BHUTAN MEDICINES RULES AND REGULATION 2025

BHUTAN FOOD AND DRUG AUTHORITY

Vision:
Excellence in protecting and advancing the health and safety of the Nation.

Mission:
To protect the health of human, animals, plants and environment by ensuring:
1. Safety and quality of food and agricultural products;
2. Effective plant and animal biosecurity systems;
3. Quality, safety and effectiveness of medical products; and
4. Reduce supply and demand of controlled substances.

BHUTAN MEDICINES RULES AND REGULATION 2025

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 Rules and 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.

In this Regulation, the medicinal products hereafter referred to include all the products classified under Schedule I of these Rules and Regulation.

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CHAPTER I
PRELIMINARY

Short Title

1. These Rules and Regulation shall be called the Bhutan Medicine Rules and Regulation 2025.

Commencement

2. These Rules and Regulation shall come into effect on 21st February 2026, corresponding to the 4th day of the 1st month of the Fire Male Horse Year of the Bhutanese Calendar.

Extent

3. These Rules and Regulation shall extend within the Kingdom of Bhutan.

Application

4. These Rules and Regulation shall apply to all medicinal products listed in Schedule I.

Purpose

5. The purpose of these Rules and Regulation shall be to:

   (1) regulate all medicinal products to ensure quality, safety and efficacy/effectiveness;

   (2) promote access and availability of safe and quality medicinal products; and

   (3) promote transparency and efficiency in the services provided by the Authority.

Supersession

6. Upon coming to force of these Rules and Regulation, the Bhutan Medicines Rules and Regulation 2019, notifications and circulars concerning the subjects shall be superseded.

Rules of Construction

7. In these Rules and Regulation, unless the context indicates otherwise, the singular shall include the plural and the masculine shall include the feminine and vice versa.

CHAPTER II
GOVERNING BOARD AND DRUGS TECHNICAL ADVISORY COMMITTEE

Composition of the Governing Board

8. The Civil Service Reform Act of Bhutan 2022 under section 13 repealed the Boards under all the existing ministries, subsequently the Lhengye Zhungtshog vide letter no. C-3/6(5)/2024/48 dated 26th March, 2024 and the Royal Civil Service Commission vide letter no. LTD/1/COM/2024/3331 dated 1st April, 2024, constituted the Bhutan Food and Drug Authority Governing Board comprising of the following members:

(1) Minister, Ministry of Health as Chairperson;

(2) Director, Department of Agriculture, Ministry of Agriculture and Livestock as Member;

(3) Director, Department of Livestock, Ministry of Agriculture and Livestock as Member;

(4) Director, Department of Trade, Ministry of Industry, Commerce and Employment as Member;

(5) Director, Department of Health Services, Ministry of Health as Member;

(6) Secretary General, Bhutan Chamber of Commerce and Industries as Member;

(7) Superintendent of Police, Integrated Check Post Management, Royal Bhutan Police as Member;

(8) Director, Department of Forest and Park Services, Ministry for Energy and Natural Resources as Member; and

(9) Director, Bhutan Food and Drug Authority, Ministry of Health as Member Secretary.

Powers and functions of the Governing Board

9. The Governing Board 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;

(3) appoint a relevant person to replace the member terminated under section 8 (2) of this Regulation.

(4) serve as strategic oversight body to Bhutan FDA to provide strategic directives for the Regulation of cross-sectoral categories of products and services that transcend various ministries and agencies;

(5) serve as an apex decision making body for resolving any matters related to Regulation of products under the purview of Bhutan FDA;

(6) facilitate mobilization of adequate resources to ensure efficient and effective regulatory services;

(7) approve policies and Regulations based on recommendation from technical advisory committee and in line with national and international standards for Regulation of products under purview of Bhutan FDA;

(8) endorse new testing, reference and appellate laboratories for analysis of the products under the purview of Bhutan FDA;

(9) endorse the amendment of any prescribed fees, fines and penalties for any regulatory services as and when necessary upon recommendation of the Bhutan FDA;

(10) coordinate national response to take appropriate actions/ measures at times of biosecurity, food safety and public health emergencies;

(11) constitute Drug Technical Advisory Committees to advise the Board on technical matters arising out of the administration of regulatory functions; and

(12) at any time, on disciplinary grounds and abuse of power may suspend or terminate any member of the technical committees constituted, and appoint another appropriate person to replace the member and such person shall serve for the remaining term of the membership.

Drugs Technical Advisory Committee (DTAC)

Composition of DTAC

10. The Drugs Technical Advisory Committee constituted under section 5.1 of the Act shall consist of the following members:

(1) Chairperson, National Drugs Committee---ex officio;

(2) Chairperson, National Veterinary Drug Committee---ex officio;

(3) One qualified medical doctor nominated by the Health Ministry;

(4) One qualified veterinary doctor nominated by the Agriculture Ministry;

(5) One Drungtsho nominated by the Health Ministry;

(6) One qualified Pharmacist nominated by the Health Ministry;

(7) The Principal Pharmacist, Department of Health Services---ex-officio

(8) The Government Analyst, Drug Testing Laboratory---ex officio;

Procedure

11. 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 Vice-chairperson of the committee shall be elected on an annual basis among themselves;

(3) in absence of the Chairperson, the Vice-chairperson shall chair the meeting;

(4) the Authority may recommend the Chairperson to invite co-opt members as and when required;

(5) the members shall attend the meeting;

(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 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.

12. The meeting shall convene only with a quorum of two third of the members.

13. The committee shall meet from time to time as required to transact its business but shall meet at least thrice a year.

Functions

14. In accordance with section 5.1 and section 9 of the Act, the committee shall:

(1) provide advice to the Governing Board on all technical areas related to Regulation of medicinal products and other technical matters as and when required by the Governing Board;

(2) recommend to the board on declaration of any article as a medicinal products; and

(3) carry out any other functions assigned by the Governing Board.

CHAPTER III
BHUTAN FOOD AND DRUG AUTHORITY

Establishment of the Authority

15. The Drug Regulatory Authority established under section 10 of the Medicines Act of the Kingdom of Bhutan 2003 shall be the Bhutan Food and Drug Authority in accordance with section 26 of the Civil Service Reform Act 2022.

Powers and functions of the Bhutan Food and Drug Authority

16. 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, export, storage, sale, dispensing, distribution, price, advertisement and promotion of medicinal product;

(2) register medicinal product and Competent Person;

(3) authorize premise for manufacture, storage, sale, dispensing and distribution;

(4) develop standards and guidelines required for implementation of this Regulation;

(5) maintain national registry of medicinal products and Competent Person;

(6) carry out inspection, sampling, vigilance and lot release of medicinal products;

(7) oversee clinical trials process;

(8) designate drug testing laboratory and an appellate laboratory for testing of medicinal products;

(9) investigate complaints made to the Authority as per the prescribed procedure;

(10) recognize international standards for medicinal products;

(11) disseminate relevant safety information and alerts of medicinal products as required;

(12) create awareness on the provisions of the Act and the Regulation;

(13) suspend and cancel registration or authorization of medicinal product, Competent Person and premises;

(14) carry out suo-motu investigation when there is a risk to the public due to quality, safety and efficacy/effectiveness of medicinal products;

(15) impose fines and penalties for non-compliances;

(16) consult with relevant stakeholders during the development, revision or amendment of regulatory frameworks;

(17) liaise with other relevant national and international organizations;

(18) constitute sub-committees, wherever necessary;

(19) communicate any regulatory decisions and notifications to the public or relevant agencies;

(20) plan, coordinate and implement regulatory measures during public health emergencies in collaboration with relevant national and international agencies; and

(21) carry out any other functions in line with the provisions of the Act and Regulation.

17. The Authority may adopt a risk-based approach, when necessary, to carry out the functions defined under section 16 of this Regulation.

Drug Controller

18. As per the section 11 of the Act, the Drug Controller shall refer to the head of the division responsible for medicinal product Regulation under the Authority.

Powers and functions of the Drug Controller

19. In accordance with section 11 of the Act, the Drug Controller, in order to provide leadership for effective implementation of the Act and the Rules and Regulation shall:

(1) set vision and strategy;

(2) secure resources to carry out functions as per these Rules and Regulation;

(3) guide preparation and formulation of policies, plans and guidelines;

(4) approve certificates, authorizations, guidelines, manuals and standard operating procedures; and

(5) carry out any other functions as assigned by the Governing Board or the Authority.

CHAPTER IV
DRUG TESTING LABORATORY

Function of Drug Testing Laboratories

20. In accordance with section 12 and 13 of the Act, the Drug Testing Laboratory shall carry out the following functions:

    (1) test samples of medicinal products forwarded by the Authority for quality assessment;

    (2) maintain adequate facilities for the testing of medicinal products;

    (3) collaborate and recognise national and international testing laboratories and their reports;

    (4) conduct quality monitoring and surveillance of medicinal products; and

    (5) carry out research emerging from issues and threats to quality of medicinal products, develop innovative analytical methods and provide evidence-based recommendations to the Authority.

Appellate Drug Testing Laboratory

21. In accordance with section 13.2 of the Act, the appellate laboratory shall be an independent laboratory to test samples in case of dispute or controversy on the report of analysis issued by the Drug Testing Laboratory.

22. The test result from the appellate laboratory appointed under section 16 of this Regulation shall be final; and if the result is not in favor of the aggrieved party, the party shall bear the entire cost incurred.

Government Analyst

23. 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 relevant fields with minimum five years work experience.

Powers and functions of the Government Analyst

24. The Government Analyst shall:

(1) set the vision and strategy for the laboratory;

(2) approve the quality testing reports of medicinal products generated by the laboratory;

(3) oversee all activities conducted by the laboratory to ensure compliance with established standards;

(4) oversee quality monitoring and surveillance of medicinal products;

(5) lead research initiatives to address emerging challenges in the quality of medicinal products and enhance testing methodologies;

(6) develop and implement laboratory policies, strategic plans, and quality control standards to ensure compliance with national and international regulatory guidelines;

(7) foster collaboration with national and international laboratories, regulatory authorities, and research organizations to improve knowledge sharing, enhance testing practices, and support capacity building; and

(8) perform any other responsibilities assigned by the Board.

CHAPTER V
COMPETENT PERSON

Requirement of Competent Person

25. In accordance with section 19.2 of the Act, any individuals engaged in the manufacture, sale, dispensing or distribution of medicinal products shall require a Competent Person registered with the Authority.

26. Notwithstanding the provisions of section 25 of these Rules and Regulation, only the key personnel engaged in manufacturing of medicinal products shall be registered as a Competent Person with the Authority.

Criteria for registration

27. The Competent Person for manufacturing of Schedule A1, A2, B, C, D, E, F, I1C, I1D, I2C, and 12D medicinal products shall have a minimum of Diploma qualification and 5 years of experience in a field relevant to the scope of medicinal products.

28. The Competent Person for manufacturing of Schedule A3, G, H, I1A, I1B, I2A and I2B medicinal products shall have a minimum of Diploma qualification and 2 years of experience in a field relevant to the scope of medicinal products.

29. Notwithstanding section 27 and 28 of these Rules and Regulation, separate Competent Persons shall be registered for the manufacture of different medicinal products as prescribed in the relevant guideline.

30. The Competent Person for sale and distribution of medicinal products shall have a minimum qualification of following disciplines:

    (1) Certificate course/Diploma/Bachelors in Pharmacy for Human and Veterinary allopathic medicines, Supplements and Medical Devices;

    (2) Certificate course/Diploma/bachelors in Traditional Medicine for Traditional Medicines (gSo-ba-rig-pa);

    (3) Certificate course/Diploma/bachelors in Nutrition for category II and III Supplements;

(4) Certificate course/Diploma/Bachelors for Veterinary/Animal Sciences for Veterinary allopathic medicines;

(5) Certificate course/Diploma/Bachelors in health sciences for Medical Devices; or

(6) any qualification as determined by the Authority.

Procedures for registration

31. Any individual who wishes to register as a Competent Person with the Authority shall apply in prescribed form BMRR I-CP along with relevant documents.

32. An individual who possesses the required qualification under section 27, 28 and 30 of these Rules and Regulation shall be eligible to sit for competency exam as set by the Authority and pay the fees as prescribed under the Schedule II of these Rules and Regulations.

33. The Authority shall issue registration certificates within a defined timeline in a prescribed format and the validity of the certificate shall be a maximum of five years or at par with that of certification issued by relevant agency.

34. Notwithstanding section 33 of this Regulation, the validity of certificate for the Competent Person at the age of seventy years and above shall be one year.

Renewal of registration certificate of Competent Person

35. The Competent Person shall apply for renewal of registration in the prescribed form BMRR I-CP along with relevant documents and pay the fees as prescribed under the Schedule II of these Rules and Regulation.

36. The Authority shall renew the Competent Person registration certificate based on the validity of the initial registration certificate without having to sit for examination.

37. The Competent Person at the age of seventy years and above shall renew the certificate annually with the valid Medical Fitness Certificate along with fee prescribed in Schedule II of these Rules and Regulation.

38. Upon expiry of the certificate of Competent Person, a grace period of 30 calendar days shall be granted after which the renewal shall be done with a daily fine of minimum wage for maximum of 30 calendar days.

39. Irrespective of the date of renewal, the validity of the renewed certificate shall be considered from the actual date of expiry of the last certificate or at par with that of certification issued by the relevant agency.

Duties of Competent Person

40. The Competent Person engaged in the manufacture, sale and distribution of medicinal products under this Regulation shall, where applicable:

(1) maintain cold chain conditions for the medicinal products if such products are stored or distributed or dispensed;

(2) not be involved in sale and distribution of unauthorised medicinal products;

(3) securely store the controlled medicinal products under lock and key;

(4) not manipulate the documents submitted to or issued by the Authority;

(5) not misuse the registration certificate issued by the Authority;

(6) segregate and label the expired, recalled and defective medicinal products and any other medicinal products declared by the Authority;

(7) dispense medicinal products other than those listed under Schedule A1, A2, D1 and E1 of this Regulation only upon presentation of lawful prescriptions;

(8) maintain copies of the prescription for sale of drugs under schedule C and antimicrobials of this Regulation till the authorised official verifies during inspection;

(9) not change the figures and information in the prescription without consulting the prescriber;

(10) maintain valid Adverse Events Following Immunization (AEFI) or Adverse Event Following Vaccination (AEFV) kit, if engaged in vaccination;

(11) not prescribe medicinal products;

(12) ensure that the premises where medicinal products are stored or dispensed or distributed have adequate space, ventilation and lighting;

(13) keep records of temperature and relative humidity at least twice daily;

(14) store the medicinal products in the temperature and humidity as specified by the manufacturer;

(15) maintain cleanliness of store, dispensary, compounding areas and, the furniture and apparatus in contact with medicinal product;

(16) maintain inventory of medicinal products as prescribed in the guideline intended for the purpose and ensure that physical quantity and ledger balance of the medicinal products tally;

(17) properly segregate and arrange the medicinal products with appropriate labels;

(18) develop and implement Standard Operating Procedures required in the handling and management of medicinal product;

(19) dispense and store medicinal products as prescribed in the guideline and standard intended for the purpose;

(20) not keep medicinal products in direct contact with the floor (where applicable);

(21) notify the Authority in the event of resignation or change in any information of initial certification issued by the Authority;

(22) carry out the duties of Competent Person only for the premise specified in the certificate;

(23) dispense medicinal products in appropriate packaging material;

(24) 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.

(25) sell the medicinal products at or below Maximum Retail Price (MRP);

(26) submit CAPA plan within specified timeline;

(27) containers used for storing the medicines shall be appropriate for the intended purpose and labeled accordingly;

(28) make a list of medicinal product wastes and dispose it as prescribed in the guideline intended for the purpose;

(29) at all times wear an apron with a name tag at the workplace;

(30) submit self inspection reports at least once in a year;

(31) sign or stamp the prescription with the pharmacy seal after dispensing the medicine;

(32) ensure proper counselling on the use of dispensed medicinal products; and

(33) provide unhindered access to the Inspector to enter with or without prior notice.

41. In addition to duties under section 40, the Competent Person for wholesale premises for medicinal products shall be responsible for carrying out duties under section 134 of these Rules and Regulation.

42. In addition to duties under section 40, the Competent Person engaged in the extemporaneous preparations shall:

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

(2) have Standard Operating Procedure and documented records which shall include name of the product, quantity, preparation date, expiry date, prepared by, and initial of the compounder for the extemporaneous preparation including the compounding formula;

(3) ensure appropriate labelling of the extemporaneously prepared products which shall include the name of the product, strength, storage conditions, preparation date and expiry date; and

(4) ensure that extemporaneously prepared products are dispensed in appropriate packaging.

43. In addition to duties under section 40, the Competent Person engaged in manufacture of medicinal products under this Regulation shall:

(1) ensure availability and implementation of Standard Operating Procedures and other documents necessary for consistent operation of the premise;

(2) monitor and control the manufacturing and storage environment;

(3) ensure proper cleanliness, sanitation and hygiene of premise, equipment and personnel;

(4) retain all the necessary documents and records; and

(5) manufacture medicinal products in compliance with current good manufacturing practices (cGMP) or any other quality system requirements.

Deregistration of the Competent Person

44. The Competent Person shall be deregistered on the following grounds:

    (1) convicted by the court of law resulting from professional misconduct/negligence as notified by the relevant agency;

    (2) defaulted timely renewal beyond the period stipulated in section 38 of these Rules and Regulation; or

    (3) any other reasons determined by the Authority at the time of deregistration.

45. The Competent Person may also voluntarily deregister and shall surrender the certificate to the Authority.

46. Any application for a Competent Person registration following the de-registration under section 44 will be considered as a new application.

CHAPTER VI
TECHNICAL AUTHORIZATION FOR MANUFACTURE

Requirements of Technical Authorization for Manufacture

47. In accordance with section 21 of the Act, all medicinal products to be manufactured in the country shall require prior approval from the Authority.

48. The Provisional Technical Authorization for Manufacture (PAM) shall be a prerequisite for obtaining a license from the relevant agency for manufacturing any medicinal products.

49. The Authority shall grant PAM prior to granting Technical Authorization for Manufacture (TAM).

50. The PAM shall be granted only if the proposal and plant layout meet the standards specified as prescribed in the relevant guideline.

51. For the TAM, the premises shall be completed as per the approved layout and ready for implementation of the quality system that incorporates current Good Manufacturing Practices (cGMP) or any other equivalent standard.

52. Depending on the type of the medicinal products intended for manufacture, manufacturers shall have appropriate facilities and equipment installed.

53. All the manufacturers shall conform to standards specified by the Authority as prescribed in the relevant guideline.

54. All manufacturers shall submit the performance report of their medicinal product to the Authority as prescribed in the relevant guideline.

55. A separate building shall be required for production of beta lactam products. The distance between the facility manufacturing beta lactam and other classes of medicinal products shall conform to standards specified by the Authority.

56. For manufacture of steroid, sex hormone, cytotoxic and immunosuppressant groups of medicinal products, a dedicated facility shall conform to standards specified by the Authority as prescribed in the relevant guideline.

Procedure

57. Any applicant intending to set up a plant for manufacturing medicinal products shall apply to the Authority in form BMRR II-PAM and pay the fees as prescribed under the Schedule II of these Rules and Regulation.

58. The applicant shall submit the documents as prescribed in the relevant guideline.

59. The Authority shall grant PAM upon fulfilment of the requirements.

60. The PAM with validity of two years shall be issued in prescribed format within the defined timeline for setting up the manufacturing plant.

61. The applicant shall construct the plant within the validity of the PAM.

62. The Authority shall conduct periodic inspection of the plant during the PAM to monitor the compliance as per the approved design.

63. Once the plant set up is complete, the applicant shall apply to the Authority in form BMRR III-TAM for Technical Authorization for Manufacture and pay the fees as prescribed under the Schedule II of these Rules and Regulation.

64. The Authority shall grant TAM upon conducting authorization inspection of the facility.

65. The Authority shall issue the TAM within a defined timeline in a prescribed format with a validity of five years.

Post-Approval Variation

66. The applicant shall apply Post-Approval Variation for any minor changes to the Authority in form BMRR IV-PAV TAM and pay the fees as prescribed under the Schedule II of these Rules and Regulation.

67. The applicant shall apply for new authorization, if the changes proposed are considered to be major by the Authority.

68. The classification and requirements for Post-approval Variation shall be as prescribed in the relevant guideline.

Renewal of Provisional Authorization and Technical Authorization for Manufacture

69. The application for renewal of Provisional and Technical Authorization for Manufacture shall be submitted in the form BMRR II-PAM and BMRR II-FAM respectively with the fee as prescribed under Schedule II of these Rules and Regulation.

70. Application for renewal shall be submitted within 90 calendar days before the expiry date of the authorization.

71. After the expiry of the authorization, a grace period of 30 calendar days shall be granted after which the renewal shall be done with a daily fine of minimum wage for maximum 30 calendar days.

72. Non-renewal of certificate within the period provided under section 64 of this Regulation shall be cancelled.

73. Provisional Authorization for Manufacture can be renewed only for two times after which it shall be considered as a new application.

74. Irrespective of the date of renewal, the validity of the renewed certificate shall be considered from the actual date of expiry of the last certificate or at par with the validity for the certificate issued by the relevant certification bodies, where applicable.

Suspension or cancellation of Provisional or Technical Authorization for Manufacture

75. The Provisional or Technical Authorization for Manufacture may be suspended when:

    (1) any conditions of the authorization have been contravened;

    (2) repeated deviations from good manufacture practices standards or quality system requirements posing high risk to the consumers as determined by the Authority;

    (3) any minor changes carried out without prior approval from the Authority;

    (4) absence of Competent Person for supervision of the production and/or quality unit; or

    (5) any other conditions as deemed necessary by the Authority.

76. The Provisional or Technical Authorization for Manufacture may be canceled when:

(1) any major changes carried without prior approval from the Authority;

(2) failure to fulfil the requirement for upliftment of suspension within stipulated timeline;

(3) non-renewal of authorizations within the stipulated timeline; or

(4) any other conditions as deemed necessary by the Authority.

77. Technical Authorization Holder for manufacture shall not operate the business during the suspension period and shall not engage in any activities under the Act and these Rules and Regulation.

Issuance of cGMP Certificate

78. The Authority shall issue a certificate of current Good Manufacturing Practices upon fulfilment of all regulatory provisions as per the standards specified by the Authority.

79. The Applicant shall apply for cGMP certificate in form BMRR V-GMP and pay the fees as prescribed under the Schedule II of these Rules and Regulation.

80. The cGMP certificate shall be valid for a period of two years.

Cancellation of cGMP Certificate

81. The Authority may cancel the certificate issued under section 79 of this Regulation under the following conditions:

(1) non-compliance to current Good Manufacturing Practices standards;

(2) repeated confirmed product defects in the domestic or international market; or

(3) any other circumstances as determined by the Authority.

CHAPTER VII
TECHNICAL AUTHORIZATION FOR SALE AND DISTRIBUTION

Requirements of Technical Authorization for Sale and Distribution

82. In accordance with section 24 of the Act, any individual shall obtain approval from the Authority prior to sale and distribution of medicinal products.

83. The Technical Authorization Holder shall conform to the conditions laid down in the Act, these Rules and Regulation and any other conditions as deemed necessary by the Authority.

84. The premises intended for sale and distribution shall have appropriate facilities to store, sale, dispense and distribute medicinal products.

85. The premise shall have Competent Person with relevant qualification for the scope of the medicinal products as per the section 30 of these Rules and Regulation.

86. The Technical Authorization for sale and distribution of medicinal products shall be a prerequisite for obtaining a license from the relevant agency.

Exemption

87. The Authority shall exempt the requirement of Technical Authorization for sale and distribution for premises involved in sale of medicinal products listed under Schedule A3 and Category I health supplements.

Procedure

88. 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 VI-TAS and pay the fees as prescribed under the Schedule II of these Rules and Regulation.

89. In accordance with section 24.1 (b) of the Act, the Authority may verify the proposed site for suitability of the premise.

90. In accordance with section 24.1 (c) of the Act, the Authority shall grant Technical Authorization for sale and distribution in the prescribed format within the defined timeline and shall be valid for five years.

Renewal of Technical Authorization for Sale and Distribution

91. The applicant shall follow section 88 of these Rules and Regulation for renewal of Technical Authorization for sale and distribution.

92. Application for renewal shall be submitted within 90 calendar days before the expiry of the authorization.

93. Upon the expiry of the authorization, a grace period of 30 calendar days shall be granted after which the renewal shall be done with daily fine of minimum wage for maximum of 30 calendar days.

94. Irrespective of the date of renewal, the validity of the renewed certificate shall be considered from the actual date of expiry of the last certificate.

Suspension or cancellation of Technical Authorization for Sale and Distribution

95. The Technical Authorization for sale and distribution may be suspended when:

    (1) any conditions under section 40 and 100 of these Rules and Regulation has been contravened;

    (2) deviation from GxP standards posing high risk to the consumers as determined by the inspection report; or

    (3) as determined by the Authority.

96. The Technical Authorization for sale and distribution may be suspended until conditions for suspension are addressed but not more than 90 calendar days or whichever is earlier.

97. Technical Authorization Holder shall not operate the business during such suspension and shall not engage in any activities under the Act and these Rules and Regulation.

98. The Technical Authorization for sale and distribution may be canceled when:

(1) the authorization is not renewed within stipulated timeline;

(2) the requirements for upliftment of suspension are not fulfilled within stipulated timeline;

(3) the Technical Authorization Holder is convicted by the court of law resulting from professional misconduct or negligence as notified by the relevant agency; or

(4) as determined by the Authority.

99. If the Technical Authorization is cancelled, a new application from the same applicant shall not be entertained for a period of one year.

Duties of a Technical Authorization Holder

100. The Technical Authorization Holder shall:

(1) ensure that in absence of a Competent Person, the Technical Authorization Holder make alternative arrangements for another Competent Person, with prior written approval from the Authority or else the premise shall remain closed;

(2) ensure that no medicinal products are sold or dispensed in the absence of Competent Person;

(3) ensure that only registered medicinal products shall be imported, distributed, sold, dispensed or stored in the premise;

(4) ensure that a separate compounding area for extemporaneous preparation is maintained with appropriate facilities where applicable;

(5) ensure that a separate room or designated space for extemporaneous preparation of antibiotic or hormones or any other ingredients as determined by the Authority;

(6) ensure certificate or document issued by the Authority is not misused or manipulated;

(7) not manipulate the documents submitted to the Authority;

(8) provide unhindered access to the Inspector to enter with or without prior notice;

(9) ensure the premises used for the sale and distribution of medicinal products are separate from residential areas and are maintained in a clean and hygienic condition at all times;

(10) ensure that the premises is maintained 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;

(11) ensure only cosmetics, toiletries, hygiene and general health products are sold from the authorized premises in addition to medicinal products. However, these categories of products shall be segregated and arranged separately with appropriate label;

(12) ensure that all medicinal products are stored in a suitable condition or as specified by the manufacturer;

(13) ensure that containers used for storing the medicines are appropriate for the intended purpose and labeled accordingly;

(14) ensure that the signboards as specified by the Authority are available for an authorised premise at all times;

(15) ensure that the Corrective Action and Preventive Action (CAPA) is submitted in stipulated timeline;

(16) ensure all medicinal products shall be sold at or below the Maximum Retail Price (MRP) submitted to the Authority at the time of registration;

(17) ensure that the vehicles or containers used for transportation or distribution of medicinal products are appropriate for the intended purpose;

(18) inform the Authority in writing during temporary closure, and the premises shall not operate during the specified period, with a notice for temporary closure displayed conspicuously;

(19) notify the Authority if the Technical Authorization Holder wants to discontinue the business;

(20) ensure that the Technical Authorization of the premise and certificate of the Competent Person are displayed conspicuously at all times in the premise;

(21) ensure that the room for the designated area is labeled both in Dzongkha and/or English;

(22) implement an effective recall procedure for removing unsafe or non-compliant medicinal products from the market; and

(23) ensure timely renewal of authorization issued by the Authority.

Post-Approval Variation

101. Where a Technical Authorization Holder of a premise wishes to change the ownership of Technical Authorization or the location of the premise or name of premise or Competent Person, the applicant shall do so by applying to the Authority.

102. The applications for change as per section 101 shall be accompanied by the required documents as prescribed in the relevant guideline along with a fee as prescribed in the Schedule II of these Rules and Regulation.

CHAPTER VIII
CLINICAL TRIAL OVERSIGHT

Requirement for clinical trial oversight

103. In accordance with section 5.9 of the Act, the Authority shall regulate all clinical trials that are to be conducted in the country.

104. All clinical trials to be conducted shall require prior approval from the Authority.

105. Notwithstanding section 104 of these Rules and Regulation, the Authority shall authorize clinical trials only during national pressing needs in collaboration with a competent regulatory Authority.

106. The Authority may expedite Clinical Trial Authorization during public health emergencies as prescribed in the relevant guideline.

107. The Authority shall maintain a registry of approved clinical trials and make it available for the public.

108. The Authority may recognize clinical trial data from regional or reference Authority as prescribed in the relevant guideline.

Procedure for Clinical Trial Authorization

109. Any proponent intending to conduct clinical trial in the country shall obtain ethical clearance from the Independent Ethics Committee (IEC) prior to submission of clinical trial application to the Authority.

110. The proponent shall submit to the Authority in the form BMRR VIII-CTA along with required documents based on the categories determined as prescribed in the relevant guideline and the fees prescribed under Schedule II of these Rules and Regulation.

111. The proponent may appoint qualified individuals to be Principal Investigators for the authorized clinical trial.

112. The proponent shall ensure that all trial subjects are monitored for any suspected adverse events and incidents and report within 24 hours to the Authority.

113. The Authority may suspend or terminate an ongoing clinical trial if necessary and provide the reasons in writing.

114. In case of premature or voluntary termination of the clinical trial, the proponent shall notify the Authority with justifications in writing.

Post-Approval Variation

115. The proponent shall notify the Authority of any variations to the original protocol along with documents as per relevant guidelines.

116. The proponent shall submit a new application if there are any major variations from the original protocol as prescribed in relevant guidelines.

117. The proponent shall implement any variation to the original protocol only after approval from the Authority.

Duties of Proponent

118. The proponent shall:

(1) develop a scientifically sound and ethically appropriate protocol;

(2) ensure the protocol is reviewed and approved by independent ethics committees and the Authority;

(3) ensure the trial is conducted ethically, scientifically, and in compliance with ethical and regulatory requirements;

(4) ensure proper closure of the trial and notify the Authority;

(5) prepare and submit a final report summarizing the trial's results and findings; and

(6) perform any other duties as per international good clinical practices and relevant guidelines.

Duties of Principal Investigator

119. The Principal Investigator shall:

(1) ensure the trial is executed according to the protocol at approved site as per Good Clinical Practice guidelines or internationally approved standards;

(2) monitor participants for adverse events and ensure appropriate medical care if necessary;

(3) ensure essential documents are available for inspection by the Authority;

(4) continuously assess the risk-benefit balance of the trial;

(5) provide all required documentation and reports to the Authority; and

(6) perform any other duties as per international good clinical practices and relevant guidelines.

CHAPTER IX
MARKETING AUTHORIZATION FOR MEDICINAL PRODUCTS

Categorization of Medicinal Products

120. The medicinal products shall be classified based on the risk to the consumers and degree of complexity on the storage of medicinal products into schedules A to I as per Schedule I of these Rules and Regulation.

Requirements of Marketing Authorization for Medicinal Product

121. 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 as per the conditions and requirements prescribed in relevant guidelines.

122. Any manufacturer or premise authorized for the purpose of sale and distribution or government agencies shall be eligible to apply for registration of medicinal products.

123. Any manufacturer outside the country registering medicinal products with the Authority shall appoint a local authorised premise or agencies based in the country for distribution.

124. The Authority may recognize relevant information on quality, safety and efficacy/effectiveness from reference authorities and international organisations for the purpose of registration of medicinal products.

125. The Authority may reject the registration of medicinal product on the following grounds:

    (1) banned in other countries;

    (2) irrational combination for medicinal product;

    (3) limited evidence of safety and efficacy/effectiveness; or

    (4) any other reasons as deemed appropriate by the Authority.

126. Multiple schedule I medicinal products fulfilling grouping criteria as per relevant guidelines, including the same product name, manufacturer, and intended purpose, may be submitted under one application.

127. Schedule I medicinal products shall demonstrate compliance to essential principles for safety and performance.

128. Separate application shall be required for different formulation, strength, packaging material, manufacturing site of the same medicinal product or for any other requirements as determined by the Authority.

129. In accordance with section 17.10 of the Act, the Authority shall evaluate medicinal product dossiers by the Marketing Authorization Committee (MAC).

130. The MAC shall comprise of at least three experts from relevant fields based on the complexity of medicinal products.

131. In accordance with section 5.11 of the Act, the Board shall constitute a Food and Drug Interface Committee (FDIC) to provide guidance and advice on categorization of Schedule H medicinal products and shall comprise at least three experts from relevant fields.

132. Schedule H medicinal products shall not have any prohibited ingredients or claims as specified in the relevant guidelines.

Responsibilities of Marketing Authorization Holder

133. The Marketing 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) report any Field Safety Corrective Actions (FSCA) carried out and the Field Safety Notice (FSN) issued for Schedule I medicinal products;

(4) notify the Authority of any changes related to products' quality, safety efficacy/effectiveness throughout the product's life cycle in the country; and

(5) carry out any other responsibilities as deemed necessary by the Authority.

Exemption of Marketing Authorization

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

(1) medicinal product for the purpose of clinical trial as approved by the relevant agency or Board;

(2) product sample for the purpose of registration as prescribed in the relevant guideline;

(3) medicinal product for personal use, in a quantity not exceeding the amount stated in the prescription by a registered Medical and Health Practitioner;

(4) medicinal products required in limited quantities for specific diseases on named patient basis;

(5) medicinal products required during the time of public health emergencies notified by relevant agencies;

(6) medicinal products required in limited quantities for approved medical camps;

(7) import of raw materials for the manufacture of medicinal products; or

(8) medicinal products required in limited quantities for time bound government approved projects.

135. The registration exemption shall be granted with the validity extending only until the conditions for the exemption are resolved or until the specified period of exemption expires, whichever comes first.

Application and Marketing Authorization fees

136. The applicant shall apply for Marketing Authorization of medicinal product in forms BMRR X-MA along with application fee prescribed under Schedule II of these Rules and Regulation.

Marketing Authorization certificate

137. The Authority shall issue a Marketing Authorization certificate in the prescribed format for approved medicinal products.

138. The evaluation outcome shall be communicated within a defined timeline from the date of receipt of complete required documents unless otherwise a longer period is required, in which case, the applicant shall be informed.

139. Notwithstanding section 138 of these Rules and Regulation, the Authority may fast-track the process of grant of Marketing Authorization under exceptional circumstances as deemed appropriate.

140. The Marketing Authorization of a product shall be valid for a period of three years which shall be specified on the certificate issued by the Authority.

Post-Approval Variation

141. In case of any variations in the product during the valid period of registration, the Marketing Authorization Holder shall apply for post-approval variation in the form BMRR XI-PAV MA along with the fee prescribed under the Schedule II of these Rules and Regulation.

142. For the purpose of approval of post-approval variation application, the requirements shall be prescribed in the relevant guidelines.

143. Post-approval variation shall be granted within a defined timeline from the date of receipt of complete required documents unless otherwise a longer period is required, in which case, the applicant shall be informed.

Renewal of Marketing Authorization

144. The Marketing Authorization Holder shall apply for renewal of Marketing Authorization within 90 calendar days before the expiry of the authorization using form BMRR X-MA along with the fee prescribed under the Schedule II of these Rules and Regulation.

145. Upon the expiry of the Marketing Authorization, a grace period of 30 calendar days shall be granted for renewal of Marketing Authorization.

146. Failure to renew the Marketing Authorization in accordance with section 145 of these Rules and Regulation, the Market Authorization Holder shall be liable for a fine of daily minimum wage for a maximum of 30 calendar days.

147. Non-renewal of Marketing Authorization within the period provided under section 146 of these Rules and Regulation shall be deemed cancelled.

148. The validity for renewed Marketing Authorization of a product shall be for a period of three years which shall be specified on the certificate issued by the Authority.

Suspension, Cancellation and Withdrawal of Marketing Authorization

149. The Authority shall cancel or suspend a Marketing Authorization if concerns arise regarding the quality, safety, efficacy or overall effectiveness of the medicinal product.

150. The Authority shall suspend the Marketing Authorization in cases where the medicinal product is suspected to pose serious public health hazards and requires further investigation.

151. The Authority shall cancel the Marketing Authorization if:

(1) any of the condition of registration has been contravened or changed;

(2) Market Authorization Holder defaults timely renewal;

(3) the information, which was furnished at the time of application, is later found to be false or misleading and not within the scope of post approval variation;

(4) the suspended medicinal product is found to pose a severe public health hazard;

(5) the premises, in which the product or part thereof is manufactured, packaged or stored by the manufacturer is unsuitable as per required standards; or

(6) in the interest of public safety as deemed necessary by the Authority.

152. The applicant shall submit an application for withdrawal of Marketing Authorization in the prescribed form in BMRR XII-WD MA.

153. The Authority shall not accept Marketing Authorization applications for a particular medicinal product for a period of one year if the Marketing Authorization has been cancelled due to concerns in the quality, safety and efficacy/effectiveness of the medicinal product.

Transfer of Marketing Authorization

154. The Marketing Authorization for a particular medicinal product may be transferred to another Market Authorization Holder during the validity period upon the fulfilment of the following conditions in form BMRR XIII-Trans MA along with prescribed fees under Schedule II of these Rules and Regulation:

(1) letter of authorization from the manufacturer; and

(2) no objection certificate/letter from the current Market Authorization Holder of the product.

CHAPTER X
IMPORT AND EXPORT AUTHORIZATION

Requirements of Import and Export Authorization

155. In accordance with section 22 and 23 of the Act, import and export of any medicinal products shall require an Import and Export Authorization from the Authority.

156. The Authority may conduct laboratory tests of the medicinal products prior to distribution.

Import Authorization

157. The Authority shall grant Import Authorization to the Market Authorization Holder, government agencies, government approved projects, international organization or the individual authorized by the Authority.

158. If the importer is not the Market Authorization Holder for the particular medicinal products, the importer shall obtain no objection certificate from the Market Authorization Holder of the medicinal product for the purpose of sale and distribution.

159. Manufacturers shall obtain Import Authorization from the Authority for raw materials which are required for the manufacture of medicinal products.

160. Import of any Investigational Medicinal Products (IMP) for the purpose of Clinical Trial shall require prior Import Authorization from the Authority.

161. The importer shall be solely responsible for the performance of non-registered medicinal products in the country.

Procedure for Import Authorization

162. The applicant shall submit an application for import authorization to the Authority in Form BMRR XIV-IA accompanying required documents as prescribed in the relevant guideline along with the fee as per the Schedule II of these Rules and Regulation.

163. A single application may be made for import of more than one drug if:

(1) imported from one manufacturer provided the consignment is in one lot; or

(2) imported from more than one manufacturer provided that consignment is in one lot by one external authorized agent.

164. An Import Authorization for medicinal products shall be issued in the specified format as per BMRR AC-VIII and shall be valid for a single import for a 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.

165. Notwithstanding the section 155 of this Regulation, the Import Authorization shall be exempted for any identifiable medicinal products, if:

(1) the products are accompanied by the person with a valid prescription from a registered Medical and Health Practitioner;

(2) the medicinal products under schedule A1 of this Regulation and the quantity does not exceed the required dose for one month;

(3) the medicinal product under schedule A3 of this Regulation; or

(4) medicinal products imported as samples upon fulfilment of conditions prescribed in the relevant guidelines.

Export Authorization

166. The Authority shall grant Export Authorization to a local manufacturer or authorized premise for:

(1) any medicinal products manufactured in the country;

(2) any medicinal products used in clinical trials and health programs or camps for the purpose of re-export; or

(3) any other conditions as determined by the Authority.

167. Export Authorization issued by the Authority shall not substitute a licence issued by the relevant agency.

168. The Authority may reject the application and seize the products based on the risk assessment and products in contravention to the provisions under the Act and this Regulation.

Procedure for Export Authorization

169. The applicant shall submit an application for Export Authorization to the Authority in form BMRR XV-EA accompanying required documents as prescribed in the relevant guideline with the fee as per Schedule II of these Rules and Regulation.

170. A single application may be made for export of more than one drug from one manufacturer provided the consignment is in one lot.

171. 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.

172. Notwithstanding the section 155 of this Regulation, the Export Authorization shall be exempted for any identifiable medicinal products, if:

(1) the products are accompanied by the person with a valid prescription from a qualified and registered Medical and Health Practitioner; or

(2) the medicinal products under schedule A1 of this Regulation and the quantity does not exceed the required dose for one month.

Certificate of Pharmaceutical Product and Free Sale Certificate

173. The Authority shall issue Certificate of Pharmaceutical Product (CPP), upon receipt of the application along with the fee prescribed in Schedule II of these Rules and Regulation.

174. The Authority shall issue a Free Sale Certificate (FSC), upon receipt of the application and fulfilment of requirements as prescribed in the relevant guideline along with the fee as per Schedule II of these Rules and Regulation.

175. The Certificate of Pharmaceutical Product and Free Sale Certificate shall be issued in a specified format and valid for a period of two years from the date of issuance.

CHAPTER XI
LOT RELEASE OF VACCINES AND BIOLOGICALS

Requirements for lot release

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

Procedure for lot release

177. The applicant shall apply for lot release using the form BMRR XVI-LR with a fee prescribed under Schedule II of these Rules and Regulation, accompanied by the following documents:

(1) batch quality control certificate from the manufacturer;

(2) summary lot protocol;

(3) import Authorization issued by the Authority;

(4) shipping documents; and

(5) any other documents as may be required by the Authority.

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

179. The Authority shall check the consignment or batch of vaccines and biologicals for cold chain conditions, temperature monitoring device, temperature, packaging, label, quantity, batch number, expiry date and perform physical verification.

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

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

182. The Authority shall conduct lot verification during the time of public health emergencies and applicant shall submit the following minimal documents:

(1) WHO Emergency Use Listing (EUL) or SRA's approved documents;

(2) Certificate of Analysis;

(3) details on storage condition, handling and transportation;

(4) shipping documents; and

(5) Import Authorization.

183. The Authority shall issue a certificate of lot release or lot verification in the prescribed format.

184. The Authority shall detain the vaccines and biologicals, if:

(1) applicants submit incomplete documents;

(2) vaccines and biologicals require further testing; or

(3) any other conditions as determined by the Authority.

185. The Authority may rely or recognize lot releases conducted by reference authorities as prescribed in the relevant guidelines.

CHAPTER XII
REGULATORY INSPECTION

Requirements of Regulatory Inspection

186. 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 products.

187. Notwithstanding section 186 of these Rules and Regulation, the Authority may authorize relevant officials or agencies, to carry out the functions of inspection as and when necessary.

188. In accordance with section 15 of the Act, the inspection may be carried out with or without prior notice.

189. In accordance with section 15.2 (b) of the Act, the Technical Authorization Holder and the Competent Person involved in manufacture, storage, sale, dispensing and distribution of medicinal products shall give unhindered access to the Inspector to:

(1) conduct inspection;

(2) take pictorial evidence and samples; and

(3) obtain information and records of medicinal products necessary for the performance of his duties.

Qualification of Drug Inspector

190. The Drug Inspector shall have a minimum qualification of certificate course with five years of experience in relevant fields.

Powers and functions of Drug Inspector

191. The Drug Inspector and Authorized official shall:

(1) inspect premises wherein any medicinal product is being manufactured, stored, sold, distributed or dispensed;

(2) inspect premises involved in clinical trial study;

(3) take samples of medicinal product for testing which is being manufactured, or being sold or stocked or offered for sale, or is being distributed;

(4) search any unauthorised individual or unlicensed premises or individual 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;

(5) issue the detention or seizure memo of the medicinal product in the prescribed forms if an offence has been or is being committed and shall release or dispose off any stock as prescribed in the relevant guideline;

(6) inspect and verify all records of disposal of medical waste as per relevant Regulations and guidelines;

(7) maintain a record of all inspections made and actions taken including the taking of samples, seizure of stocks and to submit a report of such records to the Authority;

(8) issue inspection reports for noncompliance to regulatory standards and requirements; and

(9) carry out any other duties as may be assigned by the Authority.

Procedure

192. In accordance with section 15 of the Act, the Inspectors shall carry out the inspection as prescribed under the Guideline for Inspection.

193. The Inspectors or the Authorized officials shall produce identification or letter of authorization during the course of conducting their duties.

194. The Inspector shall collect samples as per relevant guidelines.

195. Whenever the Drug Inspector or Authorized Officials takes a sample of a medicinal product from an authorized premise, the Authority shall pay a fair price against the invoice issued by the premise except when the target of inspection is government health centres.

Inspection at entry and exit points

196. At the entry and exit point for import and export of medicinal products, the inspections may be carried out by the Drug Inspectors or Authorized Official in collaboration with other relevant agencies to:

(1) ensure that the Market Authorization Holder or other importers of medicinal products fully comply with all relevant legislations and requirements;

(2) facilitate import and export of medicinal products;

(3) verify the accuracy of declarations made to the Authority and address any discrepancies;

(4) identify or detect potential risks of substandard and falsified medicinal product; and

(5) carry out any other duties as may be assigned by the Authority

Inspection of manufacturing premises

197. The Authority shall conduct inspection of authorized manufacturing premises of medicinal products to ensure compliance with current Good Manufacturing Practices (cGMP) or other relevant quality system requirements, as outlined in the relevant guidelines.

198. Notwithstanding the section 197 of these Rules and Regulation, the Authority may inspect the manufacturing premises outside Bhutan which have applied for product registration as per the relevant guideline.

199. The Authority may rely on or recognize cGMP or quality system inspections conducted by reference authorities for manufacturers outside Bhutan, in accordance with relevant guidelines.

200. Where on-site cGMP or quality system inspection shall be carried out at the request of the manufacturing premise and the manufacturer shall borne the cost of the inspection.

CHAPTER XIII
VIGILANCE OF MEDICINAL PRODUCTS

Adverse event of medicinal products

201. The Authority shall function as the National Vigilance Centre (NVC) for all categories of medicinal products.

202. The Authority shall recognise following hospitals as a Regional Vigilance Center (RVC) for various categories of medicinal products;

(1) National Referral Hospital;

(2) Regional Referral Hospitals;

(3) National Traditional Medicine Hospital; and

(4) National Veterinary Hospital.

203. Notwithstanding the section 202 of these Rules and Regulation, the Authority may recognise additional hospitals as Regional Vigilance Centre, whenever necessary.

204. In accordance with section 5.11 of the Act, the Board shall constitute a National Vigilance Committee and the members shall be as follows:

(1) the chairperson, Hospital Therapeutic Committee or equivalent committee from each Regional Vigilance Center;

(2) vigilance focal from each Regional Vigilance Center;

(3) additional technical experts as and when required; and

(4) National Vigilance Center as a member secretary.

205. The chairperson of the NVC shall be appointed from its members.

206. The NVC shall meet at least once a year to discuss issues related to the vigilance of medicinal products.

207. Each of the regional vigilance centres shall constitute a RVC comprising at least three relevant members and function as prescribed in the relevant guideline.

208. The RVC shall liaise with respective hospital managements, National Vigilance Centre, and other Regional Centers in strengthening and

promoting vigilance for medicinal products in the country.

209. Any premises involved in sale and distribution or manufacturing of medicinal products shall put in place a post market surveillance system to monitor and report any adverse events or safety information.

210. Any adverse event observed during public health programs or research or studies relating to medicinal products shall be reported to the Vigilance Centre.

211. Any Medical and Health Professionals, Competent Persons, health program coordinators or patients shall report any suspected adverse events using format as prescribed in the relevant guidelines.

212. The NVC shall maintain records of adverse events and shall liaise with the regional or international organization.

213. The Authority may rely or recognise the safety information on medicinal products issued or published by reference authorities or relevant agencies.

214. The Authority shall take appropriate regulatory measures based on the adverse event reports or safety information.

Substandard and falsified medicinal products

215. In accordance with section 21.2 and 22.1 of the Act, substandard and falsified medicinal products shall not be manufactured, imported, distributed or sold.

216. The Authority shall manage the substandard and falsified medicinal products as prescribed in the relevant guideline.

217. The Authority may suspend the use of any suspected substandard and falsified medicinal products until the completion of assessment as prescribed in the relevant guideline.

218. Medicinal product shall be subject to recall after assessment by the Authority, if:

    (1) the product is confirmed as substandard and falsified;

    (2) the Marketing Authorization of the product is cancelled;

(3) the product is banned or recalled by any Stringent Regulatory Authority (SRA) or relevant organization; or

(4) any other conditions as determined by the Authority.

219. The manufacturer or Market Authorization Holder or importer shall ensure timely removal and disposal of cancelled or recalled medicinal products or Investigational Medicinal Products as notified by the Authority.

220. The recalled medicinal products shall be treated as medical waste and disposed of as prescribed in the relevant guideline.

221. Any Medical and Health Professionals, Competent Persons, health program coordinators or patients shall report any substandard and falsified medicinal products using format as prescribed in the relevant guideline.

222. The Market Authorization Holder or manufacturer or importer shall bear the cost incurred as a result of the recall.

Detention of medicinal products

223. The medicinal product shall be liable for detention when:

(1) products are not conforming to the approved specifications during Marketing Authorization;

(2) Technical Authorization is not renewed within grace period;

(3) section 100 (1) and (2) of these Rules and Regulation has been contravened;

(4) lack of Import Authorization for registered medicinal products; or

(5) any other conditions deemed as appropriate by the Authority.

224. Wherever the medicinal products are detained in accordance with section 223(1) of these Rules and Regulation, the applicant shall apply for post approval variations specified under section 141 of these Rules and Regulation within 30 calendar days from the date of detention.

225. Failure to obtain approval for Post-approval Variation shall result in seizure of medicinal product and treated as medical waste as per the section 220 of these Rules and Regulation.

226. The detained medicinal products shall not be tampered until further notification is issued by the Authority.

Seizure of medicinal products

227. In accordance with section 29 (a), (b), (c), (e), (f) or (g) of the Act, medicinal products shall be liable for seizure where it is related to:

(1) unauthorised premises;

(2) banned products;

(3) substandard or falsified products;

(4) lack of Import Authorization for unregistered medicinal products;

(5) sale and distribution of unregistered products;

(6) tampering of detained medicinal product;

(7) not fulfilling the conditions for release of detained medicinal product; or

(8) any other conditions deemed appropriate by the Authority.

228. When the medicinal products are seized in accordance with section 227 of these Rules and Regulation, the individual shall be liable for a fine equivalent to the total invoice.

229. In the absence of invoice, the individual shall be liable for a fine equivalent to the retail value of goods.

230. The fine imposed under section 228 or 229 of these Rules and Regulation may be transferred to the importer if valid evidence is furnished.

231. When the registered medicinal products are seized in accordance with section 227 (1) or (6) of these Rules and Regulation, the Authority may donate to government health centres upon proper assessment of the medicinal products.

CHAPTER XIV
ADVERTISEMENT OF MEDICINAL PRODUCTS

Clearance of Advertisement

232. In accordance with section 27 of the Act, advertisement of any medicinal products shall require prior approval from the Authority.

233. An advertisement of a medicinal product shall be conducted as per the relevant guidelines.

234. 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;

(9) use full or any extract of the test reports issued by the Drug Testing Laboratory; or

(10) falsely show its therapeutic properties as being capable of diagnosis, curing, mitigating, treating or preventing disease or symptom thereof as notified by the Authority.

Procedure for advertisement clearance

235. The applicant shall apply for advertisement in the form BMRR XVII-AD along with the fees prescribed under the Schedule II of these Rules and Regulation.

236. The applicant shall submit content of the advertisement and any other relevant documents as per the relevant guidelines.

237. The Authority shall issue the Advertisement Clearance in the prescribed format if the application fulfils the set conditions.

238. The applicant shall seek prior approval for any changes to the approved advertisement.

Exemption for clearance of advertisement

239. The clearance of advertisement may be exempted for;

(1) product catalogues and price lists provided that they do not include any medicinal claims about the product;

(2) advertisement of location of premises or availability of medicinal products; or

(3) advertisement on discount or free offer of the medicinal products provided that they do not include any medicinal claims about the product.

Control of Advertisement

240. The Authority shall monitor and investigate any unauthorized advertisements of medicinal products through complaints or surveillance.

241. As per section 240 of these Rules and Regulation, the Authority shall take appropriate regulatory actions.

CHAPTER XV
OFFENSES AND PENALTIES

242. In addition to the offences & penalties specified in Chapter IX of the Act, the offenses and penalties prescribed in these Rules and Regulation shall be levied to efficiently enforce the provisions of the act and these Rules and Regulation.

Offences and penalties

243. Any Competent Person who contravenes sections 40(1) to (11) of these Rules and Regulation commits an offence and shall be:

(1) liable to pay a fine of minimum wage of 60 days if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 120 days if the same offence is committed for the second time;

(3) liable to pay a fine of minimum wage of 240 days if the same offence is committed for the third time;

(4) liable for suspension of certificate for 90 days if the same offence is committed for the fourth time; or

(5) liable for deregistration as a Competent Person if the offence is committed for the fifth time.

244. Any person who contravenes sections 40(12) to (28) of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the second time; or

(3) liable to pay a fine of minimum wage of 120 days if the same offence is committed for the third time or more.

245. Any person who contravenes sections 40(29) to (31) of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 30 days if the same offence is committed for the second time; or

(3) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the third time or more.

246. Any person who contravenes sections 42 or 43 of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 30 days if the same offence is committed for second time;

(3) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the third time;

(4) liable for suspension of the Certificate for a period of 90 days if the same offence is committed for a fourth time; or

(5) liable for deregistration as a Competent Person if the offence is committed for a fifth time.

247. Any individual who contravenes section 47 of these Rules and Regulation commits an offence and shall be liable to pay a fine of minimum wage of 180 days.

248. Any Technical Authorization Holder for a manufacturer who contravenes section 77 of these Rules and Regulation commits an offence and shall be:

(1) liable to pay a fine of minimum wage of 90 days if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 180 days if the same offence is committed for the second time;

(3) liable to pay a fine of minimum wage of 365 days if the same offence is committed for the third time or more.

249. Any individual who contravenes section 82 of these Rules and Regulation commits an offence and shall be liable to pay a fine of minimum wage of 90 days.

250. Any Technical Authorization Holder who contravenes section 97 of these Rules and Regulation commits an offence and shall be:

(1) liable to pay a fine of minimum wage of 30 days if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the second time; or

(3) liable to pay a fine of minimum wage of 120 days if the same offence is committed for the third time or more.

251. Any person who contravenes sections 100 (1) to (8) of these Rules and Regulation commits an offence and shall be:

(1) liable to pay a fine of minimum wage of 60 days if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 120 days if the same offence is committed for the second time;

(3) liable to pay a fine of minimum wage of 240 days if the same offence is committed for the third time;

(4) liable for suspension of certificate for 90 days if the same offence is committed for fourth time; or

(5) liable for cancellation of authorization if the offence is committed for a fifth time.

252. Any person who contravenes sections 100 (9) to (19) of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the second time; or

(3) liable to pay a fine of minimum wage of 120 days if the same offence is committed for the third time or more.

253. Any person who contravenes sections 100 (20) to (22) of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 30 days if the same offence is committed for the second time; or

(3) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the third time or more.

254. Any Technical Authorization holder who contravenes section 101 of these Rules and Regulation commits an offence and shall be liable to pay a fine of minimum wage of 30 days.

255. Any individual who contravenes section 104 of these Rules and Regulation commits an offence and shall be liable to pay a fine of minimum wage of 365 days.

256. The applicant who contravenes section 115, 116 or 117 of these Rules and Regulation commits an offence and shall be:

(1) liable to pay a fine of minimum wage of 60 days if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 120 days if the same offence is committed for the second time; or

(3) liable to pay a fine of minimum wage of 240 days if the same offence is committed for the third time or more.

257. Any Applicant who contravenes sections 118 or 119 of these Rules and Regulation commits an offence shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 30 days if the same offence is committed for second time; or

(3) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the third time or more.

258. Any Market Authorization Holder who contravenes section 133 of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 30 days if the same offence is committed for second time; or

(3) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the third time or more.

259. Any individual who contravenes section 135 of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 30 days if the same offence is committed for second time; or

(3) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the third time or more.

260. Any importer or exporter who contravenes sections 155, 159 or 160 of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 90 days if the same offence is committed for second time; or

(3) liable to pay a fine of minimum wage of 180 days if the same offence is committed for the third time or more.

261. Any individual who contravenes section 165(1), (2) or (4) of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 60 days if the same offence is committed for second time; or

(3) liable to pay a fine of minimum wage of 120 days if the same offence is committed for the third time or more.

262. Any individual who contravenes section 176 of these Rules and Regulation commits an offence and shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 30 days if the same offence is committed for second time; or

(3) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the third time or more.

263. Any individual who contravenes section 189 of these Rules and Regulation commits an offence and shall be liable as per the provision of Penal Code.

264. Any individual who contravenes section 210 of these Rules and Regulation commits an offence shall be:

(1) reprimanded in writing and rectify the offence if the offence is committed for first time;

(2) liable to pay a fine of minimum wage of 30 days if the same offence is committed for second time; or

(3) liable to pay a fine of minimum wage of 60 days if the same offence is committed for the third time or more.

265. Any Manufacturer, Market Authorization Holder or Importer who contravenes section 219 of these Rules and Regulation commits an offence and shall be liable to pay a fine of minimum wage of 90 days.

266. Any individual who contravenes sections 232 or 238 of these Rules and Regulation commits an offence and shall be liable to pay a fine of minimum wage of 30 days.

Imposition of Penalties

267. When the Competent Person commits two or more offences arising from the same inspection and offences differ in gravity, the Authority shall impose the penalty of higher gravity.

268. When the Technical Authorization Holder commits two or more offences arising from the same inspection and offences differ in gravity, the Authority shall impose the penalty of higher gravity.

Procedures of appeal:

269. Any individual aggrieved by any decision made by the Authority or any committee established under the Act or these Rules and Regulation shall submit a written petition to the Board within 10 working days from the date of issue of the decision.

270. 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.

271. If an aggrieved person is still not satisfied with the decision of the Board, the person may appeal to the Court of law within 10 working days from the date of decision.

CHAPTER XVI
MISCELLANEOUS

Donation of medicinal products

272. The Authority shall regulate the donation of medicinal products as prescribed in the relevant guideline.

Loss or damage of documents:

273. The applicant shall inform the Authority in case of loss or damage of the authorization or certificates for replacements.

274. The applicant shall apply for the duplicate document using the application form BMRR XVIII-DL along with the fees prescribed under the Schedule II of these Rules and Regulation.

Immunity

275. No action shall lie against the Authority or any authorized official working for the Authority in respect of any act done or omitted in good faith in the execution of the functions under these Rules and Regulation.

276. Such immunity shall not cover corrupt acts committed by any officials in connection with the discharge of his or her official duties.

Interpretation

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

278. In case of conflict in the interpretation of the content of the Regulation, the interpretation by the Board shall be the final and binding.

DEFINITION

In this Regulation, unless the context otherwise requires:

1. Accredited laboratory refers to the laboratory which has been accredited by ISO, ILAC or equivalent Cooperation or body.
2. Act refers to the Medicines Act of the Kingdom of Bhutan 2003.
3. Adverse Drug Reaction refers to any noxious, undesired or unintended response to a drug, which occurs at therapeutic dose.
4. Adverse events refer to 'any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment'. The basic point here is the coincidence in time without any suspicion of a causal relationship.
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.
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. Apron refers to a standard uniform to prevent cross contamination.
8. Authority refers to the Bhutan Food and Drug Authority (BFDA).
9. Authorized official refers to officials authorized by the Authority to carry out any functions under these Rules and Regulation.
10. Authorized Premise refers to the premise authorized by the Authority for the manufacture, import, export, sale, distribution, dispensing or storage of medicinal products.
11. Biologicals refers to a class of medicinal products derived from living organisms or containing components of living organisms.
12. Board refers to the BFDA Governing Board.
13. Cancellation of Marketing Authorization refers to the revocation of Market Authorization of a registered medicinal product due to the violation of the terms and conditions specified in these Rules and Regulation.

14. Certificate course refers to a short-term, specialized program designed to equip individuals with specific skills and knowledge in a particular field or area(s) of work or study.

15. Current Good Manufacturing Practices (cGMP) refers to the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.

16. Clinical Trial refers to research study that investigates the safety and effectiveness of a new medicinal product or an approved medicinal product when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use, in subjects, aiming to determine if it's safe, effective, and potentially better than existing treatments.

17. Clinical Trial Authorization refers to the authorization issued to the proponent responsible for conducting the clinical trial.

18. Conformity Assessment Body (CAB) refers to an organization recognized by the Authority who conducts various conformity assessments to ensure that medical devices comply with the applicable standards, Regulation or requirements.

19. Competency Exam refers to the examination conducted for registration as a Competent Person.

20. 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; or

    (4) distribution of medicinal products.

21. 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.

22. 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 on the same floor or may be on different floors.

23. Detention 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.

24. Essential principles for safety and performance refer to fundamental requirements that every medical device (including IVDs) must meet to ensure that it is designed, manufactured and performs safely and effectively throughout its intended use. These principles ensure that the device does not compromise the health or safety of patients, users or other, that it achieves the performance intended by the manufacturer and that any risks associated with its use are acceptable when weighed against the expected benefits.

25. Ethical Clearance refers to the clearance issued by an independent ethics committee prior to the conduct of clinical trials.

26. Export Authorization refers to the permit to export medicinal products.

27. Extemporaneous preparation refers to the pharmaceutical preparation compounded specifically for a patient.

28. Falsified medicinal product refers to medicinal products that deliberately/fraudulently misrepresent their identity, composition or source.

29. 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).

30. Field Safety Corrective Action (FSCA) refers to an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. Such actions should be notified via a field safety notice (FSN).

31. Field Safety Notice (FSN) refers to a communication sent out by a manufacturer or its representative to the device users in relation to a FSCA.

32. General Health Products refers to any products intended for human health or health care use.

33. 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.

34. Import Authorization refers to the permit to import medicinal products.

35. Investigational Medicinal Product (IMP) refers to any medicinal product that is being tested or used as a reference in a clinical trial including a product with a Marketing Authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

36. Key Personnel refers to the head of the production and quality unit in a premise manufacturing medicinal products.

37. Lot Release refers to the process of evaluating each individual lot of vaccines and biologicals before giving approval for its release into the market.

38. Marketing Authorization refers to the product registration as defined in the Medicine Act of Kingdom of Bhutan 2003.

39. Market Authorization Holder refers to the establishment who has obtained Marketing Authorization for a medicinal product.

40. Medical Device refers to all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human

beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

(1) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(3) investigation, replacement, modification, or support of the anatomy or of a physiological process;

(4) supporting or sustaining life;

(5) control of conception;

(6) disinfection of medical devices; or

(7) providing information by means of in-vitro examination of specimens derived from the human or animal body.

41. Medicinal Product refers to

(1) All substances intended for internal or external use of human beings or animals and intended to be used in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals;

(2) Such substances intended to affect the functioning of any structure found in the human and animal body; and

(3) Any other substance or device declared by the Board to be a medicinal product or a medicine or a drug and this may belong either to modern (allopathic) or traditional systems of medicine.

42. Medical Waste refers to the medicinal products which are expired, used, damaged, spoiled, rejected and recalled.

43. Minimum wage refers to the lowest legally mandated daily wage that employers are required to pay to their employees.

44. 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.

45. Physical verification during the lot release refers to the systematic inspection of products to assess key quality parameters such as freeze tests, visual examination and detection of breakages or other physical defects.

46. Post market surveillance refers to a set of activities to collect and evaluate experience gained from medicinal products that have been placed on the market and to identify the need to take any action.

47. Prescription refers to the instruction from a registered Medical and Health 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.

48. Product Dossier refers to the collection of documents about a particular medicinal product generated from the product manufacturer for the purpose of Marketing Authorization.

49. Proponent refers to the applicant who submits the application for Clinical Trial Authorization.

50. Provisional Technical Authorization for Manufacture (PAM) refers to the authorization for setting up a manufacturing plant until it becomes fully operational.

51. Public Health Emergencies refers to a serious, unexpected and often dangerous event that requires immediate action to protect public health. This includes outbreaks of infectious diseases, natural disasters, conflicts, shortages of medicinal products and other crises that pose a significant risk to health, safety and well-being of the general public.

52. Raw material refers to Active Pharmaceuticals Ingredients, excipients or components used for the production of finished medicinal products.

53. Refurbished Medical Devices refers to safe and effective reconditioned medical devices with no significant change in their performance, safety specifications or service procedures as defined by the manufacturer and their original intended use.

54. Registered Medical and Health Practitioner refers to the person who possesses the requisite qualifications and practical experience prescribed by the relevant Authority and is approved/registered to practice.

55. Regulatory measures refers to any regulatory actions taken to ensure safety, quality and efficacy/effectiveness of the regulated medicinal products. These actions include but are not limited to ADR assessment, public notification, Direct Healthcare Professional Communication (DHPC) and product recalls.

56. Safety information refers to Direct Healthcare Professional Communication (DHPC), recall notifications, FSCA and FSN.

57. Seizure refers to the act of seizing the medicinal products by the Drug Inspectors or any authorized officials.

58. Stringent Regulatory Authority (SRA) refers to a WHO Listed Authority (WLA) and any other National Regulatory Authority recognised by the Authority.

59. Standard Operating Procedures refers to the written procedures that accurately describe and detail essential job tasks.

60. Single-use medical device (SUMD) refers to a medical device or IVD medical device that is intended to be used on an individual patient during or for a single procedure and then disposed of. It is not intended to be reprocessed and used again.

61. Substandard medicinal product refers to authorized medical products that fail to meet either their quality standards or specifications, or both.

62. Suspension of Marketing Authorization refers to a precautionary measure during which, the Marketing Authorization of a medicinal product is suspended for a defined period on grounds of suspicion of public health risks or requirement of further assurance of Quality,

Efficacy, Effectiveness and Safety, until further regulatory actions can be taken.

63. Tampering refers to intentional damage caused to the packaging materials of the detained or seized medicinal products or forceful opening of the detained or seized products.

64. Technical Authorization for Manufacture (TAM) refers to the final authorization issued to establishments responsible for manufacture of medicinal products.

65. Technical Authorization for sale and distribution refers to authorization issued to establishments responsible for sale and distribution of medicinal products.

66. Technical Authorization Holder refers to any person who is authorised to manufacture or sell and distribute medicinal products.

67. Temporary Closure refers to closure of the authorised premise for not more than 90 calendar days.

68. Traditional Medicines (gSo-ba-rig-pa) refers to medicinal products used in the indigenous system of medicines practiced in Bhutan.

69. Vaccine refers to a biological preparation that improves immunity to a particular disease.

70. Vigilance refers to the monitoring of all adverse events resulting from use of medicinal products including Adverse Drug Reaction, Adverse Events Following Immunization, Adverse Event Following Vaccination and substandard and falsified medicinal products.

71. WHO Emergency Use Listing (EUL) refers to a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency.

72. Withdrawal of Marketing Authorization refers to the voluntary withdrawal of Marketing Authorization of a registered medicinal product upon request from the applicant. The request must include justifications for the withdrawal.

SCHEDULE I: CLASSIFICATION OF MEDICINAL PRODUCTS

1. 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.

2. The medicinal products shall be classified into;

   (1) Schedule A: Non-prescription medicines:

      (a) Schedule A1: Behind the Counter (BTC) medicines

      (b) Schedule A2: Over The Counter (OTC) medicines

      (c) Schedule A3: General Sale List

   (2) Schedule B: Prescription only medicines (POM)

   (3) Schedule C: Controlled medicines

      (a) Schedule C1: Narcotics

      (b) Schedule C2: Controlled psychotropic substances

   (4) Schedule D: Traditional Medicines (gSo-ba-rig-pa) and herbal products

      (a) Schedule D1: Non-prescription Traditional Medicines (gSo-ba-rig-pa) and herbal products

         (i) Schedule D1A: Non-prescription Traditional Medicines (gSo-ba-rig-pa) and herbal products for Human Use

         (ii) Schedule D1B: Non-prescription Traditional Medicines (gSo-ba-rig-pa) and herbal products for Veterinary Use

      (b) Schedule D2: Prescription Traditional Medicines (gSo-ba-rig-pa) and herbal products

         (i) Schedule D2A: Prescription Traditional Medicines (gSo-ba-rig-pa) and herbal products for Human Use

(ii) Schedule D2B: Prescription Traditional Medicines (gSo-ba-rig-pa) and herbal products for Veterinary Use

(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

(a) Schedule F1: Vaccines and Biologicals for human use.

(b) Schedule F2: Vaccines and Biologicals for veterinary use.

(7) Schedule G: Medical Gases

(8) Schedule H: Supplements

(a) Schedule H1: Health Supplements

(i) Category I: Nutritional or General Claims

(ii) Category II: Functional Claims

(iii) Category III: Disease Risk Reduction Claims

(b) Schedule H2: Feed Supplements

(i) Category I: Nutritional or General claims

(ii) Category II: Functional Claims

(9) Schedule I: Medical Devices

(a) Schedule I1: General Medical Device

(i) Risk class A: Low Risk

(ii) Risk class B: Low-moderate Risk

(iii) Risk class C: Moderate-high Risk

(iv) Risk class D: High Risk

(b) Schedule I2: In-Vitro Diagnostics

(i) Risk class A: No public health risk or low personal risk

(ii) Risk class B: Low public health risk or moderate personal risk

(iii) Risk class C: Moderate public health risk or high personal risk

(iv) Risk class D: High public health risk

3. The following criteria shall be applicable for categorization of medicinal product as Schedule A2/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 or range or 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.

4. The following criteria shall be applicable for categorization of medicinal product as Schedule A3/General sale list:

(1) product is reasonably safe and can be sold or supplied without the need for a 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 products is small.

5. Schedule A3 may not require registration with the Authority. However; the product imported shall be subject to strict post marketing surveillance.

6. The sale of Schedule A3 medicines products shall not be restricted to Pharmacies only but also permitted from the general stores.

7. Medicines under Schedule B should be sold on presentation of a prescription from a registered Medical and Health Practitioner or authorized by the parent Agency and registered with the relevant Authority.

8. Medicines under Schedule A1 shall be sold only by Competent Person defined under these Rules and Regulation.

9. Medicines under Schedule C1 and C2 shall be adopted from the relevant legislative documents.

10. Medicines listed under Schedule D2 shall be sold only on the presentation of prescription from a registered Traditional Medicine practitioner.

11. 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.

12. Medicines listed under Schedule F shall be stored under appropriate cold chain conditions required as per the product specification.

13. Medicines listed under Schedule G shall include medical grade gases which are manufactured, imported, distributed or sold in the country.

14. Refurbished schedule I1 medicinal products shall meet the same regulatory requirements as that of the original medical device as prescribed in the relevant guideline.

15. The reprocessing of Single Use Medical Devices (SUMD) of schedule I medicinal products shall be prohibited.

16. Schedule I medicinal products shall be classified and reclassified into different risk categories as per risk classification rule as prescribed in the relevant guidelines.

17. The Authority shall publish the list of medicinal products under each schedule and may revise from time to time, as deemed necessary.

SCHEDULE II: FEES

Sl. No.	Type of services or certification fees	Amount
1	Application for registration as Competent Person	Nu. 1000/-
2	Application for renewal of registration of Competent Person	Nu. 500/-
3	Application for Provisional Authorization for Manufacturing (PAM)	Nu. 5000/-
4	Application for Technical Authorization for Manufacture (TAM)	Nu. 10,000/-
5	Application for Post Approval Variation of Technical Authorization for Manufacture	Nu. 3000/-
6	Application for renewal of PAM and FAM	Nu. 1000/-
7	Application for issuance of Good Manufacturing Practice (GMP) Certificate	Nu. 5000/-
8	Application for Technical Authorization for sale and distribution of medicinal products	Nu. 2000/-
9	Application for renewal of Technical Authorization for sale and distribution of medicinal products	Nu. 500/-
10	Application for Post Approval Variation of Technical Authorization for sale and distribution of medicinal products	Nu. 500/-
11	Application for Clinical Trial Authorization of medicinal products	Nu. 5000/-
12	Application for Post Approval Variation of Clinical Trial Authorization of medicinal products	Nu. 3000/-
13	Application for Marketing Authorization of medicinal products	Nu. 2000/-
14	Application for Post Approval Variation of Marketing Authorization of medicinal products	Nu. 500/-
15	Application for renewal of Marketing Authorization of medicinal products	Nu. 500/-
16	Application for transfer of Marketing Authorization of medicinal products	Nu. 500/-
17	Application for Import Authorization of medicinal products	Nu. 200/-
18	Application for Export Authorization of medicinal products	Nu. 200/-
19	Application for lot release of vaccines and biologicals	Nu. 300/-
20	Application for clearance of advertisement of medicinal products	Nu. 300/-
21	Application for Certificate of Pharmaceutical Product	Nu. 200/-
22	Application for Free Sale Certificate	Nu. 200/-
23	Issuance of duplicate documents	Same as original fees

SCHEDULE III: APPLICATION FORMS

BMRR I-CP

APPLICATION FOR REGISTRATION AS COMPETENT PERSON

I.....hereby apply for registration/renewal as a Competent Person for the purpose of manufacture/sale by retail/sale by wholesale (Tick the appropriate one) of following category(ies) of product(s):

- ☐ Human allopathic medicines
- ☐ Traditional medicines (gSo-ba-rig-pa)
- ☐ Veterinary allopathic medicines.
- ☐ Medical devices
- ☐ Supplements

Following supporting documents are submitted.

1. Certificate of Registration from the relevant Authority.
2. Letter of recognition from equivalent agency or Course completion certificate or academic transcript (for Veterinary allopathic medicines and Medical Device).
3. Evidence of experience (For Medical Device) if the Academic Qualification is not related to medical devices).
4. Curriculum vitae (for Medical Devices only).
5. Copy of the Identity Card.
6. Two recent passport size photos.

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR II-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/we have attached the following documents:

- ☐ Proposal to manufacture medicinal products; and
- ☐ Detailed Plant Layout 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 documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR III-FAM

APPLICATION FOR TECHNICAL AUTHORIZATION FOR MANUFACTURE OF MEDICINAL PRODUCTS

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

1. Name of the firm:
2. Location/Address of the firm:
3. Provisional Authorization no (as issued by MPD):
4. Expected date of Operation:
5. Name of the proposed Competent Person(s):
6. Production Manager:
7. Quality Assurance Manager:
8. List of Products intended for manufacture:
   (Please use additional sheet)
9. List of standard operating procedures:
   (Please use additional sheet)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR IV-PAV TAM

APPLICATION FOR POST APPROVAL VARIATION OF TECHNICAL AUTHORIZATION FOR MANUFACTURE

M/s.....
hereby apply for Post Approval Variation for Manufacture.

Authorization number:

Proposed Variations along with supporting documents (as per relevant guidelines):

1.
2.
3.
4.

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR V-GMP

APPLICATION FOR ISSUANCE OF GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

M/s.....located at (address) ..... hereby apply for GMP certificate for the dosage forms, categories, list of products and activities as follows:

Dosage form(s)	Category(ies)	Activity(ies)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR VI-TAS

APPLICATION FOR TECHNICAL AUTHORIZATION FOR SALE AND DISTRIBUTION OF MEDICINAL PRODUCTS

I/We..... hereby apply for grant/ renewal of authorization to sale and distribute by Retail or Wholesale of medicinal products.

i. Proposed name of the firm: .....

   Location: .....

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

   - ☐ Human allopathic medicines;
   - ☐ Veterinary allopathic medicines;
   - ☐ Medical Devices;
   - ☐ Supplements; and
   - ☐ gSo-ba-rig-pa.

iii. State the name of the Competent Person 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 documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR VII-PAV TAS

APPLICATION FOR POST APPROVAL VARIATION OF TECHNICAL AUTHORIZATION FOR SALE AND DISTRIBUTION OF MEDICINAL PRODUCTS

I/we……of……
(name of the firm) apply for the following (Tick the appropriate one):

- ☐ Change of ownership of premise
- ☐ Change of Competent Person
- ☐ Change of location of premise
- ☐ Change of name of premise

Sl. No	Existing	Proposed

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR VIII-CTA
APPLICATION FOR CLINICAL TRIAL AUTHORIZATION OF MEDICINAL PRODUCTS

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

a. Name	
b. Organization	
c. Address	
d. Phone number	
e. E-mail	
f. Status of the sponsor (commercial or non-commercial)	

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. Estimated number of trial subjects to be included	
g. Age range of trial subjects	
h. Gender of trial subjects	
i. Investigational Medicinal Product to be tested	
j. Comparator product (if applicable)	
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 an independent ethical committee recognized by the Authority.

Declaration (please tick the boxes):

☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.

☐ 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:
Contact No:

Date: .....

BMRR IX-PAV CTA

APPLICATION FOR POST APPROVAL VARIATION OF CLINICAL TRIAL AUTHORIZATION OF MEDICINAL PRODUCTS

I/we.....hereby apply for post approval variation of the authorized clinical trial application as mentioned below:

Clinical Trial Authorization number:

Proposed Variations and supporting documents (as per relevant guidelines):

1.
2.
3.
4.

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR X-MA

APPLICATION FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

M/s .....hereby apply for registration of the product specified below for sale/distribution in Bhutan.

Route of registration (Tick the appropriate one):

- ☐ Abridged registration Please specify eligibility.....
- ☐ Full registration
- ☐ Renewal registration

Type of medicinal product (Tick the appropriate one):

- ☐ Human Allopathic
- ☐ Herbal
- ☐ Veterinary Allopathic
- ☐ API for extemporaneous preparation
- ☐ Sowa-Rigpa
- ☐ Medical device

Brand name (Generic name)	Pack size	Material of construction or Composition	Manufacturer	Permissible variants (in case of FAMILY) - For medical devices only

Please provide information as requested below for medical devices only:

Medical Device Classification:
Medical Device group:
Intended Indication:

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR XI-PAV MA

APPLICATION FOR POST APPROVAL VARIATION OF MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

I/we.....hereby apply for post approval changes of the following product:

Product Registration no:
Generic Name:
Brand Name:
Product Code (If applicable, for medical devices only):
Date of Expiry of the Registration:

Proposed Variations and supporting documents (as per relevant guideline):

Current Specification or details	Proposed Variation(s)	Reason for Variation

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR XII-WD MA

APPLICATION FOR WITHDRAWAL OF MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

I/we.....hereby apply for withdrawal of Marketing Authorization of the following medicinal product(s):

Registration number	Brand name (Generic name)	Expiry date of registration	Reason for withdrawal

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR XIII-Trans MA

APPLICATION FOR TRANSFER OF MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

I/we.....(Recipient MAH) hereby apply for transfer of Marketing Authorization of the following product:

Registration number	Brand name (Generic name)	Manufacturer	Current MAH

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR XIV-IA

APPLICATION FOR IMPORT AUTHORIZATION OF MEDICINAL PRODUCTS

I/we..... hereby apply for authorization to import the following medicinal products in Bhutan.

- ☐ Medicinal products for sale and distribution.
- ☐ Medicinal products for health camp.
- ☐ Medicinal products for research purpose.
- ☐ Medicinal products for personal use.
- ☐ Medicinal products for special purpose.
- ☐ Raw materials for manufacture of medicinal products.

Sl. No	Product Name	Registration No/Invoice number	Registration Validity (If applicable)	Manufacturer	Pack size	Quantity

(Attach separate sheet in case of multiple products)

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

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR XV-EC

APPLICATION FOR ISSUANCE EXPORT RELATED CERTIFICATES OF MEDICINAL PRODUCTS

M/s ..... (name of Competent Person) of ..... (name of firm) hereby apply for (Tick one of them):

- ☐ Export Authorization
- ☐ Certificate of Pharmaceutical Product
- ☐ Free Sale Certificate

Medicinal product details:

Sl. No	Product Name	Composition (With Strength)	Pack Size	Registration No.	Registration Validity	Importing Country

(Attach separate sheet in case of multiple products)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR XVI-LR

APPLICATION FOR LOT RELEASE OF VACCINES AND BIOLOGICALS

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

Details of the product	
Generic Name:	
Brand 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 Details	
Market Authorization Holders Name and Address	
Name of contact person and phone number:	
Address of the product stored:	

Is the Vaccine or Biological registered with the Authority or has EUA been issued?

- ☐ Yes
- ☐ No

(Please attach the following document)

1. Lot Release Certificate from country of origin
2. Summary Lot Protocol
3. Certificate of Analysis (COA) for Finished Products
4. Importing Packing List
5. Airway bill

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR XVII-AD

APPLICATION FOR CLEARANCE OF ADVERTISEMENT

I/we ..... hereby apply for clearance to advertise the following medicinal product;

i. Detail of the Product:

a) Brand Name: .....
b) Marketing Authorization no.: .....
c) Market Authorization Holder: .....
d) Type of advertisement: .....

ii. Type of material: (please tick the appropriate box)

- ☐ Poster
- ☐ Leaflet
- ☐ Cinema
- ☐ Outdoor/ Billboard
- ☐ In/on Public Transport
- ☐ Magazines/ Newspaper
- ☐ Audio or Visual
- ☐ Other, please specify .....

iii. Contents of the Advertisement (Use additional sheet if required): .....
.....

iv. Advertisement platform (Use additional sheet if required): .....
.....

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 contravene the provisions of the Act and Regulations thereunder.
- ☐ 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:
Contact No:

Date: .....

BMRR XVIII-DL

APPLICATION FOR ISSUANCE OF DUPLICATE COPY OF DOCUMENTS

I, ... hereby apply for issuance of duplicate copy of following document(s).

Document type:

- ☐ Registration certificate of Competent Person
- ☐ Technical Authorization for manufacture
- ☐ cGMP certificate
- ☐ Technical Authorization for sale and distribution
- ☐ Clinical Trial Authorization
- ☐ Marketing Authorization certificate
- ☐ Import Authorization
- ☐ Export certificates. Please specify.....
- ☐ Lot Release certificate
- ☐ Clearance for advertisement

Certificate or authorization number: .....

Authorized by the proprietor (dated signature) .....

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 contravene 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:
Contact No:

Date: .....

Medical Product Division, Bhutan Food and Drug Authority
Royal Government of Bhutan
P.O. Box No. 726
Thimphu, Bhutan

Phone: +975-02339015
Email: mpd@bfda.gov.bt
Website: www.bfda.gov.bt