NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES AND SUBSTANCE ABUSE RULES AND REGULATION 2024

BHUTAN FOOD AND DRUG AUTHORITY

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Narcotic Drugs, Psychotropic Substance and Substance Abuse Regulation 2024

In the exercise of powers conferred to the Board under section 57 (5) and section 73 (2) of the Narcotic Drugs, Psychotropic Substance and Substance Abuse Act 2015 (Amendment 2018), the Board for the purpose of giving effect to the provisions of the Act, approves the following Rules and Regulation. While implementing this Regulation, the members and employees of the Authority shall maintain the highest level of integrity and confidentiality of all clients and their technical information and shall not have improper association, not be a party to false pretences, forgery, fraud and counterfeiting.

Chapter I
Preliminary

Short title, commencement and extent

1. This Regulation shall:
   (1) be called the Narcotic Drugs, Psychotropic Substances and Substance Abuse Rules and Regulation 2024;
   (2) take effect on the 17th day of the ten month of Wood Male Dragon year of the Bhutanese calendar corresponding to the 17 December of 2024 and
   (3) extend within the Kingdom of Bhutan.

Application

2. This Regulation shall apply to all the Narcotic Drugs, Psychotropic Substances, plants, substances and preparations scheduled under the Act.

Objective

3. The objective of this Regulation shall be to:
   (1) regulate all licit Narcotic Drugs and Psychotropic Substances as per the scheduled III, IV, V and VI;
   (2) reinforce and strengthen enforcement of the Act; and
   (3) promote transparency and efficiency in the services provided by the Authority.

Supersession

4. All existing rules, regulations, notifications, and circulars in force concerning the subjects, which are covered by this Regulation, shall deem to have been superseded from the effective date of the Rule.

Interpretation

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

Chapter II
Governance

Governing Board

6. The Civil Service Reform Act of Bhutan 2022 under section 13 repealed the Boards under all the existing ministries, subsequently the Lhengye Zhungtshog vide letter no.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 Governing Board

7. The Governing Board shall exercise the powers, functions and follow procedures of the Board as specified in the Act including the following:
   (1) Serve as an advisory body to the Authority to provide strategic directives for the regulation of cross-sectoral categories of products and services that transcend various ministries and agencies;
   (2) Serve as an apex decision-making body for resolving any matters related to regulation of products under the purview of the Authority;
   (3) Facilitate mobilisation of adequate resources to ensure efficient and effective regulatory services;
   (4) Approve policies and regulations based on recommendation from Competent Technical Advisory Committee and in line with national and international standards for regulation of products under purview of the Authority;
   (5) Endorse new testing, reference and appellate laboratories for analysis of the products under the purview of the Authority;
   (6) Endorse the amendment of any prescribed fees, fines and penalties for any regulatory services as and when necessary, upon recommendation of the Authority;

(7) Coordinate national response to take appropriate actions/measures at times of biosecurity, food safety and public health emergencies;
(8) Designate competent drug testing laboratory and an Appellate Laboratory for testing of NDPS;
(9) Constitute Competent Technical Advisory Committees and any other committees as and when required to advise the Board on technical matters arising out of the administration of regulatory functions;
(10) Suspend or terminate any member of the committees constituted at any time, on disciplinary grounds and abuse of power and appoint another appropriate person to replace the member to serve for the remaining term of the membership;

(11) Dissolve the committees upon the completion of the duties assigned; and

(12) Any other functions as deemed necessary for the effective implementation of the Act and this Regulation.

Bhutan Food and Drug Authority

8. The Bhutan Narcotics Control Authority under the Narcotic Drugs, Psychotropic Substance and Substance Abuse Act 2015 (Amendment 2018) shall be the Bhutan Food and Drug Authority, Ministry of Health in accordance with the section 26 of the Civil Service Reform Act 2022.

Powers and Functions of Bhutan Food and Drug Authority

9. The Authority shall exercise powers and functions as specified under section 73 and section 74 of the Act and following:
(1) Regulate cultivation, manufacture, Import and export, storage, sales, dispensing and distribution of schedule III, IV, V and VI;
(2) Develop standards, guidelines and conditions required for implementation of this Regulation;
(3) Develop and prescribe the formats for application, certification and authorizations for the purpose of carrying out functions under this Regulation;
(4) Regulate advertisements and promotion of schedule III, IV, V and VI;
(5) Investigate complaints made to the Authority as per the prescribed procedure;
(6) Create awareness on the provisions of the Act and Regulation made thereunder;
(7) Impose fines and penalties for non-compliances;
(8) Liaise with other relevant national and international organisations;
(9) Approve/reject the authorization for manufacturing, production, import, export, wholesale, retail and distribution of substances listed under Schedule III, IV, V and VI of the Act;

(10) Submit the estimates of schedule III, IV & V annually based on the previous year consumption to International Narcotics Control Board (INCB);
(11) Submit the statistical report quarterly and annually to International Narcotics Control Board (INCB);
(12) Develop and prescribe standard forms for search and seizure, sample testing, disposal and reward disbursement.
(13) Ensure a pre-export notification system is implemented to verify the genuineness of the transaction and to notify the Competent Authority of the importing and transhipping country of the impending export;
(14) Ensure the equipment and materials for the manufacturing and production of substances and preparation listed in schedule III, IV, V and VI are exclusively used for intended purposes; and

(15) Any other functions as deemed necessary for the effective implementation of the Act and this Regulation.

Competent Technical Advisory Committee

10. The Governing Board shall constitute and approve Competent Technical Advisory Committee and shall comprise of the following:
    (1) Psychiatrist, Jigme Dorji Wangchuck National Referral Hospital, National Medical Services;
    (2) Police Officer, Narcotics Drugs and other Vices Division, Royal Bhutan Police;
    (3) Attorney, Office of Attorney General;
    (4) Clinical Pharmacist/Pharmacist, Jigme Dorji Wangchuck National Referral Hospital, National Medical Services;
    (5) Drug Analyst; Royal Centre for Disease Control, Ministry of Health;
    (6) Addiction Professional from The Pema Secretariate; and
    (7) Chief Program Officer, Controlled Substances and Medical Devices Division, Bhutan Food and Drug Authority as Member Secretary.

Procedure of meeting

11. The meeting shall be convened as and when required.

12. The Chairperson and Vice Chairperson of the Committee shall be elected amongst the members on an annual basis.

13. The Vice chairperson of the Committee shall chair the meeting in the absence of the Chairperson.

14. The members shall attend the meeting in person without fail after confirmation. If a member fails to attend meetings after confirmation the member shall provide valid explanation in writing to the Chairperson of the committee.

15. In the event the member fails to attend two consecutive meetings then the member shall be terminated and replaced by the Board.

16. The Chairperson shall recommend the Authority to invite co-opt members as and when required.

17. Quorum of at least two-third shall be required for the meeting.

Functions of the Committee

18. The Committee shall carry out the following functions:
    (1) Periodically review and recommend amendments to the schedules for the substances including quantification for the recommendation to addition or deletion;
    (2) Provide advice to the Board on all technical areas related to substances under the schedules and other related technical matters as and when required by the Board;
    (3) Review and recommend relevant national standards and technical guidelines to the Board;
    (4) Provide technical information or other relevant documents and articles related to the subject of the meetings;
    (5) Maintain confidentiality and privacy of technical information and shall not disclose any important decision of the meetings unless approved by the Board;
    (6) Recommend the Board to appoint expert(s) to address specific technical areas as and when required; and
    (7) Also carry out any other responsibilities assigned by the Board.

Chapter III
Control of Licit Activities

Classification of Drugs, Precursors and Controlled Substances

19. The classification of drugs, precursors and controlled substances shall be in accordance with the section 4 and 4A of the Act.

20. The information on the amendment of the schedules shall be submitted to the Parliament and notified to the public for information.

Authorization

21. Any individual or entity intending to cultivate, manufacture, produce, import, export, wholesale, retail, distribute, and use of plants, substances and preparations listed under Schedule III, IV, V and VI of the Act, shall obtain an authorization from the Authority.

22. The authorization obtained from the Authority shall be a prerequisite for obtaining a trade licence from the relevant agency.

23. Any individuals, institutions or agency importing for the purpose of medical or scientific research, teaching or forensic work in quantities not exceeding those strictly required for the intended purpose, may be provided with the authorization by Authority to produce, manufacture, acquire, import, use or hold plants, substances and preparations listed in Schedules I, II, III, IV and V of the Act.

24. In the event of death or medically unfit or absence of the authorization holder, the authorization shall be deemed cancelled.

25. The authorization shall not be transferable to any other person or entity.

Exemption of Authorization

26. The Authority may exempt the requirement of authorization for import, export and distribution of substances listed in schedule III, IV, V and VI for the following:
    (1) Government health and veterinary centre;
    (2) Government projects and approved non-governmental projects not engaged in commercial activities of medicinal products;
    (3) Individuals on medication with prescription; and
    (4) Use during public health emergencies notified by relevant agencies.

27. Exemptions shall be subject to the following conditions:
    (1) Individuals or institutions shall adhere the guidelines, regulations and safety measures established by the Authority;
    (2) Individuals or institutions shall maintain detailed reports and submit periodic reports to the Authority; and
    (3) Individuals or institutions shall adhere to the prescribed quantities of controlled substances authorised by the Authority.

28. The Authority may revoke the exemption, if:
    (1) Individuals or institutions is found to be in violation of the Act or the conditions of the exemption;
    (2) Evidence of misuse or diversion of controlled substances is available; and

(3) Individuals or institutions fail to comply with record-keeping, reporting, or security measures.

Duties of the Authorization Holder

29. The authorization holder shall:
    (1) Engage in activities limited to schedules III, IV, V and VI of the Act and for which the approval has been obtained;
    (2) Obtain Import/Export/Transit authorization prior to import or export or transit of plant, substances and preparations listed in schedule III, IV, V and VI of the Act;
    (3) Obtain separate import authorization for each import, whether it consists of one or more substances and/or preparations containing such substances;
    (4) Ensure that substances listed under the Act are not diverted for unauthorised use;
    (5) Declare all import/export consignments at the port of entry to the designated agency and submit import/export details immediately after effecting import;
    (6) Maintain accurate records of all activities involving the controlled substances including quantity, date, suppliers/recipients, quantities manufactured, equipment used, material used, quantity held in stock, storage and disposal;
    (7) Ensure appropriate warnings and indications on the packages, labels and the accompanying leaflets of any packages of the controlled drugs or substances;
    (8) Maintain records of statistical returns of production or manufacture of drugs, utilisation of drugs for the manufacture of other drugs, consumption of drugs, imports and exports of drugs, seizures of drugs;
    (9) Submit quarterly reports to the Authority;
    (10) Produce documents on demand by an authorised officer;
    (11) Close the establishment immediately as and when notified by the authorised agency;
    (12) Allow access to the individual's or entity's premises during ordinary or special inspections by the authorised agency;
    (13) Pay all applicable dues and penalties;
    (14) Ensure that shipment shall be made in one consignment within the validity of the import and export authorisation;
    (15) Ensure appropriate security measures to prevent unauthorised access, theft, or diversion of the controlled substances; and
    (16) Comply with any other relevant laws of the country.

Import and export of plants, substances and preparations

30. In accordance with the section 7 and 8 of the Act, any export or imports of plants, substances and preparations listed in schedule III, IV, V and VI shall require separate authorization from the Authority and such authorization shall not be transferable.

31. The authorization shall be valid for the period of six months from the date of issuance.

32. Upon expiry of the validity period of the authorization, the authorization holder shall submit a new application for authorization.

33. The authorization holder shall submit the documents of the exporter, who may be a manufacturer, wholesaler, distributor, or retailer, along with valid documents to conduct business involving substances listed in the Act Schedule III and IV.

34. The authorization holder intending to export shall furnish import authorization of the importing country to the Authority to obtain export authorizations.

Cancellation of Authorizations

35. The Authority may cancel the authorization, if the authorization holder is found:
    (1) Violating the terms and conditions of the authorization;
    (2) Providing false information in the application; or
    (3) Involved in unauthorised activities related to controlled substances.

36. The Authority shall provide prior notice for cancellation, except in cases of severe violations where immediate action is warranted.

Licit Possession and Use

37. The possession and use of plants, substances and preparation listed in Schedule III, IV and V of the Act shall be permitted only on following conditions:
    (1) Any individual, domestic or international travellers with valid prescription from registered and qualified medical practitioners;
    (2) Any institutions such as schools, healthcare centres, laboratory and research centres for educational and professional purpose; or
    (3) Any authorised officer by the Authority for official purposes.

38. In accordance with the section 12 of the Act, any person or enterprise holding authorization for professional purposes shall possess and use plant, substances and preparation listed in schedule III, IV and V of this Act and ensure to:
    (1) Maintain accurate records of all controlled substances prescribed, dispensed, or administered for audit purposes;
    (2) Comply with regulations governing maximum allowable quantities and validity periods for controlled substances and not falsify the prescription;
    (3) Maintain record of the filled prescription for a minimum of 5 years;
    (4) Submit periodic reports on the use and stock of controlled substances to the Authority in the prescribed format.
    (5) Lock the storage facilities and restrict entry for other people except to authorised personnel;
    (6) Report any loss, theft, or diversion immediately to the authorities through management;

(7) Put measures in place to ensure controlled substances are not misused, abused, or diverted for illegal purposes;
(8) Report any adverse events related to the use of controlled substances, such as overdoses or addiction to the Authority as required; and
(9) Follow any other conditions set forth by the Medical and Health Professional Council.

Advertisement

39. In accordance with section 13 of the Act, any advertisement of plants, substances and preparations listed under the Act shall be prohibited.

40. Notwithstanding the section 39 of this Regulation, upon written approval from the Authority, researchers or medical and health professionals may be permitted to conduct scientific or professional publications or publish in professional journals.

Record-keeping by Authorization Holder

41. The authorization holder shall maintain accurate and updated records of controlled substances, including:
    (1) quantities of plants, substances and preparations imported, acquired, manufactured, used and destroyed for five years as per format prescribed in Annexure I.
    (2) Details of acquisition and disposal as prescribed in the format.

42. Records shall be made available for inspection by the Authority.

Reporting

43. The authorization holders shall submit quarterly and annual statistical returns as per format prescribed in Annexure II, detailing:
    (1) Quantities of plants, substances and preparations used or destroyed;
    (2) Estimates for the next calendar year based on the previous year's consumption and buffer stock; and
    (3) Any discrepancies or incidents of loss or theft of controlled substances.

44. Any breach in security or loss or theft of controlled substances shall be reported immediately to the Authority or relevant authorities.

Duties of persons in- charge of the any premises

45. The person in-charge of the premise shall:
    (1) Ensure that no person uses controlled drugs and substances in his or her premises;
    (2) Make regular inspections of areas of the premises, including common areas, restrooms, and any other locations where illicit use of drugs are likely to occur;

(3) Display signs prohibiting use of drugs and controlled substances in the premises if the establishment is commercial;
(4) Report any suspected illicit drug use or possession on the premises to relevant authorities.

Inspection by the Authority

46. An authorised official shall produce the official identification card prior to carrying out any inspection under these Regulations.

47. In accordance with section 23 of the Act, the inspectors or authorised officer shall carry out the inspection as per the Guideline for Inspection.

48. The Authority shall conduct ordinary inspections of the establishments, premises, stocks, and records at least once every two years and extraordinary inspections at any time.

49. Any authorization holder or entity and premise involved in the operations of plants, substances, and preparations covered in the Act shall be subject to inspection by the Authority at least every two years and extraordinary inspections at any time.

50. The Authority shall inspect and monitor all entities to ensure compliance with the laws.

51. The Authority may carry out inspection in coordination with relevant law enforcement and agencies as deemed appropriate.

52. Authorised officials shall inspect containers of first aid kits in domestic and international conveyances to ensure compliance with national and international regulations governing the transport of controlled substances.

53. Authorised officials shall maintain confidentiality regarding the information obtained during the inspection and to conduct the inspection professionally and respectfully, without causing unnecessary disruption to the entity's operations.

54. Any authorization holder or entity and premise involved in operations such as plants, substances, and preparation covered by the Act shall not obstruct the Authorised Official in carrying out their duties.

55. Authorised officials may question any person during inspection, including employees, operators, or owners, about their involvement in activities related to narcotic drugs and psychotropic substances.

56. Any authorization holder or entity shall also furnish any information or documents and evidence as and when required by the Authorised Official.

57. After completing the inspection, the Authority shall prepare a detailed report documenting the findings, including any violations of the Act, substances seized, and any actions taken.

58. If necessary, the Authority may initiate follow-up inspections to ensure compliance with the corrective measures.

59. When it becomes apparent before, during, or after an inspection that a criminal offence against this Act or the Penal Code of Bhutan may have been committed, the Inspector or Authorised Officer shall report the matter to the Royal Bhutan Police and other relevant law enforcement agencies to search, seize, take samples, and investigate as per Civil and Criminal Procedure Code of Bhutan.

Chapter IV
Special Provisions

60. In accordance with section 28 of the Act, any international or domestic conveyance shall be permitted to carry the list of controlled drugs or substances in the first aid kits to be used for medical emergencies as per the relevant guidelines.

61. In accordance with section 29 of the Act, the Authority shall with due diligence submit to the Board for authorization to import a limited quantity of controlled substances to meet public emergencies such as epidemics or disaster situations.

62. In accordance with Section 30 of the Act, any international travellers or Bhutanese persons travelling for medical treatment and possessing controlled substances must carry a prescription issued by a registered and qualified medical professional with the name and quantity of controlled substances explicitly mentioned. The quantity of the controlled substances shall not exceed the quantity mentioned in the prescription.

63. In accordance with section 31 of the Act, the Authority shall develop standards for the use of controlled drugs and substances in industries other than for medical or scientific purposes.

64. The prescribed standards shall include the process of denaturation of controlled drugs or substances such that the by products are not harmful or liable to be abused and procedures for collection of data.

Chapter V
Educational Measures

65. In accordance with section 32 of the Act, the Royal Government of Bhutan in collaboration with stakeholders including Educational Institutions, Religious Organisations, Local Government, Community, Non-Governmental Organisations, Media and Parents have the responsibility to:
    (1) Inform and educate on the risks of substance abuse;
    (2) Promote healthy activities;
    (3) Prevent substance abuse; and
    (4) Management of substance abuse.

66. The Ministry of Education and Skills Development and other educational institutions shall:
    (1) Develop and implement substance abuse prevention and intervention policy and evidence-based programme;
    (2) Appoint trained/specialised counsellors in all institutions;
    (3) Provide awareness on harmful effects of substance abuse;
    (4) Carry out periodic assessments on substance abuse among students for early identification, intervention and referral;
    (5) Provide moral, spiritual and life skills education to better understand themselves and safeguard against substance abuse;
    (6) Provide alternative recreation activities and other useful vocational opportunities to promote social integration;
    (7) Provide reintegration services in collaboration with family members or guardians;
    (8) Strengthen the parenting education programs in preventing substance abuse;
    (9) Implement and strengthen anti-discrimination programs in schools; and
    (10) Maintain confidentiality.

67. The Religious organisations shall:
    (1) Create awareness to prevent substance abuse;
    (2) Develop and implement substance abuse prevention and intervention policy and programme; and
    (3) Collaborate with relevant agencies and Non-Governmental Organisations on the promotion of well-being and prevention of substance abuse.

68. The Approved Treatment Centre may:
    (1) Create awareness to prevent substance abuse from a whole of society approach;
    (2) Provide life skills education; and
    (3) Provide opportunities to promote social integration ensuring continuum of care approach.

69. The Local Government shall:
    (1) Raise awareness to prevent substance abuse;
    (2) Raise awareness on the Act;
    (3) Establish recreational facilities to encourage healthy lifestyle;
    (4) Facilitate reintegration of recovering substance abusers;
    (5) Create community support services for awareness and acceptance of substance abusers; and
    (6) Implement and support anti-discrimination programs in the community.
70. The Media shall:
    (1) Raise awareness of the risk of substance abuse;
    (2) Advocate for healthy lifestyles;
    (3) Provide a platform to showcase positive role models;
    (4) collaborate with governments and NGOs/CSOs to promote anti-drug campaigns; and
    (5) Implement and support anti-discrimination programs in the community.

71. Non-Governmental Organisations and Civil Society Organisations shall:
    (1) Raise awareness of the risk of substance abuse;
    (2) Raise awareness on the Act;
    (3) Advocate for healthy lifestyles; and
    (4) Facilitate the prevention programs in collaboration with government.

72. The Parent and guardian shall:
    (1) Facilitate self-help and peer-led support groups for substance abusers.
    (2) Communicate the risk of drug use with the child;
    (3) Participate in prevention, awareness and early detection; and
    (4) Be positive role model to the youth.

73. Workplace /employers shall:
    (1) Initiate and carry out drug abuse preventive measures in the workplace;
    (2) Establish clear policies on substance abuse that align with national regulations and best practices; and
    (3) Facilitate treatment and social reintegration.

Chapter VI
Treatment and Rehabilitation

Early detection and Diagnosis

74. In accordance with section 33 of the Act, the Authority shall designate Competent Authorities upon recommendation from the Competent Technical Advisory Committee for early detection and diagnosis of substance abusers as per the prescribed guidelines.

75. The designated Competent Authority shall develop standard operating procedures for early detection and diagnosis of substance abuse in line with the guideline.

76. The designated Competent Authorities shall identify trained professionals to determine the level of substance abusers.

77. The designated Competent Authority to strictly report any positive sample or substance abusers to the Authority and RBP.

Treatment and Rehabilitation Centre

78. In accordance with section 34 of the Act, the Board shall approve accreditation of any government, private, or non-governmental organisation/civil society organisation or institution providing treatment and rehabilitation services for substances abusers as Approved Treatment and Rehabilitation Centres upon the recommendation of the Competent Technical Advisory Committee for the purpose and effective implementation of the Act as per the prescribed guidelines.

79. In accordance with section 39 of the Act, the Board shall designate the Competent Technical Advisory Committee as the committee to review the quality, standards, and range of services offered by such institutions from time to time.

80. The accreditation accorded may be suspended or cancelled by the Authority as per the conditions prescribed in the relevant guideline.

81. The Authority shall monitor the human resources of the accredited approved treatment and rehabilitation centres and ensure that the approved treatment and rehabilitation centres have an adequate number of appropriately trained and qualified professionals to deliver effective and quality services and care as prescribed in the relevant guideline.

82. The Authority shall monitor the accredited approved treatment and rehabilitation centres that have adequate space, infrastructure, resources and technical equipment to deliver effective and quality services and care as prescribed in the relevant guideline.

83. The Authority shall develop and/or review guidelines and referral pathways for substance use detoxification, treatment, rehabilitation and reintegration for effective delivery of services.

After-care and social reintegration

84. The Authority shall monitor the provision of treatment, rehabilitation, after-care services and social reintegration of substance abusers including individual and group counselling,

detoxification and treatment, psychosocial rehabilitation and vocational skills training as per the prescribed standards.

85. The approved Treatment and Rehabilitation Centres shall facilitate adequate after-care, follow-up treatment and supervision after release as per the prescribed Guidelines.

Voluntary submission for treatment

86. In accordance with section 40 of the Act, substance abusers who voluntarily submit for detoxification, treatment, and rehabilitation before being arrested or charged for that offence shall be exempted from prosecution if that person undertakes and successfully completes the treatment without committing any further offences.

Compulsory submission

87. The treatment and referral for the individuals charged with the offence of substance abuse shall be carried out as per the prescribed guidelines.

Treatment Assessment Panel

88. In accordance with section 38 of the Act, the Board shall constitute a Treatment Assessment Panel for the purposes of this Act.

89. The Treatment Assessment Panel shall be constituted in every jurisdiction of Dzongkhag and Dungkhag Court. The Treatment Assessment Panel shall comprise of the following members:
    (1) Legal representative;
    (2) Representative from Royal Bhutan Police;
    (3) Psychiatrist/Medical Specialist/General Duty Medical Officer;
    (4) Clinical counsellor/A certified addiction professional; and
    (5) Peer mentor/recovery coach.

90. The functions of the Treatment Assessment Panel shall be to:
    (1) Screen and assess a person charged with the offence of substance abuse;
    (2) Assess the suitability for treatment;
    (3) Formulate treatment plan;
    (4) Identify and determine the support needed to successfully implement the treatment plan;
    (5) Review and evaluate the progress of treatment periodically;
    (6) Recommend additional time for treatment and rehabilitation based on reviews conducted; and
    (7) Provide recommendations for additional inputs such as community services for repeated noncompliance to treatment orders.

Role of Individual Members

91. The Legal represenatative shall seek the Court order for enforcement of treatment order issued by Treatment Assessment Panel through miscellaneous hearing.

92. The representative from Royal Bhutan Police shall ensure compliance to the treatment order as per the Court order.

93. The Treatment Assessment Panel shall meet as and when an offence of substance abuse has been charged by the RBP.

Offence in relation to treatment orders

94. Any person who has been referred to treatment in accordance with section 47 of the Act including one who has been given additional time for treatment by the Treatment Assessment Panel in accordance with section 155 of the Act shall be liable for offence per section 153 in relation to the treatment order as determined by the court in the event if he/she:
    (1) Refuses to comply with a treatment order without submission of any written reasonable justification based on evidence;
    (2) Fails to comply with a treatment order without submission of any written reasonable justification based on evidence to the approved treatment centre where the person is undergoing treatment;
    (3) Fails to inform the person-in-charge of a treatment centre of any change in address of person undergoing treatment without submission of any written reasonable justification based on evidence;
    (4) Refuses or fails to appear before the panel when ordered to without submission of any written reasonable justification based on evidence;
    (5) Fails to attend a treatment centre for assessment without submission of any written reasonable justification based on evidence; or
    (6) Fails to attend a treatment centre for treatment as ordered without submission of any written reasonable justification based on evidence.

Treatment Completion Certificate

95. Any person who has undergone compulsory treatment and rehabilitation shall be subject to drug test at the end of the treatment without which the completion certificate shall not be provided.

96. If a person undergoing treatment fails the drug test, he or she shall be treated as committing an offence in relation to treatment order and shall be treated as a repeated offender of substance abuse and be liable to undergo treatment prescribed under sections 153 and 154 of the Act.

97. The authorised officer shall submit the drug test report to the Authority with a copy to the Treatment Assessment Panel within three working days of the testing.

98. In accordance with section 48 of the Act, the treatment shall be deemed completed upon negative screening result for substance abuse and on endorsement of a certificate of completion by the Treatment Assessment Panel.

99. Notwithstanding section 98 of this Regulation, the approved treatment and rehabilitation centre shall issue a completion certificate to individuals who completed the treatment and rehabilitation programme.

Exemption from criminal liability

100. In accordance with section 49 of the Act, the individual shall be exempted from the criminal liability upon fulfilling the following conditions:
    (1) Produce certificates on successful completion of the treatment and rehabilitation;
    (2) Refrained from committing any offence while undergoing treatment; and
    (3) Possess no serious danger to himself or herself, family members or the community.

Legal Custody

101. In accordance with section 52 of the Act, a drug-dependent person shall be deemed to be in legal custody while he or she is:
    (1) Confined in, or is being taken to or from, an approved institution;
    (2) For any other valid reason required to go out of an approved institution under unavoidable circumstances but in the custody or under the control of an officer of the approved institution; or
    (3) Taken to any place to which he or she is required or authorised under this Act to be taken, or is kept in custody.

102. In accordance with section 47A of the Act, the Royal Bhutan Police shall produce the individuals charged with the offence of substance abuse before the Treatment Assessment Panel.

103. If the Treatment Assessment Panel decides to admit the person charged with the offence of substance abuse for residential treatment and rehabilitation, the custody of the individual will be handed over to the approved treatment and rehabilitation centre for the duration of treatment and rehabilitation.

104. If the Treatment Assessment Panel decides to send the person charged with substance abuse for outpatient treatment, the person is deemed to remain in the custody of the police. The police may release the person in the care of his family or guardian for the duration of

treatment after signing an undertaking by the person and obtaining surety from the parents/guardian.

Confidentiality of Records

105. In accordance with section 51 of the Act, individuals and institutions dealing with substance abusers who are undergoing voluntary treatment and rehabilitation shall maintain confidentiality of records.

106. Under voluntary submission breaching confidentiality of records shall be an offence of misdemeanour, and shall pay compensation to the victim for the damage caused, as determined by the Court.

107. Sharing of information between the members of the treatment and rehabilitation team and with the members of the Treatment Assessment Panel as per prescribed guidelines, shall be protected from prosecution for the purpose of treatment and rehabilitation.

Crime due to intoxication of controlled drugs and substances

108. The Authority shall develop treatment and referral guidelines for individuals who commit offences under the influence of controlled drugs and substances.

109. Any individuals convicted for offences under the influence of controlled drugs and substances shall undergo prison-based substance use treatment and rehabilitation while serving their prison terms.

110. Any individuals convicted for offences under the influence of controlled drugs and substances but deemed as a misdemeanour or lesser offences, who can pay *thrim thue* in lieu of imprisonment, shall undergo mandatory treatment and rehabilitation.

Monitoring, Evaluation, Research and Review

111. The Authority, in collaboration with relevant agencies, shall undertake periodic assessments and related studies to determine the nature, extent and magnitude of substance abuse and develop appropriate prevention and treatment interventions.

112. The Authority shall make periodic visits to treatment and rehabilitation centres to monitor, supervise and evaluate treatment and rehabilitation programmes and make recommendations to update the programmes.

113. The Authority shall submit the report to the Board for information, record and directives.

Human Resources Development

114. The Authority, in collaboration with relevant agencies shall develop and provide timely capacity development to effectively reduce or prevent substance abuse and effectively treat or rehabilitate substance abusers.

Roles and Responsibilities of Local Leaders in Treatment and Rehabilitation

115. The local leaders in coordination with relevant agencies shall:
    (1) Provide support for individuals to undergo aftercare services and continuum of care services in their respective community;
    (2) Facilitate and provide support for the reintegration and rehabilitation of substance abusers; and
    (3) Provide support services to facilitate individuals seeking treatment and self-help services.

Roles and Responsibilities of Schools in Treatment and Rehabilitation

116. The school shall:
    (1) Provide a supportive environment for the prevention of substance abuse;
    (2) Provide early identification of substance abusers;
    (3) Provide counselling and support to students affected by substance abuse
    (4) Support identified substance abusers to seek treatment;
    (5) Monitor students affected by substance abuse;
    (6) Engage with families and guardians of students affected by substance abuse; and
    (7) Ensure the school environment is free of drugs and alcohol.

Roles of Family and Guardians in Treatment and Rehabilitation

117. In keeping with the important role parents and guardians play in the treatment, rehabilitation, after-care, and reintegration of substance abusers, they shall take the following responsibilities:
    (1) Attend all mandatory Family Education Sessions as prescribed in the standard procedures;
    (2) Produce children to the treatment and rehabilitation centres as prescribed in the standard procedures; and
    (3) Produce their children and participate in the after-care, rehabilitation reintegration programme.

Chapter VII
Enforcement Measures

Protection of informants and complainants

118. The identities of the informants and complainants must remain confidential to protect them from potential harm or retribution from those they report.

119. If a formal complaint is received alleging the disclosure of an informant's or complainant's identity, the authorised agency shall investigate the matter, register a case and forward to the court of law for compensation as per Penal Code of Bhutan.

120. Individuals who provide false information to a relevant agency shall be subject to prosecution as per the provision prescribed in the Penal Code of Bhutan.

Sample-taking of seized substances

121. The Authority shall authorise the relevant agency or official to collect samples of seized substances.

122. The authorised agency or official shall ensure that the samples of seized substances are collected appropriately as per the provision prescribed in the Standard Operating Procedures.

123. Each sample collected must be documented with the following information:
    (1) Place, date and time of sampling;
    (2) Packaging of each sample taken;
    (3) Identification number placed on the package containing any samples taken;
    (4) Packaging place of the bulk remaining after sampling; and
    (5) Identification number placed on any package containing the bulk remaining after sampling.

124. The sample collected shall be disposed-off in a manner that ensures its complete destruction as per relevant SOP.

Drug screening and drug testing

125. The Authority or an agency designated by the Authority may conduct drug screening and testing of any person, substance, container or sample as per section 85 of the Act in line with prescribed drug screening and testing guidelines.

126. The Authority and Competent Authority may conduct drug screening and testing of any person, substance, container or sample if there is reasonable suspicion of abuse, possession or trafficking.

Disposal

127. The relevant agencies shall submit the seized or confiscated controlled drugs or substances in the prescribed Annexure III for safe disposal to the Authority as per the Standard Operating Procedures and guidelines.

128. The Authority shall on a quarterly basis schedule for disposal in the presence of the Royal Bhutan Police.

129. The Authority upon satisfaction that the substance can be disposed of and the orders of the Court have been obtained shall dispose of the substances as per the standard procedure.

Disposal report

130. The Authority shall issue the disposal report to the relevant agency upon completion of the disposal procedure indicating the details of the controlled drugs, date and time and the manner of disposal.

Chapter VIII
Reward to Informers

Eligibility to receive reward

131. Reward may be granted by the Reward Evaluation Committee and cannot be claimed by anyone as a matter of right.

132. Any person whose duties are related to the due administration or enforcement of the Act including the authorised officers shall not be provided with monetary rewards.

133. The informer shall be rewarded as per standard operating procedures and guidelines prescribed subjected to the following conditions:
    (1) When there are multiple informers for the same offence, only the first informer to report will be eligible for the reward.
    (2) When there are multiple offenders associated with the same case number, and if subsequent offenders are identified based on information provided by the initial offender, the informant is entitled to receive rewards only for the products seized in the initial case.
    (3) Where two or more types of substances are seized, the reward shall be subject to the substance having a higher quantity.
    (4) When the informer in a group reports the information, they will be considered as a single informant.
    (5) The payment of reward is subject to seizure and proof of a criminal offence of narcotic drugs, psychotropic substances, precursor chemicals. Reward shall be paid out of funds provided by the Royal Government or any other funds identified by the Board.

Reward Procedure

134. The reward proposal shall be placed in a sealed envelope signed by the Competent official and submitted to the Authorised Officer, who shall register the date and time of receipt.

135. The Authorised Officer shall immediately inform the head of the Authority on the date and time of the receipt of such information.

136. The Authorised Officer shall as soon as possible review and verify the information received for submission to the Reward Evaluation Committee and maintain a confidential file for such cases.

137. The reward will be disbursed from the relevant authorised agency, with which they have lodged complaints.

138. The Competent Authority shall notify the informer to collect the reward within one month from the date of receipt and the reward will be returned to the Authorised Officer on failure to collect it within the said time period.

139. When the informer fails to collect the reward within the stipulated time frame, the competent official shall return the reward amount to the Authority within one week and authorised officer shall inform the head of the Division.

Authorised agencies in the disbursement of rewards

140. The Authorised Agencies for the disbursement of rewards are as follows:
    (1) Bhutan Food and Drug Authority;
    (2) Royal Bhutan Police;
    (3) Department of Revenue and Customs; and
    (4) Any other agencies authorised by the Board.

Types of offences eligible for reward

141. The disclosure proving any of the following offences may be provided with rewards:
    (1) Illicit trafficking of narcotic drugs, psychotropic substances or precursor chemicals;
    (2) Illegal possession of narcotic drugs, psychotropic substances, or precursor chemicals;
    (3) Unauthorized cultivation, domestication, harvest, production, or manufacture, distribution or sales of narcotic drugs, psychotropic substances, or precursor chemicals;
    (4) Illegal Diversion of precursor chemicals; and
    (5) Any such similar crimes deemed to have been committed on narcotic drugs, psychotropic substances, and precursor chemicals as determined by the Authority.

Responsibilities of the Authorised Agencies

142. The Authorised Agency shall maintain confidentiality of the informer at all times.
143. Prepare and submit the reward proposal to the Authorised Officer in as per prescribed format
144. The reward proposal shall be submitted within one month from the date of conviction order of the accused, and

145. The Authorised Agency shall maintain a confidential record of the reward proposals and the amounts of rewards disbursed.

Roles and Responsibilities of the Reward Evaluation Committee

146. The Reward Evaluation Committee shall:
    (1) Ensure that reward proposals are managed under the Act and Rules thereof.
    (2) Evaluate the reward proposals submitted by the Authorised Officer and make appropriate decisions.
    (3) Ensure that the seized controlled substances are received, verified, and recorded by the Authority.

Chapter IX
Fines and Penalties

Non-Compliance with Licence/Authorization

147. In order to efficiently enforce the provisions of the Act and this Regulation, the following fines and penalties are prescribed as empowered under section 112 of the Act.

148. Any licensee contravening section 29 of this Regulation shall be liable to cancellation of the licence and seizure of goods or a fine equivalent to a minimum wage for a maximum of five years, or both as per the following conditions:
    (1) A licensee shall be liable to cancellation of licence and seizure of goods if the licensee contravenes technical conditions 1, 2, 3 and 4 specified in section 29 of this Regulation.
    (2) A licensee shall be liable to payment of fines if the licensee contravenes technical condition 5 and 6 specified in section 29 of this Regulation.
        (a) The first time shall pay a fine equivalent to a minimum wage of 6 months.
        (b) The second time shall result in cancellation of licence, seizure of goods and payment of a fine equivalent to minimum wage of one year.
    (3) A licensee shall be liable to payment of fines if the licensee contravenes technical conditions 7 to16 specified in section 29 of this Regulation.
        (a) The first time shall pay a fine equivalent to a minimum wage of one year.
        (b) The second time shall result in cancellation of licence, seizure of goods and payment of a fine equivalent to minimum wage for three years.
        (c) The authorised agency shall designate or identify an appropriate place to conduct the search of person.

149. Any person-in-charge contravening section 45 of the Act shall be imposed a fine of Nu. 10,000 (Ngultrum Ten Thousand only) per person found using controlled drugs and substances in his or her premises.

150. Notwithstanding section 149 a person-in-charge of any premise shall be liable to suspension of licence for a duration determined by the Authority if the establishment is commercial in addition to the fine specified in section 149 on the second instance.

151. Notwithstanding section 149 a person-in-charge of the premise/facility shall be liable to cancellation of licence if the establishment is commercial in addition to the fine specified in sections 149 on the third instance.

Duties of medical professionals

152. Any professional authorized in carrying out section 37(2) of this Regulation commits an offence of Professional Misconduct shall be dealt as per the Medical and Health Regulations of Bhutan 2005 or any equivalent laws.

Chapter X
Amendments and Definitions

Immunity

153. No action shall lie against the Authority or any officers working for the Authority in respect of any act done or omitted in good faith in the execution of the functions under these Regulations.

Revision

154. The Authority may review and revise these Regulations in consultation with relevant agencies or organisations.

Definition

155. Unless the context otherwise requires:

(1) **Act** refers to the Narcotic Drugs, Psychotropic Substance and Substance Abuse Act 2015 Amendment 2018

(2) **Authorised Agency** means designated agencies of the Authority and/or an official of an agency authorised by the Board to carry out the provisions of this Act and Regulation.

(3) **Authority** refers to the Bhutan Food and Drug Authority established under the Act and Regulation;

(4) **Board** refers to the Governing Board of the Bhutan Food and Drug Authority

(5) **Competent Authority or Competent Agency** means the Authority or any other Authority designated by the Board for the purposes of implementing or enforcing provisions of this Act;

(6) **Competent official** means an official duly assigned or designated with the approval of the Board or their respective authorised agencies for the purposes of implementing or enforcing these Rules of Procedure.

(7) **Authorization Holder** refers to the individual or entities possessing authorization issued for cultivate, manufacture, produce, import, export, wholesale, retail, distribute, and use of plants, substances and preparations listed under Schedule III, IV, V and VI of the Act.

(8) **Medically unfit** means a medical condition resulting in temporary or permanent disability of a person, which may be physical or mental or both as deemed by the Medical Board;

(9) **Non-Governmental Organisations** refers to a registered civil society organisation or any international organisation not within the purview of government.

(10) **Officer in-charge or person in-charge** refers to an individual responsible for the entity or head of the organisation or institution.

(11) **Premise** refers to the area or boundary of the business operation;

(12) **Substances Abuser** refers to the individual engaged in misuse of Schedule I, II, III, IV and VI of the Act.

(13) **Workplace/employers** refers to a location where someone works, for their employer or themselves, a place of employment

ANNEXURES

Annexure I: Quarterly and Annual Report on Controlled Substances

1. Reporting Entity

a. Name of the Establishment:	b. License Number:
c. Address:	d. Authorization Number:

e. Reporting for the Quarterly or Annually:

2. Details of the Controlled Substances Imported, Distributed and/or exported

a. Imported

Name of the Substance	Description	Date of receipt	BFDA IA No.	Received from (Name & Address)	Consignment No./Bill No	Quantity received	Custom Clearance No.

b. Distributed

Name of the Substance	Description	Date of distribution	Qty distributed	Name & Address of the purchaser	Supply order number	Bill Number

c. Exported

Name of the Substances	Description	BFDA Export Authorization No.	Import Authorization no. of importing country	Name & address of the importer	Qty.imported	Consignment no./bill no.

d. Consumption

Name of the Substances	Description	Date of receipt	Qty. received	Opening balance	Qty. used/ consumed	Date of consumption/use	Closing balance

e. Disposed/destroyed

Name of the Substances	Description	Date	Qty disposed/destroyed	Reason	BFDA approval no.

3. Declaration
I declare that to the best of my knowledge, all the information provided above is true, correct and complete. I am aware that giving false or misleading information is a serious offence and I shall be liable for the consequences.
Name of the applicant: Signature of the applicant: Official Seal Date: Place:
Note: 1. An additional sheet can be used for activity no. 2 a, b, c, d and e if required. 2. The half yearly report should be submitted by the end of each quarter and annual report on or before May 31st of the calendar year to the Competent Authority.

Annexure II: Quarterly and Annually Statistical Returns for Narcotic Drugs and Psychotropic Substances

1. Authorization Holder Information
   Name of Authorization Holder: …….
   Facility/Organization Name: ……
   Authorization Number: …….
   Reporting Period: ☐ Quarterly ☐ Annual *(√)*
   Quarter/Year: *(e.g., Q1 2024 or Annual 2024)* ……..
   Contact Information (Phone/Email): …….

2. Controlled Substance Record

Substance Name	Category or Schedule	Opening Stock	Quantity Manufactured	Quantity Imported	Quantity Used	Quantity Exported	Quantity Destroyed/ Damaged	Closing Stock

3. Detail of Record of Consumption, Sale and Distribution

Date (YYYY-MM-DD)	Consumption, Sale and Distribution	Substance Name	Quantity	Source/Destination (If applicable)	Purpose/Notes

Note: All records must be maintained for a minimum of five years from the date of each entry. Records should be kept in a secure and accessible location to ensure compliance and facilitate inspections by regulatory authorities.

I, the undersigned, declare that all information recorded in this form is accurate and complete, reflecting all controlled substance usage as required by regulatory standards.

Authorized Person's Name:

Position/Title:

Signature:

Date:

Annexure III: Disposal of Seized or Confiscated Controlled Substances

1. Submission Details
   Date of Submission:
   Submitting Agency:
   Agency Contact Person:
   Designation:
   Contact Number:
   Email Address:

2. Details of Seized/Confiscated Substance

Sl/No	Controlled Substance Name	Quantity (in gram/kg or ml)	Dosage form (e.g., tablet, powder, liquid)	Date of Seizure	Location of Seizure	Remarks/Additional Information

3. Reason for Disposal
   ☐ Public Safety
   ☐ Expired Substance
   ☐ Other (Specify):

4. Approval for Disposal
   Authorized Personnel: ……..
   Designation: …….
   Date of Approval: …….

5. Method of Disposal
   Proposed Disposal Method: …….. *(Examples: Incineration, Chemical Degradation, Burial, etc.)*
   Location of Disposal: ……
   Disposal Date: ……

6. Witness to Disposal

No	Name of Official	Designation	Agency	Signature

7. Declaration of disposal

I hereby declare that the above-listed substances were disposed of in accordance with the Standard Operating Procedures and guidelines established by the Authority.

Name:

Designation:

Signature:

Date:

For Authority's use only

The Authority hereby acknowledges the safe disposal of the seized or confiscated controlled drugs or substances as per the procedures and guidelines.

Name of Authorized Official:

Designation:

Signature:

Date:

Note: Attach any supporting documents (e.g., photos, lab reports, seizure report) as required.