and Advertising

10. A person who has been granted registration of the drug or who has obtained a licence shall abide strictly by the order, directive and conditions issued by the Board of Authority in respect of labelling and advertising.

Chapter IX Temporary Revocation or Cancellation of Licence

11. A person who has obtained a licence violates or is considered to have violated any order, directive or condition issued under this Law in respect of the manufacture, import, export, storage, distribution and sale of pharmaceutical raw material or registered drug, the Board of Authority or the organization which has been delegated for such purpose may revoke temporarily or cancel the licence subject to a time limit.

12. A person whose licence has been cancelled may hand over or drugs in his possession to another person who has obtained a licence, within 30 days with the approval of the Board of Authority or the relevant organization.

Chapter X Appeal

13. A person dissatisfied with a decision made by the organization or person delegated by the Board of Authority, in respect of the refusal to grant a licence, temporary revocation or cancellation of the licence may file an appeal to the Board of Authority within 60 days from the date of such decision.

14. The decision made by the Board of Authority shall be final and conclusive.

Chapter XI Prohibition

15. (a) No one shall manufacture, import, export, store, distribute or sell the following drug; (i) a drug which has not been registered; (ii) a drug whose regulations has been revoked temporarily or cancelled; (iii) fake drug, drug differing from standards, deteriorated drug, adulterated drug; (iv) a drug which has been manufactured with harmful substances; (v) a dangerous drug which is determined as not fit for utilization by the Ministry of Health by notification.

(b) No one shall import or export a registered drug without permission under any existing law.

16. No one shall manufacture, store, distribute or sell a pharmaceutical raw material or drug without a licence.

17. A person who has obtained a licence - (a) shall not fail to abide by any condition of the licence;

(b) shall not fail to abide by the orders and directives issued by the Ministry of Health or by the Board of Authority under this Law.

Chapter XII Offences and Penalties

18. Whoever violates any provision of section 15 shall, on conviction be punished with fine which may extend from a minimum of kyats 5,000 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.

19. Whoever violates any provision of section 16 shall, on conviction -

(a) if it is an offence relating to an unregistered drug, be punished with fine which may extend from a minimum of kyats 5,000 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, be punished with fine which may extend from a minimum of kyats 1,000 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.

20. A person who has obtained a licence and who violates any provision of section 17 shall, on conviction be punished with fine which may extend from a minimum of kyats 500 to a maximum of kyats 5,000 or with imprisonment for a term which may extend to 1 year or with both.

Chapter XIII Miscellaneous

21. Notwithstanding anything contained in the Union of Myanmar Public Health Law, 1972, the provisions of this Law shall be complied with in cases relating to drugs, with the exception of traditional drugs;

22. The Ministry of Health may exempt any Government department or organization from compliance with any provision of this Law.

23. The provisions of this Law shall not apply to drugs brought personally from abroad for personal use.

24. The Government department or organization which is authorized to grant permission to import or to export may grant permission for import or export only of drugs registered under this Law.

25. Persons engaged in drug business on the day this Law is enacted shall carry out registration and obtaining of licence within the period prescribed by the Board of Authority.

26. In instituting legal proceedings under this Law, prior sanction of the Ministry of Health or the organization or person delegated with powers for this purpose shall be obtained.

27. When a drug which has been imported or exported without any permission under any existing law is seized by the relevant Government department or organization, it shall be handed over or disposed of in the manner prescribed by the Board of Authority.

28. (a) The expenditures of the Board of Authority shall be borne by the Ministry of Health.

(b) The Ministry of Health shall employ the staff required for performance of the office work of the Board of Authority.

29. In order to administer all food and drug matters, the Ministry of Health shall form the Food and Drug Administration Department and determine the functions and duties thereof.

30. The Ministry of Health shall assign responsibility as Drug Inspectors to the staff subordinate to it, in order to carry out inspection of the drugs. In addition, it may also assign responsibility as Drug Inspectors to suitable staff, in co-ordination with other Ministries.

31. The orders and directives issued under the Union of Myanmar Public Health Law, 1972 may continue to be applicable in so far as they are not inconsistent with this Law.

32. For the purpose of carrying out the provisions of this Law -

(a) the Ministry of Health may issue rules and procedures as may be necessary, with the approval of the government;

(b) the Ministry of Health and the Myanmar Food and Drug Board of Authority may issue orders and directives as may be necessary.

Sd./ Than Shwe General

Chairman The State Law and Order Restoration Council