



NARCOTIC DRUGS,
PSYCHOTROPIC SUBSTANCES
AND SUBSTANCE ABUSE
RULES AND REGULATIONS
2026

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.

NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES AND SUBSTANCE ABUSE RULES AND REGULATIONS, 2026

In exercise of the powers conferred under Section 57 (5), Chapter VII of the Narcotic Drugs, Psychotropic Substances and Substance Abuse Act of Bhutan, 2015, the Narcotics Control Board hereby makes the following Rules and Regulations for carrying into effect the provisions of the Act.

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Chapter I

Preliminary

Short title, commencement and extent

- 1) These Rules and Regulations shall:
 - (1) be called the Narcotic Drugs, Psychotropic Substances and Substance Abuse Rules and Regulations 2026;
 - (2) take effect on the 16th day of the Fifth month of Fire Male Horse year of the Bhutanese calendar corresponding to the 1st July of 2026; and
 - (3) extend within the Kingdom of Bhutan.

Application

- 2) These Rules and Regulations shall apply to all the narcotic drugs, psychotropic substances, plants, substances and preparations scheduled under the Act.

Objective

- 3) The objective of these Rules and Regulations shall be to:
 - (1) regulate all controlled substances listed under Schedules I to VI in the Act;
 - (2) reinforce and strengthen enforcement of the Act; and
 - (3) promote transparency and efficiency in the services provided by the Authority.

Supersession

- 4) Upon coming into force of these Rules and Regulations, the Narcotic Drugs, Psychotropic Substances and Substance Abuse Rules and Regulations 2024, notifications, and circulars concerning the subjects shall be superseded.

Interpretation

- 5) In these Rules and Regulations, unless the context indicates otherwise, the singular shall include the plural and masculine shall include the feminine and vice versa.

Chapter II

Governance

Governing Council

- 6) In accordance with the powers conferred by Section 13 of the Civil Service Reform Act of Bhutan 2022, and in accordance with the decisions of the Lhengye Zhungtshog, and the Royal Civil Service Commission, the Bhutan Food and Drug Authority Governing Council shall comprise:
- (1) Minister, Ministry of Health as Chairperson;
 - (2) Director/Director General, Department of Agriculture, Ministry of Agriculture and Livestock as Member;
 - (3) Director/Director General, Department of Livestock, Ministry of Agriculture and Livestock as Member;
 - (4) Director/Director General, Department of Trade, Ministry of Industry, Commerce and Employment as Member;
 - (5) Director/Director General, Department of Health Services, Ministry of Health as Member;
 - (6) Secretary General, Bhutan Chamber of Commerce and Industries as Member;
 - (7) Senior/Superintendent of Police, Integrated Check Post Management, Royal Bhutan Police as Member;
 - (8) Director/Director General, Department of Forest and Park Services, Ministry of Energy and Natural Resources as Member;
and
 - (9) Director/Director General, Bhutan Food and Drug Authority, Ministry of Health as Member Secretary.

Powers and Functions of Governing Council

- 7) The Governing Council shall exercise the powers, functions and follow procedures as specified in the Act and 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 mobilization of adequate resources to ensure efficient and effective regulatory services;
- (4) Approve standards, policies and regulations based on the recommendation of Competent Technical Advisory Committee (CTAC) and in line with international standards for regulation of products under purview of the Authority;
- (5) Endorse the amendment of any prescribed fees, fines and penalties for any regulatory services as and when necessary, upon recommendation of the Authority;
- (6) Coordinate the national response to ensure timely and appropriate actions during emergencies related to narcotic drugs, psychotropic substances, and substance abuse;
- (7) Designate competent Appellate Laboratory for testing of controlled substances upon recommendation of the Authority;
- (8) Constitute CTAC and any other committees as and when required to advise the Council on technical matters arising out of the administration of regulatory functions;
- (9) 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;
- (10) Amend any Schedule by addition, deletion or variation on the recommendation of the CTAC;
- (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 these Rules and Regulations.

Bhutan Food and Drug Authority

- 8) In accordance with Section 26 of the Civil Service Reform Act of Bhutan 2022, the Bhutan Narcotics Control Authority under the Narcotic Drugs, Psychotropic Substances and Substance Abuse Act 2015 shall be the Bhutan Food and Drug Authority, Ministry of Health.

Powers and Functions of Bhutan Food and Drug Authority

- 9) The Authority shall exercise powers and functions in accordance with Section 73 and Section 74 of the Act and shall:
 - (1) regulate cultivation, manufacture, import and export, storage, sales, dispensing and distribution of Schedule III, IV and V substances;
 - (2) develop standards, guidelines and conditions required for implementation of these Rules and Regulations;
 - (3) develop and prescribe the formats for application, certification and authorizations for the purpose of carrying out functions under these Rules and Regulations;
 - (4) regulate advertisements and promotions of Schedule III, IV and V substances;
 - (5) investigate complaints made to the Authority in accordance with the prescribed procedures;
 - (6) create awareness of the provisions of the Act and Rules and Regulations made thereunder;
 - (7) impose fines and penalties for non-compliances;
 - (8) liaise with other relevant national and international organizations;
 - (9) approve/reject the authorization for manufacturing, production, import, export, wholesale, retail and distribution of substances listed under Schedule III, IV and V of the Act;
 - (10) submit annual estimates of substances listed under Schedule III, IV and V based on the previous year's consumption to International Narcotics Control Board (INCB);

- (11) submit the statistical report quarterly and annually to International Narcotics Control Board (INCB);
- (12) review and amend the forms as necessary;
- (13) ensure the implementation of pre-export notification system;
- (14) ensure the equipment and materials used for the manufacturing and production of substances and preparations listed under 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 these Rules and Regulations.

Competent Technical Advisory Committee

- 10) The Governing Council shall constitute and approve CTAC, and shall comprise:
 - (1) Psychiatrist, Jigme Dorji Wangchuck National Referral Hospital;
 - (2) Police Officer, Narcotics Drugs and Other Vices Division, Royal Bhutan Police;
 - (3) Attorney, Drug Prosecution and Prevention Division, Office of the Attorney General;
 - (4) Clinical Pharmacist/Pharmacist, Jigme Dorji Wangchuck National Referral Hospital;
 - (5) Drug Analyst, Royal Centre for Disease Control, Ministry of Health;
 - (6) Addiction Professional, The PEMA Secretariat; and
 - (7) Chief Program Officer, 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 shall be elected amongst the members.
- 13) The Vice Chairperson shall chair the meeting in the absence of the Chairperson.

- 14) The members shall attend the meeting without fail after confirmation. If a member fails to attend meetings after confirmation, the member shall provide a valid explanation in writing to the Chairperson.
- 15) In the event that the member fails to attend two consecutive meetings, then the member's appointment shall be terminated and replaced by the Council.
- 16) The Chairperson shall recommend the Authority to invite co-opt members as and when required.
- 17) A simple majority of the members shall constitute a quorum for the meeting.

Functions of the CTAC

- 18) The CTAC shall carry out the following functions:
 - (1) periodically review the schedules and recommend amendments including the addition, deletion or quantification of substances, based on emerging trends, scientific evidence and field data;
 - (2) provide advice to the Council on all technical areas related to substances under the schedules and other related technical matters as and when required by the Council;
 - (3) review and recommend relevant national standards to the Council;
 - (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 not disclose any important decision of the meetings unless approved by the Council;
 - (6) recommend the Council to appoint expert(s) to address specific technical areas as and when required; and
 - (7) carry out any other responsibilities assigned by the Council.

Chapter III

Control of Licit Activities

Technical Authorization for Trade

- 19) No person shall cultivate, produce, manufacture, wholesale or retail, distribute, import, export, store, transport, or use any substance listed under Schedules III, IV and V except under a valid technical authorization for trade issued by the Authority.
- 20) A technical authorization issued by the Authority shall not substitute a license issued by the relevant agency.
- 21) No establishment or premises shall be used for such activities unless expressly authorized.
- 22) No entity shall engage in international trade of substances listed under Schedules III, IV and V unless:
 - (1) authorized under its license; and
 - (2) prior import or export authorization is obtained.
- 23) All license holders shall comply with:
 - (1) conditions of technical authorization;
 - (2) record-keeping requirements; and
 - (3) inspection and enforcement provisions.
- 24) An application for technical authorization for trade shall be submitted in such form as may be prescribed by the Authority.

Eligibility for Technical Authorization for Trade

- 25) An applicant shall be eligible for a technical authorization for trade if:
 - (1) the applicant is a legal entity, a government institution, or a recognized academic or research institution established under the laws of Bhutan;
 - (2) a period of one (1) year has elapsed since the cancellation of the applicant's previous technical authorization for trade, unless exempted by the Council for justified reasons; and

- (3) the applicant demonstrates the capacity to comply with:
 - a) security and storage requirements;
 - b) record-keeping and reporting obligations;
 - c) inspection, sampling, and testing requirements; and
 - d) any other conditions prescribed by the Authority.

Suspension of Technical Authorization for Trade

- 26) The Authority may suspend a technical authorization for trade, if:
 - (1) any condition of the technical authorization for trade is not complied with; or
 - (2) the authorization holder no longer meets the eligibility requirements; or
 - (3) there is reasonable suspicion of diversion, misuse, or illegal trade; or
 - (4) there is an imminent risk to public health or safety.
- 27) A suspension imposed under Section 26 of these Rules and Regulations shall not exceed a period of three (3) months. However, the suspension may be extended where the Authority has reasonable grounds to do so.
- 28) Upon suspension of a technical authorization for trade, the authorization holder shall immediately cease all authorized activities for the duration of the suspension.
- 29) All controlled substances shall be secured under appropriate conditions and not be used, distributed, or transferred without prior approval of the Authority.
- 30) The Authority may inspect and monitor the premises and records as necessary.

Cancellation of Technical Authorization for Trade

- 31) The Authority may cancel a technical authorization for trade, if:
 - (1) the authorization holder is convicted of an offence under the Act, other than substance abuse where the person has

- successfully completed approved treatment; or
 - (2) there is repeated or persistent non-compliance with the conditions of technical authorization for trade; or
 - (3) there is failure to comply with or fulfill the corrective measures, requirements, or conditions imposed by the Authority for lifting the suspension; or
 - (4) any other condition as may be determined by the Council in the interest of public health and safety.
- 32) Upon cancellation of a technical authorization for trade, the authorization holder shall immediately cease all authorized activities.
- 33) All controlled substances shall be declared to the Authority and disposed of, transferred, or destroyed in accordance with the directions of the Authority.
- 34) The Authority may inspect and monitor the premises and records as necessary.

Technical Authorization for Research, Teaching or Forensic Work

- 35) The Authority may, without requiring a general license under Section 18 of the Act, grant provisional authorization for research to designated individuals, institutions, or agencies to produce, manufacture, acquire, import, use, possess, or hold substances listed under Schedules I, II, III, IV and V for medical or scientific research, teaching, or forensic work.
- 36) A provisional authorization for research shall:
- (1) be granted if the applicant meets the conditions laid down under Section 25 of these Rules and Regulations and any other conditions specified by the Authority;
 - (2) be valid for a limited period as determined by the Authority; and
 - (3) be subject to monitoring, inspection, and compliance requirements under these Rules and Regulations.

- 37) Where the holder of a provisional authorization for research complies with all prescribed conditions and requirements, the Authority may grant a technical authorization for research.
- 38) Where the holder of a provisional authorization for research fails to comply with any condition, the Authority may suspend or revoke the authorization.
- 39) An application for technical authorization for research shall be submitted in such form as may be prescribed by the Authority.
- 40) Any extension of, or deviation from, the approved research proposal shall require prior written approval of the Authority.
- 41) The applicant may withdraw from the proposed research at its own discretion upon written notification to the Authority and ensure all regulatory obligations are fully complied with.
- 42) The Authority may suspend or revoke an authorization where:
 - (1) any condition of authorization is breached; or
 - (2) there is risk of diversion or misuse.
- 43) Upon revocation or expiry of authorization:
 - (1) all substances shall be secured and accounted for; and
 - (2) disposal or transfer shall be carried out in accordance with the directions of the Authority.

Special Carriage and Traveler Provisions

- 44) In accordance with Section 28 of the Act, any international or domestic conveyance may, with prior written authorization from the Authority, carry specified controlled drugs or substances in its onboard emergency medical kit solely for use in medical emergencies, provided that:
 - (1) the quantity of each controlled drug or substance does not exceed ten (10) adult doses;
 - (2) such substances are stored securely and access is restricted to authorized personnel only; and

- (3) a record shall be maintained of the receipt, use, and balance of each controlled drug or substance contained in the emergency medical kit.
- 45) In accordance with Section 29 of the Act, the Council may authorize import of controlled drugs and substances to meet a public emergency.
- 46) In accordance with Section 30 of the Act, any international travelers or Bhutanese nationals travelling for medical treatment and possessing controlled substances must carry a prescription issued by a registered medical and health professional with the name, dose and quantity of controlled substances mentioned.
- 47) Notwithstanding Section 46 of these Rules and Regulations, no traveler shall be permitted to carry more than a three-month dose of controlled substances.
- 48) Any quantity exceeding the three-month dose limit shall be seized by the Competent Authority and disposed of in accordance with the provisions of the Act and in accordance with these Rules and Regulations.
- 49) The use of controlled drugs and substances in industry for purposes other than medical or scientific use shall be permitted, provided that the authorization holder:
 - (1) implements appropriate methods of denaturing or other effective measures to ensure that such drugs or substances are not susceptible to abuse, do not produce harmful effects, and cannot be feasibly recovered for misuse; and
 - (2) maintains and submits accurate statistical records, including the quantity of each controlled drug or substance utilized for such purposes.

Import and Export Authorization

- 50) All imports and exports of substances listed under Schedules III, IV, and V shall require prior authorization from the Authority.

- 51) All imports and exports of substances under Section 35 of these Rules and Regulations shall require prior authorization from the Authority.
- 52) An application for import/export authorization of substances under Schedule III, IV and V shall be submitted in such form as may be prescribed by the Authority.
- 53) The application may be rejected if the conditions specified in the relevant guidelines are not met.
- 54) The authorization may be revoked if conditions specified in the relevant guidelines are not met.

Duties of the Authorization Holder

- 55) The authorization holder shall comply with the following:
 - (1) engage in activities limited to Schedules III, IV and V 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 plants, substances and preparations listed in Schedule I, II, III, IV and V 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 unauthorized use;
 - (5) declare all import/export/transit consignments at the port of entry to the relevant agency and submit import/export/transit details immediately after effecting import/export/transit;
 - (6) maintain accurate records of all activities involving the controlled substances, including quantity, date, suppliers/recipients, quantities manufactured, equipment used, materials used, quantity held in stock, storage and disposal;
 - (7) notify the Authority in writing of any change in address or contact details, and of any intention to suspend, discontinue, or permanently close operations, prior to cessation of the activity;

- (8) maintain and submit records of statistical returns of production or manufacture, utilization for the manufacture of other drugs, consumption, imports and exports, and seizures of controlled substances;
- (9) submit quarterly and annual statistical reports to the Authority;
- (10) produce documents on demand by an authorized officer;
- (11) close the establishment immediately as and when notified by the Competent Authorities;
- (12) allow access to the premises during inspections by the Competent Authorities;
- (13) pay all applicable fines and penalties;
- (14) ensure that shipments are made in one consignment within the validity of the import and export authorization;
- (15) ensure appropriate security measures to prevent unauthorized access, theft, or diversion of the controlled substances;
- (16) ensure appropriate warnings and indications on the packages, labels and the accompanying leaflets of any packages of the controlled substances;
- (17) may transfer or distribute controlled substances with prior approval from the Authority; and
- (18) comply with any other relevant laws of the country.

Chapter IV

Record-Keeping and Reporting

Record Keeping

- 56) Every person authorized under these Rules and Regulations shall maintain accurate and complete records of all activities involving plants, substances and preparations under the Act.
- 57) Records shall be made at the time of each transaction and retained for a minimum of five (5) years from the date of the last entry.
- 58) For the purposes of these Rules and Regulations, the following shall each constitute a distinct and separately recordable transaction requiring an entry in the register:
 - (1) importation/exportation;
 - (2) acquisition from a domestic source;
 - (3) manufacture or production;
 - (4) use or consumption for therapeutic, scientific, veterinary or industrial purposes; and
 - (5) destruction or disposal.
- 59) No category of transaction listed under Section 58 of these Rules and Regulations shall be combined with or substituted for another.

Register

- 60) Each authorization holder shall maintain registers for all controlled substances handled.
- 61) Each entry shall record the information in such form as may be prescribed by the Authority.
- 62) No entry shall be erased, overwritten or rendered illegible by any means. Where a correction is necessary, the incorrect entry shall be struck through with a single horizontal line so that the original entry remains legible, and the correct entry shall be written immediately below. The correction shall be initialed and dated by the person-in-charge.

- 63) Stock audits/counts shall be conducted by the person-in-charge and reconciled against the register balance.
- 64) Registers shall be stored at all times in a secure location within the authorized premises, accessible only to the authorised personnel.
- 65) Registers shall be produced for inspection upon request by any authorized officer.

Storage of Controlled Substances

- 66) All controlled substances shall be stored as prescribed by the Authority.

Statistical Returns

- 67) The statistical return shall be submitted quarterly and annually, in such form as may be prescribed by the Authority, and it shall be verified by the person-in-charge as true, accurate and complete.
- 68) Healthcare facilities dispensing Schedule III, IV and V substances shall, in addition, submit quarterly dispensing logs in such form as may be prescribed by the Authority, within fifteen (15) days from the end of each quarter.

Chapter V

Enforcement Measures

Advertisement

- 69) In accordance with Section 156 of the Act, any display or depiction of substances listed under the Act with an intent to advertise or promote the substance or use of the substance shall be prohibited.

Inspection

- 70) The Authority shall inspect and monitor all entities for compliance with the relevant laws, and authorized officers shall produce an official identification prior to any inspection under these Rules and Regulations.
- 71) The Authority may carry out inspection in coordination with relevant competent authorities as deemed appropriate.
- 72) Authorized officers shall carry out the inspection as per the applicable inspection guidelines in accordance with Section 23 of the Act.
- 73) Any authorization holder involved in the operations of plants, substances, and preparations covered in the Act shall be subject to inspection by the Authority.
- 74) Authorized officers 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.
- 75) Authorized officers shall maintain confidentiality regarding the information obtained during the inspection and shall conduct the inspection professionally and respectfully, without causing unnecessary disruption to the entity's operations.
- 76) An authorized officer may question any person during inspection, including employees, operators, or owners, about their involvement in activities related to narcotic drugs and psychotropic substances.
- 77) Any authorization holder shall furnish any information or documents and evidence as and when required by the authorized officer.

- 78) After completing the inspection, the authorized officer shall prepare a detailed report documenting the findings, including any violations of the Act, substances seized, and any actions taken.
- 79) If necessary, the Authority may initiate follow-up inspections to ensure compliance with the corrective measures.
- 80) Any authorization holder or entity and premises involved in operations such as plants, substances, and preparation covered by the Act shall not obstruct the authorized officers in carrying out their duties.
- 81) The authorized officers may enter premises, make seizures and take samples whenever the authorized officer has reason to believe that an offence is being, or has been committed, and carry out their duties under the provisions of the Act in accordance with the Civil and Criminal Procedure Code of Bhutan and Rules and Regulations.

Chapter VI

Drug Screening and Testing

Governing Principles of Drug Testing

- 82) Drug testing shall be governed by the following principles:
- (1) Accuracy and Reliability: All testing shall be performed using validated methods with documented sensitivity and specificity;
 - (2) Procedural Fairness: Individuals shall be informed, prior to testing, of the purpose of the test, the substances to be tested for, and the potential consequences of the results;
 - (3) Dignity: Testing shall respect the dignity, confidentiality and privacy of the person;
 - (4) Chain of Custody: All specimens shall be subject to a documented chain of custody from collection through disposal;
 - (5) Connection to Treatment: Where feasible, a positive test result shall be used as a basis for referral to assessment and treatment, rather than solely for punitive action; and
 - (6) Integrity and Conflict of Interest: All persons involved in drug testing shall maintain integrity, independence, and impartiality, and shall not participate where a conflict of interest exists or is perceived.

Drug Screening Procedures

- 83) Screening tests shall be conducted using test kits approved by the Authority.
- 84) Screening shall be conducted by authorized and trained personnel in accordance with prescribed procedures.
- 85) The Authority or a designated agency may conduct drug testing:
- (1) on arrest or detention on suspicion of an offence under the Act;
 - (2) on reasonable suspicion of being under the influence of narcotic drugs and psychotropic substances;

- (3) as part of an investigation or as a condition of a treatment or probation order;
 - (4) as treatment progress monitoring;
 - (5) employment and health screening program;
 - (6) in authorized workplace settings;
 - (7) at ports of entry; and
 - (8) in any other circumstances specified by the Authority.
- 86) Any person who tests positive shall be referred, through the Royal Bhutan Police (RBP), to the Approved Treatment Centre for further assessment and treatment.
- 87) All confirmatory drug testing shall be referred to the competent laboratory designated as the Appellate Laboratory by the Council.
- 88) The result of the Appellate Laboratory shall be final and binding.

Functions of Institutions Conducting Drug of Abuse Testing

- 89) An institution authorized by the Authority to conduct Drug of Abuse (DoA) testing shall:
- (1) maintain testing facilities in a clean, secure, and controlled environment, and provide a designated enclosed area for specimen collection that ensures privacy and dignity;
 - (2) ensure that access to testing and specimen collection areas is restricted to authorized personnel only;
 - (3) obtain prior written informed consent from the individual, in such DoA test form as may be prescribed by the Authority, before conducting any DoA test in accordance with the relevant guidelines;
 - (4) ensure that all information and records, including consent forms, chain-of-custody documentation, and test results, are treated as confidential and are disclosed only to persons or agencies authorized under the Act or these Rules and Regulations;

- (5) ensure that specimen collection is carried out under the supervision of authorized personnel, in accordance with procedures prescribed by the Authority, to prevent tampering, substitution, adulteration, or contamination, and to maintain the integrity of the sample;
- (6) ensure proper labeling, sealing, handling, storage, and transportation of samples, and maintain a complete and documented chain-of-custody in accordance with procedures prescribed by the Authority;
- (7) ensure that testing is conducted in accordance with approved methods and standard operating procedures, and with guidelines issued by the Authority;
- (8) maintain complete and accurate records of all tests conducted, and submit reports to the Authority and/or any other competent agencies within the specified timeframe;
- (9) ensure that confirmed positive test results, where applicable, are reported to the RBP and the Authority together with relevant analytical and chain-of-custody documentation;
- (10) establish internal mechanisms, including a Drug Testing Committee or equivalent body, to oversee implementation, compliance, and quality assurance of DoA testing within the institution;
- (11) provide and maintain adequate infrastructure, equipment, and trained personnel;
- (12) ensure proper retention of samples for confirmatory testing, where applicable, and safe disposal of used testing materials in accordance with the relevant guideline;
- (13) comply with all requirements relating to inspection, monitoring, and audit by the Authority, and implement corrective and preventive actions where directed; and
- (14) provide necessary support for the treatment, rehabilitation, and social reintegration of individuals, in coordination with relevant agencies.

Refusal of Specimen

- 90) Where a defendant or suspect refuses or fails to provide a required biological sample without reasonable cause, the RBP may:
- (1) detain the person for the purpose of obtaining such sample; and
 - (2) proceed to obtain the sample in accordance with Section 185 of the Civil and Criminal Procedure Code of Bhutan and these Rules and Regulations.
- 91) Such refusal shall be recorded in writing and may be taken into consideration in subsequent proceedings.

Sample Taking from Seized Substances

- 92) Samples from seized substances shall be taken by an authorized officer in the presence of the accused and the whole process shall be recorded using videography. During the process, the chain of custody shall be established as per relevant guidelines.
- 93) All material evidence shall be stored in secure conditions to prevent loss, theft or misappropriation, with a documented chain of custody at all stages, with confidentiality ensured.

Appellate Laboratory

- 94) Appellate Laboratory shall be designated by the Council and shall meet the following minimum requirements:
- (1) proficiency testing participation;
 - (2) validated analytical methods;
 - (3) documented chain of custody;
 - (4) quality management system;
 - (5) secure sample storage; and
 - (6) any other requirements as determined by the Council.
- 95) The Authority shall carry out annual audits to assess and verify the competency of the laboratory.

- 96) The Reference Laboratory shall not be the same laboratory that performed the initial confirmatory analysis.
- 97) The Appellate Laboratory shall issue a Laboratory Analysis Certificate as prescribed under relevant guidelines.

Functions of Appellate Laboratory

- 98) The Appellate Laboratory shall perform the following functions:
 - (1) conduct analysis using validated and approved methods, ensuring accuracy, reproducibility, and reliability of results;
 - (2) verify seal integrity, labeling, and accompanying documentation upon receipt of samples, and record any discrepancies or observations;
 - (3) maintain a secure and continuous chain-of-custody system throughout sample receipt, handling, analysis, storage, and disposal;
 - (4) ensure that all testing is performed by competent personnel;
 - (5) ensure that all analyses are carried out impartially, independently, and free from conflict of interest and uphold utmost confidentiality;
 - (6) samples and remnants shall be stored securely and retained for six (6) months from the date of testing;
 - (7) biological sample remnants shall be disposed of after a period of six months. Seized materials shall be handed over to the Authority for disposal upon completion of six (6) months;
 - (8) submit authenticated analytical reports to the Authority or requesting agencies;
 - (9) provide expert testimony and submit laboratory records before courts, tribunals, or other authorities when required;
 - (10) participate in proficiency testing, inter-laboratory comparisons, and quality assurance programs; and
 - (11) cooperate with inspections, audits, and compliance reviews conducted by the Authority.

Disposal

- 99) The relevant agencies shall, after the appeal process has been exhausted, hand over seized or confiscated controlled drugs or substances to the Authority for safe disposal as per relevant guidelines.
- 100) The Authority shall dispose of controlled substances in the presence of representatives from the RBP and the Office of the Attorney General (OAG).
- 101) Upon verification of the Court's judgment, the Authority shall proceed to dispose of the controlled drugs, and shall maintain records as per relevant guidelines.
- 102) The Authority shall submit the disposal report to the relevant agencies upon completion of the disposal indicating the details of the controlled substances, date and time and the manner of disposal.

Chapter VII

Educational Measures

Guiding Principles for Substance Use Disorder Prevention

103) Educational measures under these Rules and Regulations shall embrace a whole of government and whole of society approach, and evidence informed and culturally grounded interventions, guided by the principles of a three-tier prevention model comprising:

- (1) universal prevention;
- (2) selective prevention; and
- (3) indicated prevention.

104) The PEMA Secretariat shall:

- (1) lead formulation of national guidelines and strategic documents for Substance Use Disorder (SUD) prevention;
- (2) establish a national prevention framework integrating education, health, social protection, and community systems in collaboration with the Authority;
- (3) guide the development of behavior change communication and public awareness strategies;
- (4) develop national life skills and resilience-building programs;
- (5) strengthen protective environments within families, schools, communities, workplaces, and other institutions through innovative life skills and resilience-building program;
- (6) build national capacity of prevention professionals and service providers;
- (7) establish monitoring, evaluation, and data systems and facilitate research and evidence generation in collaboration with relevant agencies; and
- (8) establish national systems for early detection, intervention, and referral to ensure alignment with prevention, treatment, rehabilitation, and reintegration services.

105) The Ministry of Health shall:

- (1) implement public health education and behavior change communication on risks of substance use in alignment with the national framework;
- (2) promote mental wellbeing and healthy lifestyles through health promotion activities;
- (3) integrate substance use prevention into routine health services;
- (4) screen for psychosocial vulnerabilities and mental health disorders linked to elevated SUD risk;
- (5) identify at-risk populations and refer to psychosocial service provider(s); and
- (6) conduct systematic screening using a standardized screening system for at-risk populations.

106) Educational institutions shall:

- (1) implement age-appropriate, evidence-based prevention education, including life skills, social-emotional learning, moral and value-based education, and anti-stigma initiatives;
- (2) conduct school-wide awareness and prevention program that promotes healthy, safe, and supportive school environments, student well-being, and school attachment;
- (3) build the capacity of educators and school personnel to deliver SUD prevention, early identification, counselling, and referral interventions;
- (4) establish transparent, non-punitive school policies and procedures relating to substance use;
- (5) conduct periodic risk assessments and provide school-based counselling, psychosocial support, targeted interventions, and referral pathways for students with emotional, behavioral, or substance use-related concerns;
- (6) strengthen parenting education and family engagement in prevention and early intervention efforts; and

- (7) provide safe recreational, vocational, mentoring, and reintegration programs for at-risk learners and vulnerable students.

107) Religious organizations shall:

- (1) promote ethical values and responsible living;
- (2) conduct community awareness through spiritual teachings;
- (3) strengthen resilience through value-based education;
- (4) foster compassion, social harmony, and recovery acceptance;
- (5) provide psychosocial and spiritual support to vulnerable groups; and
- (6) collaborate with community services for prevention outreach.

108) Media organizations shall:

- (1) disseminate accurate public education on the risks associated with substance use;
- (2) promote healthy lifestyles and positive social norms;
- (3) showcase positive role models;
- (4) support national awareness campaigns in combination with other prevention components;
- (5) encourage responsible portrayal of substance-related issues;
- (6) target parents and caregivers through campaigns to support protective family environments; and
- (7) support anti-discrimination messaging in the community.

109) Local Governments shall:

- (1) facilitate and promote community-based awareness and outreach initiatives;
- (2) establish recreational and healthy lifestyle infrastructure;
- (3) promote community participation in prevention;
- (4) support enforcement of drug control policies at the local level;

- (5) support stigma reduction and inclusive environments;
- (6) raise awareness on the provisions of the Act and these Rules and Regulations;
- (7) develop community-based support networks for at-risk populations;
- (8) provide structured recreational and vocational engagement for at-risk populations;
- (9) collaborate with civil society organizations and educational institutions;
- (10) facilitate mentoring and peer-support initiatives in the community;
- (11) facilitate access to community-based counselling and support;
- (12) promote acceptance and reintegration of affected individuals; and
- (13) support community recovery networks.

110) Families shall:

- (1) foster open communication regarding substance use risks;
- (2) model healthy behaviors and promote protective family environments;
- (3) participate in parenting education program;
- (4) support early behavioral monitoring and prevention efforts;
- (5) engage with schools and community services;
- (6) participate in family-based interventions;
- (7) support treatment referrals and recovery processes; and
- (8) facilitate peer and self-help support participation.

111) Workplaces and employers shall:

- (1) conduct substance use prevention, awareness, and workplace wellness program;

- (2) promote and maintain healthy, safe, non-discriminatory, and recovery-supportive workplace environments;
- (3) establish and implement substance-free workplace policy and related procedures;
- (4) identify and support employees with psychosocial or substance use-related vulnerabilities through intervention, and confidential referral to appropriate health, treatment, and rehabilitation services; and
- (5) support the treatment, recovery, and reintegration of affected employees into the workplace.

112) Research and academic institutions shall:

- (1) support the development and adaptation of culturally grounded, evidence-based prevention program and national screening and data collection instruments;
- (2) analyze national drug data, conduct prevalence studies and vulnerability assessments, and evaluate the effectiveness of demand and supply reduction program to inform population-wide strategies, with prior research clearance where required; and
- (3) publish and disseminate research findings to strengthen the national evidence base and support evidence-informed policy and practice.

113) Law enforcement agencies shall:

- (1) support implementation of drug control policies in community settings;
- (2) initiate and participate in community-based multi-component prevention initiatives;
- (3) raise awareness on the provisions of the Act through community engagement;
- (4) participate in diversion programs that link individuals showing early signs of substance use to health and counselling services, in preference to punitive measures; and

- (5) collaborate with health and social services on referral pathways for individuals identified as at risk.

114) Approved Treatment Centre shall:

- (1) support early intervention services;
- (2) provide motivational counselling and psychosocial support;
- (3) maintain coordinated referral systems linking prevention and treatment;
- (4) deliver relapse prevention education;
- (5) support reintegration and recovery capital development; and
- (6) provide brief interventions for individuals showing early signs of substance use or dependence.

115) All educational measures shall operate within a continuum of care ensuring:

- (1) seamless referral between prevention, treatment, rehabilitation, and reintegration services;
- (2) community-based recovery support; and
- (3) reduction of relapse risk through sustained psychosocial support.

Chapter VIII

Treatment, Rehabilitation and Reintegration

Guiding Principle

116) Treatment shall be governed by the following principles:

- (1) Health First: Drug dependence is a health and social issue. Treatment must be evidence-based, rights-respecting, confidential and culturally appropriate.
- (2) Individual Care: Every person shall receive an Individualized Treatment Plan developed collaboratively, taking account of their health, family, culture and social circumstances.
- (3) Continuum of Care: All services shall follow a seamless continuum-of-care model ensuring consistent support from initial assessment through aftercare.
- (4) Non-Discrimination: No person shall be refused treatment on grounds of the substance used, gender, age, religion, ethnicity or disability. Services shall be sensitive to culture, age and gender.
- (5) Family and Community Partnership: Families shall be actively involved in treatment. Communities shall support awareness, safe referrals and the reduction of stigma.

Accreditation

- 117) In accordance with Section 34 of the Act, the Council shall, upon the recommendation of the CTAC, approve the accreditation of any government, private, civil society organization or institution providing treatment and rehabilitation services for persons with SUD as an Approved Treatment Centre.
- 118) An application for accreditation shall be submitted in such form as may be prescribed by the Authority.
- 119) No Centre shall operate as an Approved Treatment Centre without valid accreditation from the Council.
- 120) The Authority shall monitor Approved Treatment Centre for compliance with standards.

- 121) The Council shall suspend or cancel accreditation upon recommendation by the CTAC in accordance with the relevant guidelines and in exercise of the powers conferred by the Act.

Treatment Assessment Panel

- 122) Pursuant to Section 38 of the Act, a Treatment Assessment Panel (TAP) shall be established as a dedicated operational unit.
- 123) The Authority shall provide the TAP with the necessary administrative support.
- 124) The TAP shall comprise the following:
- (1) one representative from the Royal Bhutan Police;
 - (2) one representative from the Office of the Attorney General;
 - (3) the Bhutan Food and Drug Authority as the Member Secretary; and
 - (4) representatives from the Approved Treatment Centre may be co-opted as members on an as-needed basis, to provide clarification on the clinical assessment report.
- 125) The representatives of the RBP and the OAG shall be deputed to the TAP on a full-time basis as their primary duty station.
- 126) The Treatment Assessment Panel shall:
- (1) review the clinical assessment report and substance abuse history of every person referred to it;
 - (2) formulate treatment recommendations applying the treatment periods prescribed under Section 153 and 154 of the Act;
 - (3) monitor the treatment progress of all persons subjected to a Treatment Order;
 - (4) submit recommendations to the Court for extension of any Treatment Order as deemed necessary;
 - (5) maintain records and data on all cases and report periodically to the Authority;

- (6) seek Treatment Orders in respect of first, second, and third offences, undertake prosecution relating thereto, and coordinate and monitor the implementation of community service as directed by the Court; and
 - (7) enforce cases of non-compliance with Treatment Orders.
- 127) Where the person is under eighteen (18) years of age, an identified child protection service provider shall be involved during the review by the TAP for the formulation of treatment recommendations to be submitted to the Court.
- 128) Pursuant to Section 155 of the Act, the TAP may recommend an extension of a Treatment Order where one or more of the following conditions are established:
- (1) the prescribed treatment goals have not been achieved; or
 - (2) the clinical risk of relapse without further intensive support remains elevated; or
 - (3) the person has suffered relapse during the treatment period; or
 - (4) outstanding co-occurring health or mental health conditions have not been adequately addressed; or
 - (5) any other clinically justified grounds determined by the registered medical and health professional.

Multi-Disciplinary Assessment Committee

- 129) A Multi-Disciplinary Assessment Committee (MAC) at the Ministry of Education and Skills Development (MoESD) shall be established, comprising:
- (1) the Head of the relevant Department under MoESD;
 - (2) officials of the Career Education and Counselling Division; and
 - (3) a minimum of three qualified Addiction Professionals.
- 130) The MAC shall:
- (1) assess voluntary submissions of students and determine appropriate treatment interventions;

- (2) monitor treatment progress and recommend continuation, modification, or discharge from the program; and
- (3) report instances of non-compliance to the RBP for initiation of the compulsory treatment pathway.

Referral Flow for Compulsory Treatment

- 131) Upon apprehension of a person under Section 152 of the Act, the RBP shall, within two (2) working days:
 - (1) refer the person to the identified Approved Treatment Centre/SUD Unit for clinical assessment; and
 - (2) concurrently notify the TAP.
- 132) Following apprehension, the RBP may release the person on a signed legal undertaking in the prescribed form NDPS-RR-LU-1 or NDPS-RR-LUM-2, executed by the person and their guarantor, unless the person is assessed as a risk to the self/public, in which case the RBP shall seek remand order.
- 133) The Approved Treatment Centre/SUD Unit shall conduct a clinical assessment using validated assessment tools and submit a written Clinical Assessment Report and recommended treatment plan to the TAP within five (5) working days of referral, as prescribed in relevant guidelines.
- 134) The TAP shall review the Assessment Report together with the person's substance abuse history and, where satisfied, apply to the Court for a Treatment Order within five (5) working days of receiving the report.
- 135) The Court shall consider the application and, in accordance with Section 153 and 154 of the Act, issue a Treatment Order.
- 136) Upon issue of the Treatment Order, the person shall be admitted to an Approved Treatment Centre, which shall assign a Case Manager to oversee the person's treatment, monitoring and progress reporting to the TAP at regular intervals.

- 137) Upon successful completion of treatment, the Approved Treatment Centre shall issue a Treatment Completion Certificate to the person, and notify the TAP and the Court.

Functions of Competent Authorities

- 138) Royal Bhutan Police shall:

- (1) apprehend any person violating Section 152 of the Act;
- (2) enforce Treatment Orders, including the apprehension and return of any person who absconds from treatment;
- (3) deliver treatment program within prison and correctional facilities, with technical support from The PEMA Secretariat;
- (4) investigate cases of non-compliance and refer them to the TAP for review and further action; and
- (5) apply to the Court for appropriate directions for any non-compliance with the legal undertaking.

- 139) Office of the Attorney General shall:

- (1) provide legal advice and support to the TAP in preparing applications for Treatment Orders and extensions;
- (2) undertake prosecution for offences exceeding the third offence and shall coordinate and monitor the implementation of community service orders as decreed by the Court.

- 140) The Authority shall:

- (1) regulate the use of controlled substances in treatment, detoxification, and pharmacotherapy;
- (2) set and enforce minimum treatment standards in coordination with the CTAC; and
- (3) exercise regulatory oversight over, and monitor the compliance of all Approved Treatment Centre with the provisions of the Act and these Rules and Regulations.

141) Approved Treatment Centre shall:

- (1) conduct clinical assessments and submit the clinical assessment report and a recommended treatment plan to the TAP as prescribed in relevant guidelines;
- (2) provide acute withdrawal management and medical stabilization where clinically indicated;
- (3) admit and treat persons referred under a Treatment Order or through the voluntary submission pathway;
- (4) assign a Case Manager to every person admitted for treatment;
- (5) report any escape, absconding, or material non-compliance to the TAP within twenty-four (24) hours of discovery;
- (6) submit periodic treatment progress reports to the TAP; and
- (7) certify completion of treatment and issue the Treatment Completion Certificate to the person, and notify the TAP and the Court.

142) Case Manager shall:

- (1) participate in the development of the Treatment Plan in coordination with the clinical team;
- (2) maintain regular contact with the person and monitor attendance at all scheduled sessions and drug tests;
- (3) submit written progress reports to the TAP at the prescribed schedule;
- (4) coordinate referrals to medical services where required;
- (5) document a complete case file for the person and retain it for a minimum of five (5) years from the date of discharge; and
- (6) approve leave for a person/client for a maximum of two (2) scheduled sessions. Any request for leave exceeding this limit shall be formally referred to and notified to the TAP for further review and approval.

- 143) Every Approved Treatment Centre shall operate in accordance with the prescribed standards and guidelines.

Legal Undertaking and Conditional Release

- 144) A person shall remain under the custody of the authorized officer or law enforcement agency or released on a legal undertaking until the completion of the treatment process, including but not limited to attendance for clinical assessment and production before the Treatment Assessment Panel in accordance with Section 47A of the Act.
- 145) A person who is unable to provide a guarantor or execute a legal undertaking in accordance with these Rules and Regulations shall remain under the custody of the authorized officer or law enforcement agency until the completion of the treatment.

Obligations of Persons in Treatment

- 146) Whether undergoing voluntary or compulsory treatment, every person in treatment shall:
- (1) attend all scheduled sessions and TAP reviews, and notify their Case Manager in advance if unable to attend;
 - (2) submit to drug testing as and when required;
 - (3) remain available for monitoring; and
 - (4) refrain from any conduct that undermines recovery, including the commission of further offences.

Social Reintegration

- 147) The PEMA Secretariat shall serve as the central coordinating agency for reintegration, aftercare, and monitoring services.
- 148) The Approved Treatment Centre and The PEMA Secretariat, in partnership with relevant agencies and civil society organizations, shall provide persons who have completed treatment with equal opportunities to rebuild their lives.

- 149) The PEMA Secretariat shall develop and maintain a national social reintegration program covering employment support, educational reintegration, housing assistance, and community recovery networks.
- 150) The PEMA Secretariat shall provide technical support to the RBP in delivering prison-based treatment programs, and maintain reintegration and aftercare records.
- 151) No person shall be subjected to discrimination on the basis of a history of substance use or participation in a treatment program.

Certificate of Treatment Completion

- 152) Upon satisfaction of the completion criteria, the Approved Treatment Centre shall issue the Treatment Completion Certificate as prescribed in form NDPS-RR-TCC-3 to the person, and notify TAP and the Court.
- 153) A negative drug test shall be required before treatment is considered complete.

Non-Compliance

- 154) Any person who fails to comply with an obligation under these Rules and Regulations, or with a condition of a Treatment Order, shall constitute non-compliance and shall be liable under the Act and these Rules and Regulations.
- 155) Where a person subject to a Treatment Order, escapes or is absent from an Approved Treatment Centre without approval, the Centre shall immediately:
 - (1) report the escape or absence to the TAP; and
 - (2) contact the person and the person's family or guardian simultaneously.
- 156) Where a person fails to follow the prescribed treatment plan, the Approved Treatment Centre shall immediately notify the TAP.

Community Service Program

- 157) Community service imposed as a condition of a Treatment Order shall be administered under the authority of the Court in accordance with a community service framework developed and coordinated by the OAG.
- 158) The community service framework shall provide the coordination, assignment, supervision, monitoring, reporting, and completion of community service, including collaboration with relevant agencies, institutions, or community organizations.
- 159) Community service shall be properly supervised and structured, and shall not place the offender in environments where controlled substances are accessible or likely to be encountered. Such service shall be age-appropriate, gender-sensitive, rehabilitative in nature, and aligned with the offender's condition and reintegration objectives.
- 160) For first, second, and third offences under Section 152 of the Act, the implementation and enforcement of community service orders shall be carried out by the TAP in accordance with the framework developed by the OAG.
- 161) The agencies or institutions designated for community service placement shall be responsible for the day-to-day supervision, monitoring, and reporting of the offender's attendance, performance, and compliance.
- 162) Any non-compliance with the requirements of community service, including unauthorized absence or failure to duly complete the assigned service without reasonable cause, shall be reported to the TAP where such community service is imposed pursuant to a court order for a third offence under Section 152 of the Act, and to the OAG where such community service is imposed pursuant to a court order for a fourth offence under Section 152 of the Act.
- 163) Upon satisfactory completion of the assigned community service, the TAP/OAG shall issue a completion letter and submit the same to the Court for record and further orders, if any.

Chapter IX

Reward to Informers

Eligibility to receive reward

- 164) Reward may be granted by the Reward Evaluation Committee and cannot be claimed by anyone as a matter of right.
- 165) Any person whose duties are related to the due administration or enforcement of the Act including the authorized officers shall not be provided with any form of reward.
- 166) The informer shall be rewarded in accordance with the prescribed guidelines, subject to the following conditions:
- (1) when there are multiple informers for the same offence, only the first informer to report shall 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 informer is entitled to receive rewards only for the products seized in the initial case;
 - (3) where two or more types of substances are seized in a single case, only one reward shall be payable, and the reward shall be based on the substance with the highest reward value;
 - (4) when the informer in a group reports the information, they shall be considered as a single informant; and
 - (5) the payment of reward is subject to seizure and proof of a criminal offence of controlled substances under this Act. Reward shall be paid out of funds provided by the Royal Government or any other funds identified by the Council.
- 167) The eligibility of the person as informer shall be based on the following conditions:
- (1) has provided the information voluntarily, resulting in conviction; and
 - (2) not be a party to the case.

Reward Procedure

- 168) The reward proposal shall be placed in a sealed envelope and submitted to the authorized officer, who shall register the date and time of receipt.
- 169) The identity of the informer and all information that may reveal the informer's identity shall be kept confidential and shall not be disclosed except as required by law.
- 170) The authorized officer shall review and verify the information received for submission to the Reward Evaluation Committee and maintain a confidential file for such cases.
- 171) The reward shall be disbursed from the relevant Competent Authority, with which the complaint was lodged.

Types of offences eligible for reward

- 172) The disclosure proving any of the following offences may be eligible for reward:
 - (1) illicit trafficking of controlled substances under this Act;
 - (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.

Reward Evaluation Committee

- 173) The reward evaluation committee shall comprise:
 - (1) Chief Program Officer, Bhutan Food and Drug Authority;
 - (2) Legal Officer, Ministry of Health;
 - (3) Accounts Official, Ministry of Health; and
 - (4) Authorized officer, Bhutan Food and Drug Authority.

Roles and Responsibilities of the Reward Evaluation Committee

174) The Reward Evaluation Committee shall:

- (1) ensure that reward proposals are managed under the Act and Rules and Regulations thereof;
- (2) evaluate the reward proposals submitted by the authorized officer and make appropriate decisions; and
- (3) ensure that the seized controlled substances are received, verified, and recorded by the Authority.

Chapter X

Fines and Penalties

- 175) In order to efficiently enforce the provisions of the Act and these Rules and Regulations, the following fines and penalties are prescribed as empowered under Section 112, 113, 114 and 115 of the Act.
- 176) Any authorization holder who contravenes Section 55 of these Rules and Regulations shall be liable to cancellation of the technical authorization and, depending on the nature of the contravention, seizure of goods or payment of a fine equivalent to the prevailing minimum wage, as follows:
- (1) where the contravention relates to Section 55(1), 55(2), 55(3), and 55(4), the authorization holder shall be liable to cancellation of the technical authorization and seizure of the goods;
 - (2) where the contravention relates to Section 55(5) and 55(6), the authorization holder shall be liable to cancellation of the technical authorization and payment of a fine equivalent to one year's minimum wage; and
 - (3) where the contravention relates to Section 55(7) to 55(15), the authorization holder shall be liable to cancellation of the technical authorization and payment of a fine equivalent to two years' minimum wage.
- 177) Any authorization holder who contravenes Section 55(16) of these Rules and Regulations shall be liable to payment of fines as follows:
- (1) for the first contravention, a fine equivalent to three months' minimum wage;
 - (2) for the second contravention, a fine equivalent to six months' minimum wage; and
 - (3) for the third contravention, a fine equivalent to one year's minimum wage.

- 178) Any person-in-charge contravening Section 148 of the Act shall be imposed a fine of Ngultrum Ten Thousand only (Nu. 10,000) per person found using controlled drugs and substances in his or her premises.
- 179) Where a person-in-charge liable under Section 178 of these Rules and Regulations operates a commercial establishment, the Authority may, in addition to the fine imposed for the second contravention under Section 178, suspend the license of the establishment for such period as the Authority may determine.
- 180) Where a person-in-charge liable under Section 178 of these Rules and Regulations operates a commercial establishment, the Authority may, in addition to the fine imposed for the third contravention under Section 178, cancel the license of the establishment.
- 181) A person-in-charge of any premises shall not be held liable under Section 178 of these Rules and Regulations where:
- (1) the use of controlled substances occurred within a private room or enclosed space over which the person-in-charge has no right of entry without prior notice;
 - (2) the person-in-charge had no actual or constructive knowledge of the substance use and took all reasonable precautions; and
 - (3) the person-in-charge demonstrates that upon becoming aware of the substance use, they reported the matter to the relevant authorities without undue delay.

Chapter XI

Miscellaneous

Procedures of appeal

- 182) Any individual aggrieved by any decision made by the Authority established under the Act or these Rules and Regulations shall submit a written petition to the Council within ten (10) working days from the date of issue of the decision.
- 183) The Council shall form a committee to review the issues of the petition in consultation with relevant agencies. The committee shall submit a report of the investigation to the Council within thirty (30) working days from the date of formation of the committee.
- 184) If an aggrieved person is still not satisfied with the decision of the Council, the person may appeal to the Court of law within ten (10) working days from the date of decision.

Immunity

- 185) 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 Rules and Regulations.

Transitional Provisions

- 186) Any license or authorization valid immediately before commencement of these Rules and Regulations shall remain valid for the remainder of its term, subject to compliance with these Rules and Regulations.
- 187) Existing authorization holders shall submit any additional information required by the Authority within one hundred and eighty (180) days to bring records into conformity.
- 188) Ongoing investigations and proceedings commenced before commencement shall continue under the procedures in force at that time.

Power to Issue Circulars and Guidelines

- 189) The Authority may issue circulars, guidelines, and tools for the implementation of these Rules and Regulations. Such instruments shall be consistent with the Act and these Rules and Regulations. In the event of any inconsistency, the Act or these Rules and Regulations shall prevail.

Amendment of Rules

- 190) These Rules and Regulations may be amended by the Council in accordance with Section 57(5) of the Act.

Matters Not Covered

- 191) Any matter not expressly provided for in these Rules and Regulations shall be dealt with in accordance with the Act, the Penal Code of Bhutan, the Civil and Criminal Procedure Code of Bhutan and any other relevant laws of Bhutan.

Definition

- 192) In these Rules and Regulations, unless the context otherwise requires:
- (1) **Act** means the Narcotic Drugs, Psychotropic Substances and Substance Abuse Act of Bhutan 2015, as amended.
 - (2) **Adult dose** means the usual therapeutic dose prescribed for an adult patient, as determined by a competent medical professional.
 - (3) **Approved Treatment Centre** means a hospital, nursing home, hostel, health facility, treatment and rehabilitation, drop-in centre or other institutions that the Royal Government or Council may designate from time to time as an Approved Treatment Centre to provide treatment for persons with SUD.
 - (4) **Authority** means the Bhutan Food and Drug Authority.
 - (5) **Authorization Holder** means the individual or entities possessing authorization issued to cultivate, manufacture, produce, import, export, wholesale, retail, distribute, and use of plants, substances and preparations listed under Schedule III, IV and V of the Act.

- (6) **Authorized Officer** means the designated official of the Authority and/or an official of an agency authorized by the Council to carry out the provisions of this Act.
- (7) **Competent Authority** means the Authority or any other authority designated by the Council for the purposes of implementing or enforcing provisions of this Act.
- (8) **Council** means the Governing Council of the Bhutan Food and Drug Authority.
- (9) **Export authorization** means the permit to export controlled substances.
- (10) **Import authorization** means the permit to import controlled substances.
- (11) **Person-in-charge** means an owner, manager, supervisor or a person responsible for the operation of their respective premises or public place or public transport.
- (12) **Premise** means the area or boundary of the business operation.
- (13) **Technical Authorization** means the approval granted by the Authority to an individual, institution, agency, or establishment to undertake a specified activity involving controlled substances certifying that such activity complies with the prescribed technical standards, requirements, and specifications.
- (14) **Trade** means the cultivation, production, manufacture, wholesale or retail sale, distribution, import, export, storage, transport, or use of controlled substances listed under Schedules III, IV and V.
- (15) **Treatment Plan** is a personalized, structured plan of care developed collaboratively with the individual, based on comprehensive clinical assessment, co-occurring conditions, family situation, cultural background, and social circumstances, to guide tailored interventions, treatment, and recovery support.

Annexure

Annexure I: Legal Undertaking

NDPS-RR-LU-1 LEGAL UNDERTAKING

Date:.....

I, Mr/Miss.....

Date of Birth..... S/o, D/o.....

Village..... Gewog..... Dzongkhag.....

holding House No..... Thram No..... and Identity Card no.....

would like to undertake that as an individual submitted to compulsory treatment and rehabilitation for offence of substance abuse as per Section 47 of the Narcotic Drugs, Psychotropic Substances and Substance Abuse Act of Bhutan 2015, as amended, shall:

1. report to the Approved Treatment Centre for clinical assessment on the specified date and time;
2. report to the TAP as and when required;
3. appear before the Court for issuance of the Court Order on the specified date and time;
4. notify the Case Manager within seventy-two (72) hours of any change in address, telephone number, or legal status; and
5. refrain from committing any further offence.

In the event that the undertaking is not honored, I, the undertaker and the guarantor will be held liable as per Section 47A of the Narcotic Drugs, Psychotropic Substances and Substance Abuse Act of Bhutan 2015, as amended

Undertaken:

(Affix legal stamp)

(Signature)

Guarantor:

Name:

P/address:

Occupation:

Mobile:

Relation:

Annexure II: Legal Undertaking (minors)

NDPS-RR-LUM-2
LEGAL UNDERTAKING (MINOR)

Date:.....

I, Mr/Miss.....
Date of Birth..... S/o, D/o.....
Village..... Gewog..... Dzongkhag.....
holding House No..... Thram No..... and Identity Card no.....
would like to state that as a child in conflict with law as per Section 72 of
the Child Care and Protection Act, 2011 being submitted to compulsory
treatment and rehabilitation for offence of substance abuse as per Section
47 of the Narcotic Drugs, Psychotropic Substances and Substance Abuse
Act of Bhutan 2015, as amended and provided diversion as per Section
187 of the Child Care and Protection Act, 2011 shall:

- 1. report to the Approved Treatment Centre for clinical assessment
on the specified date and time;
- 2. report to the TAP as and when required;
- 3. appear before the Court for issuance of the Court Order on the
specified date and time;
- 4. notify the Case Manager within seventy-two (72) hours of any
change in address, telephone number, or legal status; and
- 5. refrain from committing any further offence.

In the event that the undertaking is not honored, I, the undertaker and
the guarantor will be held liable as per Section 47A of the Narcotic Drugs,
Psychotropic Substances and Substance Abuse Act of Bhutan 2015, as
amended and Section 195 of the Child Care and Protection Act.

Undertaken:
(Affix legal stamp)
(Signature)

Guarantor:
Name:
P/address:
Occupation:
Mobile:
Relation:

Annexure III: Treatment Completion Certificate

NDPS-RR-TCC-3

TREATMENT COMPLETION CERTIFICATE

1. PERSON			
Full Name		Identification Number	
Sex / Age		Contact Number	
Treatment Centre		Pathway (Voluntary/ Compulsory)	
Date of commencement of treatment		Date of Completion of Treatment	
Court Order Ref. (if any)			
2. TREATMENT COMPLETION CRITERIA			
Treatment goals substantially achieved?	☐ Yes ☐ No		
Negative drug test obtained	☐ Yes ☐ No Date: _____		

Declaration

It is hereby certified that the individual named in this report has completed drug treatment and rehabilitation in accordance with the Narcotic Drugs, Psychotropic Substances and Substance Abuse Rules and Regulations 2026, and has undergone the required discharge assessment.

Name of authorized Officer: _____

Signature: _____

Date: _____



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Royal Government of Bhutan
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Thimphu, Bhutan

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