

The State Law and Order Restoration Council
The Traditional Drug Law
(The State Law and Order Restoration Council Law No. 7/96)
The 10th Waxing Day of 2nd Waso, 1358 M.E.
(25th July, 1996)

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

Chapter I
Title and Definition

1. This Law shall be called the Traditional Drug Law.
2. The following expressions contained in this Law shall have the meanings given hereunder:-
 - (a) Traditional Drug means a local concoction for use either directly or indirectly, whether internally or externally, in the diagnosis, prevention and treatment of diseases, promotion of health or for any beneficial effect in human beings and animals. This expression also includes a substance determined as a traditional drug by the Ministry of Health by notification from time to time;
 - (b) Traditional Medicine means medicine for the physical well-being and longevity of people in accordance with anyone of the four nayas of traditional medicine, namely Desana naya, Bethitsa naya, Netkhata vedanaya and Vissadara naya;
 - (c) Board of Authority means the Myanmar Food and Drug Board of Authority constituted under the National Drug Law and incorporated under the provision of section 4 of this Law;
 - (d) Essential Traditional Drug means a traditional drug which is determined by the Board of Authority and which is essential for the health care of the majority of the people;
 - (e) Traditional Drug Differing from Standards means traditional drug which is concocted not in conformity with the formula mentioned at the time of its registration;
 - (f) Deteriorated Traditional Drug means a traditional drug, the expiration date of which has been reached or passed or a traditional drug which has so denatured in any manner that it has become a traditional drug differing from standards;
 - (g) Expiration Date means the date mentioned on the label of a traditional drug by the producer of the traditional drug with the approval of the Board of Authority to indicate that such a drug no longer possesses the claimed efficacy, potency, safety and quality;

- (h) Label means the indication in any manner, displayed on the material in which the traditional drug is contained or with which the traditional drug is packed;
- (i) Traditional Pharmaceutical Raw Material means the substance to be used mainly in the manufacture of a traditional drug and which is determined by the Board of Authority;
- (j) Traditional Drug Registration means the registration of the traditional drug which is to be manufactured, with the Board of Authority;
- (k) Licence means a permit granted for the manufacture of the traditional drug;
- (l) Traditional Drug Manufacture means the operations to be carried out in the manufacture of a traditional drug. This expression also includes the performance of all or any one of the operations carried out in processes. It does not, however, include compounding of drugs according to traditional medical practitioner's prescription for use in his treatment of patients at a hospital, dispensary or pharmacy for indigenous medicinal ingredients or to the prescription of any drug or homely remedy of any person for his own personal use;
- (m) Homely Remedy means a traditional concoction from readily available materials, ingredients, or folk medicine;
- (n) Quality Assurance means the warranty of the manufacturer of the traditional drug that it is effective, genuine and safe in the treatment of one or more diseases it claims to cure;
- (o) Advertising means carrying out measures in any manner to inform the public in order to promote distribution and sale of the traditional drugs;
- (p) Primary Laboratory means a laboratory prescribed by the Board of Authority by notification to analyse samples of the traditional drug;
- (q) 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 of the traditional drug after re-analysis of samples, when a problem arises in respect of the analysis report of drugs from primary laboratories or when either party is dissatisfied and files an appeal.

Chapter II

Aims

3. The aims of this law are as follows:-

- (a) to promote and develop traditional medicine and traditional drugs;
- (b) to enable the public to consume genuine quality, safe and efficacious traditional drugs;

- (c) to register traditional drugs systematically;
- (d) to control and regulate systematically the manufacture of traditional drugs.

Chapter III

Formation of the Board of Authority and Functions thereof

4. For the purpose of carrying out measures relating to traditional drugs mentioned in this Law, the Government shall incorporate in the Myanmar Food and Drug Board of Authority expert pharmacologists and other qualified persons.

5. Non-governmental members of the Board of Authority are entitled to remuneration prescribed by the Ministry of Health.

6. The functions and duties of the Board of Authority formed under section 4 are as follows:-

- (a) laying down policy relating to registration of traditional drugs;
- (b) causing experiments, analyses and tests to be carried out as may be necessary, in order to determine whether the traditional drugs for which registration is applied for are in conformity with the traditional medicine treatises used by generations of traditional medical practitioners, whether they are up to the standard in quality and effectiveness, whether they are safe for consumption;
- (c) determining the qualifications of persons entitled to apply for licence and the terms and conditions thereof for the manufacture of the registered traditional drug;
- (d) stipulation terms and conditions relating to labeling of drugs, altering of labels and advertising;
- (e) stipulating terms and conditions relating to the quality assurance of the registered traditional drug;
- (f) selecting and determining essential traditional drugs;
- (g) declaring substances determined as traditional pharmaceutical raw materials;
- (h) determining traditional drugs and raw materials which are unfit for use by the public and submitting them to the Ministry of Health;
- (i) co-coordinating with the Ministries concerned to conserve and prevent the traditional pharmaceutical raw materials from the danger of extinction;

- (j) disseminating of techniques and methods relating to collection, production, storage and preservation of traditional pharmaceutical raw materials;
- (k) giving guidance to conduct research work for raising the standard and modernization of traditional drugs;
- (l) giving advice to Government departments and organizations which produce or import traditional pharmaceutical raw materials;
- (m) carrying out educative activities for extensive use of traditional drugs by the public;
- (n) forming of committees as may be necessary to deal with technical matters and determining the functions and duties thereof;
- (o) forming of Traditional Drug Supervisory Committees in States and Divisions, Districts and Townships and determining the functions and duties thereof;
- (p) determining Primary and Appellate Laboratories.

7. If there arises a controversy or dispute with respect to a substance, the Board of Authority shall determine whether it is a traditional drug or a traditional pharmaceutical raw material.

8. The Board of Authority may co-ordinate with the Ministry concerned in order to supervise the collection, production, storage, marketing, export and import of traditional pharmaceutical raw materials.

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

Chapter IV **Registration of Traditional Drugs**

10. A person desirous of registering a traditional drug with the Board of Authority may do so in accordance with the stipulations.

11. The Board of Authority may, after carrying out analyses, experiments and tests, as may be necessary, permit or refuse the registration.

12. The tenure of registration, registration fees and the fees for extension of the tenure of registration are as prescribed by the Board of Authority.

13. A person who is permitted to register the traditional drug:-
(a) shall pay the prescribed registration fees;

(b) shall abide by the conditions relating to registration and shall also abide by the orders and directives issued by the Board of Authority;

(c) on the expiry of the tenure of registration, may extend it by paying the prescribed fees for extension of the term of registration.

14. If a person who has been permitted to register the traditional drug is found on investigation to have violated any condition relating to permission for registration or any order or directive issued by the Board of Authority the organization or person to whom the Board of Authority has assigned responsibility may revoke the registration subject to a time Limit or cancel it.

15. A person whose registration has been revoked subject to a time limit may apply for renewal of the registration to the Board of Authority on the expiry of the time limit.

16. A person whose registration of the traditional drug has been cancelled shall, with respect to the traditional drugs in his possession comply with the direction of the Board of Authority.

Chapter V

Application for Licence

17. A person desirous of manufacturing a registered traditional drug shall apply for a licence to the Board of Authority in accordance with the stipulations.

18. The Board of Authority may cause scrutiny to be made as to whether or not the application is in conformity with the stipulations and may if necessary issue the licence or refuse to issue the licence.

19. The tenure of the licence, the licence fees and the fees for extension of the tenure of the licence shall be as prescribed by the Board of Authority.

20. A person who has obtained a licence shall:-

(a) pay the prescribed licence fees;

(b) abide by the conditions contained in the licence as well as the orders and directives issued by the Board of Authority;

(c) on expiry of the tenure of the licence pay the fees for extension of the tenure of the licence and extend the tenure of the same.

21. If a person who has obtained a licence is found on investigation to have violated any condition of the licence or any order or directive issued by the Board of Authority, the

organization to which or the person to whom the Board of Authority has assigned responsibility may revoke the licence subject to a time limit or cancel it.

22. A person whose licence has been revoked subject to a time limit may apply for renewal of the licence to the Board of Authority on expiry of the time limit.

23. A person whose licence has been cancelled:-

(a) shall not apply for a new licence;

(b) may hand over or sell the traditional drugs in his possession which are determined by the Board of Authority as of standard quality to another person who has obtained a licence, within 60 days;

(c) with respect to traditional drugs in his possession, which are below standard quality shall dispose them of as directed by the Board of Authority.

24. The Department of Traditional Medicine may direct the State and Divisional, District and Township Traditional Drugs Supervisory Committees to seize the traditional drugs which are below standard quality and which have been manufactured and distributed by a person whose licence has been cancelled.

Chapter VI Appeals

25. A person dissatisfied with any of the following decisions made by the organization or person assigned responsibility by the Board of Authority in respect of a traditional drug may file an appeal to the Board of Authority within 60 days from the date of such decision:-

(a) Refusal to permit registration, revocation subject to a time limit or cancellation of registration;

(b) Refusal to grant licence, revocation subject to a time limit or cancellation of licence.

26. The decision of the Board of Authority shall be final and conclusive.

Chapter VII Prohibition

27. No one shall manufacture the following traditional drug:-

(a) a traditional drug which has not been registered;

- (b) a drug for which registration has been revoked subject to a time limit or cancelled;
- (c) a traditional drug differing from standards;
- (d) a traditional drug which is determined as unfit for use by the Ministry of Health by notification.

28. No one shall sell the following traditional drug:-

- (a) a traditional drug which has not been registered;
- (b) a traditional drug for which registration has been revoked subject to a time limit or cancelled;
- (c) a deteriorated traditional drug;
- (d) a traditional drug which is determined as unfit for use by the Ministry of Health by notification.

29. No one shall manufacture a traditional drug without a licence.

30. 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, the Board of Authority, or the Department of Traditional Medicine~

Chapter VIII

Offences and Penalties

31. Whoever violates any provision of section 27 or section 28 of this Law shall, on conviction, be punished with fine which may extend to kyats 30,000 or with imprisonment for a term which may extend to 3 years, or with both. In addition, the exhibits involved in the offence shall also be liable to be confiscated.

32. Whoever violates any provision of section 29 shall, on conviction:-

- (a) if it is an offence relating to an unregistered traditional drug, be punished with fine which may extend to Kyats 30, 000, or with imprisonment for a term which may extend to 3 years, or with both;
- (b) if it is an offence relating to a registered traditional drug, be punished with fine which may extend to Kyats 10,000, or with imprisonment for a term which may extend to two years, or with both;
- (c) the exhibits involved in the offence shall also be liable to be confiscated.

33. A person who, has obtained a licence and who violates any provision of section 30 shall, on conviction, be punished with fine which may extend to Kyats 5,000, or with imprisonment which may extend to one year, or with both.

Chapter IX Miscellaneous

34. 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 traditional drugs.

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

36. The Government department or organization which is authorized to issue export permits may issue export permits only for traditional drugs registered under this Law.

37. A person engaged in manufacturing of traditional drugs shall, on the day this Law is enacted, take steps to register and obtain the required licence within the period prescribed by the Board of Authority.

38. 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.

39. When a traditional drug which is 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.

40. The office work of the Board of Authority shall be carried out by the Department of Traditional Medicine.

41. The Ministry of Health shall assign responsibility as Traditional Drug Inspectors to the staff subordinate to it for inspection of traditional drugs. In addition, it may also assign responsibility as Traditional Drug Inspectors to suitable staff in co-ordination with other Ministries.

42. 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.

43. 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, the Board of Authority and the Department of Traditional Medicine may issue orders and directives as may be necessary.

Sd./ Than Shwe
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