

Bhutan Medicines Rules and Regulation 2012



Table of Contents

Chapter I Preliminary.....	4
Chapter II Board, Drug Technical Advisory Committee, Drug Regulatory Authority and Drug Testing Laboratory.....	5
Chapter III Drug controller, Government analysts, Drug Inspectors- qualification and duties.....	9
Chapter IV Registration of medicinal products	12
chapter V Import & Export Authorization	18
Chapter VI Technical Authorization for manufacture of medicinal products	22
Chapter VII Technical authorization for sale and distribution	26
Chapter VIII Registration and Duties of competent persons.....	30
Chapter IX Adverse Drug Reaction monitoring system & Pharmacovigilance.....	34
Chapter X Management of expired, seized, recalled and defective medicinal product or unregistered medicines	36
Chapter XI Advertisement of medicinal products	38
Chapter XII Lot release of vaccines, biologicals & special products.....	40
Chapter XIII Drug Inspection and Investigation of Offences.....	41
Chapter XIV Fines and Penalties	44
Chapter XV Classification of medicines	50
Chapter XVII Appeal	52
Miscellaneous provisions	52

Bhutan Medicines Rules and Regulation 2012

In the exercise of powers conferred to the Bhutan Medicines Board under Chapter II, Section 5.2 and Section 5.10 of the Medicines Act of the Kingdom of Bhutan 2003, the Board for the purpose of giving effect to the provisions of the Act, makes the following Rules and Regulation. This Regulation shall be revised as and when required.

While implementing this Regulation, the members and employees of the Authority shall maintain highest level of integrity and confidentiality of all clients and their technical information and shall not have improper association, not be a party to false pretences, forgery, fraud and counterfeiting.

CHAPTER I
PRELIMINARY

Short Title

1. This Regulation shall be called the BHUTAN MEDICINES RULES AND REGULATION, 2012.

Commencement

2. This Regulation shall come into force on the *twenty seven* of the *ninth* month of *Water Male Dragon Year* of the Bhutanese calendar corresponding to the 11th November of 2012.

Repeal

3. Upon commencement of this Regulation, The earlier Bhutan Medicines Rules and Regulation 2005(2nd Edition 2008) shall be repealed.

Application

4. This Regulation shall apply to medicinal products in relation to drugs, vaccines and biologicals intended for internal and 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 or matters connected therewith.

Rule of Construction

5. In this Regulation, unless the context indicates otherwise, the singular shall include the plural and masculine shall include the feminine.

CHAPTER II

BOARD, DRUG TECHNICAL ADVISORY COMMITTEE, DRUG REGULATORY AUTHORITY AND DRUG TESTING LABORATORY

Procedures for the Board

6. The Board shall regulate its own procedures as follows:
 - a. The Board shall consist of members as listed under Section 4.2, Chapter II of the Act.
 - b. In absence of the Chairperson, the Vice-Chairperson of the Board shall convene the meeting.
 - c. The Board shall exercise the powers and functions stated under Section 5 and Section 6 of the Act which includes, but not limited to the following:
 - i. The Board may delegate the authority to the Drug Regulatory Authority known as Authority to carry out the functions of the Board prescribed under the provisions of the Act under the written order;
 - ii. The Board may revise the prescribed fees from time to time as and when necessary and such fees shall be notified vide executive order of the Chairperson of the Board.
 - iii. The Chairperson of the Board, at any time, on disciplinary grounds and abuse of power, may suspend or terminate any member of the committees constituted under the provisions of the Act, and the Board shall appoint another appropriate person to replace the member and such person shall serve for the remaining term of the membership;
 - iv. The Board shall recommend the qualification and experience requirements of technical personnel to be appointed or recruited by the Royal Government in the Authority and Drug Testing Laboratory; and
 - v. The Board shall recommend to the Royal Government for an appropriate disciplinary action as per the existing Government Rules and Regulation, against any technical personnel appointed under the provisions of the Act by the Government, if the Board is so convinced of the incompetence of the said personnel or his failure to perform duties, or professional misconduct, or found abusing his power or position.

Procedures for the Drug Technical Advisory Committee (DTAC)

7. The Drug Technical Advisory Committee known as Committee shall regulate its own procedures as follows:
 - a. The Committee shall constitute of members as stated under Section 9.1 of the Act;
 - b. The Committee may recommend the Board to appoint expert(s) to address specific technical areas as and when required;
 - c. The Chairperson of the Committee shall be rotated on an annual basis among the Ex-officio members constituted under Section 9.1 the Act and the nomination shall be based on the consensus of the members.
 - d. The members shall attend the meeting in person. If a member fails to attend three consecutive meetings, he shall forfeit the membership unless otherwise a valid explanation is submitted to the Board. The Board shall appoint appropriate replacement for such members;
 - e. The Authority shall co-ordinate and organise the Committee meetings and shall maintain records of the meetings, which shall be retained for a period of five years and other important documents may be stored in electronic form.

Terms of reference of the Committee

8. The Committee shall;
 - a. Provide advice to the Board on all technical areas related to registration of medicinal products and other technical matters as and when required by the Board;
 - b. Review and recommend national standards and technical guidelines to the Board;
 - c. Recommend the Board to call any relevant person(s) from any agency to attend the meeting of the Board and Committees, to provide technical information or other relevant documents and articles related to the subject of the meetings;
 - d. Maintain the confidentiality and privacy of technical information and shall not disclose any important decision of the meetings unless approved by the Authority;

- e. Declare the nature of interest in the form I-CI of this Regulation; and abstain oneself from the particular meeting in case of any conflict of interest;
- f. Avail remuneration for attending the Committee meetings as per the existing Government Rules and Regulations; and
- g. Also carry out any other responsibilities assigned by the Board.

Functions of the Drug Regulatory Authority

- 9. The Authority established under Section 10 the Act shall carry out the functions as delegated by the Board as under:
 - a. Control and regulate manufacture, import and export, sale, stocking and distribution of medicinal products;
 - b. Control and regulate advertisement, drug promotion of medicinal products.
 - c. Regulate the prices of medicinal products through reviewing the price structure provided at the time of product registration and sale of products in the market in collaboration with the relevant agency.
 - d. Register medicinal products and Competent Person(s) for manufacture, sale, import, export and distribution of medicinal products;
 - e. Inspect premises for manufacture, sale, import, export and distribution of medicinal products;
 - f. Obtain and receive all such evidences to examine all such person(s) involved in the contravention of the provisions of the Act, whether by himself or as a witness to it.
 - g. Identify a Laboratory for drug analysis upon approval by the Board.
 - h. Promote, educate and create awareness on the Act, this Regulation and Notifications passed thereunder.
 - i. Maintain and publish an up-to-date Bhutan National Formulary of all registered medicines for both human and animals as specified in the Act.
 - j. Publish the updated list of medicines periodically which are registered with the Authority thorough the official web page.

- k. Notify on the safety and product performance status in the country as deemed required.
- l. Liaise with other relevant agencies to carry out the functions assigned by the Board; and
- m. Carry out any other responsibilities assigned by the board.

Functions of the Drug Testing Laboratory

10. The Drug Testing Laboratory established under Section 12.1 of the Act shall carry out the following functions:
- a. Test samples forwarded by the Authority and other relevant agencies as per approved tests and procedures;
 - b. Submit drugs test reports to the Authority in the prescribed format.
 - c. Develop standard sampling procedures for the Authority and the Laboratory; and
 - d. Furnish the drug testing results to the Court of Law as and when required;

Appellate Laboratory

11. In the event, where the Laboratory tests as provided in the section 10 of this Regulation is challenged by the aggrieved; the test result from the appellate laboratory as identified by the Board shall be final.
12. Where the result of the appellate laboratory under Section 11 of this Regulation is in favour of party who is not the Authority, the Authority shall bear the cost of such appellate laboratory test or vice versa.

CHAPTER III

DRUG CONTROLLER, GOVERNMENT ANALYSTS, DRUG INSPECTORS- QUALIFICATION AND DUTIES

Qualifications of Drug Controller

13. The Drug Controller shall:
- a. Have a minimum of a bachelor degree in pharmacy or pharmaceutical sciences and;
 - b. Have a minimum of five years experience in relevant field or three years experience with proven record of capability.

Duties of Drug Controller

14. The Drug Controller shall:
- a. Be accountable to the Bhutan Medicines Board;
 - b. Implement and supervise all functions of the Drug Regulatory Authority;
 - c. Guide preparation and formulation of policies and plans on regulations and control measures;
 - d. Develop control and regulatory strategies related to drugs and vaccines;
 - e. Set vision for the authority and prepare both long and short term plans;
 - f. Approve documents required for registration of medicinal products;
 - g. Approve protocols and standard operating procedures for Authority;
 - h. Liaise with Drug Testing Laboratory, Appellate Laboratory, Courts, Department of Revenue and Customs, Ministry of Health, Ministry of Economic Affairs, retail pharmacies, Royal Bhutan Police, Agriculture, Bhutan Medical and Health Council(BMHC), Bhutan Narcotic Control Agency(BNCA) and any other relevant national and international agencies on regulatory and enforcement matters;
 - i. Function as the Chairperson of the Registration Committee of the Competent Person, and Member Secretary to the Bhutan Medicines Board.

Qualification Government Analyst

- 15.** The Government Analyst shall:
- a. Have a minimum of a bachelor degree in pharmacy or Pharmaceutical sciences or chemistry and;
 - b. Have a minimum of five years experience in relevant field or three years experience with proven record of capability.

Duties of Government Analyst

- 16.** The Government Analyst shall:
- a. Head the Drug Testing Laboratory
 - b. Cause analysis or testing of such samples of drugs sent by Authority or other persons under Section 14 of the Act and shall furnish reports of the test analysis in the prescribed form.
 - c. Provide the test analysis report to the Authority in the form II-GA upon completion of the test or analysis.
 - d. Develop protocols for sampling, testing and analysis of the medicinal products.
 - e. Carry out any other responsibilities assigned by the board.

Qualification of Drug Inspector

- 17.** The Drug Inspectors shall;
- a. Have a minimum qualification of Diploma in Pharmaceutical Sciences/Pharmacy/Veterinary science; or
 - b. Have a minimum of two years certificate in Pharmacy with at least 5 (five) years experience in the field of pharmaceuticals.
- 18.** A person with qualification of certificate in Pharmacy under the section 17(b) of this Regulation without 5(five) years experience shall be called as Assistant Drug Inspector who shall be supervised by a Drug Inspector in the course of his duties.
- 19.** An Inspector for manufacturing premises shall be a person who has a minimum qualification of degree in the relevant field.

Duties of Drug Inspector

- 20.** An Inspector and the officials authorized under section 15.2 of the Act shall;
- a. Satisfy himself that the duties and conditions of the licensees and Competent Persons are being observed;
 - b. Take the sample of the suspected defective product for testing;
 - c. Inspect and verify all records of disposal of pharmaceutical waste in accordance to the Waste Prevention and Management Regulation and Guidelines prescribed thereunder;
 - d. Cause to seize the unregistered medicinal products by issuing seizure memo in the form III-SM as prescribed under this regulation;
 - e. Cause to embargo the unregistered or unauthorized medicinal products by issuing Embargo memo in the form IV-EM as prescribed under this regulation;
 - f. Investigate any complaint made to him in writing as per the procedure laid down under this Regulation;
 - g. Maintain record of all inspections made and actions taken by him in the performance of his duties including the taking of samples, seizure of stocks and to submit report of such records to the Authority;
 - h. Make such inquiries and inspections as may be necessary to detect sale of medicinal products in contravention of the Act; and
 - i. Not disclose any information acquired by him in the course of his official duties without the sanction in writing from the Authority except when required by the court of law and for official business.

CHAPTER IV

REGISTRATION OF MEDICINAL PRODUCTS

Principles and General Requirements

21. In accordance with the section 16.2 of the Act, all the medicinal products manufactured, imported, exported, sold, distributed shall be registered with the Authority.
22. The principle of risk based approach to the consumers shall apply to the documentation requirement for product registration whose registration shall be carried out through full evaluation route or abridged evaluation route.
23. The market authorization holder shall be any medicinal product manufacturer within or outside Bhutan, or a local pharmacy licensed firm.
24. In case where the medicinal products are directly registered by the manufacturer outside Bhutan under Section 23 of this Regulation, the manufacturer shall appoint a local pharmacy licensed firm or government agencies for supplying the product to the country.
25. The firm or the government agency authorized by the manufacturer under section 24 of this Regulation shall thereof be responsible for the product performance in the market including product recall.
26. The market authorization holder shall ensure that all of the information given in the application form and supporting documents are true and valid at the time of application submission.
27. The market authorization holder shall notify the Authority of any changes related to products' quality, efficacy or safety throughout the product's life cycle in the country.
28. The market authorization holder shall provide the price structure of the medicinal products as part of the documentation requirement for product registration.
29. All the certificates or testimonies for registration of medicinal products obtained from other agencies or authorities shall be submitted in original or in case of duplicate or electronic submission, it shall be attested by the Public Notary or a Court of Justice.
30. The documents required for registration shall be in English or Dzongkha or both and submitted in bound form in A4 size paper.

31. The documents for registration shall be accepted only if they are complete and as per specifications prescribed under the Guidelines for Product Registration set by the Authority.
32. Separate applications shall be made in respect of different formulation of same medicinal product.
33. The technical evaluation of the medicinal product dossier shall be done by the technical committee as approved by the Board.

Registration Exemption

34. In accordance with section 5.13 of the Act, medicines may be exempted from registration requirement in following cases;
 - a. Importation of any medicinal product for the purpose of research as approved by the relevant agency or board set up for the purpose.
 - b. Product Samples for the purpose of registration as specified in the guideline for product registration.
 - c. Medicinal products which are meant for personal use, in the quantity not exceeding the amount stated in the prescription unless justified by a registered medical practitioner.
 - d. List of quantified products intended for treatment of a serious life-threatening situations with strict time-bound treatment regime verified by the Chairman, National Drug / Veterinary Drug Committee and as approved by the Chairman of the Board.
 - e. In Public Health Emergencies as defined by the Board.
 - f. List of Orphan drugs verified by the Chairman, National Drug/ Veterinary Drug Committee and as approved by the Chairman of the board.
 - g. Medicinal products imported for named patients as sanctioned by the registered medical practitioners in a government Health and Veterinary centres.
 - h. List of medicines for temporary medical camps for a duration not more than one month.

- i. All the raw materials which are required for manufacture of the medicinal products by the pharmaceutical manufacturers.
- j. List of Products not registered or not available in the local market at the time of application but required in a government initiated or approved projects for duration not more than one year.
- k. Medicinal Products which are supplied to government approved agencies in kind by an external government agency as approved by the Chairman of the Board.

Procedure for registration;

Abridge evaluation route criteria

35. Abridge evaluation shall be applicable to;

- a. A product that has been approved by at least one of the following referenced drug regulatory agency at the time of submission of application for registration;
 - i. Australia Therapeutic Goods Administration (TGA);
 - ii. Health Canada (HC);
 - iii. US Food and Drug Administration (FDA);
 - iv. European Medicines Agency (EMA)
 - v. UK Medicines and Healthcare Products Regulatory Agency (UK MHRA)
 - vi. Japan DRA
 - vii. Health Science Authority of Singapore (HSA)
 - viii. Drug Control Authority of Malaysia (BPFK)
 - ix. Thai Food and Drug Administration(FDA)
- b. Medicinal product including the vaccines which are pre-qualified by WHO, UN, OIE or other UN recognized international organizations.

Full evaluation route criteria

36. Full evaluation route shall be applicable to;

- a. All human, veterinary allopathic medicines, gSo-ba-rig-pa or products not applicable for abridge evaluation route under section 35 of this Regulation.
- b. Complimentary medicines, active pharmaceutical ingredients for extemporaneous preparation, medical gas, antiseptics and medicines falling under General Sale List (GSL) of this regulation.

37. The list of products requiring bioequivalence data shall be published in the guidelines for Product Registration.

Documentation and Application Fees

38. The application for registration of each product under section 35 and 36 shall be made in form V-PAR and form VI-PFR respectively along with the required documents as provided in the Guidelines for Product Registration approved for the purpose.
39. The application made under section 38 of this Regulation shall be accompanied by the application fees as prescribed by the Authority.

Priority review for registration

40. The applicant may submit for priority review for life-saving drugs as per the criteria prescribed in the guidelines for Product Registration.

Issuance of Registration Certificate

41. The registration certificate shall be issued in a specified format.
42. The registration certificate shall be issued within 30 working days from the date of receipt of complete required documents unless otherwise a longer period is required, in which case, the party shall be informed.
43. The registration of a product shall be valid for a period of three years and shall be specified on the certificate.

Post Registration Changes

44. The market authorization holder may apply for any post registration changes during the valid period of registration under the following procedure and conditions:
 - a. Apply to the Authority in form VIIa-PRC with proposed changes for allopathic medicines and form VIIb-PRC for gSo-ba-Rig-pa medicines.
 - b. Import the product only upon the confirmed incorporation of the post registration changes by the Authority.
 - c. The post registration changes shall be applicable to the following;
 - i. shelf life or stability data,
 - ii. packaging specification and pack sizes,
 - iii. dosage regimen,
 - iv. additional indication and target species,
 - v. price structure,
 - vi. change of market authorization holder and/or
 - vii. other minor changes as determined by the Registration Committee.

- d. In case of gSo-ba-Rig-pa medicine;
 - i. substitute for raw materials,
 - ii. specifications of the product,
 - iii. pre-processed raw materials,
 - iv. packaging materials,
 - v. label designs,
 - vi. price structure,
 - vii. change of market authorization holder and/or
 - viii. other minor changes as determined by the Registration Committee

45. Application for Post Registration changes other than provided in section 44(c) and 44(d) of this Regulation shall be treated as a new application.

Renewal of registration

46. The followings are the procedure for renewal for registration of medicinal products;
- f. Application for renewal shall be submitted in form VIII-PRR at least 30 days before expiry date of registration along with the fee as prescribed by the Authority.
 - g. The procedure for renewal shall be same as the first registration under section 35 or 36 of this Regulation.
 - h. Notwithstanding section 46 (b) of this Regulation, one time renewal of registration shall be granted with the fulfilment of the documents and conditions for renewal as per the Guidelines for the product registration.
 - i. A grace period of three months may be given if the current market authorization provides a written justification with evidence of having carried out the renewal process with the manufacturers prior to the date of expiry.
 - j. Upon the completion of the grace period or failure to provide the evidence under section 46(d) of this Regulation, the product shall be deemed deregistered from the actual registration expiry date, in which case, the procedure under section 35 or 36 shall apply.

Fees for registration

47. The fees shall be as specified by the Authority and shall be subject to revision from time to time.
48. The certification fee shall be paid at the time of issuance of registration certificate.
49. Prior to registration of the product, the Authority may charge the applicant such costs as it may incur for the purpose of carrying out laboratory investigation as and when necessary.

Cancellation of registration

50. The Authority may, in the interest of public safety, reject or cancel the registration of any product.
51. The Authority shall cancel the registration/ registration certificate of the product if:
 - a. Any of the conditions of registration of the product has been contravened;
 - b. Any report on adverse drug reactions of serious nature have been received from National Pharmacovigilance Centre or any other national or international sources;
 - c. Market authorization holder defaults timely renewal beyond three month of grace period;
 - d. Manufacturer or market authorization holder obstructs the inspection of the Manufacturing firms or premises; or
 - e. For any other matters as specified by the Board at the time of cancellation.

Product Registration Transfer

52. The market authorization may be transferred to another authorized individual or firm eligible under section 23 of this Regulation with the following procedure and conditions:
 - a. Application for transfer accompanied by letter of authorization from the manufacturer and no objection certificate from the current market authorization holder of the product.
 - b. Notwithstanding the section 52(a), if without any justifiable reason, the market authorization holder does not provide an objection certificate, the Authority may consider the letter of authorization as sole documentation requirement for change of market authorization holder.
 - c. The product registration shall be valid at the time of application.

CHAPTER V

IMPORT & EXPORT AUTHORIZATION

Principles and General Requirements

53. In accordance to section 22 and section 23 of the Act, import and export of any medicinal product shall require an Import Authorization and export authorization respectively from the Authority.

Import Authorization

54. The Import Authorization shall be granted only for registered medicines and medicinal products that are exempted under the Section 34 of this regulation.
55. The Import Authorization shall be granted to the market authorization holder, local pharmacy licensee, government procurement agencies and international organization or the individual authorised by the Authority.
56. For the purpose of sale and distribution, the importer shall be a market authorization holder or local pharmacy licensee and/or government procurement agencies.
57. If the importer under section 55 of this regulation is not the market authorization holder for that particular product, the importer shall obtain no objection certificate or statement from the market authorization holder with the validity.
58. The Importer under section 54 and 55 of this Regulation shall have a licensed premise where the imported drugs are stored prior to distribution.
59. All the medicinal raw materials which are required for manufacture of the medicinal products by the pharmaceutical manufacturers shall require the Import Authorization from the Authority.
60. The importer shall ensure that all imported registered medicines conform to the sample medicinal products or packaging specifications submitted at the time of product registration.
61. The importer shall be responsible for timely removal of deregistered or confirmed defective medicinal products from the market based on GMP Inspection report of the manufacturing premise and/or from drug testing reports as notified by the Authority.

62. The applicant shall provide unhindered access to Inspector(s) authorised by the Board or Authority to enter with or without prior notice and inspect the premises where the imported products are stored;
63. Import authorization for vaccines and biologicals shall be issued only if the conditions prescribed under schedule F of this Regulation are complied with.

Export Authorization

64. In accordance to section 23 of the Act, export of any medicinal product shall require an export authorization from the Authority for the purpose of obtaining export license.
65. The export authorization shall be granted for any medicinal products or raw materials used as Active Pharmaceutical ingredient that are produced or manufactured or extracted in the country.
66. The applicant shall maintain records and provide to the Authority with all particulars of products including product specifications, quantities exported, date of exportation as and when asked or required.
67. The applicant shall provide unhindered access to an Inspector authorised by the Authority to enter with or without prior notice to inspect the premises where the exported products are stored.
68. The export authorization shall be granted to the market authorization holder, local pharmacy licensee, government procurement, exporting agency and international organization or the individual authorised by the Authority.

Exemption from Import Authorizations and Export Authorizations

69. Except for medicinal products that are imported through postal services or as parcels of any kind, a person may be given an exemption from obtaining import authorization and export authorisation of importing or exporting any identifiable medicinal product in primary packaging provided;
 - a. The products are accompanied by the person who has a prescription from a qualified and registered medical practitioner, in which case, the provision under Section 26 of the Act shall be applicable; or
 - b. The medicinal product that are listed under schedule A1 and A2 of this Regulation and the quantity does not exceed the required dose for one month.

Procedure for Import Authorization

70. An application for an authorization to import medicinal product shall be made to the Authority in form IX-IA accompanied by Profoma Invoice or any documentary evidence of the source from the principle manufacturer or authorised agent as indicated in the registration dossier at the time of registration, or authorised agent notified by the manufacturer to the Authority. Application for personal use for the medicines to be imported through the Postal services or parcels of any kind shall be applied in IX-IAP.
71. A single application may be made for import of more than one drug from one manufacturer provided the consignment is imported in one lot.
72. An application for import of controlled and restricted drugs under Schedule C1 and C2 of this Regulation shall be made in the same form IX-IA of section 70 of this Regulation.

Issuance of Import Authorization

73. An import authorization for medicinal products shall be issued in the specified format and shall be valid for a single import for period of three months.
74. An import authorization for controlled and restricted drugs shall be issued in the specified format and shall be valid for a single import for six months.
75. Import authorization is not a substitute for import licence issued by the Ministry of Economic Affairs and import permit in case of controlled drugs from Bhutan Narcotic Control Agency.
76. Import Authorization may be issued in prescribed format upon declaration by the applicant for the medicines to be imported through the Postal services or parcels of any kind.
77. The Authority reserves the right to reject the application and seize the products imported based on the risk assessment and products in contravention to the provisions under the Act and Regulation.

Procedure for Export Authorization:

78. An application for an authorization to export medicinal product shall be made to the Authority in form X-EA.
79. A single application may be made for export of more than one drug from one manufacturer provided the consignment is in one lot.

80. An application for export of controlled medicines under Schedule C1 and C2 of this Regulation shall be made in the same form X-EA of section 78 of this Regulation.

Issuance of Export Authorization

81. An export authorization for medicinal products shall be issued in a specified format and shall be valid for a single export for period of three months.
82. Export authorization is not a substitute for export licence issued by the Ministry of Economic Affairs and export permit in case of controlled drugs from Bhutan Narcotic Control Agency.
83. Export Authorization may be issued in prescribed format upon declaration by the applicant for the medicines intending to be sent or exported through the Postal services.
84. The Authority reserves the right to reject the application and seize the products imported based on the risk assessment and products in contravention to the provisions under the Act and Regulation.

CHAPTER VI

TECHNICAL AUTHORIZATION FOR MANUFACTURE OF MEDICINAL PRODUCTS

Principle and General Requirements

85. The Pharmaceutical factories shall be located in a hygienic location at acceptable and required distance from any other factory-boundaries to prevent pollution and contamination;
86. The firm manufacturing biopharmaceuticals or biotechnology products shall have the safety measures against pathogens and shall not pose any risk to the public health and safety.
87. The firm manufacturing controlled medicinal products falling under schedule C1 and C2 shall have addition approval from Bhutan Narcotic Control Agency.
88. All pharmaceutical manufacturers shall conform to the current Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products and the relevant annexure of PIC/S and other standards as set by the Authority.
89. Pre-approval and routine GMP inspections shall be conducted to assess the conformance of pharmaceutical manufacturers to GMP standards.
90. For operational manufacturing pharmaceutical firms, a Site Master File or Quality manual is mandatory which shall include; General Information on manufacturing site or plant, Personnel, Premises & Equipment, Documentation, Production, Quality Control, Contract Manufacture & Analysis, Distribution, Complaints & Recalls and Self inspection.
91. The personnel employed at various processes of manufacturing possess suitable qualifications required for their jobs and the manufacture is conducted under the supervision of the qualified Competent Person(s) approved for the purpose.
92. There shall be a separate quality control unit from the production unit with quality control laboratory with qualified staff and appropriate equipment to carryout tests of raw materials and the finished products.

Exemption from Technical Authorization for Manufacture

- 93.** The requirement for a Technical Authorization to manufacture does not apply to dispensing or preparation of extemporaneous formulations/compounding, which is necessary for the dispensing of any drug for the purpose of it being used for medical treatment by the following persons and in the following circumstances:
- a. A pharmacist or pharmacy Technician registered by the Bhutan Medical and Health Council or a registered person working under the supervision of a registered pharmacist in a retail pharmacy;
 - b. A person who is working in a Government hospital or dispensary and acting in the course of his duties under the supervision of a registered pharmacist or pharmacy technician; and
 - c. A medical, veterinary Practitioner or a *Drungtsho* registered by relevant agencies, if the drug in question is for the use of such practitioners or of his patients.

Procedure for Technical Authorization for setting up a Manufacturing Plant

- 94.** Any person intending to set up a Pharmaceutical Manufacturing Plant for medicines shall apply to the Authority in form XI-PAM along with a provisional authorization fee as prescribed by the Authority, and shall submit the followings:
- a. Location of the proposed site with pictorial presentation or sketch map of the proposed factory site plan,
 - b. Memorandum of Association or Article of Incorporations of the firm including organizational chart,
 - c. Graphic Layout of the premise detailing on the intended production facilities and traffic routes for material and personnel,
 - d. Description of the layout of the premise,
 - e. List of key technical personnel (Production head, Quality Control, Store In-charge),
 - f. List of Medicinal Products indicating the formulation, composition, strength, pharmacopeial specifications intended to be manufactured,
 - g. List of equipments and machinery to be employed for manufacture and testing, and
 - h. Waste management plan(Effluent Treatment Plant)

Provisional Authorization for setting up a Manufacturing Plant

95. Upon receipt of the application with complete set of documents, the Authority shall assess the application and verify the location and the premise site. If the Authority is satisfied, the technical report shall be forwarded to the Board for provisional approval.
96. The provisional authorization for setting up a Manufacturing Plant shall be issued in a prescribed format, specifying the next date of inspection as indicated on the application.
97. In case of the application considered deficient, the authority shall provide the reasons in writing including the grounds for refusal and advice for improvements as the case may be.
98. The validity of the Provisional Authorization shall be two years from date of issuance or on an earlier date where the applicant applies for final approval for authorization.
99. For grant/approval of additional medicinal products in same therapeutic categories proposed for manufacture or approval in the changes on the layout of the premises, the applicant shall follow the above procedure by submitting the revised or additional documents depending on the degree of change proposed within the valid period of the Provisional Authorization.
100. If the changes proposed are major such as change of location, or different type of formulation, or different therapeutic group, or changes in facilities and equipments, or change in operation and process or such other changes as deemed major by the Authority, a new application shall be required.
101. The Provisional Authorization for setting up a Manufacturing Plant is not a substitute for Technical Authorization for manufacture.
102. The Authority reserves the right to revoke or cancel the Provisional Authorization where any deviation from the proposed Technical Lay out or any unapproved changes under the section 99 and 100 of this Regulation is observed, as the case may be.

Renewal of Provisional Authorization

103. The Provisional Authorization for setting up a Manufacturing Plant shall be subjected to renewal upon submission of the same application form XI-PAM accompanied by the prescribed fees.

Approval for Technical Authorization for Manufacture

104. Once the premise or facility is ready for production, the applicant shall apply to the Authority on the form XII-FAM, and the Authority shall cause inspection of the facilities to observe and verify the Good Manufacturing Practices (GMP) as per the PIC/s standard.
105. In case of the application considered deficient, the Authority shall provide the reasons in writing including the grounds for refusal and direction for improvements, if any.
106. The Board shall approve or reject the application based on the inspection report of the Authority and the recommendation of Drug Technical Advisory Committee.
107. Upon approval by the Board, the Authority shall issue the Technical Authorization for manufacture in a prescribed format.
108. The Technical Authorization for manufacturing shall be a pre-requisite for issuance of trade license from the Ministry of Economic Affairs.
109. The approval for Technical Authorization for manufacturing shall be valid for a period of one year.

Renewal of Authorization for Manufacture

110. The Technical Authorization for Manufacture shall be subject to renewal annually upon submission in the same application form XII-FAM accompanied by the prescribed fees.

CHAPTER VII

TECHNICAL AUTHORIZATION FOR SALE AND DISTRIBUTION

Principle and General Requirements

111. The premises for conducting sale of medicinal products by both retail and wholesale shall be authorized by the Authority in accordance with section 20 of the Act.
112. The sale of all medicinal products shall be conducted under the supervision of a Competent Person certified by the Authority for the specified purpose.
113. The licensee shall conform to the conditions laid down in the Act and Regulation and all other such conditions as deemed necessary by the Authority.
114. The establishments or firms engaged in health spas, wellness centre, and sport's health club and as the case may be, shall not be permitted for sale or distribution of medicinal products other than General Sale List (GSL) as notified by the Authority.
115. The Premise for sale and distribution shall have adequate storage area and appropriate storage conditions for the medicinal products.
116. All the medicinal products shall be sold at or below MRP (Maximum Retail Price) and in case of non-availability of the price; the Market Authorization Holder shall affix the price as per the price submitted to the Authority at the time of registration.

Exemption

117. The government health and veterinary institutions shall be exempted from the requirement of technical authorization for sale/distribution, provided such institutions or agencies shall subject to the conditions or duties provided under section 129 of this regulation and any other provisions wherever applicable.
118. Stocking and dispensing of medicines by Government initiated projects and approved non-governmental or private projects is exempted from the requirement of technical authorization for sale/distribution provided they are not engaged in commercial activities of medicinal products. However, such projects shall require technical clearance under section 124 of this regulation and are subject to the conditions or duties laid under section 129 of this regulation and any other provisions, wherever applicable.

Procedure for application for Technical Authorization for Sale and distribution

119. An application for technical authorization for sale by retail or wholesale shall be made in form XIII-TAS accompanied by application fees as prescribed by the Authority.
120. The applicant shall submit the following Documents:
 - a. Copy of certificate of registration as Competent Person and/or of the employee(s), who shall supervise the sale of medicinal products,
 - b. Name of the proposed firm, and
 - c. Category of medicinal products whether human, veterinary or gSo-ba-rig-pa.
121. Upon receipt of the application, the proposed site shall be inspected by the Authority for suitability of the premise.
122. Technical Authorization for Sale by retail or wholesale shall be issued by the Authority in the prescribed format after completion of the inspection and shall be valid for one year or unless otherwise suspended or revoked by the Authority.
123. Technical authorization for sale by retail or wholesale is not a substitute for a licence for sale from the Ministry of Economic Affairs.

Technical Clearance for storage and dispensing

124. The Government initiated projects and approved non-governmental projects dealing with medicinal products for importation, storage and dispensing shall apply to the Authority in form XIV-TC. The Technical Clearance shall be issued by the Authority in a prescribed format upon verification of the application and premise.

Renewal of Technical Authorization for sale and distribution

125. Application for renewal of technical authorisation for sale shall be submitted in the same form XIII-TAS at least 30 days before expiry date of registration along with copy of the registration certificate of the competent person and the fee as prescribed by the Authority.
126. After expiry of the technical authorization, grace period of 1 (one) month shall be granted after which the renewal shall be done with a daily fine of Nu. 100 (one hundred only) for further two months.

127. Non renewal of technical authorisation within the period provided under section 125 of this Regulation shall be deemed deregistered after three months from the date of expiry, in which case, the procedure under section 119 and 120 shall apply for application of Technical Authorization for sale.
128. Irrespective of the date of renewal, the validity of the authorization shall be considered from the actual date of expiry.

Duties of a licensee

129. The licensee shall fulfill the following conditions:
- a. A green cross sign along with an inscription "Pharmacy" written both in English and Dzongkha, shall be prominently displayed and visible at all times in front of the sale premises;
 - b. The business hours of the pharmacy shall be clearly written in both English and Dzongkha and displayed at a conspicuous place in the premise;
 - c. The License of the premise and Certificate of Competent Person shall be displayed conspicuously at all times.
 - d. The pharmacy premises shall be separate from rooms for residential use and shall be clean and hygienic at all times. The premises should be structurally sound, dry, well-lit and ventilated and of sufficient space to allow the medicinal products to be kept in a clearly visible and appropriate manner;
 - e. The furniture and apparatus in the premises shall be suitable and of appropriate size for intended purpose.
 - f. Different categories of medicines shall be segregated from others and stored under appropriate conditions.
 - g. All medicinal products, except when specified on the label, shall be stored under appropriate conditions below 28 °C to ensure their quality, efficacy and to prevent deterioration.
 - h. Veterinary medicines, if sold from the retail premise along with human medicines, shall be stored separately and conspicuously labeled in red font with appropriate signs.
 - i. Vaccines and biologicals shall be stored under appropriate cold chain conditions and separated from each other. The temperature of the cold chain

equipment shall be monitored at least twice a day and relevant records maintained.

- j. Where applicable, a separate compounding area for extemporaneous formulations shall be maintained with appropriate facilities.
 - k. In absence of a competent person, the licensee shall make alternative arrangement for another competent person, with prior written approval from the Authority or else the pharmacy shall remain closed.
 - l. Containers used for storing the medicines shall be appropriate for the intended purposes and labelled accordingly.
 - m. Written procedure or instructions shall be available for storing and dispensing of the products to avoid cross contamination and to ensure the quality of the products.
- 130.** The duties laid down under section 129 sub-clause (d), (e), (f),(g), (i), (j), (k), (l) and (m) of this regulation shall also be applicable to premises engaged in storage and distribution of medical products in the Government Health centre, Livestock centre and project facilities.

Change of ownership, location, name of Pharmacy & Competent Person

- 131.** Where a licensee of a wholesale or retail pharmacy wishes to change the ownership of technical authorization for sale of medicinal products or the location of the premise, name of Pharmacy & Competent Person, he shall do so by applying to the Authority in form XV-OC of this regulation. The clearance for the same shall be issued by the Authority in a prescribed format.

CHAPTER VIII

REGISTRATION AND DUTIES OF COMPETENT PERSONS

Principle and General Requirements

- 132.** In accordance to the section 19.2 of the Act, only Competent Persons shall be engaged in the manufacture, sale and distribution of medicinal products.
- 133.** The key personnel involved in manufacturing shall be required to register with Authority as competent persons.
- 134.** The registration Committee for Registration of the Competent Person instituted under the Act shall register the competent person involved in manufacture, stock, sale, distribution, import and export of Medicinal products.
- 135.** The Authority shall recognize the certification of Bhutan Medical and Health Council for health professional involved in dispensing and distribution of medicinal products in health centres as competent person and shall recognise certification of such other equivalent Council/Agency established under Ministry of Agriculture and Forest as competent person for veterinary medicines.
- 136.** Any person registered as Competent Person under this regulation for the purpose of manufacture, import, export, store, sale and distribution of the medicinal products as per section 132 and 133 of this Regulation shall not engage in prescribing medicines.

Exemption

- 137.** The health and veterinary professionals involved in dispensing, stocking and distribution of medicinal products in a Government health centres/Livestock centres registered with Bhutan Medical and Health Council or equivalent Council/Agency of Ministry of Agriculture and Forest is exempted from requirement of Competent Person.
- 138.** The exemption under section 137 of this Regulation shall not be substitute for competent person registration for manufacture, sale and distribution under the Act.

Qualification for registration

- 139.** For registration of competent person for manufacture of medicinal products, the person shall have a bachelor degree in relevant field with minimum of working experience of two years in their relevant field.

- 140.** For registration of competent Person for import, export, stock, sale and distribution of medicinal products, he/she shall possess any of the following qualifications;
- a. Bachelors degree in Pharmacy/ Pharmaceutical Sciences or minimum of certificate in Pharmacy of duration not less than two year; or
 - b. Bachelors degree in Medicines for human medicines and veterinary medicines; or
 - c. Bachelors degree in Veterinary Sciences & Animal Husbandry for veterinary medicines, or minimum of Diploma in veterinary Sciences, and/or
 - d. Diploma in gSo-ba Rig-pa Medicine or Bachelor in Traditional Medicines in case of gSo-ba Rig-pa medicines.

Procedures for registration

- 141.** Any person who wishes to register as a Competent Person with Authority shall apply in form XVI-CP along with the registration certificate from the Bhutan Medical and Health Council or with a letter of recognition from department of Livestock or other equivalent agency.
- 142.** The registration committee formed under section 19.6 of the Act shall empower the Registration Division of the Authority to conduct the competency examination, provided that the Registration committee shall be notified twice in a year, who shall endorse the report of the Registration Division.
- 143.** A person who have required qualification under section 139 and 140 of this Regulation is eligible to sit for competency exam as set by the registration Division, upon which he shall sit for the said exam upon the payment of exam fees as prescribed by the Authority.
- 144.** Where a person does not qualify in the first attempt under section 143, he shall be allowed for another two attempts upon payment of examination fees.

Award of Registration Certificate

- 145.** The registration certificate shall be issued by the Authority in a prescribed format which shall be valid for a period of three year unless suspended or revoked or otherwise.

Renewal of Registration Certificate of Competent Person

- 146.** Application for renewal shall be submitted in the same form XVI-CP at least 30 days before expiry date of registration along with copy of the registration certificate of the competent person and the fee as prescribed by the Authority. The renewal is subjected to following conditions;
- a. The procedure for renewal shall remain same as first registration.
 - b. Notwithstanding section 146(a) of this Regulation, one time renewal shall be made without having to sit for competency examination.
- 147.** After expiry of the certificate of competent person, grace period of 1 month shall be granted after which the renewal shall be done with a daily fine of Nu. 100 (one hundred) for further two months.
- 148.** Non renewal of registration within the period provided under section 147 of the Regulation shall deem deregistered, in which case the procedure for registration under section 141 of this Regulation, shall apply.
- 149.** Irrespective of the date of renewal, the validity of the certificate shall be considered from the actual date of expiry.

Duties of a Competent Person

- 150.** The competent person in carrying out functions in relation to sale and distribution under the Act, shall;
- a. At all times wear a white apron with a name tag at the work place;
 - b. Dispense medicinal products only upon presentation of lawful prescriptions other than listed under Schedule A1, A2, D1, E1;
 - c. Maintain stock ledger once the medicines for prescription only medicines (schedules B,D2,E2 & F) are sold along with:
 - i. Name of the medicine
 - ii. Quantity received & dispensed
 - iii. Batch number &
 - iv. Expiry date ;
 - d. Maintain an inventory of products in a specified format(s) for schedule C drugs;
 - e. Maintain patient or customer's detail in the format prescribed in relation to drugs under Schedule "C1 and C2" of this regulation or wherever applicable;

- f. Maintain copies of the prescription for a period of 3 years for sale of drugs under schedule C1 and C2 of this Regulation;
- g. Provide the total quantity of controlled drugs both in words and figures on the prescription in addition to the general requirements on prescription.
- h. Make a list of pharmaceutical wastes and apply to the Authority using the prescribed form XVII-DEM based on which the Authority shall grant clearance for disposal in a specified format.
- i. Set up a temperature monitoring system for the medicines in its storage areas and maintain the records.
- j. Maintain proper segregation of the medicines with appropriate labels.
- k. The competent person shall not change the figures and information in the prescription without consulting the prescriber.

Extemporaneous Preparations

- 151.** Notwithstanding section 93 of this Regulation, In accordance with the requirement under section 21.1 of the Act, the Competent Person engaged in the extemporaneous preparations within the meaning of manufacturing under 34(xx) of the Act shall:
- a. Ensure appropriate use of premises, equipments and instruments suitable for the intended activities.
 - b. Have written procedures and documented records for the extemporaneous preparation including the compounding formula.
 - c. Ensure a separate room or designated space for antibiotic preparations or hormones or any other ingredients as deemed to be contaminant and pose risk to the consumers by the Authority.
 - d. Ensure appropriate labelling of the finished products which shall include name of the product, strength and expiry medicines and name or initial of the dispenser or for the stock compounded.
 - e. Ensure that dispensing is done using appropriate containers, and
 - f. The compounded product shall be verified for release by the concerned focal person or supervisor wherever applicable depending on the nature of the product.

- 152.** Any violation of duties under section 150 of this Regulation shall be offence and shall be liable for fines as prescribed under Chapter XIV of this Regulation.
- 153.** Where the conditions or duties under section 151 of this regulation are not complied with, the Authority may notify for suspension of such compounding activities and may provide such necessary remedial measures for improvement and compliance.

CHAPTER IX

ADVERSE DRUG REACTION MONITORING SYSTEM & PHARMACOVIGILANCE

Principle and General Requirements

- 154.** The Board shall establish a National Pharmacovigilance Centres (NPC) at the Authority for all the medicinal products under this Act.
- 155.** The Board shall establish such other Pharmacovigilance centres such as;
- a. Allopathic Medicines at Pharmacy Department, Jigme Dorji Wangchuck National Referral Hospital,
 - a. Veterinary Medicines at the Veterinary Hospital, Thimphu, and
 - b. Traditional/herbal medicine at Division of Traditional Medicine Services

Procedure for Monitoring of Adverse Drug Reactions

- 156.** Each of these centres established under section 155 of this Regulation shall develop its procedure and constitute an expert committee who will meet on quarterly basis to discuss and assess the reports and make recommendations to National Pharmacovigilance Centre.
- 157.** The ADR reports from all the traders and retail outlets of medicines for allopathic medicines shall be forwarded to the Pharmacovigilance Centres at National Referral Hospital using ADR forms through the Authority.
- 158.** The members of the National Pharmacovigilance Committee shall be as follows:
- a. Chairman and Member Secretary of expert committee of each centres as and when related;
 - b. The Authority shall be the Member Secretary, and
 - c. Technical experts as and when required.
- 159.** Any reports of adverse events following immunization shall be forwarded to the National Pharmacovigilance Centres using ADR forms.

- 160.** Any ADR reports observed in the course of any health related research or study shall be forwarded to the National Pharmacovigilance Centres.
- 161.** Any ADR reports observed in the course of any animal health related research or study shall be forwarded to the National Pharmacovigilance Centres.
- 162.** The National Pharmacovigilance Committee shall meet from time to time to discuss and review the ADR reports.
- 163.** The National Pharmacovigilance Centres shall maintain the records of confirmed ADR Reports and may liaise with the regional or international organization.
- 164.** The National Pharmacovigilance Centres shall take regulatory measures and issue public notification based on severity of the ADR report from the centres, and such other matters related to it.

CHAPTER X

MANAGEMENT OF EXPIRED, SEIZED, RECALLED AND DEFECTIVE MEDICINAL PRODUCT OR UNREGISTERED MEDICINES

Principles and General Requirements

- 165.** In accordance with section 28 of the Act, no expired medicines including defective or recalled medicinal products shall be sold, distributed or dispensed
- 166.** Expired, defective, recalled and deregistered medicines that are seized due to non-registration or banned status shall be treated as pharmaceutical waste which shall be segregated and stored separately.
- 167.** The Pharmaceutical waste shall be disposed off at regular intervals in accordance with Waste Preventions and Management Regulation 2012 and Technical Guidelines prescribed for the purpose.
- 168.** The licensee shall maintain records of the disposed drugs or any form of handling Pharmaceutical wastes in accordance with the Waste Prevention and Management Regulation 2012.

Procedure for management of seized medicinal products

- 169.** The medicines shall be liable for seizure where it is related to:
- Unauthorised personnel or premises
 - Banned products
 - Counterfeit/Fraudulent products, or
 - Breach of conditions under the Regulation.
- 170.** Wherever the seizure of medicinal products is due to section 169(a) of this Regulation, the Authority shall review the quality of the medicines and explore possibilities of auctioning to private retailers/wholesalers or Government health centres.

Procedure for management of embargoed medicinal products

- 171.** The medicines shall be liable for embargo in case of the following:
- Lack of Import Authorization
 - Unregistered products, or

- c. Imported registered products not conforming to the sample medicinal products or packaging specifications as per the registered product.
- 172.** Wherever the medicinal products are embargoed due to section 171 (a) of this Regulation, the applicant will be given fourteen working days to process the Import Authorization upon payment of the prescribed fines under section 224 of this regulation. Not obtaining import authorization within fourteen working days shall deem to be seized under section 169 of this Regulation.
- 173.** Wherever the medicinal products are embargoed due to section 171 (b) of this Regulation, the applicant will be given six months from date of notification or otherwise specified in the notification to register the product. Not registering the product within six months shall deem to be seized under section 169 of this Regulation and the fine equivalent to the total value of goods. He shall also be liable to compensate the damage caused by this violation as specified under section 29(c) of the Act.
- 174.** Wherever the medicinal products are embargoed due to section 171 (c) of this Regulation, the applicant will be given three months from date of notification or otherwise specified in the notification to apply for post registration changes specified under section 44 of the Regulation. Not registering the product within three months shall deem to be seized under section 169 of this Regulation.

Tampering of the embargoed medicinal products

- 175.** The embargoed products under section 171 of this Regulation shall not be tampered whether or not for sale or distribution unless notification for release is issued by the Authority.

Procedure for management of recalled and defective medicinal products

- 176.** A medicinal product shall be recalled if there is:
- a. Confirmed defective product as notified by the Authority;
 - b. An adverse event linked to the product; and/or
 - c. Any other reason recognised by the Board to cause potential risk or harm to human or animal health.
- 177.** The defective medicinal products shall be dealt according to the Procedure or guidelines prescribed by the Authority.
- 178.** The confirmed defective or recalled medicinal products shall be disposed off as per the procedures for disposal of pharmaceutical waste or shall be removed from the country if necessary.

179. The cost incurred as a result of the recall shall be borne by the manufacturer or market authorization holder or importer.

CHAPTER XI

ADVERTISEMENT OF MEDICINAL PRODUCTS

Principle and General Requirements

180. Only the Board shall approve the advertisement of any medicinal products as per Section 27 of the Act; and no sale of drugs shall be advertised by means of a gift or lottery drawing.
181. Section 180 of this Regulation does not apply to the statements on the product labels and information leaflets accompanying products registered by the Authority.
182. An advertisement of a medicinal product shall:
- a. Not be boastful of its therapeutic properties or of its ingredients as being miraculously or completely capable of curing, mitigating, treating or preventing a disease or illness, nor shall any other wording of similar meaning be used;
 - b. Not falsely or exaggeratedly show its therapeutic properties;
 - c. Not falsely cause to understand that the product has a substance as its active or component ingredient in quantities larger than the amount that is actually present;
 - d. Not falsely cause to understand that it is an abortifacient or a strong emmenagogue;
 - e. Not falsely cause to understand that it is an aphrodisiac;
 - f. Not falsely cause to understand that it is a birth control drug;
 - g. Not falsely show the therapeutic properties of a dangerous or a specially-controlled drug;
 - h. Not contain certification or laudation of its therapeutic properties by any other person;

- i. Not falsely show its therapeutic properties as being capable of curing, mitigating, treating or preventing disease or symptom thereof as notified by the Board in any of its notification.

Procedure for Advertisement Clearance

- 183.** The applicant shall apply for advertisement in the form XVIII-CAM stating the details of the advertisement.
- 184.** In case of the application considered deficient, the authority shall provide the reasons in writing including the grounds for refusal and advice for improvements as the case may be.
- 185.** The Board shall approve or reject the application based on the recommendation of the Authority.
- 186.** Upon approval by the Board, the Authority shall issue the Advertisement Clearance in the prescribed format.

CHAPTER XII

LOT RELEASE OF VACCINES, BIOLOGICALS & SPECIAL PRODUCTS

Principle and General Requirements

187. Both the vaccines manufactured in the country and imported from outside shall require lot release.
188. Lot release of vaccines manufactured in the country shall be subjected to periodic review by the Authority.

Procedure for Lot Release

189. The concerned agencies, importing the vaccines, shall inform the Authority as and when lot release is done to get certification that will be done by the Authority in the prescribed format.
190. In case of the imported vaccines, the following documents shall be required and reviewed at the time of lot release from the central distribution point:
 - a. Batch quality control certificate from the manufacturer;
 - b. Summary Lot Protocol; and
 - c. Shipping documents received.
191. The documents received before and along with the consignment of vaccines must be checked to see the completeness, compatibility, authenticity and validity of information.
192. The Authority shall check the consignments or batches of vaccines for cold chain conditions and perform visual tests, freeze tests, verify temperature monitors, temperature, packaging, label, quantity, batch number and expiry dates.
193. The cold chain conditions must be as per the product requirements during storage, transportation and distribution of all vaccines and biologicals.
194. The list of documents to be reviewed may be revised from time to time in keeping with the changing needs or as per the detail procedure prescribed by the Authority.

CHAPTER XIII

DRUG INSPECTION AND INVESTIGATION OF OFFENCES

Principle and General Requirements

195. In accordance with powers of the inspectors under Section 15.2 of the Act, the Drug inspectors or the officials authorized by the Authority shall be empowered to carry out the inspection.
196. Inspection shall be carried out to observe the compliance of the licensees, appropriateness of the premises for storage and distribution of medicinal products.
197. The Inspection under section 196 of this Regulation may be carried out with or without prior notice as deemed necessary and appropriate by the Authority.
198. As per section 15.2 (b) of the Act, the Licensee or the Competent Person(s) shall give unhindered access to the Inspector, and provide, on demand, all the information required by him and produce all records of medicinal products necessary for performances of his duties.
199. As per section 15.2 (a) of the Act, the person who is the custodian or proprietor of the premise engaged in stocking or distribution or manufacturing of medicinal products shall provide unhindered access to the Inspector.
200. Any individual or premises is subject to inspection or search if there is reasonable belief that an offence is being committed or has been committed under the provisions of the Act and regulation in accordance with Civil and Criminal Procedure Code .

Procedures for inspection of sale premises

201. The inspectors shall carry out the inspection as per the detail procedure laid down by the Authority.
202. The inspectors or officials authorised by the Authority shall produce his identification or letter of authorization during the course of conducting their duties.
203. Whenever an Inspector takes a sample of a medicinal product from a licensed firm, he shall offer a fair price and shall issue written acknowledgement except when the target of inspection is government health centre, the price for the sample is not applicable.

204. Wherever necessary, the Authority shall collaborate and conduct joint inspections with other law enforcement agencies in the Kingdom.
205. The Inspector shall collect samples as per the sampling guidelines prescribed by the Drug Testing Laboratory or any Laboratory as identified by the Board.

Procedures for inspections at exit and entry points for import and export of medicinal products

206. At the entry and exit points for import and export of medicinal products, the inspections may be carried out by the Drug Inspectors in collaboration with the Department of Revenue & Customs and any other relevant law enforcement agencies.

Inspection of Manufacturing firms overseas

207. The authority shall cause inspection of the Manufacturing firms outside Bhutan who has applied for product registration applying risk based approach to verify the quality assurance system or GMP of the Manufacturing firms supplying or intending to supply medicines to Bhutan.
208. The GMP inspection shall be carried out by the Authority, where on-site routine GMP inspection is carried out at the request of the manufacturing firm, the cost of the inspection shall be borne by the manufacturer.

Procedures for inspection of Manufacturing Premises

209. The Authority shall conduct inspection of the Manufacturing premise to ensure the compliance to the standards of Good Manufacturing Practice (GMP) for Medicinal Products and other standards as set by the authority.

Investigation for prosecution under the Act and Regulation

210. The inspectors or official authorised by the Authority may at any reasonable time enter any place with a search warrant that he believes contains/store a product or medicinal product in contravention to the provision of the Act, or amounting to offence under the Act, or this Regulation.
211. Whenever an Inspector has reason to suspect that any person or premise is in possession of controlled drugs that are in contravention to the provisions of the Act and Regulation, he shall perform interrogation and investigation of persons and premises in collaboration with other law enforcement agencies in the country.

- 212.** An authorized officer shall exercise power of search and seizure in accordance with section 15.2 (iv) of the Act and relevant provision of the Civil and Criminal Procedure Code of Bhutan.
- 213.** If a person is arrested during the course of the investigation/ inspection under section 211 and 212 of this Regulation, he shall be handed over to the Royal Bhutan Police in accordance with the Police Act.
- 214.** The Royal Bhutan Police shall produce the person so detained under section 213 of this Regulation before the court in accordance with the Civil and Criminal Procedure Code, provided the investigation shall be carried out by the Authority whether with or without collaboration with other enforcement agencies.

CHAPTER XIV

FINES AND PENALTIES

Principle and General Requirements

- 215.** In order to enforce effectively, the provisions of the Act and the Regulation, the following fines and penalties are prescribed as empowered under the section 29(i) of the Act.

Fines and Penalties

- 216.** In addition to the offences & penalties specified in Chapter IX of the Act, following penalties and fines shall be levied;
- 217.** Any person who obstructs the authorised person to perform any duty under the Act or a regulation shall be liable for:
- a. Suspension of registration of competent person or/ and the technical authorization on the first offence,
 - b. Revocation or cancellation of the certificate or Technical Authorization on the next offence.
 - c. Provision of obstruction to a Lawful authority under the Penal Code of Bhutan.
- 218.** Any Licensee who violates sections 129(a) or 129(e) or 129 (g) or 129 (j) or 129 (l) of this Regulation shall be :
- a. Given a warning on first two consecutive offence,
 - b. Suspension of the technical authorization on the next offence.
- 219.** Any Licensee who violates sections 129(d) or 129(f) or 129(i) or 129(k) 128(m) or 131 or of this Regulation shall be:
- a. Given a warning on the first offence.
 - b. Punishable with a fine of Nu. 1000 (Ngultrum one thousand) on second offence.
 - c. Suspension of the technical Authorization on the third offence.
- 220.** Any Licensee who violates sections 129(h) 129(b) or 129(c) of this Regulation shall be:
- a. Given a warning on the first offence.
 - b. Punishable with a fine of Nu. 1000 (Ngultrum one thousand) on second offence and third offence.

- c. Suspension of the technical Authorization on the subsequent offence.
 - d. Revocation or cancellation of the certificate on the next subsequent offence.
- 221.** Any Competent Person who violates Sections 150(a) or 150(b) or 150(c) or 150(g) or 150(i) or 150(j) or 166 of this Regulation shall be:
- a. Given a warning on the first offence.
 - b. Punishable with a fine of Nu. 1000 (Ngultrum one thousand) on second offence and third offence.
 - c. Suspension of the registration certificate on the subsequent offence.
 - d. Revocation or cancellation of the certificate on the next subsequent offence.
- 222.** Any Competent Person who violates Section or 150(d) or 150(e) or 150(f) or 150(k) or 150(h) or 151 of this Regulation shall be:
- a. Given a warning on the first offence.
 - b. Suspension of Registration of Competent person or/ and the technical Authorization on the second subsequent offence.
 - c. Revocation or cancellation of the certificate or Technical Authorization on the next subsequent offence.
- 223.** Any importer who do not comply with section 60 of this Regulation shall be:
- a. Given a time of three months to register the product or to apply for the post registration changes.
 - b. Non compliance to section 223(a) shall be given a warning with time extension for removal of the defective medicinal products or deregistered products as deemed appropriate by the Authority; and
 - c. Further, non compliance with section 223(b) of this regulation shall be imposed fine equivalent to the total amount of goods seized upon the seizure of the products by the Authority.
- 224.** Any importer who do not comply with section 61 and 176 of this Regulation shall be:
- a. Warning and time extension as deemed necessary by Authority on the first offence.
 - b. Liable for fine equivalent to the total amount of goods seized and the cost associated for disposal as determined by the Authority or other Relevant Agencies.
 - c. Non compliance with section 224(b) of this regulation shall lead to suspension of Importation Authorization for six months or till the payment of the prescribed fines.
 - d. Further, non compliance with section 224(c) of this regulation shall lead to suspension of Technical Authorization for three months and further non-compliance shall lead to cancellation of Technical Authorization.

- 225.** Any person who do not comply with the procedure for import and export authorization under section 70 or 78 or 187 of this Regulation shall be:
- a. Imposed fine of Nu. 1000 (one thousand) with fourteen working days to process the Import Authorization on the first offence and second offence,
 - b. Imposed fine equivalent to the total amount of goods on second subsequent offence.
 - c. Punishable with seizure of the goods and a fine equivalent to the total value of the goods on third subsequent offences.
 - d. Revocation or cancellation of the certificate or Technical Authorization on the next subsequent offence.
- 226.** Any person failing to comply with the conditions of section 167, 168 & 177 of this Regulation shall be;
- a. Given a warning on the first offence,
 - b. Suspension of the certificate or Technical Authorization,
 - c. Fines and penalties prescribed under Waste Prevention and Management Regulation 2012.
- 227.** Any person who violates Section 175 of this Regulation shall be an offence under Section 29 (c) of the Act and shall be punishable with seizure of the goods and a fine equivalent to the total value of the goods embargoed.
- 228.** Any person who violates Section 116 of this Regulation shall be:
- a. Imposed with a fine equivalent to the double the total value of the goods sold on the three incidences of the offences.
 - b. Suspension of Registration of Competent person or/ and the technical Authorization on the fourth subsequent offence.
 - c. Revocation or cancellation of the certificate or Technical Authorization on the fifth subsequent offence.

Violation of more than one count of offences

- 229.** Where there is simultaneous commission of offence under different sections of this Regulation by the same person, he shall be liable for fines and penalties for each violation of the sections separately.

Procedure on payment of fines and collection

- 230.** The monetary fines imposed under chapter XIV of this regulation shall be paid directly to the office within two weeks from date of violation or at a later date as notified by the Authority.

231. Failure to pay the prescribed fines within the stipulated time under section 230 of this Regulation shall be given a period of 45 working days with the payment of Nu. 100 per day as penalty, along with the fines imposed
232. Defaulting to pay the fines beyond the grace penalty period under section 231 of this Regulation shall lead to suspension or revocation of the certificate as deemed appropriate by the Authority.

Administrative Action

233. Where the offence specified under Section 129 or Section 150 of the Regulation is committed by Government Health Centers and Livestock centre and where the said offence has been resulted by the person's commission or omission of an act or duty, such person shall be met with administrative action by the management of specific organization as per the Civil Service Rules and Regulation or any other governing laws of the country.
234. The administrative order shall specify actions the violator must undertake to come into compliance, set deadline by which compliance must be undertaken, including immediate compliance and provide for administrative sanctions for failure to comply with the order.
235. The imposition of the administrative action under section 234 of this Regulation, or imposition of fines and penalties on anyone whether manufacturer or licensee for contravening the provision of the Act and Regulation does not excuse any criminal liability under the Act or any other laws of the Country.

Suspension, cancellation or revocation of Technical Authorization for Manufacture

236. The manufacturing license may be suspended in following conditions:
 - a. Deviation from GMP standards posing high risk to the consumers as determined by the GMP inspection report.
 - b. Where the manufacturing firm fails to show substantial improvement in the GMP compliance post regulatory inspection and observation as determined by the GMP inspection report.
 - c. Reports of confirmed cases of adverse drug reaction from the products manufactured using the common facility and equipments.
 - d. Addition of different therapeutic group products without prior approval.
 - e. Absence of competent registered personnel for supervision of the production or quality at three different instances as confirmed during inspection.
237. The manufacturing license may be cancelled in following conditions:
 - a. Change of manufacturing premises without prior approval from the authority

- b. Where the manufacturing firm fails to show substantial improvement in the GMP compliance post regulatory inspection and observation on three instances of inspection as determined by the GMP inspection report.

Suspension and revocation of license

- 238.** The Authority shall suspend technical authorization for a period of not more than 90 days each time or where a licensee is prosecuted for an offence under this Act.
- 239.** A licensee whose Technical Authorization has been suspended shall close the business premise and during such suspension, he may not apply for any other licence or authorization under the Act.
- 240.** A licensee whose licence has been revoked must cease the production or sale of drugs, or the importation or order of drugs into the country, as the case may be, and may not apply for any licence under this Act until a period of 2(two) years from the date of the revocation. It shall be the discretion of the Board whether or not to issue another technical authorization.
- 241.** The order of suspension or revocation of a licence shall be notified in writing to the licensee by the Ministry of Economic Affairs upon the request of the Authority.
- 242.** Wherever necessary, the orders of suspension and revocation of a Technical Authorization or license may be published in a newspaper or by other means of public media by the relevant agencies.
- 243.** The Authority with the advice of the Board, may request the Ministry of Economic Affairs for lifting the suspension of a licence before the expiration of the suspension time limit on the satisfaction that the licensee whose licence has been suspended has complied with or made good with the provisions of the Act or this Regulation.
- 244.** The licensee whose licence has been suspended or revoked has a right to appeal to the Board within thirty days from the date of the order. The Board may dismiss the appeal or amend the order of the Authority.
- 245.** In case of a licensee whose licence has been suspended or revoked desires to sell his remaining drugs to another licensee, he shall apply in written to the Authority within a period of sixty days from the date of the order of the suspension or revocation of the licence or the decision of the Board, providing the details of the drugs to be disposed/sold. The Authority, after examination of

the particulars and the inspection of the premises, may grant approval for sale or disposal thereof.

Deregistration of the Competent Person

246. The Authority shall de-register the competent person in following cases:

- a. If Competent Person has made gross violation of the provisions of the Act and regulation including the misuse of registration certificate;
- b. Convicted in the court of law resulting from professional misconduct/ negligence as notified by the Bhutan Medical and Health Council and other equivalent Agency;
- c. Defaults timely renewal beyond three month of grace period; or
- d. For any other reason which shall be specified by the Authority at the time of deregistration.

Protection of Action in good faith

247. No suit, prosecution or other legal proceedings shall lie against the Authority, Drug controller, or other person authorised by the Authority for anything which is in good faith done or intended to be done in pursuance of the Act or rules and regulation or order made thereunder.

CHAPTER XV

CLASSIFICATION OF MEDICINES

Principle and General Requirements

- 248.** The medicines shall be classified into different schedules according to the of risk for the consumers and degree of complexity on the storage of medicinal products
- 249.** The medicines shall be classified into;
- a. Schedule A: Non-prescription drugs
 - i. Schedule A1: Pharmacy Only Medicines
 - ii. Schedule A2: General Sale List (Over the Counter)
 - b. Schedule B: Prescription only medicines (POM)
 - c. Schedule C: Controlled Drugs
 - i. Schedule C1: Controlled narcotic drugs
 - ii. Schedule C2: Controlled psychotropic substances
 - d. Schedule D: Traditional medicines and herbal products
 - i. Schedule D1: Non-prescription traditional medicines and herbal products
 - ii. Schedule D2: Prescription traditional medicines and herbal products
 - e. Schedule E: Medicinal products for veterinary use
 - i. Schedule E1: Non-prescription medicines for veterinary use
 - ii. Schedule E2: Prescription medicines for veterinary use
 - f. Schedule F: Vaccines, Biological and special products
- 250.** The following criteria shall be applicable for categorization of medicines as Schedule A1/Pharmacy Only Medicine:
- a. Medicines with no serious side effects or major systemic side effects and do not require constant medical supervision
 - b. Medicines with wide therapeutic window/range/Safety margin, and do not require injectables for administration,
 - c. Conventional medicines which have well established indications and safety
- 251.** The following criteria shall be applicable for categorization of medicines as Schedule A2: General Sale List (Over the Counter)
- a. Medicines with minimal side effects associated with its use;

- b. Medicines with established conventional wide indications (Eg: Boroline/Boroplus Antiseptic creams/ointments, Dettol Preparations, Vicks cold rubs, hand sanitizers);
- c. Products which are indicated for both healthy clients and patients; and
- d. Products with ease of applications without the need for clinical counselling

Mechanism of Regulation of General Sale List

- 252.** Schedule A2 shall be registered with the DRA using the full registration process similar to complimentary medicines.
- 253.** The sale of Schedule A2 medicines products shall not be restricted to Pharmacies only but also permitted from the general stores.
- 254.** The import of GSL shall be permitted to Pharmacy License holder(s) only applying same principle of no objection certificate or statement from the Market Authorization Holders as per the section 57 of this Regulation.
- 255.** Medicines under Schedule B should be sold on presentation of a prescription from a registered medical Practitioner or authorized by the parent Agency and registered with the Bhutan Medical and Health Council.
- 256.** Medicines listed under Schedule D2 shall be sold only on the presentation of prescription from a registered Drungtsho.
- 257.** Medicines prescribed under Schedule E2 shall be sold only on the presentation of a prescription from a registered veterinarian or veterinary professional authorised to prescribe by the parent agency.
- 258.** Medicines listed under Schedule F shall be stored under appropriate cold chain conditions required as per the product specification.
- 259.** List of Medicinal Products under each schedule may be revised from time to time by the Authority.

CHAPTER XVII

APPEAL

Procedures of appeal:

- 260.** Any individual aggrieved by any decision made by the Authority or any Committee established under the Act or this Regulation shall submit a written petition to the Board within thirty days from the date of issue of the decision.
- 261.** The board shall form a committee who shall investigate to study the issues of the petition in consultation with relevant agencies. The committee shall submit the report of the commission of investigation to the board within thirty days from the date of formation of the committee.
- 262.** If an aggrieved is still not satisfied with the decision of the Board, he/she may appeal to the Court of law.

Miscellaneous provisions

Authorization for First Aid medicines

- 263.** Any agency or corporation or private enterprise within definition of this Regulation may stock medicines for the purpose of providing first aid services for their staff or employees complying with the approved list of the medicines and conditions set by the Authority.
- 264.** The agency or corporation or private enterprise shall apply to the Authority in the prescribed form no XIX MA.
- 265.** The list of the first aid medicines shall be revised from time to time or as deemed appropriate by the Authority.
- 266.** Non-compliance to conditions stated under 263 shall be liable for seizure of medicines and fines equivalent to the total amount of medicines stocked without prior approval from the Authority.

Authoritative Text

267. In the Instances of differences in the meaning between the Dzongkha and English text, each text shall be regarded as equally authoritative and the implementing body shall reconcile the difference.

Loss or damage documents

268. The applicant shall inform the Authority within 15 days from the date of notice in case of loss or damage of the authorization(s), permits or certificates for replacements.

Fees structure

269. All kinds of fee as referred under the Act and this Regulation shall be prescribed in a separate notification which may be amended from time to time.