SECTION A - RULES AND REGULATIONS

In the exercise of powers conferred to the Bhutan Medicines Board under Chapter II, Section 5.2 of the Medicines Act of the Kingdom of Bhutan 2003, the Board for the purpose of giving effect to the provisions of the Act, makes the following medicines regulations: -

PART I

PRELIMINARY

1. Short Title, Commencement and Extent:

1.1 Short Title:

These Regulations shall be called the **MEDICINES RULES AND REGULATIONS, KINGDOM OF BHUTAN 2005.**

1.2 Commencement:

1.2.1 These regulations shall come into force on the 3rd day of the 9th month of the Bhutanese calendar corresponding to the 6th day of 10th month of 2005.

1.2.2 The Chairman of the Board may by public notification:
Appoint different commencement dates for different products;
Appoint different commencement dates for different provisions of these Regulations.

1.3 Extent:

It shall extend to the whole Kingdom of Bhutan.

2. Repeal, Interpretation and Authoritative Text:

2.1 Repeals:

2.1.1 Upon coming into force of the Regulation, any existing regulation in the country pertaining to the subject matters addressed by this Regulation shall be dealt with this Regulation.

2.1.2 Not withstanding the repeal in Clause 2.1.1, anything done or any action taken before coming into force of this Regulation shall be deemed to have been done or taken under such regulations.

2.2 Interpretation:

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

2.3 Authoritative Text:

In case of conflict in the interpretation of the Regulation between English and Dzongkha, the matter shall be interpreted by the Board.

PART II

PROCEDURES AND FUNCTIONS OF THE BOARD, DRUGS TECHNICAL ADVISORY COMMITTEE, DRUG REGULATORY AUTHORITY AND DRUG TESTING LABORATORY

3. Procedures for the Board:

3.1 The Board shall consist of members as listed under Section 4.2, Chapter II of the Act.

3.2 In absence of the Chairman, the Vice-Chairman of the Board shall convene the meeting.

3.3 The Board members shall not fail to attend more than two consecutive meetings. Should any member of the Board fail to attend three consecutive Board meetings the said member shall submit a written explanation to the Board.

3.4 The Board shall exercise the powers and functions stated under Section 5 and Section 6, Chapter II of the Act respectively; and

3.4.1 The Board may delegate the authority to the Drug Regulatory Authority to carryout the functions of the Board prescribed under the provisions of the Act;

3.4.2 The Board may revise the prescribed fees from time to time as and when necessary;

3.4.3 The Chairman of the Board, at any time, on disciplinary grounds and abuse of power, may suspend or terminate any member of the committees constituted under the provisions of the Act and the Board shall appoint another appropriate person to replace the member who vacates the post before the completion of his term on resignation or death or any other valid reason and such person shall serve for the remaining term of the membership;

3.4.4 The Board shall recommend the qualification and experience requirements of technical personnel to be appointed by the Royal Government in the Drug Regulatory Authority, Drug Testing Laboratory and any committees established under the Board;

3.4.5 The Board shall recommend the Royal Government for appropriate disciplinary action as per the existing Government rule and regulations, against any technical personnel appointed under the provisions of this Act by the Government, if the Board is so convinced of the incompetence of the said personnel or his failure to perform duties, or professional misconduct, or found abusing his power or position.

4. Procedures for the Drugs Technical Advisory Committee:

4.1 Membership:

4.1.1 The Committee shall constitute of the members as stated under Section 9.1, Chapter II of the Act;

4.1.2 The Committee may recommend the Board to appoint experts as temporary members to address specific technical areas as and when required;

4.1.3 The members shall attend the meeting in person. If the member fails to attend three consecutive meetings, he shall forfeit the membership unless otherwise a valid explanation is submitted to the Board;

4.1.4 The Chairmanship of the Committee shall be rotated on an annual basis among the members (a), (b), (g) and (h) constituted under Section 9.1 of the Act and the nomination shall be based on the consensus of the members;

4.1.5 The Member Secretary of the Committee shall be nominated from among the members and shall serve in the post till the end of his term unless otherwise suspended or terminated and maintain records of the meetings, which shall be retained for a period of five years and important documents could be stored in electronic form;

4.1.6 The logistics for convening DTA Committee meetings shall be organized by the Authority.

4.2 Terms of reference:

4.2.1 To provide advice to the Board on all technical areas related to registration of medicinal products and other technical matters as and when required by the Board;

4.2.2 The Committee may recommend the Board to call any relevant person from any agency to attend the meetings of the Committees and to the board to provide technical information or other relevant articles related to the subject of the meetings;

4.2.3 The remuneration for attending the Committee meetings shall be as per the existing Government rules and regulations;

4.2.4 The members shall maintain the confidentiality and privacy of technical information and shall not disclose any important decision of the meetings and ensure fair and just evaluation of the technical documents as and when done.

5.0 Functions of the Drug Regulatory Authority:

The Drug Regulatory Authority established under Section 10 of the Act shall carryout the functions as per the powers delegated by the Board as under:

5.1 Authorization for licensing for manufacture, sale, import, export and distribution of medicinal products;

5.2 Registration of medicinal products and Competent Persons for sale, manufacture and distribution of medicinal products;

5.3 Inspection of premises for manufacture, sale and distribution of medicinal products;

5.4 Control prices of medicinal products;

5.5 To obtain and receive all such evidence, written or oral and to examine all such persons involved and in witness of violations of the provisions of the Act.

5.6 The employees of the Authority shall maintain highest level of integrity and confidentiality of all the clients and their technical information and shall not have improper associations, not be a party to false pretences, forgery, fraud and counterfeiting.

6.0 Functions of the Drug Testing Laboratory:

The Drug Testing Laboratory established under Section 12.1 of the Act shall carryout the following functions:

6.1. Testing of samples forwarded by the Authority;

6.2. Submit drugs test reports to the Board and Authority;

6.3. Develop standard sampling procedures for the Authority and the Laboratory.

6.4. All reports submitted shall be as per the format (Form XIA and Form XIIA) prescribed in the Regulation.

6.5. The testing and analysis of drugs shall be carried out as per the good laboratory practices and standard sampling procedures.

6.6. The Drug Testing Laboratory shall have the privilege to deposit the drug testing results to the Court of Law as and when required.

6.7. The employees of the Drug Testing Laboratory shall maintain integrity and confidentiality of technical information and shall not have improper associations, not manipulate the results and practice forgery.

PART III

REGISTRATION OF MEDICINAL PRODUCTS

7. Application for Registration:

7.1 The application for registration of the product shall be made along with the required documents during the notified period, in Form I, accompanied by a token fee for product registration dossier assessment (refer part XXI).

7.2 The documents required for registration should be in English or *Zhungkha* and submitted in bond form in A4 size paper.

7.3 The documents for registration shall be accepted only if they are complete and as per specifications.

7.4 Separate applications shall be made in respect of different formulation of same medicinal product.

8. Award of registration certificate:

8.1 The registration certificate shall be issued in Form IA.

8.2 The registration certificate may be issued within 30 days from the date of receipt of complete documents unless otherwise a longer period is required in case of which the party will be notified.

8.3 The registration of a product shall be valid for a period of three years and shall be specified in the certificate.

8.4 A specified quantity (annexed) of sample along with the unit price of the product to be registered must be submitted along with the application and other documents as prescribed under Clause 9.

8.5 The Authority may, in the interest of public safety, reject the registration of any product.

8.6 The medicinal products used in *gSo-ba Rig-pa* will be registered using the following criteria till such time a revised registration criteria is notified by the Board:

8.6.1 Submit master formulation along with the abstract of the text of *gSo-ba Rig-pa* and sample packaging material, label and sample of the product;

8.6.2 Submit quality control certificate from the authorised agency designated for the purpose by the Royal Government.

8.7 The traditional medicines other than those used in *gSo-ba Rig-pa* shall be registered as per the registration document developed by the Sub-Committee for Traditional Medicines constituted by the Board under Section 5.11 of the Act.

9. Documents for registration of medicinal products.

All the other medicinal products not falling under Clause 8.6 and 8.7 above shall be registered with the following criteria:

9.1 General Documents:

9.1.1 Company profile
9.1.2 cGMP certificate
9.1.3 Manufacturing licence
9.1.4 WHO Model Certificate of Pharmaceutical Product
9.1.5 Free Sale Certificate
9.1.6 Summary of product information sheet
9.1.7 Letter of authorization from the manufacturer for registration (in case of registration by a dealer)
9.1.8 Dealership certificate (in case of registration by a dealer)
9.1.9 Credentials of the dealer
9.1.10 Product sample
9.1.11 Price structure

9.2 Pharmaceutical Documents

9.2.1 Name of drug, its composition, physico-chemical properties of active and inactive ingredients
9.2.2 Analytical method for identification of active substance and excipients
9.2.3 Manufacturing process for the product
9.2.4 List of raw material and specifications
9.2.5 QC procedure and report on raw materials
9.2.6 Finished product specifications
9.2.7 Disintegration and dissolution profile
9.2.8 Analytical method for the finished product
9.2.9 Certificate of analysis
9.2.10 Stability test report for Zone IV
9.2.11 Packaging specifications
9.2.12 Specimen of package, label and package insert
9.2.13 QC procedure and report on label and package

9.3 Pharmacological Documents:

9.3.1 Data on basic pharmacological and microbiological studies
9.3.2 Toxicity data *
9.3.3 Teratogenicity data *

9.3.4 Mutagenicity data *
9.3.5 General pharmacology
9.3.6 Pharmaco-kinetics data
9.3.7 Data on clinical studies
Phase I, Phase II, Phase III & Phase IV *
9.3.8 Clinical pharmaco-kinetics *
9.3.9 Bio-availability and bio-equivalence data (in case of generic drugs)

9.4 The pharmacological documents marked with asterisk (*) shall be applicable only for registration of new molecules or new formulation of old molecules or molecules with very little post-marketing experience.

9.5 All the documents listed under 9.1, 9.2 and 9.3 of Clause 9 shall be submitted either in original or in copies attested by the relevant control authorities.

9.6 Not withstanding the conditions stated above under Clause 9, some products may be registered with some exceptions considering the national needs.

9.7 Wherein there is a proof of the product being already registered in a developed country, appropriate considerations wherever applicable may be made in the registration of the products.

9.8 Any person, who wishes to import any product for the purpose of research in a school of pharmacy or research or training institution or in order to obtain samples for the purpose of registration, may be exempted from the provisions of Section 16.2.1 of the Act with prior approval from the Board.

10. Temporary registration of drugs:

10.1 Temporary registration will be granted upon request by relevant government agencies for medicinal products specially required in emergency, disease out-break and for specific needs of patients.

10.2 The application for such registration shall be made in Form VI with the following documents:

10.2.1 Therapeutic indication details
10.2.2 Free sale certificate of the product;
10.2.3 Product registration certificate issued in the country of origin;
10.2.4 Package specification;
10.2.5 Finished product specification.

10.3 The registration will be granted in Form IA stamped with an authorised seal indicating so.

10.4 The temporary registration shall be granted for duration of three months at a time with a maximum of six months.

11. Renewal of registration:

11.1 Application for renewal should be made before three months from the date of expiry of registration.

11.2 A grace period shall extend to one month after the specified expiry date.

11.3 Defaulter shall pay a penalty of Nu. 100 per day after the expiry of grace period up to one month.

12. Cancellation of registration:

The Authority shall cancel the registration of the product if:

12.1 Any of the conditions of registration of the product has been contravened or changed, or

12.2 Any report on adverse drugs reactions of serious nature have been received from relevant national or international sources, or

12.3 Defaulting of timely renewal beyond one month after grace period, or

12.4 For any other matters as specified by the Board at the time of cancellation.

13. Fees for registration

13.1 The fees for registration of medicinal products shall be as outlined under Part XXI and will be subjected to revision from time to time.

13.2 The registration fee shall be paid at the time of issuance of registration certificate.

13.3 The Authority may charge any applicant such costs as it may incur for the purpose of carrying out laboratory investigation if and when necessary prior to registration of the product.

PART IV

AUTHORIZATION FOR IMPORT

14.0 Application for Import Authorization:

14.1 An application for an authorization to import medicinal product shall be made to the Authority in Form II, accompanied by a token fee (refer part XXI).

14.2 A single application may be made and an authorization may be issued in respect of import of more than one drug manufactured by the same manufacturer.

14.3 Only the individual or group of individuals or organization that is authorised by the Authority shall be permitted for import of any medicinal product.

14.4 An import authorization for medicinal products shall be issued in Form IIA.

14.5 An application for special import authorization shall be made in Form VIII for import of controlled and restricted drugs under Schedule C1 and Schedule C2

14.6 An import authorization for controlled and restricted drugs shall be issued in Form VIIIA and valid for a single import for three months.

14.7 Import license shall be issued by a relevant agency only upon the presentation of the import authorization from the Authority.

14.8 Import authorization is not a substitute for import licence.

15. Conditions for issuance of import authorization:

An import authorization shall be issued only if:

15.1 The applicant is either a Competent Person or has a Competent Person employed to supervise and monitor the sale and distribution of medicinal products;

15.2 All the necessary documents as specified in the Form II are attached along with the application;

15.3 The Authority is convinced that there is a licensed premise where the imported drugs will be stored before sale and distribution;

15.4 The applicant shall maintain records and inform the Authority of all particulars of products including product specifications, quantities imported, date of importation and to whom sold.

15.5 The applicant shall provide unhindered access to an Inspector authorised by the Board or Authority to enter with or without prior notice and inspect the premises where the imported products are stored.

15.6 Import authorization for vaccines and biologicals shall be issued only if the conditions prescribed under schedule F of the regulation is complied with.

15.7 A special import licence or permit shall be issued by the relevant agencies for importation of narcotic drugs and psychotropic substances listed under Schedule C1 and Schedule C2 of the Regulation, based on the special import authorization issued by the Authority in Form VIIIA.

16. Import of medicines for personal use:

16.1 Any person who wishes to bring into the country any medicinal product listed under schedule A, shall be allowed in a quantity not exceeding the quantity required for one month, or

16.2 In case of prescription drugs, the provision under Section 26 (i) of the Act shall be applicable only in case of suspected criminal activities, or

16.3 Any person who has a prior approval from the Authority or prescription is exempted from the requirement of an import licence; the authorization shall be issued in Form IIB.

PART V

LICENSING FOR MANUFACTURE

17. Application for Manufacturing Licence:

17.1 Any person intending to manufacture a medicinal product for sale or distribution shall apply to the Authority in Form III accompanied by a token fee (refer part XXI).

17.2 The following documents should be submitted along with the application for provisional clearance for manufacturing:

17.3 Master plan;

17.4 Technical design and layout details of the premises;

17.5 List and description of intended production facilities (tablet section, capsule section, liquid formulation section, antibiotic section, etc);

17.6 List of technical competent persons and employees;

17.7 Environmental clearance certificate;

17.8 Waste management plan;

17.9 Occupational safety standards;

17.10 Industrial establishment clearance;

17.11 List of products to be manufactured.

17.12 Upon receipt of application for a Manufacturing Authorization with complete set of documents, the Authority shall issue provisional clearance with the condition that the Authority shall cause periodic inspection of the manufacturing premise during the construction period for compliance.

17.13 Upon completion of construction of the manufacturing premise the Authority shall cause inspection to verify that:

17.14 All equipment and facilities and other requirements as documented are complied with;

17.15 There is Standard Operating Procedures (SOPs) in place;

17.16 All the critical units such as raw material section, quarantine, production section, quality control section, documentation section and finished product section are well defined and operational.

18.0 Award of approval for manufacturing:

18.1 The Board may accord the final approval for provisional manufacturing in Form IIIA based on recommendation of the inspection report of the Authority and shall be valid for period of one year or till the date of grant of an approval for manufacturing licence which ever is earlier.

18.2 The approval for manufacturing is not a substitute for a manufacturing licence.

19. Validity of the approval for manufacturing licence:

19.1 The manufacturing licence shall be issued by the Ministry of Trade and Industry only upon the submission of the approval for manufacturing from the Board.

19.2 The approval for Technical Authorization for manufacturing licence shall be issued in Form IIIB and valid for a period of one year.

19.3 The manufacturing premise shall be subjected to routine and ad-hoc inspection by the Authority and the manufacturing licence shall be valid only if:

19.3.1 The personnel employed at various processes of manufacturing possess suitable qualifications required for their jobs and the manufacture shall be conducted under the active direction and personal supervision of the qualified Competent Person(s) approved for the purpose;

19.3.2 The products manufactured, processed, packed, labelled and tested in the manufacturing premises are in accordance with the GMP standards set by the Board under Schedule M;

19.3.3 There is quality control laboratory with qualified staff and appropriate equipment to carryout tests of raw materials and the finished products, and quality control unit should not be under the production unit;

19.3.4 There is adequate separate storage areas for the starting, rejected or recalled, intermediate and finished product;

19.3.5 The applicant shall furnish institutional development plans for the technical employees involved in the manufacture and quality control to refresh and update their knowledge and skills from time to time.

20. Exemption from a manufacturing licence:

The requirement of a licence to manufacture does not apply to the dispensing, or the doing of any act falling within the definition of "manufacture", which is necessary for the dispensing of any drug for the purpose of its being used for medical treatment by the following persons and in the following circumstances:

20.1 A pharmacist registered by the Bhutan Medical and Health Council or a registered person working under the supervision of a registered pharmacist in a retail pharmacy;

20.2 A person who is working in a Government hospital or dispensary and acting in the course of his duties under the supervision of a registered pharmacist; and

20.3 A medical, veterinary doctor or a *Drungtsho* registered by relevant agencies, if the drug in question is for the use of such doctor or of his patients.

PART VI

TECHNICAL AUTHORIZATION FOR SALE

21.0 Application for Technical Authorization for Sale:

21.1 An application for technical authorization to sell by retail or by wholesale shall be made in Form IV, accompanied by a token fee (refer part XXI).

21.2 The applicant shall submit the following documents along with the duly filled application form:

21.3 Registration certificate from the Medical and Health Council;

21.4 Certificate of registration as Competent Person issued by the Authority for the applicant or of the employee(s) who shall sell the medicinal products; provided the applicant is not over 60 years of age and on producing the following documents:

21.5 Valid security clearance;

21.6 Copy of citizenship identity card;

21.7 Medical Fitness Certificate;

21.8 Categories of products.

21.9 Technical Authorization for Sale shall be issued in Form IV and shall be valid till the validity of license issued by the Ministry of Trade & Industry, in case the competent person is the license owner

21.10 Technical authorization for sale by retail or wholesale is not a substitute for a licence for sale.

22. Validity of technical authorization for sale:

The technical authorization for sale by retail or wholesale shall be valid for a period of 1(one) year if a licence is obtained and the pharmacy/business operational, unless otherwise suspended or revoked by the Authority.

23. Renewal of authorization for sale:

The Authority shall renew the technical authorization annually and the application for licence shall made to the Ministry of Trade and Industry through the Authority.

24. Duties of a licensee and conditions to be observed:

24.1 The sale of medicinal products shall be conducted under the supervision of a Competent Person certified by the Authority for the specific premise.

24.2 The licensee shall inform the Authority of any changes in the ownership, location of premise and change of Competent Person.

24.3 The licensee shall conform to the conditions laid down by the Board from time to time.

24.4 The licensee shall fulfil the following requirements of pharmacy premises:

24.4.1 A green cross sign along with an inscription "Pharmacy" written both in English and *Zhungkha*, shall be prominently displayed and visible at night in front of the sale premises;

24.4.2 The premises of pharmacy should be separated from rooms for residential use and should be clean and hygienic. The premises should be structurally sound, dry, well lit and ventilated and, of sufficient dimensions to allow the goods in stock, especially medicaments to be kept in a clearly visible and appropriate manner;

24.4.3 The furniture and apparatus in a pharmacy should be suitable to the uses for which they are intended and appropriate to the size and requirements of the establishment.

24.5 Different categories of drugs should be segregated from others and stored under appropriate conditions:

24.5.1 Drugs, chemicals and medicaments should be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the containers or the contents kept in them;

24.5.2 Restricted and controlled drugs wherever applicable, should be kept separately under lock and key;

24.5.3 Every container should bear a label of appropriate size, easily readable with names of medicaments as given in the Pharmacopoeias;

24.5.4 The medicines should be separated from the other goods such as cosmetics and sanitary items;

24.5.5 Veterinary drugs, herbal preparations and health products should be kept separately;

24.5.6 Vaccines, biologicals and laboratory reagents should be stored under appropriate cold chain conditions and separated from each other.

24.6 A separate suitable place is required for compounding of drugs in Hospitals.

24.7 The business hours of the pharmacy shall be clearly written in both English and *Zhungkha* and displayed at a conspicuous place in the premise.

24.8 The Competent Person working in Pharmacy should wear a clean white lab coat at all times at the work place and should also have a name tag on him.

24.9 In absence of a Competent Person due to any reasons, with prior written approval from the Authority, the licensee shall make an alternative arrangement for another competent person or otherwise, the pharmacy should remain closed.

25. Conditions for sale of medicinal products:

25.1 No prescription is required for sale of medicinal products listed under Schedule A.

25.2 Medicinal products listed under Schedule B, C1, C2, D2, E2 and F shall be sold only on presentation of a prescription from a registered medical or veterinary doctor or a *Drungtsho* or other authorised relevant personnel. The prescription should bear the signature, name and seal of the registered doctor or *Drungtsho* or other authorised relevant personnel.

26. Duties of Competent Person:

26.1 The name of the patient, name of the prescriber, date of sale, name, quantity, expiry date, batch number and price of medicines should be clearly mentioned on the cash memo.

26.2 The prescription should be stamped with a seal of the Pharmacy while dispensing the medicines.

26.3 Wherever applicable, patient or customer details should be maintained in the format prescribed for the purpose in case of Schedule “C1 and C2” drugs.

26.4 Copies of the prescription should be serially numbered as per the list in the format and maintained for a period of 3 (three) years for sale of drugs under Schedule C1 and Schedule C2, wherever applicable.

26.5 The Competent Person shall not manipulate the figures and information.

26.6 If the proprietor of a pharmaceutical company or the retail pharmacy wishes to change the ownership, the person shall apply to the Authority in writing in Form IV – 1 and the clearance for the same shall be issued in Form IV – 1 A and the Ministry of Trade and Industry shall make the relevant changes in the ownership upon submission of the clearance for change issued by the Authority.

PART VII

AUTHORIZATION FOR EXPORT

27.0 Application for Export Authorization:

27.1 An application for an authorization to export medicinal product shall be made to the Authority in Form V, accompanied by a token fee.

27.2 A single application may be made and an authorization may be issued in respect of export of more than one drug manufactured by the same manufacturer.

27.3 Only the individual or group of individuals or organization that is authorised by the Authority shall be permitted for export of any medicinal product.

27.4 An export authorization for medicinal products shall be issued in Form VA.

27.5 Export license shall be issued by a relevant agency only upon the presentation of the export authorization from the Authority.

27.6 Export authorization is not a substitute for export licence.

28. Conditions for issuance of export authorization:
An export authorization shall be issued only if:

28.1 The list of products to be exported are manufactured under a valid licence in Bhutan;

28.1 All the necessary documents as specified in the Form V are attached along with the application;

28.2 The Authority is convinced that there is a licensed premise where the exported drugs will be stored before export;

28.3 The applicant shall maintain records and provide the Authority with all particulars of products including product specifications, quantities exported, date of exportation as and when asked.

28.4 The applicant shall provide unhindered access to an Inspector authorised by the Authority to enter with or without prior notice to inspect the premises where the exported products are stored.

28.5 The Authority may reject the export of any medicinal product or raw materials for reasons specified at the time of rejection (see Section 23.3 of the Act).

28.6 The Ministry of Trade and Industry shall issue export licence based on the export authorization.

PART VIII

DUTIES OF DRUG INSPECTOR AND PROCEDURES FOR INSPECTION

29. Duties of the Drug Inspector:

29.1 The Drug Inspector empowered under Section 15.1 of the Act shall inspect premises for sale and manufacture of medicinal products subject to the instructions of the Authority, following the prescribed procedures. An Inspector shall:

29.1.1 Satisfy himself that the conditions of the licenses are being observed;

29.1.2 Procure and send for test or analysis if necessary, sample of imported packages suspected of containing medicinal products in contravention of the provisions of the Act. A detention memo shall be served in Form X not to dispose off any stock of such product for a specified period; and the remaining products shall be sealed by both the parties;

29.1.3 Investigate any compliant made to him in writing with full name and address;

29.1.4 Maintain record of all inspections made and actions taken by him in the performance of his duties including the taking of samples, seizure of stocks and to submit copies of such records to the Authority;

29.1.5 Make such inquiries and inspections as may be necessary to detect sale of medicinal products in contravention of the Act.

29.2 An inspector shall not without the sanction in writing from the Authority disclose any information acquired by him in the course of his official duties, except when required by the court of law and for official business.

29.3 The Inspector must ensure that the sample of medicinal products taken for test or analysis are appropriately packed, fastened, sealed, stored and transported in accordance with the instructions specified on the label of the medicinal products.

29.4 The sample shall be considered as appropriately fastened and sealed if it is packed in a container or package that is marked with the name and address of the person and premises from where the sample was taken so as to prevent the opening of the vessel and the removal of the name and address, without breaking the seal.

30. Procedures for inspection of sale premises:

30.1 The Authority shall serve notice to the proprietor of the sale or distribution premises that an inspection shall be conducted.

30.2 In the course of conducting the duties, the Inspector or officials authorised by the Authority shall show his identification or letter of authorization if demanded by the concerned individual.

30.3 Whenever an Inspector takes a sample of a medicinal product from a pharmacy or a drug store for testing, he shall offer the fair price thereof and may give a written acknowledgement.

30.4 Whenever an Inspector has reason to suspect that any person or premise is in possession of controlled and restricted drugs that are in contravention to the provisions of the Act and Regulation, he shall perform interrogation and investigation of persons and premises in collaboration with other law enforcement agencies in the Kingdom.

30.5 Whenever an inspection is conducted in specific area for a specific purpose, the Inspector shall submit a report of the findings in writing to the Authority within a week after completion of the inspection.

30.6 When an Inspector takes a sample for the purpose of test or analysis from a sales premise, he shall divide the sample into four portions or take four containers and effectively seal the same, also allowing the Competent Person to add his own seal.

30.7 The Inspector shall intimate his purpose in writing in Form IX to the person from whom he takes the sample.

30.8 The Inspector shall treat the four portions of sample as follows:

30.8.1 One portion he shall hand over to the person from whom he takes it;

30.8.2 One portion he shall send to the Government Analyst for analysis along with Form XI

30.8.3 One portion he shall keep in custody to be produced to the Court if the prosecution is launched; and

30.8.4 One portion he shall send to the person, if any, from whom the product has been purchased.

31. Procedures for inspection of Manufacturing Premises:

31.1 The Authority shall inspect manufacturing premise may not necessarily give prior notice to the proprietor.

31.2 In the course of conducting the duties, the Inspector or official authorised by the Authority shall show his identification or letter of authorization if demanded by the concerned individual.

31.3 When an Inspector takes a sample for the purpose of test or analysis from a manufacturing premise, he shall intimate the purpose in writing in Form IX, and the sample shall be in three portions and treated as follows:

31.3.1 One portion he shall hand over to the head of the manufacturing firm from where the sample is taken;

31.3.2 Second portion he shall send to the Government Analyst for analysis along with Form XII;

31.3.3 The third portion he shall keep in custody to be produced to the Court if the prosecution is launched.

31.4 The Inspector must ensure that the sample of products taken is appropriately packed, fastened, sealed, stored and transported in accordance with the instructions specified on the label of the products.

31.5 The sample shall be considered as appropriately fastened and sealed if it is packed in a container or package that is marked with the name and address of the person from whom the sample was taken so as to prevent the opening of the vessel and the removal of the name and address, without breaking the seal.

32. Procedures for inspections at exit and entry points:

32.1 At the entry and exit points the inspections for compliance to export and import regulations shall be carried out by the Department of Revenue and Customs. However, wherever necessary, the inspections may be carried out jointly in collaboration with the Drug Inspectors stationed in the area.

32.2 The inspections of export and import premises within the Kingdom shall be conducted by the Drug Inspectors.

32.3 Wherever necessary, the Authority shall collaborate and conduct joint inspections with other law enforcement agencies in the Kingdom.

PART IX

REGISTRATION OF COMPETENT PERSONS FOR MANUFACTURE, SALE OR DISTRIBUTION OF MEDICINAL PRODUCTS

33.0 Procedures for registration as Competent Person:

33.1 Any person who wishes to register as a Competent Person for manufacture or sale or distribution of medicinal products shall apply with the following documents in Form VI, accompanied by a token fee (refer part XXI):

33.1.1 The registration certificate from the Medical and Health Council;

33.1.2 Valid security clearance;

33.1.3 Copy of citizenship identity card;

33.1.4 Medical Fitness Certificate.

33.2 Upon receipt of complete documents, the Authority shall submit the documents to the Registration Committee constituted under Section 19.4 of the Act for review and recommendation.

34. Award of Registration Certificate:

34.1 Certificate will be awarded only if the Registration Committee recommends.

34.2 The certificate shall be awarded in Form VIA and shall be valid for a period of three years unless otherwise revoked.

PART X

QUALIFICATIONS AND JOB EXPERIENCE OF COMPETENT PERSONS

35.0 The qualifications of Drug Inspectors for sales or manufacturing premises

35.1 An Inspector shall be a person:

35.1.1 Who has a minimum qualification of Diploma in Pharmaceutical Sciences/Pharmacy and is registered by the Medical and Health Council and other relevant agencies in the Kingdom, or

35.1.2 Who is registered as a Pharmacy Technician by the Medical and Health Council and other relevant agencies in the Kingdom and has at least 5 (five) years experience dealing with pharmaceuticals.

35.2 An Inspector for manufacturing premises shall have a minimum qualification of degree in Pharmacy and is registered by the Medical and Health Council and other relevant agencies in the Kingdom and at least two years experience in the related field.

36.0 Qualification for Competent Persons for manufacture, sale by retail or wholesale:

36.1 A Competent Person for the manufacture of drugs shall be the person who:

36.1.1 has a degree in Pharmacy and is registered by the Medical and Health Council;

36.1.2 Has a Diploma in Pharmacy and has at least 4(four) years experience in the related field, or

36.1.3 Is registered as a Pharmacy Technician by the Medical and Health Council and has at least 5 (five) years experience in the related field.

36.1.4 Competent Person under provision 36.1.2 and 36.1.3 above shall be registered as a Competent Person with the condition that they will be working under the close supervision of 36.1.1

36.2 A Competent Person for sale of drugs by retail or by wholesale shall be a person who has a minimum qualification of certificate in Pharmacy and is registered by the Medical and Health Council.

36.3 A Competent Person for sale of *gSo-ba Rig-pa* medicines by retail or wholesale shall be a person who has a minimum qualification of Diploma in *gSo-ba Rig-pa* Medicine and involved in the dispensing and compounding and registered by the Bhutan Medical and Health Council.

36.4 A Competent Person for sale of traditional medicines other than those used in *gSo-ba Rig-pa*, by retail or wholesale shall be a person who has a minimum qualification of Diploma in Traditional Medicine Science with experience in the dispensing and compounding and registered by the Bhutan Medical and Health Council.

PART XI

DUTIES OF GOVERNMENT ANALYST

37. Duties of a Government Analyst:

37.1 The Government Analyst shall cause analysis or testing of such samples of drugs as may be sent to him by Inspectors or other persons under Section 14 of the Act and shall furnish reports of the test of analysis in the prescribed form.

37.2 On receipt of a package from an Inspector containing sample for test or analysis, the Government Analyst shall compare the seals on the packet (or portion of sample or container) with the specimen impression received separately and shall note the condition of the seals on the packet of portion of sample.

37.3 The Government Analyst shall upon completion of the test or analysis shall forthwith supply to the Authority a report in triplicate in the Form XIA or Form XIIA of the results of the test or analysis. He shall submit the results in Form XIA for samples from sales premises and in Form XIIA for those of manufacturing premises.

37.4 He shall develop protocols for sampling, test and analysis for the medicinal products.

37.5 The Government Analyst and employees of the Drug Testing Laboratory shall not disclose any information acquired by him in the course of his official duties, except when required by the Court of Law and for official business.

PART XII

RESTRICTED AND CONTROLLED DRUGS

38. Mechanism of Control:

38.1 Any person or premise suspected of possessing or storing any controlled or restricted drugs listed under schedule C1 and schedule C2 without a valid medical prescription or licence or in excess of the quantity permitted in the prescription or licence shall be considered as an offence under the provisions of the Act and shall be dealt as per the Law of the Kingdom;

38.2 In the above event the subject under suspicion shall be forwarded to the Court and the Authority shall cause the seizure or detention of all or any article against which offence was committed and any mode of transport or equipment, which has been used for the conveyance, or storage of such article till such time the verdict of the court is issued.

38.3 All the controlled and restricted drugs shall be stored under lock and key (in case of Hospitals).

38.4 Consumption record of narcotic drugs shall be maintained in Form XIII and that of psychotropic substances in Form XIV and the reports shall be submitted to the Authority as and when asked, wherever applicable.

PART XIII

STORAGE AND DISPOSAL OF EXPIRED, SEIZED, RECALLED, UNSAFE, DEFECTIVE AND INAPPROPRIATELY LABELLED MEDICINAL PRODUCTS

39. Storage and disposal procedures:

39.1 All the expired medicines, seized, recalled, unsafe and inappropriately labelled medicinal products shall not be sold; such products shall be stored in separate containers from the month of expiry or date of notification by the Authority.

39.2 The expired, seized and recalled medicinal products shall be disposed off at appropriate intervals.

39.3 Wherever the seizure of medicinal products is due to lack of documents and not because of quality problems, the Authority shall review the quality of the medicines and explore possibilities of auctioning to private retailers or to Government Hospitals. In case of auction, the fund generated will be deposited in the Government revenue.

39.4 The request for disposal of expired medicines shall be made to the Authority in Form XV.

39.5 The Authority shall compile the list of medicines and inform the concerned agency of the disposal.

39.6 The application for disposal of recalled and seized products, if any, shall also be made to the concerned agency in the same form.

39.7 The Authority shall provide the directives for the disposal and shall be carried out in the presence of a local committee identified for the purpose consisting of the following:

39.7.1 One official from the Authority, wherever possible

39.7.2 One official from the Police

39.7.3 One official from the local authority

39.7.4 One official from Health Ministry in case of human medicine

39.7.5 One official from Livestock Sector of Ministry of Agriculture in case of veterinary medicine

39.8 The expired medicines should be incinerated (in a proper incinerator) in an identified centre.

PART XIV

ADVERTISEMENT OF MEDICINAL PRODUCTS

40.0 Advertisement:

40.1 Only the Board shall approve the advertisement of any medicinal products as per Section 27 of the Act; and no sale of drugs shall be advertised by means of a gift or lottery drawing.

40.2 An advertisement of a medicinal product shall:

40.2.1 Not be boastful of its therapeutic properties or of its ingredients as being miraculously or completely capable of curing, mitigating, treating or preventing a disease or illness, nor shall any other wording of similar meaning be used;

40.2.2 Not falsely or exaggeratedly show its therapeutic properties;

40.2.3 Not falsely cause to understand that the product has a substance as its chief or component ingredient in quantities larger than the amount that is actually present;

40.2.4 Not falsely cause to understand that it is an abortifacient or a strong emmenagogue;

40.2.5 Not falsely cause to understand that it is an aphrodisiac

40.2.6 Not falsely cause to understand that it is a birth control drug;

40.2.7 Not falsely show the therapeutic properties of a dangerous or a specially-controlled drug;

40.2.8 Not contain certification or laudation of its therapeutic properties by any other person;

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

40.3 Product labels and information leaflets accompanying drugs already registered by the Authority.

PART XV

SUSPENSION AND REVOCATION OF LICENCES

41. Suspension and revocation of licences:

41.1 When the Authority has substantial evidence that any licensee has not complied with the Act or the Regulation issued under the Act, the Authority, with the approval of the Board, shall request the suspension of the licence to the Ministry of Trade and Industry for a period of not more than 90 days each time or where a licensee is prosecuted for an offence under this Act, the same may order the suspension of the licence pending the final judgment.

41.2 A licensee whose licence has been suspended must cease the production or sale of drugs, or the importation or order, of drugs into the Kingdom, as the case may be; during such suspension, he may not apply for any other licence or authorization under the Act.

41.3 When the Authority has substantial evidence that a licensee lacks the qualifications mentioned under Part X of the Regulation, the Authority with the approval of the Board shall request the Ministry of Trade and Industry to revoke the licence.

41.4 A licensee whose licence has been revoked must cease the production or sale of drugs, or the importation or order of drugs into the Kingdom, as the case may be, and may not apply for any licence under this Act until a period of 3(three) years from the date of the revocation. It shall be at the discretion of the Board whether or not to issue another technical authorization.

41.5 The order of suspension or revocation of a licence shall be notified in writing to the licensee by the Ministry of Trade and Industry upon the request of the Authority and where the person whose licence has been suspended or revoked is not found or refuses to accept the said order, it shall be posted in a conspicuous place at the premises of manufacture, sale or import or order of drugs, and the licensee shall be deemed to have knowledge thereof from the date of its posting.

41.6 Wherever necessary, the orders of suspension and revocation of a licence may also be published in a newspaper or by other means of public media by the relevant agencies.

41.7 The Authority with the advice of the Board, may request the Ministry of Trade and Industry for withdrawal of the suspension of a licence before the expiration of the time limit when it is satisfied that the licensee whose licence has been suspended has complied with this Act or the Regulation issued under the Act.

41.8 The licensee whose licence has been suspended or revoked has a right to appeal to the Board through the Authority within thirty days from the date of knowledge of the order. The Board may dismiss the appeal or amend the order of the Authority in a way favourable to the appellant.

41.9 In case of a licensee whose licence has been suspended or revoked, desires to sell his remaining drugs to another licensee he shall apply in written to the Authority within a period of sixty days from the date of knowledge of the order of the suspension or revocation of the licence or the decision of the Board, with details of the drugs to be disposed. The Authority may after examination of the particulars and the inspection of the premises by an Inspector grant approval for disposal.

PART XVI

CLASSIFICATION OF MEDICINES

42. Under the provisions of the regulation the medicinal products shall be classified as follows:

42.1 Schedule A:
Non-prescription drugs on general sales list.
Medicines under this schedule can be sold without a prescription over the counter through a licensed retail shop.

42.2 Schedule B:
Prescription only medicines.
Medicines under Schedule B should be sold strictly on presentation of a prescription from a registered medical professional privileged to prescribe as per the Bhutan Medical and Health Council.

42.3 Schedule C: controlled and restricted drugs.

42.3.1 Schedule C1:
Controlled narcotic drugs which shall be available for medical use only in the Government Hospital settings and any sale of these medicines by retail is prohibited.

42.3.2 Schedule C2:
Controlled psychotropic substances, which will be available for medical use only in the Government Hospitals and any sale of these medicines by retail is prohibited.

42.4 Schedule D: Traditional medicines and herbal products.

42.4.1 Schedule D1:
Non-prescription traditional medicines and herbal products. Medicines under Schedule D1 shall be sold without the presentation of a prescription from a registered *Drungtsho*.

42.4.2 Schedule D2:

Prescription traditional medicines and herbal products. Medicines under Schedule D2 shall be sold only on the presentation of prescription from a registered *Drungtsho* unless otherwise declared by the Board as a health product.

42.5 Schedule E: medicinal products for veterinary use.

42.5.1 Schedule E1:

Non-prescription medicines for veterinary use.

Medicines prescribed under Schedule E1 shall be sold without a prescription from a registered veterinarian or veterinary professional authorised to prescribe by the parent agency.

42.5.2 Schedule E2:

Prescription medicines for veterinary use. Medicines prescribed under Schedule E2 shall be sold only on the presentation of a prescription from a registered veterinarian or veterinary professional authorised to prescribe by the parent agency.

42.6 Schedule F: Biologicals and special products.

Medicines listed under Schedule F shall not be sold through retail unless otherwise authorised by the Board. Such products should be stored under appropriate cold chain conditions as required as per the product specification.

PART XVII

LOT RELEASE OF BIOLOGICALS & SPECIAL PRODUCTS

43. Lot release of vaccines

43.1 Both the vaccines manufactured in the country and imported from outside will require the lot release. The lot release will be done by the concerned manufacturing agencies but reviewed and certified from time to time by the Authority.

43.2 The concerned agencies shall inform the Authority as and when lot release is done to get certification that will be done by the Authority in Form XVI.

43.3 In case of the imported vaccines, the following documents will be required and reviewed at the time of lot release from the central distribution point:

42.3.1 Batch quality control certificate from the manufacturer;

42.3.2 Summary Lot Protocol;

42.3.3 Shipping documents received.

43.4 The documents received before and along with the consignment of vaccines must be checked to see the completeness, compatibility, authenticity and validity of information.

43.5 The concerned agencies must check the consignments or batches of vaccines for cold chain conditions and perform visual tests, freeze tests, VVM status, temperature, packaging, label, quantity, batch number and expiry dates.

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

43.7 The list of documents to be reviewed will be revised from time to time in keeping with the changing needs.

PART XVIII

RECALL SYSTEM FOR SUBSTANDARD QUALITY, UNSAFE, DEFECTIVE AND INAPPROPRIATELY LABELLED PRODUCTS

44.0 Recall system:

44.1 The recall Form XVI shall be filled up by the relevant agencies and forwarded to the Authority.

44.2 The Authority, upon advice of the Board shall institute an evaluation of the recall requests.

44.3 A medicinal product shall be recalled if there is:

44.3.1 A quality problem, product problem, label problem or such complaints;

44.3.2 An adverse event linked to the product;

44.3.3 Any other reason recognized by the Board to cause potential risks or harm to human and animal health.

44.4 Any cost incurred by the Authority as a result of the recall shall be charged to the manufacturer or dealer of the product.

44.5 Any unsafe and defective medicinal products shall be recalled and destroyed in the presence of appropriate Committees formed by officials from relevant agencies.

PART XIX

ADVERSE DRUG REACTION MONITORING SYSTEM & PHARMACOVIGILANCE

45. Adverse Drug Reaction Monitoring Procedures and Pharmacovigilance

45.1 The Board shall establish a National Pharmacovigilance Centres (NPC) at National Referral Hospital and National Pharmacovigilance Sub-centres for Veterinary medicines at the Veterinary Hospital, Thimphu and for traditional/herbal medicine at National Institute of Traditional Medicine Services and the secretariat shall be based at respective organizations.

45.2 Each of these centres will have an expert committee who will meet regularly on quarterly basis to discuss and assess the reports and take necessary actions.

45.3 The Chairman of each sub-centre shall be the member on the National Pharmacovigilance Committee.

45.4 The Adverse Drug Report of different hospital shall be sent to their respective Sub-Centres and from the sub-centres, the reports shall be sent to the National Pharmacovigilance Centre at the National Referral Hospital. The National Pharmacovigilance Centre shall in turn send the reports to the Authority if it so warrants.

45.5 The ADR reports from all the traders and retail outlets of medicines shall be forwarded to the National Pharmacovigilance Centres through the Authority.

45.6 Any reports of adverse events following immunization shall be forwarded to the National Pharmacovigilance Centres.

45.7 Any ADR reports observed in the course of any health related research or study should be forwarded to the Research Advisory Board for clearance before submission to the Authority.

45.8 Based on the recommendation of the expert committees, the Authority may take appropriate regulatory actions like recall, withdrawal of the product, cancellation of registration etc. if there are any safety issues regarding the drug.

PART XX

APPEAL

46. Procedures of appeal:

46.1 Any individual aggrieved by any decision made by the Authority or any Committee established under the Act and the Regulation, shall submit a written petition to the Board

within one month from the date of notice of such incidence specifying the details of information on such matters.

46.2 The Authority shall investigate to study the issues of the petition in consultation with relevant agencies and Committees and give an explanation report to the individual concerned within one month from the date of receipt of the petition.

46.3 Any corrective action, if required to correct the mistakes made by the Authority or the Committee shall be made upon the advice of the Board within an appropriate time frame.

46.4 If the individual is still not satisfied with the explanation, then the individual shall apply to the Chairman of the Board along with the required documents within two weeks from the date of receipt of the explanation from the Authority.

46.5 The Board shall order for investigation and review of the case to a team of relevant personnel. The findings of the investigation and the corrective actions taken, if any, shall be informed to the petitioner.

46.6 If the individual is still not satisfied with the decision of the Board, the individual may appeal to any District Court in the Kingdom.

PART XXI

TOKEN AND REGISTRATION FEES

47. Under this Regulation the fees shall be as follows and shall be revised from time to time to keep in line with the changing needs.

47.1	Token fee for product registration dossier assessment per product	Nu. 150.00
47.2	Fee for product registration per product per product	Nu. 1500.00
47.3	Fee for temporary registration per product	Nu. 500.00
47.4	Penalty for late renewal of registration per day	Nu. 100
47.5	Token fee for import authorization per application	Nu. 150.00
47.6	Token fee for provisional manufacturing authorization per application	Nu. 5000.00
47.7	Token fee for approval for manufacturing	Nu. 200.00

47.8	Token fee for renewal of approval for manufacturing	Nu. 500.00
47.9	Token fee for authorization for sale	Nu. 150.00
47.10	Token fee for renewal of authorization for sale	Nu. 150.00
47.11	Token fee for authorization for export	Nu. 150.00
47.12	Token fee for registration of Competent Persons	Nu. 150.00
47.13	Token fee for renewal of registration certificate of Competent Persons	Nu. 150.00
47.14	Token fee for special import permit	Nu. 100.00

PART XXII

DEFINITIONS

48. Under the Regulations, the definitions of words defined in the Act shall have the same meaning and effect:

48.1 "Act" means the Medicines Act of the Kingdom of Bhutan 2003.

48.2 "Committee" means the Drugs Technical Advisory Committee or any other sub-committees constituted under the Act.

48.3 "*gSo-ba Rig-pa*" means the system of traditional medicines practised and recognised by the Medical and Health Council, Kingdom of Bhutan.

48.4 "Medical and Health Council" means the Medical and Health Council, Kingdom of Bhutan.

48.5 "Regulation" means the Medicines Rules & Regulations, Kingdom of Bhutan.

48.6 "Traditional medicines" means all medicines such as Ayurvedic, Unani, and Siddha prepared based on the ancient texts.

48.7 "Other authorised relevant personnel" means health personnel or a *sMen-pa* authorised to prescribe by the Bhutan Medical and Health Council and veterinary personnel authorised by the Ministry of Agriculture.

48.8 “Health product” means any product that promotes the healthy well being of an individual other than the medicinal products or any other product declared by the Board to be a health product.

48.9 “Person” means any individual or group of individuals or institution or corporate agency or company.

48.10 “Technical authorization” means the authorization for sale, export or import of medicinal products issued by the Drug Regulatory Authority for issuance of a licence by the Ministry of Trade and Industry.