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**THE MEDICINES ACT OF THE
KINGDOM OF BHUTAN
2003**

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The Medicines Act of the Kingdom of Bhutan 2003 the year of water female sheep:

Preamble:

Be it enacted by the National Assembly of Kingdom of Bhutan on **eighth day of the sixth month** of the Bhutanese calendar corresponding to **fifth day of the August** during the Water Female Sheep Year 2003 of the glorious rule of His Majesty the King, Druk Gyalpo Jigme Singye Wangchuck and in the light of the development of the Kingdom as follows:-

An Act to regulate the import, export, manufacture, sale, transportation and distribution of medicinal raw materials & products and for other matters connected therewith.

Whereas it is necessary to safeguard the human and animal health against harm resulting from the poor quality of medicinal products available in the Kingdom;

Whereas it is necessary to control the sales of medicinal products in the effort of ensuring safety, efficacy and quality at affordable prices;

Whereas it is necessary to regulate the licensing of premises and Competent Persons where the activities in regard to the medicines are carried out;

And whereas it is necessary to adopt and strengthen the laws relating to medicinal products and control the manufacture, storage, transportation, sale, import and export of such products and for matters related therewith and incidental thereto;

CHAPTER I

1. Short Title, Enactment, Commencement & Extent:

a. Short Title:

This Act shall be called THE MEDICINES ACT OF THE KINGDOM OF BHUTAN 2003

b. Enactment:

This act has been enacted upon approval of the 81st session of the National Assembly on the fifth day of August of 2003 corresponding to Water Female Sheep Year of the Bhutanese Calendar.

c. Commencement:

It shall come into force on eighth day of the sixth month of the Bhutanese year corresponding to fifth of August 2003.

d. Extent:

It shall extend to the whole Kingdom of Bhutan.

2. Repeals:

2.1 Upon coming into force of this Act, any law or by-law pertaining to the subject matter addressed by this Act shall be dealt with under this Act.

2.2 Notwithstanding the repeal in section 2.1, anything done or action taken before coming into force of this Act shall be deemed to have been done or taken under such laws or by-laws.

3. Interpretation:

In this Act, unless the context indicates otherwise, the singular shall include the plural and masculine shall include the feminine and vice versa.

CHAPTER II THE BHUTAN MEDICINES BOARD & DRUGS TECHNICAL ADVISORY COMMITTEE

4. The Bhutan Medicines Board:

4.1 The Government shall constitute a Board known as Bhutan Medicines Board to advise the Government on technical matters connected with the manufacture, import, sale and distribution of medicinal products and carry out other functions assigned to it by this Act.

4.2 The Board shall consist of the following members:

- (a) The Minister, Ministry of Health, ex-officio, who shall be Chairman of the Board
- (b) The Secretary, Ministry of Agriculture, ex-officio, who shall be the Vice-chairman of the Board
- (c) The Vice-President, Medical & Health Council, ex-officio
- (d) The Director, Department of Medical Services, ex-officio
- (e) The Director, Department of Livestock, ex-officio
- (f) The Secretary, Ministry of Trade and Industries, ex-officio
- (g) The President, Bhutan Chamber of Commerce and Industry, ex-officio
- (h) The Drug Controller, Drug Regulatory Authority who shall be the Member-Secretary of the Board.

5. Powers of the Board:

- 5.1 The Board shall constitute Drugs Technical Advisory Committee to advise the Board on technical matters arising out of the administration of this Act and carry out the other functions assigned to it from time to time by the Board.
- 5.2 The Board shall formulate and make Regulations for the purpose of giving effect to the provisions of this Act.
- 5.3 The Board shall decide and lay down the qualification and experience required for registration as Competent Persons.
- 5.4 The Board shall lay down the qualifications required to be technical persons in the Drug Regulatory Authority.
- 5.5 The Board shall appoint an Appellate Laboratory to be used in cases of dispute or controversy on the report of analysis issued by the Drug Testing Laboratory.
- 5.6 The Board shall empower Drug Regulatory Authority to regulate the prices of medicinal products.
- 5.7 The Board shall, if found necessary, make exemption or inclusion orders about any article as a medicinal product.
- 5.8 The Board shall be the sole authority to accord approval for production of any medicinal product, such approval in advance being mandatory for any such production.
- 5.9 The Board shall regulate any other aspect relevant to the enforcement of the provisions of this Act.

- 5.10 The Board may make byelaws, regulate its own procedure and the conduct of all business to be transacted by it, and shall publish such byelaws and regulations for public information.
- 5.11 The Board may constitute sub-committees of qualified technical personnel for such periods as necessary to consider particular matters and give reports.
- 5.12 The Board may at its own discretion revise the conditions under which any medicinal product is registered.
- 5.13 The Board may exempt registration requirement of any medicinal product or group of products for reason, which shall be specified by the Board while granting exemption.
- 5.14 The Board may make declaration of any article to be a medicinal product.
- 5.15 Without prejudice to any other provision contained in this Act, if the Board is convinced that the use of any product is likely to result in health risk to human beings or animals, or that any product does not have the therapeutic value claimed, or contain ingredients in such quantity for which there is no therapeutic justification, then on grounds that in the public interest it is necessary or expedient so to do, then the Board may, by notification, authorize the Drug Regulatory Authority to prohibit the import, sale and use of such products.

6. Functions of the Board:

Without prejudice to the generality of the provisions contained in Section 5 of this Act, the Board may make regulations and such regulations may:

- (a) Prescribe the application forms for:
 - (i) registration of medicinal products,
 - (ii) registration of personnel as Competent Persons and
 - (iii) licensing of premises for manufacture, sale & distribution of medicinal products;
 - (iv) import and export of medicinal products.
- (b) Prescribe the procedures and fees for registration of products, services, persons and for licensing of premises;
- (c) Prescribe the forms of Registration Certificate for medicinal products, Competent persons and the license of premises;
- (d) Prescribe the details and format of information to accompany the applications for registration of the medicinal product;
- (e) Prescribe the minimum standards required for licensing of premises;
- (f) Prescribe the conditions and standards of license to be observed by the manufacturers and sellers of medicinal products;

- (g) Prescribe the standards to which medicinal products should conform;
- (h) Prescribe the records, registers and documents to be kept and maintained by the licensees;
- (i) Prescribe the forms of report to be given by the Government Analyst;
- (j) Prescribe such other matters as are incidental to the performance of the functions specified in this section;
- (k) The Board shall ensure the establishment and maintenance of an up-to-date Bhutan National Formulary of all medicines for both humans and animals by the Drug Regulatory Authority, in which shall be published:
 - (i) All medicinal products approved for registration specifying the therapeutic classification of each product;
 - (ii) Essential medicinal products procured for use in the public health system/animal health care;
 - (iii) List of restricted and controlled medicinal products;
 - (iv) Any other matters considered by the Board to merit the publication.

7. Meeting of the Board:

- 7.1 The Board may meet from time to time to transact its business but shall meet at least twice a year. The Chairman of the Board may convene a meeting of the Board at such time as he deems fit, if in his opinion any business of an urgent nature is to be transacted.
- 7.2 In the absence of the Chairman the Vice-Chairman will convene the Board meeting.
- 7.3 The Member Secretary of the Board shall maintain written records of minutes of the proceedings of all Board meetings, which shall be kept for minimum of ten years.

8. Quorum

- 8.1 A Board meeting shall be conducted if two third of its members are present.
- 8.2 Any decisions taken by the Board shall be based on simple majority.
- 8.3 In case of equal votes, the chairman shall give the casting vote.

9. Drugs Technical Advisory Committee

- 9.1 The Drugs Technical Advisory Committee constituted under section 5.1 shall consist of the following members:
 - (a) Chairperson, National Drugs Committee---ex officio;
 - (b) Chairperson, National Veterinary Drug Committee---ex officio;
 - (c) One qualified medical doctor nominated by the Health Ministry;

- (d) One qualified veterinary doctor nominated by the Agriculture Ministry;
 - (e) One Drungtsho nominated by the Health Ministry;
 - (f) One qualified Pharmacist nominated by the Health Ministry;
 - (g) The Principal Pharmacist, Department of Health Services---ex-officio.
 - (h) The Government Analyst, Drug Testing Laboratory---ex officio;
- 9.2 The committee members nominated under (c), (d), (e) and (f) under Section 9.1, shall hold office for a term of three years and shall be eligible for maximum of two terms.
- 9.3 The committee shall elect its Chairman and the Member Secretary among themselves for the meeting.
- 9.4 The committee shall meet from time to time as required to transact its business but shall meet at least thrice a year.
- 9.5 The meeting shall convene only with a quorum of two third of the members.

CHAPTER III DRUG REGULATORY AUTHORITY

10. Drug Regulatory Authority:

The Government shall establish a Drug Regulatory Authority to be managed by an appropriate number of technical people with adequate qualifications and experience to carry out the functions under this Act and Regulations made there under.

11. Drug Controller:

- 11.1 The Government shall appoint Drug Controller possessing adequate qualification and experiences in Pharmaceuticals as the Head of the Drug Regulatory Authority.
- 11.2 The Drug Controller shall carry out the functions under this Act.
- 11.3 The Drug Controller shall liase with other enforcement agencies, both within and outside the country.

CHAPTER IV DRUG TESTING LABORATORY

12. Drug Testing Laboratory:

- 12.1 The Board shall establish Drug Testing Laboratory (DTL) under the Board to carry out the functions entrusted to it by this Act or Regulations made there under.
- 12.2 Provided that if the Board so prescribes, the functions of Drug Testing Laboratory in respect of any drug or class of drugs or biological/vaccines shall be carried out at any other laboratory recognized for the purpose.

13. Functions of Drug Testing Laboratory:

- 13.1 The Board shall make regulations prescribing the functions of the Drug Testing Laboratory, the procedure of submitting samples for analysis, the forms for reporting the results of analysis and the fees payable, if any, and such other matters as may be necessary to enable the said laboratory to carry out its functions.
- 13.2 In case of a dispute or controversy on the report of analysis issued by the Drug Testing Laboratory the report/result of the Appellate Laboratory shall be final.

14. Government Analyst:

- 14.1 The Government Analyst, having the prescribed qualifications and experience, appointed by the Government shall head the Drug Testing Laboratory.
- 14.2 He shall carry out test and analysis of specified class of medicinal products and such other functions as may be specified by the Board or Drug Regulatory Authority.

**CHAPTER V
INSPECTION**

15. Inspection:

The Drug Inspectors and the Officials authorized by the Authority shall carry out inspection under this Act.
Inspection shall be carried out as per the procedures laid down under the Rules and regulations of this Act.

15.1 Drug Inspector:

The Government shall, upon recommendation of the Board, appoint Drug Inspectors possessing the prescribed qualifications and experience.

15.2 Powers of Drug Inspector:

- (a) The Drug Inspector appointed under Section 15.1 of this Act and official authorized by the Authority may:
- (i) Inspect premises wherein any medicinal product is being manufactured;
 - (ii) Inspect premises wherein any medicinal product is being sold, stocked or offered for sale, or distributed;
 - (iii) Take samples of medicinal product for testing which is being manufactured, or being sold or stocked or offered for sale, or is being distributed;
 - (iv) Search any person, enter any premises, whenever he has reason to believe that an offence is being, or has been committed, and carry out his duties under the provisions of this Act in accordance with the Civil and Criminal Procedure Code of the Kingdom of Bhutan, 2001;

- (v) Issue the detention/seizure memo in the prescribed form to the person in possession of the medicinal product in respect of which the offence has been or is being committed, not to dispose off any stock of such product for a specific period.
 - (vi) Carry out any other duties as may be assigned by the Authority.
- (b) The Competent Person(s) of the licensed premises shall give unhindered access to the Inspector, and to provide, on demand, all the information required by him and produce all records of medicinal products necessary for performance of his duties.
- (b) Inspectors shall take the sample for testing as per the procedure laid down in the regulation.

CHAPTER VI REGISTRATION

16. Registration:

16.1 The Authority shall maintain a register in which may be recorded among others, the following details in respect of all medicinal products approved by the Board under Section 16.2 of this Act:

- (i) Name of the medicinal product and biological/ vaccines;
- (ii) Full composition with accurate description of all active and inactive ingredients;
- (iii) Name and address of the manufacturer;
- (iv) Name and address of the importer/exporter;
- (v) Registration number given after approval;
- (vi) Date of registration;
- (vii) Whether prescription or non-prescription medicine/ traditional medicine.

16.2 Medicinal products:

- 16.2.1 All medicinal products, manufactured, sold, distributed and imported /exported from Bhutan shall be registered under the provisions of this Act.
- 16.2.2 Drug manufacturers within or outside Bhutan intending to sell or distribute their products in Bhutan shall register their products under this Act.

- 16.2.3 Unregistered products that are distributed, sold by wholesale or retail, imported and exported shall be registered within six months from the date of notification or a date specifically fixed by the Board for the purpose. If not registered within the notified period, such products shall be withdrawn from use and offender shall be dealt as per the provisions of this Act.

17. Procedures:

- 17.1 Applicants shall apply for registration to the Drug Controller using the form prescribed for the purpose, furnishing all relevant information regarding the product to be registered.
- 17.2 The product should be labelled in generic or International Non-proprietary Name (INN).
- 17.3 Branded product will be registered but in INN or generic if a separate patent licence is not obtained.
- 17.4 The WHO Model Certification Scheme on the Quality for Pharmaceutical moving in International Commerce should be submitted along with the application for the product.
- 17.5 In case of biological and veterinary products, Quality Control certificates from OIE/ recognised International Organisations should be submitted.
- 17.6 Applicants should furnish the bio-equivalence study result in case of generic products. The Drug Controller shall publish a list of products, which require bio-equivalence testing.
- 17.7 In the case of products that have no established bio-equivalence test, the dissolution testing result of the product as per United States Pharmacopoeia (USP) or British Pharmacopoeia (BP) should be submitted.
- 17.8 The Drug Controller shall put up all such applications before the Board.
- 17.9 The Board after being convinced of the quality, safety, efficacy, national standards, price and other information furnished by the applicant, may approve or disapprove for registration of such medicinal products.
- 17.10 The Board may, if considered necessary, constitute a sub-committee of experts to assess applications for registration. This committee, after examination of all aspects, shall forward their assessment with reasons in writing to the Drug Controller for consideration by the Board.
- 17.11 The Drug Controller, after approval by the Board, shall allocate to each approved medicinal product a registration number and he shall record the same along with other particulars in the register.
- 17.12 The Drug Controller shall issue to the applicant a Registration Certificate in the form prescribed for the purpose.

- 17.13 The Registration Certificate shall be valid for a period of three years and can be renewed. The procedure for renewal is same as the first registration.
- 17.14 In case there is any change in the formulation or in respect of any information furnished at the time of registration, the applicant shall inform the Authority with complete details.

18. Cancellation:

The Board shall authorize the Authority to cancel the registration of any product and order withdrawal from the market if: -

- (a) The composition of the product has been changed; or
- (b) Any of the conditions of registration has been contravened; or
- (c) Reports of toxic or adverse reactions of the product have come to notice from national or international sources; or
- (d) The information, which was furnished at the time of application, is later found to be false or insufficient.

19. Competent Persons:

- 19.1 From such date as notified by the Board, no person shall engage his services for manufacture, sale & distribution of medicinal products unless the Board registers his name as a Competent Person.
- 19.2 Under the provisions of this Act, only Competent Persons shall be engaged in the manufacture, sale and distribution of medicinal products.
- 19.3 The Board may refer the Medical & Health Council of Bhutan/Ministry of Agriculture for the registration of Competent Persons.
- 19.4 The Board may set up a Registration Committee to consider registration of Competent Persons in accordance with the qualifications and experience as laid down. The committee shall consist of: -
- (i) Drug Controller as Chairman;
 - (ii) One qualified medical doctor;
 - (iii) One qualified veterinary doctor;
 - (iv) Two other persons nominated by the Board, one of whom shall be a Drungtsho and other a Pharmacist.
- 19.5 The Registration Committee shall examine the person who apply for registration, as to their qualification and experience as prescribed and to their knowledge of drugs and ability to be entrusted with the manufacture or sale of medicinal products.

- 19.6 The Board shall, on the recommendation of the Registration Committee, grant registration as Competent Person to engage in the manufacture or sale of medicinal products.

CHAPTER VII LICENSING

20. Licensing:

- 20.1 The Ministry of Trade and Industry shall issue licenses for manufacture, import, export, and sale of medicinal products by retail or wholesale based on the approval of the Authority.
- 20.2 The Board shall authorize the Authority and Ministry of Trade and Industry to suspend or cancel any such license if it is satisfied that conditions have developed which has caused such premises not conforming to the requirements and conditions laid down or a court of law has convicted the licensee under this Act or regulations there under.

21. Manufacture of medicinal products:

- 21.1 The manufacture of medicinal products shall be carried out under the supervision of a Competent Person approved for the purpose;
- 21.2 The drugs to be manufactured shall be those which are registered and of standard quality.

22. Import of medicinal products:

- 22.1 From such date as notified by the Board, no person shall import: -
- (a) Any medicinal product, which is not registered by the Board under the provisions of this Act; or
 - (b) Any medicinal product which is not of standard quality; or
 - (c) Any misbranded drug; or
 - (d) Any adulterated drug; or
 - (e) Any spurious drug.
- 22.2 Applicant for importation of the medicinal product shall apply to the Authority in the prescribed form giving relevant information about the product to be imported.
- 22.3 The Authority shall issue Pre-Export Notification (PEN) for import of all medicinal products and raw materials with information to the relevant Authorities.

23. Export of medicinal products:

- 23.1 The exporter shall submit an application to the Drug Controller in the prescribed form for approval of the Export License.
- 23.2 The Drug Controller shall, after all the prescribed requirements are fulfilled, recommend for an Export License to be issued from the Ministry of Trade and Industry.
- 23.3 The Board may authorize the Authority and the Ministry of Trade and Industry to cancel any Export License or prohibit the export of any medicinal product or raw materials including parts of plant/animal considered to be of endangered species or for any other reasons in the interest of the Government.

24. Sales and distribution of medicinal products:

- 24.1 Any premises used for storage, sales and distribution of any medicinal products will be subject to approval of the Authority.
- (a) The applicant shall submit an application to the Drug Controller in the prescribed form for Sale License;
- (b) The Drug Controller shall, after fulfillment of the registration requirements, instruct inspection of the premises by the Drug Inspector.
- (c) The Drug Controller shall approve or disapprove the Sale License based on the reports submitted by the Drug Inspector.

25. Restricted or Controlled Medicinal Products:

No person other than those authorised by the Board shall import, manufacture or sell any medicinal products, which are listed under the restricted and controlled items by the Board.

26. Possession of medicinal product by an individual:

A person is prohibited from possessing:

- (i) Any medicinal product in quantity that exceeds than stated in the prescription unless medically justified by a registered medical doctor; or
- (ii) Any medicinal product other than those, which are exempted from the prescription requirements; or
- (iii) Any medicinal product, which are restricted or controlled in the country.

27. Advertisement:

Only the Board shall approve advertisement of any medicinal products in any form whatsoever and this shall also include sponsorship of any kind.

CHAPTER VIII
STORAGE AND DISPOSAL OF EXPIRED MEDICINES

28. Procedures:

- 28.1 From such date as notified by the Board, no expired medicines shall be sold or distributed through any Pharmacy.
- 28.2 Proper containers shall be maintained to store the expired medicines.
- 28.3 The expired medicines shall be disposed off as per regulation after obtaining an approval from the authority concerned.
- 28.4 The Competent Person shall seek approval in writing from the Authority for the disposal of the expired medicines when adequate quantities of such supplies are collected.

CHAPTER IX
OFFENCES & PENALTIES

29. Offences & penalties:

Whoever himself or by any other person on his behalf,

- (a) Imports or manufactures any drug not registered/ without Importation permit as per Section 16.2 shall be punishable with the seizure of the goods and a fine equivalent to the total value of the goods. He shall also be liable to compensate the damage caused by this violation and may be imprisoned depending upon the gravity of the offence which may extend from three months to six years;
- (c) Imports any drug deemed to be misbranded, adulterated, spurious under Section 22.1 shall be punishable with the seizure of the consignment and fine equivalent to the total value of the consignment or an imprisonment depending upon the gravity of the offence which may extend from six months to six years or both. He shall also be liable to compensate the damage caused by this violation;
- (c) Sells or distributes any drug not registered under Section 16.2 shall be liable to the seizure of the consignment and fine equivalent to the total value of the consignment or an imprisonment which may extend from six months to six years or both. He shall also be liable to compensate the damage caused by this violation;
- (d) Engages in the sale, distribution & manufacture of any drug without being registered, as Competent Person under Section 19 shall be liable to the closure of his establishment. He is also liable to a fine equivalent to a national daily wage of three years or an imprisonment, which may extend up to three years or both. He shall also be liable to compensate the damage caused by this violation;

- (e) Engages in the sale, distribution & manufacture of any drug without a license under Sections 21 and 24 shall be liable to the closure of the premises and seizure of the goods. He shall also be liable to a fine equivalent to the total value of the goods or an imprisonment, which may extend from six months to six years or both. He shall also be liable to compensate the damage caused by this violation;
- (f) Violates Section 25 shall be liable to the seizure of the goods and closure of the premises. He shall be dealt as per existing law of the Country;
- (g) Violates Section 26 shall be liable to the seizure of the excess quantity and liable to a fine equivalent to national daily wages of six months to five years or to the imprisonment as per the existing laws of the country or both;
- (h) Contravenes Section 27 shall be liable for a fine or imprisonment or both as per the gravity of the offence determined by the Board for conviction and shall be not less than a fine equivalent to national daily wages of three months to three years or to the imprisonment which may extend from six months to six years or both;
- (i) Contravenes the provisions of this Act or who obstructs any person authorized to perform, any duty under this Act or a regulation made there under shall be guilty of an offence and on conviction thereof shall be liable to fine or the penalty made there under in the Rules and Regulations from time to time;
- (j) Contravenes Section 28 shall be liable for a fine equivalent to national daily wages of three months to one year or imprisonment which may extend from six months to three years or both. As per the gravity of the offence determined by the Board for conviction, the establishment may be liable for closure. He shall also be liable to compensate the damage caused by this violation;

30. Cognisance of offences:

The Board shall authorize the Authority to institute and prosecute all cases under this Act except for cases of serious nature and of grave consequences to the country wherein appropriate authority of the country will prosecute such cases.

31. Appeals:

Any person aggrieved by any individual or collective decision of the Authority may appeal to the Board. Any person aggrieved by any individual member of the Board or the Authority may appeal to the Court of Justice in the Kingdom.

CHAPTER X AMENDMENT, SAVINGS AND DEFINITIONS

32. Amendment:

The Board may review this Act from time to time and propose amendments thereto as and when necessary to the National Assembly of Bhutan for approval.

33. Savings:

In case of conflict in the interpretation of the content of the Act, the interpretation in the Zhungkha version will be the final and binding.

34. Definitions:

In this Act, unless the context otherwise requires: -

- (i) “Adulterated drug” means drug: -
 - (a) consisting of, in whole or in part, any filthy, putrid or decomposed substances; or
 - (b) if it has been prepared, packed or stored under unsanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
 - (c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
 - (d) if it contains any harmful or toxic substance which may render it injurious to health; or
 - (e) if any substance has been mixed therewith so as to reduce/increase its quality or strength.
- (ii) “Advertise” with its grammatical variations means any representation conveyed by any means whatsoever for the purpose of promoting directly or indirectly the sale or distribution of any medicinal product.
- (iii) “Appellate Laboratory” means a laboratory specified by the Board in case of a dispute or controversy on the report of analysis issued by the Drug Testing Laboratory and if the party files an appeal for re-analysis.
- (iv) “Authority” means the Drug Regulatory Authority.
- (v) “Board” means the Bhutan Medicines Board constituted under Section 4 of this Act.
- (vi) “Competent Person” means any person who possesses the requisite qualification and practical experience prescribed by the Board and is approved/registered to undertake:
 - (a) Manufacture of medicinal products;
 - (b) Retail sale of medicinal products;
 - (c) Sale by wholesale trade and distributions of medicinal products.
- (vii) “Drug Controller” means the Head of the Drug Regulatory Authority appointed by the Government under Section 11.1 of this Act.
- (viii) “Drug Regulatory Authority” means the authority appointed by the Government under Section 10 of the Act.

- (ix) “Drug Technical Advisory Committee” means the committee appointed under Section 5.1 of this Act.
- (x) “Drug Testing Laboratory” means the laboratory set up under Section 12.1 of this Act.
- (xi) “Drungtsho” means the practitioner of Traditional Medicine registered under the Medical & Health Council of Bhutan.
- (xii) “Export” with its grammatical variations and cognate expression means to take out of Bhutan by land or air.
- (xiii) “Generics” means the universally accepted name of the drug, which can be a chemical name or a common name.
- (xiv) “Government” means the Royal Government of Bhutan.
- (xv) “Government Analyst” means an Analyst appointed by the Government under Section 14.1 of this Act.
- (xvi) “Import” with its grammatical variations and cognate expression means to bring into Bhutan by land or air.
- (xvii) “Inspector” means a Drug Inspector appointed by the Government under Section 15.1 of this Act.
- (xviii) “Label” means a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a medicinal product package.
- (xix) “License” means a license granted in accordance with the provisions of this Act or any regulation made therein.
- (xx) “Manufacture”, means any or all of the operations to be carried out in the manufacture of a medicinal product. It includes all operations involved in the processing, production, altering, formulating, filling, finishing, packing, repackaging and labelling of a medicinal product.
- (xxi) “Medicinal Products” include: -
 - (a) All substances intended for internal or external use of human beings or animals and intended to be used in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals; and
 - (b) Such substances intended to affect the functioning of any structure found in the human and animal body;
 - (c) Any other substance or device declared by the Board to be a medicinal product or a medicine or a drug and this may belong either to modern (allopathic) or traditional system of medicine;

- (xxii) The words “Medicinal Product”, “Medicine” and “Drug” are used as synonyms in the text of the Act and Regulations made there under and have the same meaning.
- (xxiii) “Minister” means the Minister for Health.
- (xxiv) “Misbranded drug” - is defined if: -
- (a) It is so coloured, coated, powdered or polished to conceal the damage or it is made to appear of better or greater therapeutic value than it really is; or
 - (b) It is not labelled in the prescribed manner; or
 - (c) Its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular manner.
- (xxv) “Qualified medical doctor,” means medical doctor recognized and registered by the Medical & Health Council and allied agencies in the Government.
- (xxvi) “Qualified veterinary doctor” means veterinary doctor recognised and registered by the Ministry of Agriculture or allied agencies in the Government.
- (xxvii) “Registration” means the registration of a medicinal product with the Bhutan Medicines Board before a product can be manufactured, or imported for later sale and distribution in Bhutan.
- (xxviii) “Retail Sale” means a sale other than a sale by wholesale dealing and “Sale by Wholesale” means sale to a person for the purpose of selling again and includes sales to hospitals and institutions.
- (xxix) “Spurious drug” - is defined as spurious if: -
- (a) it is imported under a name which belongs to another drug; or
 - (b) it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
 - (c) the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or doesn't exist; or
 - (d) it has been substituted wholly or in part by another drug or substance; or
 - (e) it purports to be the product of a manufacturer of whom it is not truly a product.

- (xxx) “Standard quality“ means – in relation to a medicinal product, that the medicinal product complies with the standard set by the Board under this Act & Regulations therein.
- (xxxi) “Animal” means all ruminants and monogastric animals except man; any kind of mammals except man; any kind of four-footed beast which is not a mammal; fish, reptiles, crustaceans or other cold-blooded creatures of any species.



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