



BHUTAN MEDICINES RULES AND REGULATION 2019

TABLE OF CONTENTS

CHAPTER I	: PRELIMINARY	3
CHAPTER II	: BHUTAN MEDICINES BOARD AND DRUGS TECHNICAL ADVISORY COMMITTEE.....	4
CHAPTER III	: DRUG REGULATORY AUTHORITY	6
CHAPTER IV	: DRUG TESTING LABORATORY AND GOVERNMENT ANALYST	8
CHAPTER V	: CLINICAL TRIAL OVERSIGHT.....	9
CHAPTER VI	: TECHNICAL AUTHORIZATION FOR MANUFACTURE .	11
CHAPTER VII	: TECHNICAL AUTHORIZATION FOR SALE AND DISTRIBUTION	15
CHAPTER VIII	: COMPETENT PERSON	20
CHAPTER IX	: MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS.....	25
CHAPTER X	: IMPORT AND EXPORT AUTHORIZATION	31
CHAPTER XI	: INSPECTION.....	35
CHAPTER XII	: SURVEILLANCE OF MEDICINAL PRODUCTS	38
CHAPTER XIII	: ADVERTISEMENT OF MEDICINAL PRODUCTS.....	42
CHAPTER XIV	: LOT RELEASE OF VACCINES AND BIOLOGICALS	43
CHAPTER XV	: OFFENCES AND PENALTIES.....	44
CHAPTER XVI	: CLASSIFICATION OF MEDICINAL PRODUCTS.....	48
CHAPTER XVII	: APPEAL AND MISCELLANEOUS PROVISION.....	50
DEFINITION		52
APPLICATION FORMS AND ANNEXURE		58

BHUTAN MEDICINES RULES AND REGULATION 2019

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 the 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, commencement and extent

1. This Regulation shall:
 - (1) be called the Bhutan Medicines Rules and Regulation, 2019;
 - (2) take effect on the *fifth* of the *ninth* month of *Earth Female Pig* year of the Bhutanese calendar corresponding to the 1st November of 2019 and
 - (3) extend within the Kingdom of Bhutan.

Application

2. This Regulation shall apply to all medicinal product including health supplement.

Objective

3. The objective of this Regulation shall be to:
 - (1) regulate all medicinal products to ensure quality, safety and efficacy;
 - (2) promote access and availability of medicinal products; and
 - (3) promote transparency and efficiency in the services provided by the Authority.

Revocation

4. Upon coming to force of this Regulation, the Bhutan Medicines Rules and Regulation 2012 shall be revoked.

Interpretation

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

CHAPTER II

BHUTAN MEDICINES BOARD AND DRUGS TECHNICAL ADVISORY COMMITTEE

Functions of the Board

6. The Board constituted in accordance with section 4.2 of the Act shall:
- (1) exercise the powers and functions stated under section 5 and section 6 of the Act and delegate the Authority to carry out the functions of the Board prescribed under the provisions of the Act;
 - (2) suspend or terminate any nominated member of the committees constituted under the provisions of the Act, on disciplinary grounds; and
 - (3) appoint relevant person to replace the member terminated under section 6(2) of this Regulation.

Drugs Technical Advisory Committee (DTAC)

Procedure

7. In accordance with section 5.1 and section 9 of the Act, the Drugs Technical Advisory Committee shall regulate its own procedures as follows:
- (1) the Authority shall seek nominations from the respective agencies which shall be put up to the Board for endorsement;
 - (2) the Chairperson and the Vice-chairperson of the Committee shall be elected on an annual basis among the *ex-officio* members;
 - (3) in absence of the Chairperson, the Vice-chairperson shall chair the meeting;
 - (4) the Chairperson shall recommend the Authority to invite co-opt members as and when required;
 - (5) the members shall attend the meeting in person;
 - (6) if a member fails to attend three consecutive meetings, he shall forfeit the membership unless otherwise there is a valid justification;
 - (7) the members shall maintain the confidentiality and privacy of information discussed in the meeting; and
 - (8) the Authority shall serve as the secretariat to the committee to coordinate 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.

Functions

8. In accordance with section 5.1 and section 9 of the Act, the Committee shall:
 - (1) provide advice to the Board on all technical areas related to regulation of medicinal products and other technical matters as and when required by the Board;
 - (2) review and recommend relevant national standards and technical guidelines to the Board; and
 - (3) carry out any other responsibilities assigned by the Board.

CHAPTER III

DRUG REGULATORY AUTHORITY

Powers and functions of the Drug Regulatory Authority

9. In accordance with section 10 of the Act, the Authority shall carry out the functions delegated by the Board as follows:
- (1) regulate manufacture, import and export, storage, sales, dispensing and distribution of medicinal product, health supplements and feed supplements;
 - (2) register medicinal product for manufacture, import, export, stocking, sales and distribution;
 - (3) register Competent Person for manufacture, sale, distribution and dispensing of medicinal products;
 - (4) develop standards, guidelines and conditions required for implementation of this Regulation;
 - (5) develop and prescribe the formats for application, certification and Technical Authorizations for the purpose of carrying out functions under this Regulation;
 - (6) maintain national registry of medicinal products and Competent Person;
 - (7) regulate advertisements and promotion of medicinal products and health supplements;
 - (8) regulate the prices of medicinal products and health supplements;
 - (9) designate drug testing laboratory and an Appellate Laboratory for testing of medicinal products and health supplements;
 - (10) investigate complaints made to the Authority as per the prescribed procedure;
 - (11) notify on the safety and product performance status of medicinal products in the country as required;
 - (12) create awareness on the provisions of the Act and Regulation made thereunder;
 - (13) oversee clinical trials process;
 - (14) conduct lot release of vaccines and biologicals;
 - (15) develop mechanisms to minimize the generation of pharmaceutical waste from pharmaceutical firms;
 - (16) impose fines and penalties for non-compliances;
 - (17) liaise with other relevant national and international organisations; and
 - (18) carry out any other functions in line with the provisions of the Act and this Regulation.

Powers and functions of the Drug Controller

10. In accordance with section 11 of the Act, the Drug Controller, in order to provide leadership for effective implementation of the Act and the Regulation shall:
- (1) set vision and strategy for the Authority;
 - (2) secure resources for the Authority;
 - (3) guide preparation and formulation of policies, plans and guidelines;
 - (4) initiate suo-motu investigation when there is a risk to the public due to quality, safety and efficacy of medicinal products, health supplements and feed supplements;
 - (5) approve certificates, Technical Authorizations, protocols, guidelines, manuals and Standard Operating Procedures;
 - (6) liaise with other national and international agencies;
 - (7) serve as the Member Secretary to the Board as per section 4.2 (h) of the Act;
 - (8) be the Chairperson of the Registration Committee constituted under section 19.4 of the Act;
 - (9) constitute sub-committees, wherever necessary;
 - (10) carry out any other functions as assigned by the Board.

CHAPTER IV

DRUG TESTING LABORATORY AND GOVERNMENT ANALYST

Functions of the Drug Testing Laboratory

11. In accordance with section 12 and 13 of the Act, the Drug Testing Laboratory shall carry out the following functions:
- (1) test the samples of medicinal products forwarded by the Authority as per the prescribed procedures;
 - (2) submit drugs test reports to the Authority in form the BMRR I-DTL; and
 - (3) develop adequate facilities for testing of medicinal products;
 - (4) liaise with national and international testing laboratory for capacity development.

Appellate Drug Testing Laboratory

12. In accordance with section 13.2 of the Act, the appellate laboratory appointed by the Board shall test samples in case of dispute or controversy on the report of analysis issued by the Drug Testing Laboratory.
13. The test result from the appellate laboratory appointed under section 12 of this Regulation shall be final; and if the result is not in favour of the aggrieved party, the party shall bear the entire cost incurred.

Government Analyst

14. In accordance with section 14 of the Act, the Government shall appoint the Government Analyst possessing a minimum of a bachelor's degree in pharmacy or pharmaceutical sciences or analytical chemistry with minimum five years work experience in relevant field.

Powers and functions of the Government Analyst

15. The Government Analyst shall:
- (1) set vision and strategy for the Laboratory;
 - (2) secure resources for the Laboratory;
 - (3) develop protocols for sampling, testing and analysis of medicinal products;
 - (4) oversee the testing of samples sent by the Authority;
 - (5) approve the test report upon completion of the test or analysis; and
 - (6) carry out any other responsibilities assigned by the Board.

CHAPTER V

CLINICAL TRIAL OVERSIGHT

16. In accordance with section 5.9 of the Act, the Authority shall regulate all clinical trials that are to be conducted in the country.
17. The Authority shall maintain a registry of approved clinical trial and shall make it available for the public.
18. All stakeholders shall comply with the Good Clinical Practice Guidelines prescribed by the Authority.
19. Separate application shall be made for Clinical Trial Authorization of each investigational medicinal product or new chemical entity.
20. Notwithstanding section 19 of this Regulation, the Authority may exempt or recognize relevant clinical trial data from other regional or international organizations for the purpose of registration of medicinal products.
21. The application for the import of medicinal products for clinical trial shall fulfil the following requirements:
 - (1) cGMP certificate of the facility where the product is manufactured; and
 - (2) Import Authorization from the Authority.
22. The applicant shall obtain prior permission to re-export or destroy the medicinal product from the trial.

Procedure for Clinical Trial Authorization.

23. Any applicant intending to conduct a clinical trial in the country shall apply to the Authority for authorization in the form BMRR II-CTA along with the fees prescribed under the Annexure I.
24. The applicant shall submit ethical clearance from the independent ethics committee along with the application.
25. In accordance with section 5.11 of the Act, the Board shall constitute separate Clinical Trial Review Committee or designate an existing relevant committee to:
 - (1) review the clinical trial protocol and other relevant documentation;

- (2) review the clinical trial results;
- (3) recommend the Authority to authorize or reject the trial application;
- (4) review serious adverse events; and
- (5) provide technical guidance on any matters related to clinical trials.

- 26. The Authority shall review the application for clinical trial, and if necessary seek guidance from the Clinical Trial Review Committee.
- 27. The Authority upon endorsement from the Board shall grant Clinical Trial Authorization in a prescribed format to the applicant.
- 28. The applicant shall monitor all trial subjects for adverse events and report serious adverse events within 24 hours.

Clinical trial inspection

- 29. The Authority shall conduct on-site inspections of the clinical trials.
- 30. The Authority may suspend or terminate an ongoing clinical trial if necessary and provide the reasons in writing.
- 31. The applicant shall notify the Authority with reasons in writing in case of premature suspension or termination of the clinical trial.

Post-approval variation

- 32. The applicant shall notify the Authority of variation to the original protocol.
- 33. Implement any variation to the original protocol only after according approval from the Authority.

CHAPTER VI

TECHNICAL AUTHORIZATION FOR MANUFACTURE

34. In accordance with section 21 of the Act, all medicinal products to be manufactured in the country shall require prior approval from the Authority unless otherwise exempted under section 42 of this Regulation.
35. The Technical Authorization for Manufacture shall be a prerequisite for obtaining a license from the Ministry of Economic Affairs for manufacturing any medicinal products.
36. For the final authorization to manufacture, the premises shall be completed as per the approved layout and ready for implementation of the quality system that incorporates Good Manufacturing Practices (GMP).
37. Depending on the type of the products intended for manufacture, manufacturers shall have appropriate facility and equipment installed.
38. All the manufacturers shall conform to standards specified by the Authority as per the Guideline for Technical Authorization for Manufacture.
39. The firm manufacturing controlled medicinal products falling under schedule C1 and C2 shall obtain separate approval from the Bhutan Narcotics Control Authority.
40. A separate building shall be required for production of beta lactam products. The distance between the facility manufacturing beta lactam and other class of medicinal products shall conform to standards specified by the Authority.
41. For manufacture of steroid, sex hormone, cytotoxic and immunosuppressant group of medicinal product, a dedicated and self-contained facility shall conform to standards specified by the Authority in the Guideline for Technical Authorization for Manufacture.

Exemption from Technical Authorization for Manufacture

42. The requirement for a Technical Authorization to Manufacture will be exempted for dispensing or preparation of extemporaneous formulations, which is necessary for the dispensing of any drug for the purpose of it being used for medical treatment.

Procedure

43. Any applicant intending to set up a plant for manufacturing medicinal products shall apply to the Authority in form BMRR III-PAM and pay the fees as prescribed under the Annexure I.
44. The applicant shall submit the documents as per the Guideline for Technical Authorization for Manufacture.
45. The Authority shall submit the technical report to the Board seeking approval for Provisional Authorization upon fulfilment of the requirements.
46. The Provisional Authorization with validity of two years shall be issued in prescribed format for setting up the manufacturing plant.
47. The applicant shall construct the plant within the validity of the Provisional Authorization.
48. The Authority shall conduct periodic inspection of the plant during the Provisional Authorization to monitor the compliance as per the approved design.
49. Once the plant set up is complete, the applicant shall apply to the Authority in form BMRR IV-FAM for final Technical Authorisation for manufacture and pay the fees as prescribed under the Annexure I.
50. The Authority shall conduct an inspection of the facility to verify the Good Manufacturing Practices (GMP) requirements and submit a report to the Board.
51. Upon approval by the Board, the Authority shall issue the Technical Authorization for Manufacture in a prescribed format with a validity of two years.
52. Pre-approval and routine GMP inspections shall be conducted to assess the conformance of the manufacturer to standards specified by the Authority.

53. Manufacture of any medicinal products not listed in the initial approval or any changes in the layout of the premises and any other matters shall require prior approval from the Authority.
54. The Authority may cancel the Provisional Authorization in case of any deviation from the proposed technical layout or any unapproved changes under section 53 of this Regulation.

Renewal of Provisional Authorization and Technical Authorization for Manufacture

55. The application for renewal of Provisional Authorization for Manufacture shall be submitted in form BMRR III-PAM and Technical Authorization for Manufacture in BMRR IV-FAM.
56. The application shall be submitted along with the fees as prescribed under the Annexure I.
57. After the expiry, a grace period of fifteen working days shall be granted after which the renewal shall be done with a daily fine of ngultrum one hundred for further fifteen working days.
58. Non-renewal of the Provisional Authorization as per section 57 of this Regulation shall result in cancellation of the Authorisation.
59. Non-renewal of the Technical Authorization as per section 57 of this Regulation shall result in cancellation of the Authorisation.
60. Provisional Authorisation for Manufacture can be renewed only for two times after which it shall be considered as a new proposal.

Suspension or cancellation of Technical Authorization for Manufacture

61. The Technical Authorization for Manufacture may be suspended when:
- (1) any conditions of the Technical Authorisation has been contravened;
 - (2) deviation from GxP standards posing high risk to the consumers as determined by the GxP inspection report;
 - (3) where the manufacturing firm fails to show substantial improvement in the GMP compliance to the corrective and preventive action during first instances of inspection;
 - (4) addition of different therapeutic group products without prior approval; or

(5) absence of Competent Person for supervision of the production or quality unit as confirmed during inspection.

62. The Technical Authorization for Manufacture may be cancelled when:

- (1) there is change of manufacturing premises without prior approval from the Authority; or
- (2) the manufacturing firm fails to show substantial improvement in the GMP compliance to the corrective action and preventive action on second instances of inspection as determined by the GxP inspection report.

Issuance of certificates

63. The Authority shall issue a certificate of Good Practices (GxP) and the Certificate of Pharmaceutical Product upon fulfilment of all regulatory provision as per the standards specified by the Authority.

Suspension or cancellation of certificates

64. The Authority may suspend or cancel the certificate issued under section 63 of this Regulation under the following conditions:

- (1) non-compliance to GxP standards;
- (2) confirmed product defect in the domestic or international market; and
- (3) any other circumstances as determined by the Authority.

CHAPTER VII

TECHNICAL AUTHORIZATION FOR SALE AND DISTRIBUTION

65. In accordance with section 24 of the Act, any individual or firm shall obtain approval from the Authority prior to sale and distribution of medicinal products.
66. The Technical Authorization Holder shall conform to the conditions laid down in the Act, Regulation and any other conditions as deemed necessary by the Authority.
67. The premises intended for sale and distribution shall have appropriate facilities to store, sale, dispense and distribute medicinal products.
68. In accordance with section 5.6 of the Act, all medicinal products, health supplements and feed supplements shall be sold at or below the price submitted to the Authority at the time of registration.
69. Technical Authorization for Sale and Distribution is not a substitute for a license for sale from the Ministry of Economic Affairs.
70. In case of closure of the premise or non-availability of Competent Person, the Market Authorization Holder shall surrender the Technical Authorization.
71. Sale and distribution of medicinal products, health supplements and feed supplements through electronic platform (e-pharmacy, e-portal etc.) shall not be allowed.

Exemption

72. The Authority shall exempt the requirement of Technical Authorization for sale and distribution for the following premises:
 - (1) Government health and veterinary centre
 - (2) Government projects and approved non-governmental projects not engaged in commercial activities of medicinal products
 - (3) Involved in sale of medicinal products listed under Schedule A2 and Category-I health supplements.

73. Notwithstanding the section 72(2) of this Regulation, projects shall obtain Technical Clearance and be subjected to the conditions or duties laid under section 91 of this Regulation and any other provisions, wherever applicable.

Procedure

74. In accordance with section 24.1(a) of the Act, the applicant shall apply for the Technical Authorization for Sale and Distribution in form BMRR V-TAS and pay the fees as prescribed under the Annexure I.
75. The applicant shall submit the following documents:
- (1) Copy of certificate of registration as Competent Person and/or of the employee(s), who shall supervise the sale of medicinal products;
 - (2) Name of the proposed firm; and
 - (3) Category of medicinal products whether human, veterinary or traditional medicines.
76. In accordance with section 24.1 (b) of the Act, the Authority may verify the proposed site for suitability of the premise.
77. In accordance with section 24.1 (c) of the Act, the Authority shall grant Technical Authorization for Sale and Distribution in the prescribed format and shall be valid for three years.
78. 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 BMRR VI-TC for Technical Clearance.
79. The Technical Clearance shall be issued by the Authority in the prescribed format upon verification of the premise.

Renewal of Technical Authorization for Sale and Distribution

80. The applicant shall follow section 74 and section 75 of this Regulation for renewal of Technical Authorization for Sale and Distribution.
81. After the expiry of the Technical Authorization for Sale and Distribution, a grace period of fifteen working days shall be granted after which the renewal shall be done with a daily fine of Nu. 100 (one hundred only) for a further fifteen working days.

82. Non-renewal of Technical Authorization within the period provided under section 80 of this Regulation shall be deregistered and new application from the same applicant shall not be entertained for one year.
83. Irrespective of the date of renewal, the validity of the Technical Authorization shall be considered from the actual date of expiry.

Suspension or cancellation of Technical Authorization for Sale and Distribution

84. The Authority shall suspend Technical Authorization for a period of not more than ninety days each time or where a Technical Authorization Holder is prosecuted for an offence under the Act.
85. Technical Authorization Holder shall close the business during such suspension and shall not apply for any other licence or authorization under the Act and Regulation.
86. The order of suspension or cancellation of a licence shall be notified in writing to the Technical Authorization Holder by the Ministry of Economic Affairs upon the request of the Authority.
87. The Technical Authorization Holder who's Technical Authorization has been suspended or cancelled may appeal to the Board within thirty working days from the date of the order. It shall be the discretion of the Board to issue another Technical Authorization.
88. In case of a Technical Authorization Holder whose Technical Authorization has been suspended or cancelled desires to sell his remaining products to another Technical Authorization Holder, he shall apply in writing to the Authority within a period of sixty working days from the date of the order of the suspension or cancellation of the licence or the decision of the Board, providing the details of the products.
89. The Technical Authorization for Sale and Distribution may be suspended when:
- (1) any conditions under section 91 and section of 116 of this Regulation has been contravened;

- (2) deviation from GxP standards posing high risk to the consumers as determined by the inspection report;
- (3) where the firm fails to show substantial improvement in the GxP compliance to the corrective and preventive action during third instances;
- (4) Competent Person and Technical Authorization Holder contravenes any section of law of the country; or
- (5) as determined by the Authority.

90. The Technical Authorization for Sale and Distribution may be cancelled when:

- (1) Technical Authorization is suspended for two times;
- (2) Competent Person and Technical Authorization Holder is proven guilty of the section 89 (4); or
- (3) as determined by the Authority.

Requirements and duties of a Technical Authorization Holder

91. The Technical Authorization Holder shall abide by the following conditions:

- (1) the pharmacy premises shall be separate from rooms for residential use and shall be clean and hygienic at all times;
- (2) the premises should be structurally sound, dry, well-lit and ventilated with sufficient space to allow the medicinal products to be kept in a clearly visible and appropriate manner;
- (3) only cosmetics, medical device and health supplements may be sold from the authorized premises in addition to medicinal product. However, these categories of products shall be segregated and arranged separately;
- (4) all medicinal products shall be stored below 30°C and 70% relative humidity unless otherwise specified on the label by the manufacturer;
- (5) veterinary medicinal products, if sold from the same pharmacy along with human medicinal products, shall be stored separately and conspicuously labelled in red font with appropriate sign;
- (6) in absence of a Competent Person, the Technical Authorization Holder shall make alternative arrangements for another Competent Person, with prior written approval from the Authority or else the pharmacy shall remain closed;
- (7) containers used for storing the medicines shall be appropriate for the intended purpose and labelled accordingly;
- (8) in absence of Competent Person, no medicinal products shall be sold;
- (9) sale and distribution shall be restricted to medicinal products registered with the Authority;

- (10)for private retail or wholesale pharmacy, the sign board shall be as per the sample prescribed by the Authority;
- (11)for government health facility, the sign board shall be as per the specifications prescribed by the relevant agency;
- (12)the business or visiting hours of the pharmacy shall be clearly written in both English and Dzongkha and displayed at a conspicuous place in the premises;
- (13)the Technical Authorization of the premise and certificate of the Competent Person shall be displayed conspicuously at all times;
- (14)the furniture and apparatus in the premises shall be suitable and of appropriate size for intended purpose;
- (15)where applicable, a separate compounding area for extemporaneous formulations shall be maintained with appropriate facilities;
- (16)during temporary closure exceeding seven days, a notice for temporary closure shall be displayed conspicuously in Dzongkha and English in front of the premises;
- (17)ensure certificate or document issued by the Authority is not used as a means to promote the sale of medicinal products; and
- (18)not manipulate the documents submitted to or issued by the Authority.

92. The duties laid down under section 91. (2), (4), (7), (11), (12), (14) and (15) of this Regulation shall also be applicable to premises engaged in storage and distribution of medicinal products in the Government Health centre, Livestock centre and project facilities.

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

93. Where a Technical Authorization Holder of a wholesale or retail pharmacy wishes to change the ownership of Technical Authorization or the location of the premise or name of Pharmacy or Competent Person, he shall do so by applying to the Authority in form BMRR VII-OC of this Regulation.

94. The applications for change as per section 93 shall be accompanied by a fee as per Annexure I.

CHAPTER VIII

COMPETENT PERSON

95. In accordance with section 19.2 of the Act, only Competent Person shall engage in the manufacture, sale, dispensing and distribution of medicinal products.
96. The Authority shall register the key personnel involved in manufacturing as Competent Person.
97. In accordance with section 19.4 of the Act, the Registration Committee shall be constituted to:
- (1) set the requirements for registration
 - (2) conduct competency examination; and
 - (3) recommend the Authority on any matters related to the Competent Person.
98. Notwithstanding section 97(2) of this Regulation, the Authority may, in order to expedite the process of registration, conduct the competency examination and submit for endorsement to the Chairperson of the committee.
99. The Authority shall recognize the certification of Bhutan Medical and Health Council for health professionals and certification of such other equivalent organizations for veterinary professionals.
100. Any person registered as the Competent Person under section 95 and 96 of this Regulation shall not engage in prescribing medicines.
101. Separate Competent Person shall be required for wholesale and retail pharmacy.

Exemption

102. The professionals involved in dispensing, stocking and distribution of medicinal products in Government health centres or Livestock centres registered with the Bhutan Medical and Health Council or equivalent Agency of relevant Ministry, respectively shall be exempted from the requirement of registration as Competent Person.

103. The exemption granted under section 102 of this Regulation shall not serve as a substitute for Competent Person registration for manufacture, sale and distribution under the Act.

Criteria for registration as Competent Person

104. For registration of key personnel in the manufacturing of medicinal products as Competent Person, he shall have a Bachelor's degree in a relevant field with minimum work experience of two years or Diploma in relevant field with minimum work experience of five years.
105. Any person possessing the minimum qualification of following shall be registered as Competent Person for import, export, sale, storage, distribution of relevant products:
- (1) certificate in Pharmacy or Bachelor of Medicine and Bachelor of Surgery (Human Medicines);
 - (2) certificate in Veterinary or Animal Science (Veterinary Medicines);
 - (3) diploma in Traditional Medicines;
 - (4) diploma in Nutrition or Food Science (Health Supplements); or
 - (5) qualification as determined by the Board for other category of medicinal products.

Procedures for registration as Competent Person

106. Any person who wishes to register as Competent Person with the Authority shall apply in form BMRR VIII-CP along with the registration certificate from the Bhutan Medical and Health Council or with a letter of recognition from the Department of Livestock or other equivalent agency.
107. A person who possesses the required qualification under section 104 and 105 of this Regulation is eligible to sit for competency exam as set by the Authority and pay the fees as prescribed under the Annexure I.
108. The Authority shall conduct the competency examination and issue registration certificates as per the Guidelines for Registration of Competent Person.
109. The Authority shall issue registration certificate in prescribed format and the validity of the certificate shall be a maximum of five years or at par with that of registration certificate issued by the Bhutan Medical and Health Council or other equivalent agency.

Renewal of registration certificate of Competent Person

110. The applicant shall apply for renewal of registration in the form BMRR VIII-CP along with a copy of the registration certificate of the Competent Person and pay the fees as prescribed under the Annexure I.
111. The Authority shall renew the Competent Person registration certificate based on the validity of certificate of registration issued by the Bhutan Medical and Health Council without having to sit for examination.
112. An applicant above the age of seventy shall submit valid medical fitness certificate annually.
113. After the expiry of the certificate of Competent Person, a grace period of fifteen working days shall be granted after which the renewal shall be done with a payment of a fine of Nu. 100 (one hundred) daily for a further fifteen working days.
114. Non-renewal of registration within the grace period provided under section 113 of the Regulation shall be deregistered, in which case the procedures for registration under section 106 of this Regulation shall apply.
115. Irrespective of the date of renewal, the validity of the renewed certificate shall be considered from the actual date of expiry of last certificate.

Duties of a Competent Person

116. The Competent Person responsible for carrying out functions in relation to sale and distribution under the Act, shall:
 - (1) dispense medicinal products other than those listed under Schedule A1, A2, D1, E1 only upon presentation of lawful prescriptions;
 - (2) maintain copies of the prescription for a period of 3 years for sale of drugs under schedule C1 and C2 of this Regulation;
 - (3) provide the total quantity of controlled drugs both in words and figures on the prescription in addition to the general requirements on prescription;
 - (4) ensure physical quantity and ledger balance of schedule C1 and C2 tally;
 - (5) maintain temperature and relative humidity records at least twice a day;
 - (6) not change the figures and information in the prescription without consulting the prescriber;
 - (7) maintain cleanliness of store, dispensary, compounding areas and, the furniture and apparatus in contact with medicinal product;
 - (8) not involve in sale and distribution of unauthorised medicinal products;

- (9) keep controlled drugs under lock and key;
- (10) at all times wear an apron with a name tag at the workplace;
- (11) maintain inventory of medicinal products as per the guideline intended for the purpose;
- (12) make a list of pharmaceutical wastes using prescribed form BMRR XVII-DEM and dispose it as per the Waste Prevention and Management Regulation;
- (13) maintain proper segregation and arrangement of the medicines with appropriate labels;
- (14) develop and implement Standard Operating Procedures required in the management of medicinal product;
- (15) report Adverse Drug Reactions and product defects of medicinal products;
- (16) dispense medicinal products in appropriate packaging material;
- (17) label the dispensed medicine incorporating at least the following details:
 - (a) Generic name of the medicine,
 - (b) Strength,
 - (c) Quantity,
 - (d) Dose,
 - (e) Dosage,
 - (f) Expiry date, and
 - (g) Special precaution where applicable
- (18) maintain valid Adverse Events Following Immunization kit, if engaged in vaccination;
- (19) ensure that physical quantity and ledger balance of the medicinal products tally;
- (20) sign and stamp the prescription with the pharmacy seal after dispensing the medicine;
- (21) dispense and store medicinal products as per the guideline and standard intended for the purpose;
- (22) not keep medicinal products in direct contact with the floor; and
- (23) not manipulate the documents submitted to or issued by the Authority.

117. Notwithstanding section 42 of this Regulation, In accordance with the requirements 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:

- (1) ensure appropriate use of premises, equipment and instruments suitable for the intended activities.

- (2) have written procedures and documented records for the extemporaneous preparation including the compounding formula.
- (3) ensure a separate room or designated space for antibiotic preparations or hormones or any other ingredients as deemed to be contaminants and pose a risk to the consumers by the Authority.
- (4) ensure appropriate labelling of the finished products which shall include the name of the product, strength and expiry medicines and name or initial of the dispenser or for the stock compounded.
- (5) ensure that dispensing is done using appropriate containers, and
- (6) verified the compounded product for release wherever applicable depending on the nature of the product

Deregistration of the Competent Person

118. The Authority shall deregister the Competent Person, if:

- (1) Competent Person has made gross violation of the provisions of the Act and Regulation including the misuse of registration certificate;
- (2) convicted in the court of law resulting from professional misconduct/negligence as notified by the Bhutan Medical and Health Council and other equivalent Agency;
- (3) defaults timely renewal beyond three month of grace period; or
- (4) for any other reason which shall be specified by the Authority at the time of deregistration.

CHAPTER IX

MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

Registration of Medicinal product

119. In accordance with section 16.2 of the Act, any medicinal product manufactured, imported, exported, sold, dispensed, stored and distributed shall be registered with the Authority.
120. Any manufacturer both within or outside the country or firm authorized for the purpose of sale and distribution or government agencies shall be eligible to apply for registration of medicinal product.
121. Any manufacturer outside the country registering medicinal product with the Authority shall appoint a local licensed firm or government agencies for sale and distribution.
122. The Authority shall adopt the following routes of registration based on the risk to the consumers as per the Guidelines for Registration of Medicinal Products:
- (1) full registration; or
 - (2) abridged registration; or
 - (3) expedited registration
123. The Authority may recognize relevant information on quality, safety and efficacy from other competent national regulatory authority and international organization for registration of medicinal product.
124. The Authority may reject the registration of medicinal product on the following grounds:
- (1) banned in other countries; or
 - (2) irrational combination; or
 - (3) limited evidence of safety and efficacy; or
 - (4) any other reasons as deemed appropriate by the Authority.
125. Separate application shall be required for different formulation or strength or packaging material or pack size or manufacturing site of the same medicinal product.

126. In accordance with section 17.10 of the Act, the Authority shall evaluate medicinal product dossier by the Product Registration Committee as approved by the Board.
127. The Authority may, when necessary conduct laboratory test of the medicinal product prior to registration, the cost of which shall be borne by the applicant.

Responsibilities of Market Authorization Holder

128. The Market Authorization Holder shall:

- (1) be responsible for the product performance in the market including product recall.
- (2) ensure that all the information given in the application form and supporting documents are true and valid at the time of application submission.
- (3) notify the Authority of any changes related to products' quality, safety or efficacy throughout the product's life cycle in the country.
- (4) submit the price structure of the medicinal product as a part of the documents during the product registration application.

Registration exemption

129. In accordance with section 5.13 of the Act, the Board may exempt the registration requirement of medicinal product on the following grounds:

- (1) medicinal product for the purpose of research as approved by the relevant agency or Board;
- (2) product sample for the purpose of registration as per the Guideline for Registration of Medicinal Products;
- (3) medicinal product for personal use, in a quantity not exceeding the amount stated in the prescription unless justified by a registered medical practitioner.
- (4) limited quantities of medicinal products for specific diseases on named patient basis;
- (5) in public health emergencies notified by relevant agencies;
- (6) limited quantities of medicines required for approved medical camps;
- (7) all the raw materials for the manufacture of medicinal products;
- (8) products not registered but required in limited quantities for time bound government approved projects;
- (9) medicinal products donated to government agencies or international organizations;

Abridged registration

130. Abridged registration shall be applicable for product:

- (1) that has been approved by at least one of the regulatory agencies as specified under the Guideline for Registration of Medicinal Products; or
- (2) Which is prequalified by the World Health Organization (WHO) or World Organization of Animal Health (OIE).

Expedited registration

131. Expedited registration shall be applicable for product:

- (1) from manufacturer with a minimum of five products registered with the Authority for a period of two years at the time of application; and
- (2) with no past record of product recall or withdrawal from Bhutan; and
- (3) not more than two post approval variations for a single product within one year.

Full registration

132. The Authority shall register product which does not qualify for registration under section 130 and 131 of this Regulation under this route as per Guideline for Registration of Medicinal Products.

Application and registration fees

133. The applicant shall apply for registration of product under section 130, 131 and 132 of this Regulation in forms BMRR IX-ARM, BMRR X-EPR and BMRR XI-FRM respectively along with application fee prescribed under Annexure I.

Registration certificate

134. The Authority shall issue a registration certificate in the format prescribed.

135. The Authority shall collect product registration fee prescribed under the Annexure I of this Regulation at the time of issuance of registration certificate.

136. The registration certificate shall be issued within sixty calendar days from the date of receipt of complete required documents unless otherwise a longer period is required, in which case, the parties shall be informed.

137. Notwithstanding section 136 of this Regulation, the Authority may fast-track the registration under exceptional circumstances as deemed appropriate.

138. The registration of a product shall be valid for a period of three years and shall be specified on the certificate by the Authority.

Post-approval variation

139. In case of any variations in the product during the valid period of registration, the Market Authorization Holder shall apply for post-approval variation in the form BMRR XII-PAV along with the fee prescribed under the Annexure I of this Regulation.
140. Post approval variation shall be granted within thirty working days from the date of receipt of complete required documents unless otherwise a longer period is required, in which case, the parties shall be informed.

Renewal of registration

141. The Market Authorization Holder shall apply for renewal in form BMRR XIII-PRR before the expiry date of registration along with the fee as per the Guidelines for Registration of Medicinal Products.
142. The procedure for renewal shall be same as the first registration under section 130, 131 or 132 of this Regulation.
143. Notwithstanding section 142 of this Regulation, one time renewal of registration shall be granted based on the submission of additional documents as per the Guidelines for Registration of Medicinal Products.
144. The Authority may consider a grace period of thirty working days upon submission of a written justification with evidence of having carried out the renewal process with the manufacturer prior to the date of expiry.
145. Upon the completion of the grace period or failure to provide the justification under section 144 of this Regulation, the product shall be deemed deregistered, in which case, the procedure under section 130, 131 or 132 shall apply.

Cancellation of registration

146. The Authority shall cancel the registration if:
- (1) any of the condition of registration has been contravened or changed;

- (2) any serious life threatening adverse events have been reported from national or international sources;
- (3) Market Authorization Holder defaults timely renewal beyond one month of grace period; or
- (4) for any other matters as specified by the Board.

Product registration transfer

147. The market authorization may be transferred during the valid period of registration to another Market Authorization Holder upon the fulfilment of the following conditions along with payment of fees prescribed under Annexure I. of this Regulation:

- (1) Letter of authorization from the manufacturer; and
- (2) No objection certificate/letter from the current Market Authorization Holder of the product.

148. Notwithstanding the section 147 of this Regulation, if without any justifiable reason, the market authorization holder does not provide no objection certificate, the Authority may approve the product registration transfer based on the letter of authorization from the manufacturer.

Listing of health or feed supplements

149. In accordance with section 16.2 of the Act, all health supplements and feed supplements manufactured, imported, exported, sold and distributed shall be listed with the Authority.

150. Any manufacturer both within or outside the country or firm authorized for the purpose of sale and distribution or government agencies shall be eligible to apply for listing of health or feed supplements.

151. In accordance with section 5.11 of the Act, the Board shall establish Food-Drug Interface Committee to review and recommend the standards related to health or feed supplements and assess the health or feed supplement listing applications as and when required.

152. The Authority shall list the health or feed supplements based on the risk to the consumers as per the corresponding Guidelines into following categories:

- (1) Category I- Health supplements with nutrient or general claim;
- (2) Category II- Health supplements with functional claim; or

(3) Category III- Health supplements with disease risk reduction claim.

153. Notwithstanding section 149 of this Regulation, the Authority may exempt listing for those health or feed supplement which shall be specified by the Authority.
154. The Authority shall restrict the sale of category II and III health or feed supplement to a licensed pharmacy or any other authorized premises.
155. Health or feed supplements shall not contain any prohibited ingredients as specified in the corresponding Guidelines.
156. A manufacturer shall ensure that claims on the product labels are consistent with the definition of health or feed supplement and it must not be advertised or promoted for any specific medicinal purpose.
157. The manufacturer shall ensure that health or feed supplements comply with the labelling requirements as prescribed in the corresponding Guidelines.
158. The Importer shall be responsible for timely removal from the market in case of product recall.
159. The Market Authorization Holder shall notify the Authority in case of any change on the product label.

Procedure for listing health supplement

160. The applicant shall apply to Authority for listing of health supplement in the form BMRR XIV-LS and pay the application fee prescribed under the Annexure I.
161. The Authority may reject application for listing health or feed supplement if the product contains prohibited claims or ingredients as specified in the Guideline for Regulating Health or Feed Supplements.
162. Upon satisfactory completion of the assessment of scientific evidence, the Authority shall accord status of listing for the product and the listed products shall be made publicly available.

CHAPTER X

IMPORT AND EXPORT AUTHORIZATION

163. In accordance with 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

164. The Authority shall grant Import Authorization for registered medicines and medicinal products that are exempted in accordance with section 128 of this Regulation.

165. The Authority shall grant Import Authorization to the Market Authorization Holder, government procurement agencies and international organization or the individual authorised by the Authority.

166. For the purpose of sale and distribution, the importer shall be a Market Authorization Holder or government procurement agencies.

167. If the importer under section 165 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.

168. The importer under section 164 and 165 of this Regulation shall have an authorized premises where the imported medicinal products are stored prior to distribution.

169. Pharmaceutical manufacturers shall obtain Import Authorization from the Authority for active ingredients which are required for the manufacture of medicinal products.

170. The importer shall:

- (1) ensure that all imported registered medicines conform to the sample medicinal products or packaging specifications submitted at the time of product registration.
- (2) 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.

- (3) provide unhindered access to Inspector to enter with or without prior notice and inspect the premises where the imported products are stored; and
- (4) furnish periodic data of the imported medicinal product in the prescribed form to the Authority.

171. The Authority shall issue Import Authorization for vaccines and biologicals only if the conditions prescribed under schedule F of this Regulation are complied with.

Export Authorization

172. In accordance to section 23 of the Act, the export of any medicinal product shall require Export Authorization from the Authority for the purpose of obtaining export license.

173. The Authority shall grant Export Authorization for any medicinal products or raw materials used as Active Pharmaceutical Ingredient that are produced or manufactured or extracted in the country.

174. 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.

175. 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 products to be exported are stored.

176. The Authority shall issue Export Authorization to a local manufacturer or authorized exporter.

177. 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 Narcotics Control Authority.

178. The Authority reserves the right to reject the application and seize the products based on the risk assessment and products in contravention to the provisions under the Act and Regulation.

Exemption from Import Authorizations and Export Authorizations

179. 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:
- (1) 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;
 - (2) 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; or
 - (3) for import of medicinal products as samples for registration or tendering purposes and the Authority is accordingly notified in advance.

Procedure for Import Authorization

180. An application for an authorization to import medicinal product shall be made to the Authority in form BMRR XV-IA accompanied by Proforma 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.
181. A single application may be made for import of more than one drug from one manufacturer provided the consignment is imported in one lot.
182. An application for import of controlled and restricted drugs under Schedule C1 and C2 of this Regulation shall be made in the same form BMRR XV-IA of section 180 of this Regulation.
183. An Import Authorization for medicinal products shall be issued in the specified format and shall be valid for a single import for period of six months for the non-registered products and one year for the registered products or till the validity of the product registration certificate, if shorter than one year.

Procedure for Export Authorization

184. An application for an authorization to export medicinal product shall be made to the Authority in form BMRR XVI-EA.

185. A single application may be made for export of more than one drug from one manufacturer provided the consignment is in one lot.
186. An Export Authorization for medicinal products shall be issued in a specified format and shall be valid for a single export for a period of six months.

CHAPTER XI INSPECTION

187. In accordance with section 15 of the Act, the Authority shall carry out inspection of premises for manufacture, storage, sale, dispensing and distribution of medicinal product;
188. Notwithstanding section 187 of this Regulation, the Authority may empower other official or agency to carry out the inspection as and when required.
189. In accordance with section 15 of the Act, the inspection may be carried out with or without prior notice.
190. Drug Inspector shall inspect or search any individual or premises 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.
191. In accordance with section 15.2 (b) of the Act, the Technical Authorization Holder or the Competent Person involved in storage or distribution or manufacture of medicinal product shall give unhindered access to the Inspector to:
- (1) conduct inspection;
 - (2) take pictorial evidence and samples;
 - (3) provide on demand, all the information required; and
 - (4) produce all records of medicinal products necessary for the performance of his duties.

Qualification of Drug Inspector

192. The Drug Inspector shall have at least five years work experience with minimum qualification of Certificate in the relevant field for inspection of premises for sale and distribution.
193. A person with qualifications of Certificate stated under section 192 of this Regulation with less than five years work experience shall be called Assistant Drug Inspector who shall be supervised by a Drug Inspector in the course of his duties.

194. The Drug Inspector who is responsible for inspecting of premises for manufacturing shall have a minimum qualification of Degree in the relevant field.

Powers and functions of Drug Inspector

195. The Drug Inspector and authorized official shall:

- (1) inspect premises wherein any medicinal product is being manufactured, stored, sold, sale, distribution or dispensed;
- (2) take samples of medicinal product for testing which is being manufactured, or being sold or stocked or offered for sale, or is being distributed;
- (3) search any premises or person identified by the Authority whenever there is a reason to believe that an offence has been committed in accordance with the Civil and Criminal Procedure Code of Bhutan;
- (4) issue the embargo or 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 specified period;
- (5) inspect and verify all records of disposal of pharmaceutical waste in accordance to the Waste Prevention and Management Regulation and Guidelines prescribed thereunder;
- (6) maintain a 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 a report of such records to the Authority;
- (7) issue inspection reports for noncompliance to regulatory standards and requirements; and
- (8) carry out any other duties as may be assigned by the Authority.

Procedure

196. In accordance with section 15 of the Act, the inspectors shall carry out the inspection as per the Guideline for Inspection.

197. The inspectors or officials authorised by the Authority shall produce identification or letter of authorization during the course of conducting their duties.

198. Whenever an Inspector takes a sample of a medicinal product from an authorized 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.

199. Wherever necessary, the Authority shall collaborate and conduct joint inspections with other law enforcement agencies.
200. The Inspector shall collect samples as per Guideline for Sampling of Medicinal Products.

Procedure for inspection at entry and exit points.

201. At the entry and exit point for import and export of medicinal product, 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 premises

202. The Authority may inspect the manufacturing firms outside Bhutan which have applied for product registration as per Inspection Guideline.
203. Where on-site routine Good Manufacturing Practice (GMP) inspection is carried out at the request of the manufacturing firm, the cost of the inspection shall be borne by the manufacturer.

Investigation for prosecution under the Act and Regulation

204. The inspector 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 provisions of the Act, or amounting to offence under the Act, or this Regulation.
205. 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.
206. An authorized officer shall exercise power of search and seizure in accordance with section 15.2 (iv) of the Act and relevant provisions of the Civil and Criminal Procedure Code of Bhutan.

CHAPTER XII

SURVEILLANCE OF MEDICINAL PRODUCTS

Pharmacovigilance

207. The Authority shall function as the National Pharmacovigilance Centre for all categories of medicinal products.
208. The Authority shall notify selected hospital as a Regional Pharmacovigilance Center for various categories of medicinal products.
209. In accordance with section 5.11 of the Act, the Board shall establish National Pharmacovigilance Committee to analyse and review the serious adverse events as per the Guideline for Pharmacovigilance.
210. The members of the National Pharmacovigilance Committee shall be as follows:
- (1) Chairman and member secretary of relevant expert committee of each centre;
 - (2) the Authority shall be the member secretary; and
 - (3) additional technical experts as and when required for respective vigilance committee.
211. The National Pharmacovigilance Committee shall meet from time to time to discuss and review the Adverse Event reports.
212. The National Pharmacovigilance Committee shall also function as National Materiovigilance Committee and Serious Adverse Event Committee for clinical trials.
213. Each of the Pharmacovigilance centres shall constitute an expert committee and function as per the Guideline for Pharmacovigilance.
214. Any reports of adverse events of medicinal product from hospital and retail pharmacy shall be forwarded to the nearest Pharmacovigilance Centre in a prescribed reporting form as per the Guideline for Pharmacovigilance.
215. The pharmaceutical manufacturing firm shall establish a pharmacovigilance unit to monitor and report any adverse events from the registered product to the National Pharmacovigilance Centre.

216. The National Pharmacovigilance Centre shall maintain records of adverse events and may liaise with the regional or international organization.
217. The Authority shall take appropriate regulatory measures and issue public notification as and when necessary based on the adverse event reported.
218. All health centres and private pharmacies shall report any adverse events associated with medicinal products in the prescribed format to the Pharmacovigilance Centres.
219. Any adverse event observed in the course of research or studies relating to medicinal products shall be forwarded to the National Pharmacovigilance Centre

Product defect and recall of medicinal products

220. In accordance with section 28 and section 29 of the Act, expired, defective, substandard falsified, recalled and deregistered medicinal products shall not be distributed, sold or dispensed.
221. The Authority shall manage the defective medicinal products as per the Guideline for Management and Handling of Defective Medical Product.
222. 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.
223. Medicinal product shall be recalled if there is:
- (1) confirmed defective product as notified by the Authority;
 - (2) an adverse event linked to the product; or
 - (3) any other reason recognised by the Board to cause potential harm to consumers.
224. The manufacturer or market authorization holder or importer shall ensure timely removal and disposal of deregistered or recalled medicinal products from the market as notified by the Authority.
225. The market authorization holder or manufacturer or importer shall bear the cost incurred as a result of the recall.

226. Expired, defective, recalled and deregistered medicinal products that are seized due to non registration or banned status shall be treated as pharmaceutical waste which shall be segregated and stored separately.
227. The pharmaceutical waste shall be managed as per Waste Preventions and Management Regulation and Guideline for Pharmaceutical Waste Disposal.

Seizure of medicinal products

228. In accordance with section 29 of the Act, medicinal products shall be liable for seizure where it is related to:
- (1) unauthorised personnel or premises;
 - (2) banned products;
 - (3) substandard or falsified products;
 - (4) lack of Import Authorization;
 - (5) unregistered products;
 - (6) tampering of embargoed medicinal product; or
 - (7) breach of conditions under the Regulation.
229. Wherever the seizure of medicinal product is due to section 228 of this Regulation the offender shall be liable for a fine equivalent to the total value of goods.
230. Wherever the medicinal product is registered and seizure is due to section 228 (1) and (4) of this Regulation, the Authority shall review the quality of the medicines and explore possibilities of auctioning to private pharmacies or government health centres.

Embargo of medicinal products

231. The medicinal product shall be liable for embargo where it is related to:
- (1) products not conforming to the registration conditions;
 - (2) temporary closure of pharmacy; or
 - (3) any other cases where deemed appropriate by the Authority.
232. Wherever the medicinal products are embargoed due to section 231 (1) of this Regulation, the applicant shall apply for post approval variations specified under section 139 of the Regulation within three months from the date of embargo upon payment of the prescribed fines under Chapter XV of

this Regulation. Failure to register through Post-approval Variation shall result to seizure of medicinal product under section 226 of this Regulation.

233. The embargoed products under section 231 of this Regulation shall not be tampered whether or not for sale or distribution unless notification for release is issued by the Authority.

CHAPTER XIII

ADVERTISEMENT OF MEDICINAL PRODUCTS

234. In accordance with section 27 of the Act, any advertisement of medicinal products shall require prior approval from the Authority.
235. Section 234 of this Regulation shall not apply to the statement on the product label and information leaflet accompanying product registered by the Authority.
236. An advertisement of a medicinal product shall not:
- (1) boast of therapeutic properties or the ingredient as being miraculously or completely capable of diagnosis, curing, mitigating, treating or preventing a disease or illness, nor shall any other wording of similar meaning be used;
 - (2) falsely or exaggeratedly show its therapeutic properties;
 - (3) 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;
 - (4) falsely cause to understand that it is an abortifacient or a strong emmenagogue;
 - (5) falsely cause to understand that it is an aphrodisiac;
 - (6) falsely cause to understand that it is a birth control drug;
 - (7) falsely show the therapeutic properties of a dangerous or a specially-controlled drug;
 - (8) contain certification or laudation of its therapeutic properties by any other person; or
 - (9) falsely show its therapeutic properties as being capable of diagnosis, curing, mitigating, treating or preventing disease or symptom thereof as notified by the Board.

Procedure for advertisement clearance

237. The applicant shall apply for advertisement in the form BMRR XVII-CAM stating the details of the advertisement.
238. When the application is rejected, the Authority shall provide the reasons for refusal in writing.
239. If the application fulfils the set conditions, the Authority shall issue the Advertisement Clearance in the prescribed format.

CHAPTER XIV

LOT RELEASE OF VACCINES AND BIOLOGICALS

240. All vaccines and biologicals manufactured in the country and imported from outside shall require lot release prior to sale and distribution.

Procedure for lot release

241. The concerned agencies and individual importing the vaccines shall apply for lot release using the form BMRR XVIII-LR along with the required documents to the Authority.

242. 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:

- (1) batch quality control certificate from the manufacturer;
- (2) summary lot protocol; and
- (3) shipping documents.

243. The documents received before and along with the consignment of vaccines shall be verified for completeness, compatibility, authenticity and validity of information.

244. The Authority shall check the consignment or batch of vaccines for cold chain conditions, temperature monitoring device, temperature, packaging, label, quantity, batch number, expiry date and, perform visual and freeze tests.

245. The cold chain conditions must be as per the product requirements during storage, transportation and distribution of all vaccines and biologicals.

246. The Authority may revise the list of documents from time to time in keeping with the changing needs or as per the detail procedure prescribed by the Authority.

247. The Authority shall issue a certificate of lot release in the prescribed format.

CHAPTER XV OFFENCES AND PENALTIES

248. In order to efficiently enforce the provisions of the Act and the Regulation, the following fines and penalties are prescribed as empowered under section 29 of the Act.

249. The penalties will range from reprimand, monetary fine, suspension and cancelation of the certificates.

Fines and penalties

250. In addition to the offences & penalties specified in Chapter IX of the Act, following penalties and fines shall be levied:

- (1) Any person who obstructs an authorised personnel to perform any duty under the Act or Regulation shall be liable for:
 - (a) a fine of Nu.5000 (Ngultrum five thousand) on first and second offence;
 - (b) suspension of Competent Person registration certificate or Technical Authorization Holder for a duration of not more than ninety working days on the third offence; and
 - (c) cancellation of the Competent Person certificate or Technical Authorization on subsequent offence.

251. Any Technical Authorization Holder who violates section 91 (1), (2), (3), (4), (5), (6), (7), (8) or (9) of this Regulation shall be liable for:

- (1) reprimand on first offence;
- (2) a fine of Nu.5000 (Ngultrum five thousand) on second and third offence;
- (3) suspension of the Technical Authorization for a period of ninety working days on the fourth offence; and
- (4) cancellation of the Technical Authorization on the subsequent offence.

252. Any Technical Authorization Holder who violates section 91 (14), (15), (16) or (17) of this Regulation shall be liable for:

- (1) reprimand on the first offence;
- (2) a fine of Nu. 3000 (Ngultrum three thousand) on second and third offence; and
- (3) suspension of the Technical Authorization for a period of two months of on the subsequent offence.

253. Any Technical Authorization Holder who violates section 91 (10), (12) or (13) of this Regulation shall be liable for:
- (1) reprimand on the first offence;
 - (2) a fine of Nu. 1000 (Ngultrum one thousand) on second offence and third offence;
 - (3) suspension of the Technical Authorization for a period of one month on the subsequent offence.
254. Any Competent Person who violates section 116 (1), (4), (5), (6), (7), (8), or (9) of this Regulation shall be liable for:
- (1) reprimand on the first offence;
 - (2) a fine of Nu. 5000 (Ngultrum five thousand) on second offence and third offence;
 - (3) suspension of the registration certificate for a period of three months on the subsequent offence; and
 - (4) cancellation of the Competent Person registration certificate on the next subsequent offence.
255. Any Competent Person who violates section 116 (2), (3), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (20), (21) or (22) of this Regulation shall be liable for:
- (1) reprimand on the first offence;
 - (2) a fine of Nu. 3000 (Ngultrum three thousand) on second and third offence;
 - (3) suspension of the Competent Person registration certificate for a period of two months on the subsequent offence; and
 - (4) cancellation of the Competent Person registration certificate on the next subsequent offence.
256. Any importer who violates section 158 and 170 of this Regulation shall be liable for:
- (1) reprimand and given time extension as necessary by the Authority on the first offence;
 - (2) fine equivalent to the total amount of goods seized and the cost associated for disposal as determined by the Authority or other relevant Agencies, if the products are not recalled; and
 - (3) non-compliance with section 256(2) of this regulation shall lead to cancellation of Technical Authorization.

257. Any person who violates section 163 or section 240 of this Regulation shall be liable for:
- (1) fine of Nu. 5000 (five thousand only) with seven working days from the date of notification to process the Import Authorization on the first offence;
 - (2) seizure of the goods and a fine equivalent to the total value of the goods on second offence; and
 - (3) cancellation of the certificate or Technical Authorization on subsequent offence.
258. Any person who violates the conditions of section 227 of this Regulation shall be liable for:
- (1) fines and penalties prescribed under Waste Prevention and Management Regulation 2012.
 - (2) suspension of the certificate or Technical Authorization on subsequent offence.
259. Any person who violates section 68 of this Regulation shall be liable for:
- (1) reprimand on the first offence;
 - (2) fine equivalent to Nu. 3000 on second offence;
 - (3) suspension of Registration of Competent person or the Technical Authorization on third offence; and
 - (4) cancellation of the certificate or Technical Authorization on subsequent offence.

Violation of more than one count of offences

260. Where there is simultaneous violations of different sections of this Regulation by the same person, he shall be liable for fines and penalties for each violation of the section separately.

Procedure on payment of fines

261. The monetary fines imposed under Chapter XV of this regulation shall be paid directly to the Authority within fifteen working days from the date of notification.
262. Failure to pay the prescribed fines within the stipulated time under section 259 of this Regulation shall be given a grace period of fifteen working days with the payment of Nu. 100 (hundred) per day as penalty, along with the fines imposed.

263. Defaulting to pay the fines beyond the grace period under section 262 of this Regulation shall lead to suspension or cancellation of the certificate as deemed appropriate by the Authority.

Administrative action

264. Where the duties and conditions specified under section 91 or section 116 of the Regulation is violated in government agency, the Authority shall:

- (1) reprimand on the first offence;
- (2) recommend administrative action on second offence; or
- (3) inform Bhutan Medical and Health Council, Royal Civil Service Commission and other relevant agencies for non-compliance and negligence of duties on third subsequent offence.

265. The imposition of the administrative action under section 264 of this Regulation, or imposition of fines and penalties under 260 on anyone whether manufacturer or Technical Authorization Holder for contravening a provision of the Act and Regulation does not excuse any criminal liability under the Act or any other laws of the Country.

Protection of action in good faith

266. 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 XVI

CLASSIFICATION OF MEDICINAL PRODUCTS

267. The medicinal products shall be classified into different schedules according to the risk for the consumers and degree of complexity on the storage of medicinal products.
268. The medicinal products shall be classified into;
- (1) Schedule A: Non-prescription medicines:
 - (a) Schedule A1: Over the counter (OTC) medicines
 - (b) Schedule A2: General Sale List
 - (2) Schedule B: Prescription only medicines (POM)
 - (3) Schedule C: Controlled medicines
 - (c) Schedule C1: Narcotics
 - (d) Schedule C2: Controlled psychotropic substances
 - (4) Schedule D: Traditional medicines and herbal products
 - (a) Schedule D1: Non-prescription traditional medicines and herbal products
 - (b) Schedule D2: Prescription traditional medicines and herbal products
 - (5) Schedule E: Medicinal products for veterinary use
 - (a) Schedule E1: Non-prescription medicines for veterinary use
 - (b) Schedule E2: Prescription medicines for veterinary use
 - (6) Schedule F: Vaccines and Biologicals
 - (7) Schedule G: First Aid Medicines
 - (8) Schedule H: Health or Feed Supplements
269. The following criteria shall be applicable for categorization of medicinal product as Schedule A1/Over-the-counter medicine:
- (1) medicines with no serious side effects or major systemic side effects and do not require constant medical supervision;
 - (2) medicines with wide therapeutic window/range/safety margin, and do not require injectable for administration;
 - (3) conventional medicines which have well established indications and safety; and
 - (4) non-prescription medicines which shall be available from a pharmacy.

270. The following criteria shall be applicable for categorization of medicinal product as Schedule A2/General sale list:
- (1) product is reasonably safe and can be sold or supplied without the need for supervision by a health professional;
 - (2) contraindications, interactions, precautions and warnings are easily recognised by the consumer; or
 - (3) the hazard to health, the risk of misuse, the risk of misdiagnosis, or the need to take special precautions in the storage and handling of product is small.
271. Schedule A2 may not require registration with the Authority, however; the product imported shall be subject to strict post marketing surveillance.
272. The sale of Schedule A2 medicines products shall not be restricted to Pharmacies only but also permitted from the general stores.
273. 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.
274. Medicines under Schedule C1 and C2 shall be adopted from the Narcotic Drugs and Psychotropic Substance and Substance Abuse Act.
275. Medicines listed under Schedule D2 shall be sold only on the presentation of prescription from a registered Drungtsho.
276. 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.
277. Medicines listed under Schedule F shall be stored under appropriate cold chain conditions required as per the product specification.
278. Medicines listed under Schedule G may be stored for the purpose of providing first aid services in compliance with the conditions set by the Authority.
279. List of Medicinal Products under each schedule may be revised from time to time by the Authority.

CHAPTER XVII

APPEAL AND MISCELLANEOUS PROVISION

Procedures of appeal:

280. 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 working days from the date of issue of the decision.
281. 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 a report of the commission of investigation to the board within thirty working days from the date of formation of the Committee.
282. If an aggrieved is still not satisfied with the decision of the Board, he/she may appeal to the Court of law.

Loss or damage of documents

283. The applicant shall inform the Authority within fifteen working days from the date of notice in case of loss or damage of the authorization, permits or certificates for replacements.
284. The applicant shall apply for the duplicate document using the application form BMRR XIX-LDD along with the fees prescribed under the Annexure I.

Donation of medicinal products

285. The concerned agency shall inform the Authority prior to agreement with the donors and shall abide by the conditions set by the Authority.
286. The agency responsible for negotiating or receiving the medicines shall communicate the regulatory requirements to the donors prior to the agreement.
287. Donation in form of medicines shall be accepted in the following situations:
- (1) Emergency situation (disease outbreaks/shortages of medicines) as determined by Ministry of Health or, Ministry of Agriculture and Forests;
 - (2) Negotiated with the external agencies/governments for providing Essential Medicine; or

- (3) For the purpose of conducting research (provided separate clearance for research is obtained).

288. Conditions for the donated medicines:

- (1) The list of medicines shall preferably be the Essential Medicines List of Ministry of Health or Ministry of Agriculture and Forests;
- (2) The list of medicines other than in Essential Medicines List shall require approval from National Drug Committee or Drugs Technical Advisory Committee;
- (3) The recipient shall ensure that all the regulatory provisions are fulfilled at the time of receiving through Standard Operating Procedure;
- (4) The recipient shall seek Import Authorization from the Authority;
- (5) The medicines shall require adequate labelling as per Product Registration Guideline of DRA and it shall be either in English or the national language of Bhutan(Dzongkha);
- (6) The medicines shall have minimum of 70% of shelf life at the time of importation.
- (7) For products requiring cold chain, the medicines shall be transported in the appropriate containers to maintain the storage requirements;
- (8) The agency responsible for accepting and distribution of the medicines shall be responsible for proper disposal of the expired medicines; and
- (9) DRA shall be responsible for post-market surveillance and the recipient shall be responsible for timely recall and withdrawal.

DEFINITION

In this regulation, unless the context otherwise requires:

1. **Abridged Evaluation route** refers to the route of evaluation of product dossier which fulfils the criteria for Abridge registration.
2. **Accredited laboratory** refers to the laboratory which has been accredited by ISO, ILAC or equivalent Cooperation or body.
3. **Act** refers to the Medicines Act of the kingdom of Bhutan 2003
4. **Adverse Drug Reaction** refers to any noxious, undesired or unintended response to a drug, which occurs at therapeutic dose
5. **Advertisement** refers to any representations conveyed by any means whatsoever for the purpose of promoting directly or indirectly the sale or distribution of any medicinal products including health supplements.
6. **Appellate Laboratory** refers to the 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.
7. **Authority** refers to the Drug Regulatory Authority
8. **Authorized Premise** refers to the premise authorized by the Authority for the manufacture, import, export, sale, distribution, dispensing or storage of medicinal products including health supplements.
9. **Bhutan National formulary** refers to the compilation of list of medicines available in the country with their preparation, properties, uses and effects.
10. **Board** refers to the Bhutan Medicines Board.
11. **Clinical trial** refers to the trial to evaluate the effectiveness and safety of medicinal products by monitoring their effects on large groups of people.
12. **Clinical trial Authorization** refers to the authorization issued to sponsor responsible for conducting the clinical trial.

13. **Competency Exam** refers to the examination conducted for registration as Competent Person.
14. **Competent Person** refers to any person who possesses the requisite qualifications and practical experience prescribed by the Board and is approved to undertake:
- 1) manufacturing of medicinal products;
 - 2) dispensing of medicinal products
 - 3) retail sale of medicinal products;
 - 4) distribution of medicinal products.
15. **Conflict of Interest** refers to a conflict between the official duties and the private interests of a civil servant, including not only his vested interest but also those of his family.
16. **Cosmetics** refers to the preparations designed for use by applying, rubbing, powdering, spraying, or otherwise applying to any part of the body to cleanse or beautify, including skin-care products but excluding ornaments and clothing. It may include substances intended for use as admixtures in the manufacture of cosmetics (Thai guide on cosmetics)
17. **Dedicated facility** refers to the facility within the same building with no common access and with separate heat, ventilation and air conditioning system and having common utilities and waste treatment. It may be in the same floor or may be in different floors.
18. **Drugs Technical Advisory Committee(DTAC)** refers to the committee appointed under section 5.1 of The Medicines Act of the Kingdom of Bhutan 2003
19. **Embargo** refers to the act of sealing the medicinal products by the Drug inspector or any other authorized official for temporary suspension of the sale and distribution of medicinal products.
20. **e-pharmacy** refers to the business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any other electronic mode.

21. **e-pharmacy portal** refers to the web or electronic portal or any other electronic mode established and maintained by the e-pharmacy registration holder to conduct business of e-pharmacy.
22. **Ethical Clearance** refers to the clearance issued by an independent ethics committee prior to conduct of clinical trial.
23. **Expedited Registration route** refers to the route of evaluation of product dossier which fulfils the criteria for Expedited registration.
24. **Export Authorization** refers to the permit to export medicinal products.
25. **Extemporaneous Formulation** refers to the pharmaceutical preparation compounded specifically for a patient.
26. **Feed supplements** refers to products intended for animals containing concentrated sources of nutrients (i.e. mineral and vitamins) or other substances with a nutritional or physiological effect that are marketed in “dose” form (e.g. pills, tablets, capsules, liquids, powders in measured doses)
27. **Full Evaluation Route** refers to the route of evaluation of product dossier which fulfils the criteria for full registration.
28. **Good Manufacturing Practices** refers to the system for ensuring that products are consistently produced and controlled according to quality standards (WHO).
29. **GxP** refers to good practices; where 'X' stands for various fields including manufacturing, distribution, clinical, dispensing, storage and laboratory.
30. **Health Supplement** refers to the product that is used to supplement a diet, with benefits beyond those of normal food, and or to support or maintain the healthy functions of the human body.
31. **Import Authorization** refers to the permit to import medicinal products
32. **Key Personnel** refers to head of production and quality unit in pharmaceutical manufacturing firm

33. **Lot Release** refers to the process of evaluating each individual lot of vaccines before giving approval for its release into the market.
34. **Market Authorization** refers to the product registration.
35. **Market Authorization Holder** refers to the establishment having technical authorization for sale and distribution by wholesale or the product manufacturer or government agency/body.
36. **Medicinal Product** refers to
- 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 disease of any disorder in human beings or animals including vaccines and biologicals;
 - Such substances intended to affect the functioning of any structure found in the human being and animal body;
 - 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 or (allopathic) or traditional system of medicine; and
 - Active Pharmaceutical Ingredients.
37. **National Drug Committee/Veterinary Drug Committee** refers to the committee approved by the Ministry of Health or Ministry of Agriculture and Forests respectively for the purpose of reviewing national drug policy and selection of essential medicines to be used in the government institutional establishments.
38. **New Chemical Entity (NCE)** refers to a drug that contains no active moiety that has been approved by the Authority in any other application submitted
39. **Orphan Drug** refers to any medicinal product that is intended for the treatment of a rare disease or disorder or medical condition in human beings or animals. It shall include the medicines required for the treatment of neglected diseases.
40. **Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S)** Guide refers to the set of guidelines for Good Manufacturing Practices of pharmaceutical products and provides a basis for GMP inspection.

41. **Pharmaceutical Waste** refers to the medicines, biological products (blood, serum, vaccine) which are expired, incompletely used, damaged, spoiled, rejected medicinal products, and recalled medicinal products as defined in the Waste Prevention and Management Regulation 2012.
42. **Pharmacovigilance** refers to the monitoring of Adverse Drug Reaction, Medication Error, Adverse Events Following Immunization and any adverse events of medicinal products and medical devices.
43. **Prescription** refers to the instruction from a Registered medical practitioner to a patient, written by hand or in any electronic mode duly signed, to dispense a drug and quantity of drug to a patient;
44. **Product Dossier** refers to the collection of documents about a particular product generated from the product manufacturer for the purpose of the product registration.
45. **Provisional Technical Authorization** refers to the authorization for setting up a manufacturing plant until it becomes fully operational.
46. **Quantified Product** refers to the list of medicines quantified for the patients based on past consumption and any other criteria set by the Ministry of Health or Ministry of Agriculture and Forests
47. **Registered Medical Practitioner** refers to the person who possesses the requisite qualifications and practical experience prescribed by the Bhutan Medical and Health Council and is approved/registered to practice medicine.
48. **Sale by way of e-pharmacy** refers to the sale whether to a hospital, or dispensary, or a medical, educational or research institute or to any other person through e-pharmacy by way of retail sale.
49. **Seizure** refers to the act of seizing the medicinal products by the Drug Inspectors or any authorized officials.
50. **Special product** refers to the products similar/related to vaccines and biologicals which may require lot release.

51. **Sponsor** refers to the applicant who submits the application for clinical trial authorization.
52. **Standard Operating Procedures** refers to the written procedures that accurately describe and detail essential job tasks.
53. **Tampering** refers to intentional damage caused to the packaging materials of the embargoed or seized medicinal products or forceful opening of the embargoed or seized products.
54. **Technical Authorization** refers to the authorization issued to establishment responsible for manufacture or sale and distribution of medicinal products.
55. **Technical clearance** refers to the clearance issued to establishment responsible for stocking and dispensing of medicinal products without involvement of sale.
56. **Traditional Medicines** refers to the traditional medicines practice in Bhutan.

APPLICATION FORMS AND ANNEXURE

ANNEXURE - I: SCHEDULE OF FEES

Sl. No.	Type of services/certification fees	Amount
1.	Application for Clinical Trial Authorization	Nu.5000/-
2.	Application for Provisional Authorization for Manufacturing (PAM).	Nu.5000/-
3.	Application for Technical Authorization for Manufacture (TAM).	Nu.5000/-
4.	Application for renewal of PAM and TAM	Nu.1000/-
5.	Application for Technical Authorization (TA) Sale and Distribution	Nu.1000/-
6.	Application for renewal of TA for Sale and Distribution	Nu. 1000/-
7.	Application for change of ownership, location, firm name and Competent Person	Nu. 500/-
8.	Application for registration of Competent Person	Nu. 500/-
9.	Application for renewal of registration of Competent Person	Nu. 500/-
10.	Application for Product Registration	Nu. 500/-
11.	Application for renewal of Product Registration	Nu. 500/-
12.	Issuance of Product Registration Certificate	Nu. 1500/-
13.	Application for Post-approval Variation	Nu. 500/-
14.	Application for Product registration transfer	Nu. 500/-
15.	Application for Listing of Health Supplements or Feed Supplements	Nu. 500/-
16.	Issuance of duplicate documents	Same as original fees

Form: BMRR I-DTL

CERTIFICATE OF ANALYSIS

AR No.:

Date:

Name of Sample:

Batch No.:

Mfg. Date:

Exp. Date:

Manufactured by:

Sample received on:

Sample Quantity received:

Sampling by:

Sample ID:

Composition:

TEST	OBSERVATIONS	STANDARDS	Results

Remarks: The sample (*Complies/does not comply*) with respect to the test parameters mentioned above.

*****End of Report****

Analyzed by:

Verified by:

Name:

Name:

Date:

Date:

Form: BMRR II-CTA

APPLICATION FOR CLINICAL TRIAL AUTHORIZATION

Part I: Details of the Trial Applicant

a. Name	
b. Organization	
c. Address	
d. Phone Number	
e. E-mail	

Part II: Details of the Trial Sponsor *(Skip this section if trial sponsor and applicant are same)*

a. Name	
b. Organization	
c. Address	
d. Phone Number	
e. E-mail	
f. Status of the sponsor (Commercial or Noncommercial)	

Part III: Details of the Trial

a. Full Title of the Trial:	
b. Objectives of the trial:	
c. Trial Type (Phase I, Phase II, Phase III, Phase IV):	
d. Design of the Trial:	
e. Group of Trial Subjects:	
f. Planned Number of subjects to be included:	
g. Age Range of Trial Subjects:	
h. Gender of Trial Subjects:	
i. Investigational Medical Product(IMP) to be tested:	
j. Investigational Medical Product (IMP) used as a comparator:	
k. Clinical Trial Site:	
l. Expected Duration of the Trial:	

The prescribed fee has been deposited to the Royal Government of Bhutan
(Please submit a copy)

In support of this application, following documents are enclosed:

1. *Clinical Trial Protocol as per Good Clinical Trial Practice Guideline prescribed by the Authority.*
2. *Ethical Clearance from independent ethical committee identified by the Authority.*

Applicant Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no.:

Date:

Form: BMRR III-PAM

**APPLICATION TO SET UP A MANUFACTURING PLANT FOR
MEDICINAL PRODUCTS**

I/we.....of.....

..

hereby apply for the grant/renewal of a provisional authorization to set up a manufacturing plant for medicinal products, and I have attached the following documents(Circle the appropriate one)

1. *Principle approval letter from DRA:*
2. *Detail Plant lay out with description:*

The Plant is expected to be operational with effect
from.....

Application fee has been deposited to the Royal Government of Bhutan
(*Please submit a copy*)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR IV-FAM

**APPLICATION FOR TECHNICAL AUTHORIZATION FOR
MANUFACTURE OF MEDICINAL PRODUCTS**

I/we.....of..... hereby
apply for the grant/renewal of authorization to manufacture the medicinal products
as the following firm is ready for production;

Name of the firm:

Location/Address of the firm:

Provisional Authorization no. :

(As issued by DRA)

Expected dated of Operation:

(If different from what was indicated on the Provisional Authorization application):

Name of the Proposed Competent Person(s):

Production Manager:

Quality Assurance Manager:

List of Products intended for manufacture:

(Please use additional sheet)

List of standard operating procedures:

(Please use additional sheet)

The prescribed fee has been deposited to the Royal Government of Bhutan

(Please submit a copy)

Declaration (please tick the boxes):

☐ I hereby declare that the documents submitted above/all information
provided in the document above is true to my knowledge and will be liable
for any consequences if any information provided is proved to be false or
misleading.

☐ I declare that I have read the regulation and I am fully aware that my
application may be rejected if I do not fulfill the conditions or contravenes
the provision(s) of the act and regulations made there under.

☐ If my application is granted, I shall abide by the Medicines Act and
Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR V-TAS

**APPLICATION FOR AUTHORIZATION
TO SELL OR DISTRIBUTE MEDICINAL PRODUCTS**

I/we.....hereby apply for grant/renewal of authorization to sell by
Retail/Wholesale of medicinal products. (*Circle whichever is applicable*)

i. Proposed name of the firm:

Location.....

ii. Category of medicines(*please tick the appropriate category*);

a) Human modern/allopathic medicines

b) Veterinary

c) gSo-ba-rig-pa.

iii. State the name of the Competent Person or the employee(s), who shall supervise
the sale of medicinal products.

Name(s):

Competent Person Registration Number:

Application fee has been deposited to the Royal Government of Bhutan

(*Please submit a copy*)

Declaration (please tick the boxes):

☐ I hereby declare that the documents submitted above/all information provided in the
document above is true to my knowledge and will be liable for any consequences if
any information provided is proved to be false or misleading.

☐ I declare that I have read the regulation and I am fully aware that my application may
be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act
and regulations made there under.

☐ If my application is granted, I shall abide by the Medicines Act and Regulations and
any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR VI-TC

**APPLICATION FOR TECHNICAL CLEARANCE
FOR STOCKING AND DISTRIBUTION OF MEDICINAL PRODUCTS**

I/we hereby apply for grant of technical clearance to stock and distribute medicinal products.

i. Name of the firm:

Location:

ii. Category of medicines(*please tick the appropriate category*);

a) Human modern/allopathic medicines

b) Veterinary

c) gSo-ba-rig-pa.

iii. State the name of the Competent Person or the employee(s), who shall supervise the sale of medicinal products.

Name(s):

Competent Person Registration Number:

Declaration (please tick the boxes):

☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.

☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR VII-OC

**APPLICATION FOR CHANGE OF OWNERSHIP/NAME OF
PHARMACY/COMPETENT PERSON /LOCATION**

I/we of apply
for the change of ownership/name of Pharmacy/name of Competent
Person/location for the following Pharmacy. (Circle the appropriate one)

Sl. No	Existing Name	Proposed Name

Application fee has been deposited to the Royal Government of Bhutan
(*Submit a copy*)

NB: A maximum of two changes is permitted per application.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR VIII-CP

APPLICATION FOR REGISTRATION AS A COMPETENT PERSON

I,.....hereby apply for grant/renewal of registration as a Competent Person to manufacture / sell by retail / sell by *wholesale (*Circle the appropriate one*) and the following certificates and documents are attached herewith.

☐ Certificate from the Council or with a letter of recognition from equivalent agency

☐ Copy of the Identity Card

☐ Two Recent passport size photos

Application fee has been deposited to the Royal Government of Bhutan
(*Please submit a copy*)

Signature of applicant:

Name, address, contact no:

Date:

Form: BMRR IX-ARM

APPLICATION FOR ABRIDGE REGISTRATION OF MEDICINES

I/wehereby apply for abridged registration of the product specified below for sale/distribution in Bhutan.

The product has been approved by one of the PIC/S member countries; or by International agencies.

Name of the country(s)/agency(s):

.....

Product	Pack size	Composition (With Strength)	Manufacturer

Market Authorization Holder/Direct Manufacturer:

Application fee has been deposited to the Royal Government of Bhutan
(Please submit a copy)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR X-EPR

APPLICATION FORM FOR EXPEDITED REGISTRATION OF MEDICINES

I/We hereby apply for expedited registration of the product specified below for sale/distribution in Bhutan as per the Product Registration Guideline.

In support of registration of medicinal product by above process, following documents are attached:

- i. Letter of Authorization from the Manufacturer.
- ii. Specimen of package, label and insert.
- iii. Product Samples
- iv. Price structure Details of Medicinal Product

(Use one application per product)

Product	Pack Size	Composition with strength	Manufacturer

Market Authorization Holder/Direct Manufacturer:

.....

Application Fee has been deposited to the Royal Government of Bhutan

(Please submit a copy)

I hereby declare that following conditions are fulfilled: (Tick the box):

- ☐ Minimum of 5 products with valid registration status registered with DRA for minimum of 2 years at the time of application;
- ☐ No past record of product recall or withdrawal from Bhutan (voluntarily recalls by Manufacturers do not apply);
- ☐ Not more than 2 post registration change applied for a single product in one year;

- ☐ For parenteral, at least one parenteral product to be registered amongst the 5 valid.

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR XI-FRM

APPLICATION FOR FULL REGISTRATION OF MEDICINES

I/wehereby apply for registration of the product specified below for sale/distribution in Bhutan.

Type of medicines (*Circle the appropriate one*):

- i. Allopathic
- ii. gSo-ba-rig-ba
- iii. GSL
- iv. Veterinary

Details of Medicinal Product (*Use one application per product*)

Product	Pack	Composition (With Strength)	Manufacturer

Market Authorization Holder/Direct Manufacturer:

Application fee has been deposited to the Royal Government of Bhutan

(*Please attach copy*)

Declaration (*please tick the boxes*):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR XII-PAV

APPLICATION FOR POST APPROVAL VARIATIONS OF MEDICINES

I/wehereby apply for post registration of the product for the details below:

Product Registration Number:

Name of the Product:

Proposed Variations (*Circle the appropriate changes*):

- a. Shelf life or stability data,
- b. Packaging specification and pack sizes,
- c. Dosage regimen,
- d. Additional indication and target species,
- e. Price structure,
- f. Market authorization holder and/or
- g. other minor changes(*Please specify the details*)

Application Fee has been deposited to the Royal Government of Bhutan
(*Please submit a copy*)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR XIII-PRR

APPLICATION FOR RENEWAL OF REGISTRATION OF MEDICINES

I/wehereby apply for renewal of registration
of the product specified below for sale/distribution in Bhutan.

Product Registration no:

Name of the product:

Date of Expiry of the Registration:

Product	Pack Size	Composition with strength	Manufacturer

Name of the Market Authorization Holder:.....

Application fee has been deposited to the Royal Government of Bhutan
(Please attach copy)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR XIV-LS

APPLICATION FOR LISTING OF SUPPLEMENTS

I/we.....hereby apply for listing of following Health
Supplements manufactured
by.....
....

Details of Health Supplement (*Use one application per product*)

Name of Product	Pack size	Intended Use/Indication as printed on label and leaflet	Major ingredients

Application fee has been deposited to the Royal Government of Bhutan
(*Please submit a copy*)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

BMRR XV-IA

**APPLICATION FOR AUTHORIZATION TO IMPORT MEDICINAL
PRODUCT(S) FOR SALE/DISTRIBUTION**

I/we,hereby apply for authorization to
import for following medicinal products in Bhutan for sale and distribution.

Sl. No.	Product Name	Registration No.	Registration validity	Manufacturer	Pack size

Address of the premise(s)/Store(s):

Is the product registered by the applicant? Yes ☐ No ☐
(Please tick the appropriate box)

(Please attach the following Documents)

- a. Copy of Proforma invoice or evidence for the source of distribution
(if the product is not registered)
- b. No Objection letter from the Market Authorization holder in case the
importer is different from the Market Authorization holder.

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information
provided in the document above is true to my knowledge and will be liable
for any consequences if any information provided is proved to be false or
misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my
application may be rejected if I do not fulfill the conditions or contravenes
the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and
Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

Form: BMRR XVI-EA

**APPLICATION FOR AUTHORIZATION TO EXPORT MEDICINAL
PRODUCT(S)**

I/we, hereby apply for a authorization to
export for following medicinal products for sale and distribution.

Sl. No.	Product Name	Pack	Composition (With Strength)	Registration No.

Address of the premise(s)/Country(s) where it is to be exported:

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information
provided in the document above is true to my knowledge and will be liable
for any consequences if any information provided is proved to be false or
misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my
application may be rejected if I do not fulfill the conditions or contravenes
the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and
Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

APPLICATION FOR CLEARANCE FOR ADVERTISEMENT OF MEDICINAL PRODUCTS

I/we hereby apply for authorization to advertise the following medical product;

i. Detail of the Product:

- a) Product Name:
- b) Product Registration no.:
- c) Market Authorization Holder:

ii. Contents of the Advertisement:

.....
.....
.....

(Use additional sheet if required)

iii. Advertisement platform *(how it will appear to the public)*:

.....
.....

(Use additional sheet if required)

iv. Copy of the Clinical Evidence of the product applied for (if any)

Declaration (please tick the boxes):

☐

I hereby declare that the documents submitted above/all information provided is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

☐

If my application is granted, I shall abide by the Medicines Act and Medicines Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

FOR OFFICE USE

- i. Verified by *(Name and Signature)*:
- ii. Approved/Not approved/Cancelled/Do not require approval.....
- iii. Approval date.....

APPLICATION FOR VACCINES LOT RELEASE

I/We.....hereby apply for Lot Release of following vaccine.

Vaccines Information	Generic Name:	
	Trade Name:	
	Lot Number:	
	Lot Size/Quantity:	
	Manufacturer:	
	Arrival Date:	
	Expiry Date:	
	Port of entry:	
	Diluent (If applicable):	
	Diluent lot No (If applicable):	
	Storage conditions:	
Applicant Information	Market Authorization Holders Name and Address	
	Name of contact person and phone number:	
Address of the vaccine stored:		

Is the Vaccine registered with DRA? **YES** ☐ **NO** ☐ (Please tick the appropriate boxes).

(Please attach the following document)

- a) Lot Release Certificate from country of origin
- b) Lot Summary Protocol
- c) Certificate of Analysis (COA) for Finished Products
- d) Importing Packing List
- e) Airway bill

I hereby declare that all information provided on this application is complete, true and correct to the best of my knowledge and will be liable for any consequences if any information provided is proven to be false or misleading.

Signature of applicant:
Name, address, contact no:

Date:.....

Form: BMRR XIX-LDD

**APPLICATION FOR ISSUANCE OF DUPLICATE COPY OF
DOCUMENTS**

I,.....hereby apply for issuance of duplicate
copy of document.

Duplicate copy request for
.....

Authorized by the proprietor.....
.....

Application fee has been deposited to the Royal Government of Bhutan
(Please submit a copy)

Declaration (please tick the boxes):

- ☐ I hereby declare that the information submitted above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that this is a genuine case of replacement of the document and I will be liable for consequences if it is found to be otherwise.
- ☐ I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:
Name, address, contact no:

Date:

DRUG REGULATORY AUTHORITY

Towards promoting consumer's confidence in medicinal products

Drug Regulatory Authority
Royal Government of Bhutan
P.O. Box No. 1556
Thimphu, Bhutan

Phone: +975-2-337074/337075
Fax: +975-2-335803
Website: <http://dra.gov.bt>



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MEDICAL DEVICE
CONSULTING
SERVICES



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CENTER



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ECENTEROF
MEDICAL DEVICE



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