

*Medicines and Related Substances (General) Regulations, 2025*

STATUTORY INSTRUMENT NO. \_\_\_\_ OF 2026

***MEDICINES AND RELATED SUBSTANCES ACT, 2025***

(Act No. \_\_\_\_ of 2025)

***MEDICINES AND RELATED SUBSTANCES***

***(GENERAL) REGULATIONS, 2026***

(Published on \_\_\_\_\_, 2025)

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**IN EXERCISE** of the powers conferred on the Minister of Health by section 123 of the Medicines and Related Substances Act, 2025, the following Regulations are hereby made.

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## ***PART I - PRELIMINARY***

### **Citation and commencement**

1. (1) These Regulations may be cited as the Medicines and Related Substances General Regulations, 2025.

(2) These Regulations shall come into operation on such date as the Minister may, by notice published in the Gazette, appoint.

### **Interpretation**

2. In these Regulations, unless the context otherwise requires

“**Act**” means the Medicines and Related Substances Act, 2025;

“**authorised officer**” means an officer of the Authority or any other person designated by the Chief Executive Officer to perform functions under these Regulations;

“**distributor**” means premises procuring, purchasing, holding, storing, selling, supplying, importing, exporting or facilitating the movement of medical products, excluding premises dispensing or providing medical products directly to a patient or his or her agent;

“**export licence**” means a licence issued to an entity authorising it to export regulated products;

“**export permit**” means a permit issued for a specific consignment of regulated products to be exported;

“**Good practices (GxP)**” means the group of good practice guides governing the preclinical, clinical, manufacture, testing, storage, distribution and post-market activities for regulated medical products;

“**guidelines**” means documents issued by the Authority outlining regulatory requirements and procedures;

“**import licence**” means a licence issued to an entity authorising it to import regulated products;

“**import permit**” means a permit issued for a specific consignment of regulated products to be imported;

“**key personnel**” means any person who performs critical functions in the manufacture, quality assurance, quality control, distribution, storage, or dispensing of regulated products; holds qualifications and competencies required by the Authority for his or her designated role; is

specifically designated in the licence or approved by the Authority; and exercises professional judgment that directly affects product quality, safety, or regulatory compliance; and includes responsible pharmacists, qualified persons, production managers, quality assurance managers, quality control managers, regulatory affairs officers, and such other persons as may be designated by the Authority in guidelines;

**“local technical representative”** means a person resident or incorporated in Botswana appointed by a non-resident applicant to act on his or her behalf;

**“marketing authorisation”** means a registration certificate issued by the Authority permitting a regulated product to be placed on the market;

**“marketing authorisation holder”** means the person or entity to whom a marketing authorisation has been granted;

**“product-specific regulations”** means regulations made under the Act pertaining to specific categories of regulated products;

**“qualified person”** means a person registered with the relevant professional body to undertake work or practise within a specific technical field, meeting minimum requirements specified in the guidelines;

**“quality risk management”** means the systematic assessment, control, communication and review of risks to product quality throughout the product lifecycle;

**“regulated establishment”** includes wholesalers, pharmacies, veterinary retailers, dispensaries, and authorised premises for medicines, medical devices, cosmetics, vaccines and biologics, and traditional medicines; manufacturing facilities; bonded warehouses and distribution centres; online sales platforms and mobile retail operations; quality control laboratories; and any other premises designated by the Authority as requiring oversight;

**“responsible person”** in relation to a regulated establishment, means a person who is designated in the licence or authorisation as having overall responsibility for the operations of the regulated establishment; holds qualifications and experience appropriate to the activities authorised; is accountable to the Authority for compliance with the Act and conditions of the licence or authorisation; and has authority to bind the licensee in regulatory matters;

**“risk-based approach”** means the systematic application of quality risk management principles to prioritise regulatory decisions and activities according to the level of risk to public or animal health, as guided by international standards and quality risk management guidelines;

**“serious adverse event”** means an adverse event that results in death, is life-threatening, requires hospitalisation, results in significant disability, or is a congenital anomaly;

**“traceability”** means the ability to trace the history, application or location of a regulated product through all stages of production, processing and distribution;

**“variation”** means a change to an approved marketing authorisation or to the particulars, conditions, scope, or specifications of a licence issued under the Act, classified as major, minor or notification based on potential impact.

### **Application**

3. (1) These Regulations apply to

- (a) all regulated products as defined in section 2 of the Act;
- (b) all persons engaged in the manufacture, import, export, distribution, sale, supply, storage, dispensing, or administration of regulated products;
- (c) all premises where regulated products are manufactured, stored, distributed, sold, supplied, dispensed, or administered;
- (d) clinical trials and investigations involving regulated products; and
- (e) advertising and promotion of regulated products.

(2) These Regulations shall be read together with product-specific regulations made under the Act.

(3) Where there is any conflict between these Regulations and product-specific regulations, the product-specific regulations shall prevail to the extent of the inconsistency.

### **Regulatory principles**

4. (1) The Authority shall exercise its functions under these Regulations in accordance with the following principles

- (a) protection of public health as the paramount consideration;
- (b) evidence-based and science-based decision-making;
- (c) transparency, consistency and predictability in regulatory processes;
- (d) proportionality between regulatory requirements and risk to public health;
- (e) efficiency and timeliness in processing applications and conducting assessments;
- (f) accountability and good governance;

- (g) collaboration and international cooperation; and
- (h) continuous improvement and adaptation to emerging challenges.

(2) The Authority shall apply a risk-based approach to regulatory oversight as set out in Schedule 2.

(3) In exercising its functions, the Authority shall have regard to

- (a) international best practices including World Health Organization guidance;
- (b) harmonisation initiatives within the Southern African Development Community and the African region;
- (c) the need to facilitate access to safe, effective and quality-assured regulated products;
- (d) the development of local pharmaceutical manufacturing capacity; and
- (e) the need to support innovation while protecting public health.

## ***PART II - GOVERNANCE AND ADMINISTRATION***

### **Board declarations and conflict of interest**

5. (1) Every Board member and committee member shall, within thirty days of appointment and before assuming duties, sign a declaration in Form GEN-01 set out in Schedule 1

- (a) declaring any financial, professional or personal interests that may conflict with his or her duties, including interests of immediate family members;
- (b) committing to scientific independence and evidence-based decision-making;
- (c) acknowledging confidentiality requirements under section 23 of the Act; and
- (d) committing to good regulatory practices and international cooperation principles.

(2) Declarations shall be updated

- (a) annually, within thirty days of the anniversary of appointment;
- (b) within fourteen days whenever circumstances materially change; and
- (c) before participation in any decision where a new interest may exist.

(3) Where a conflict of interest exists or may reasonably be perceived to exist

- (a) the member shall immediately disclose the interest;
- (b) the disclosure shall be recorded in the minutes;

(c) the member shall recuse himself or herself from discussion and voting on the matter; and

(d) the member may, at the discretion of the Chairperson, be required to leave the meeting during discussion of the matter.

(5) A decision made in contravention of this regulation shall be voidable at the discretion of the Board.

#### **Technical committees**

6. (1) The Board, or the CEO subject to approval of the Board, may establish technical committees in accordance with section 21 of the Act.

(2) Each committee shall

(a) include multidisciplinary expertise relevant to its functions;

(b) include, where appropriate, international expertise;

(c) operate transparently with documented procedures;

(d) make evidence-based recommendations; and

(e) coordinate with other committees on cross-cutting issues.

(3) The Board shall establish terms of reference for each committee specifying

(a) the committees mandate and scope;

(b) composition and quorum requirements;

(c) meeting frequency and procedures;

(d) reporting requirements; and

(e) review and sunset provisions.

(4) Committee recommendations shall be documented and shall form the basis of regulatory decisions, which shall be recorded with reasons.

(5) Committees may hold joint sessions to address matters affecting multiple product categories.

#### **Delegation of powers**

7. (1) The Board may, in accordance with section 25 of the Act, delegate any of its powers or functions under these Regulations, except

(a) the power to make policy;

(b) the power to approve the annual budget;

- (c) the power to appoint senior staff; and
- (d) any power the Board determines should not be delegated.

(2) Every delegation shall

- (a) be in writing;
- (b) specify the power or function delegated;
- (c) specify any conditions or limitations;
- (d) identify the delegate by name or office; and
- (e) specify the duration or circumstances of delegation;

(3) The Board may at any time

- (a) revoke or amend a delegation;
- (b) exercise any delegated power itself; or
- (c) give directions to the delegate regarding exercise of the power.

(4) The Board retains accountability for all delegated decisions and shall receive regular reports on the exercise of delegated powers.

(5) The Chief Executive Officer may, with Board approval, sub-delegate administrative functions to senior staff.

#### **Secretary of Board**

8. (1) The Chief Executive Officer shall, in accordance with section 20 of the Act, recommend a suitably qualified person to serve as Secretary of the Board.

(2) The Secretary shall

- (a) attend all meetings of the Board and its committees;
- (b) ensure proper notice of meetings is given;
- (c) prepare and distribute agenda and meeting papers;
- (d) record accurate minutes of proceedings;
- (e) maintain registers and records required under the Act;
- (f) coordinate communication between the Board and management;
- (g) ensure compliance with governance requirements; and
- (h) perform such other duties as the Board may assign.

(3) The Secretary shall have no vote in Board or committee proceedings.

(4) The Secretary shall be accountable to the Board for governance matters and to the Chief Executive Officer for administrative matters.

### ***PART III - REGISTRATION OF REGULATED PRODUCTS***

#### **Requirement for registration**

9. (1) In accordance with section 35 of the Act, no person shall

- (a) import or export;
- (b) manufacture;
- (c) distribute;
- (d) sell or offer for sale;
- (e) promote or advertise;
- (f) store for commercial purposes; or
- (g) dispense,

any regulated product unless it is registered with the Authority.

(2) Subregulation (1) does not apply to

- (a) products exempted under regulation 14;
- (b) products for which a special access scheme applies under product-specific regulations;
- (c) products in transit in accordance with regulation 49;
- (d) products imported for personal use in accordance with regulation 51;
- (e) investigational products used in approved clinical trials;
- (f) samples imported for registration purposes in quantities approved by the Authority; and
- (g) products imported under emergency provisions during declared public health emergencies.

(3) Registration under this regulation does not exempt a product from requirements under other applicable laws.

#### **Application for registration**

10. (1) An application for registration of a regulated product shall be made in Form GEN-02 set out in Schedule 1 and shall be accompanied by

- (a) the prescribed application fee as set out in the Fees Regulations;
  - (b) technical documentation in the format specified in the relevant guidelines;
  - (c) evidence of quality, safety and efficacy appropriate to the product category;
  - (d) samples as required by the guidelines;
  - (e) proof of good manufacturing practice compliance for the manufacturing site;
  - (f) labelling and packaging artwork;
  - (g) appointment of a local technical representative where required; and
  - (h) such other information as may be specified in the guidelines.
- (2) The Authority shall acknowledge receipt of an application within five working days and assign a unique application reference number.
- (3) The Authority shall, within thirty working days of receipt, conduct a validation review to determine whether the application is complete and may
- (a) accept the application for evaluation; or
  - (b) return the application with written reasons if incomplete.
- (4) An application returned for incompleteness may be resubmitted within ninety days without payment of additional fees, provided the deficiencies are rectified.
- (5) Applications not resubmitted within ninety days shall be deemed withdrawn, and a new application with full fees shall be required.

**Local presence requirement**

11. (1) In accordance with section 36 of the Act, an applicant for registration shall
- (a) be a company registered in Botswana; or
  - (b) if not resident in Botswana, appoint a local technical representative who is a natural person ordinarily resident in Botswana or a company incorporated in Botswana.
- (2) The local technical representative shall
- (a) be responsible for all communications with the Authority;
  - (b) ensure compliance with regulatory requirements;
  - (c) receive and process safety reports and complaints;
  - (d) facilitate inspections and information requests;
  - (e) maintain required records in Botswana; and

(f) have authority to act on behalf of the marketing authorisation holder.

(3) The appointment of a local technical representative shall be

- (a) in writing using Form GEN-03 set out in Schedule 1;
- (b) signed by both parties;
- (c) filed with the Authority before or with the application; and
- (d) updated within fourteen days of any change.

(4) A change of local technical representative shall not affect the validity of an existing registration but shall be notified to the Authority within fourteen days.

#### **Assessment of applications**

12. (1) The Authority shall assess applications in accordance with section 37 of the Act, having regard to

- (a) the quality, safety and efficacy of the product;
- (b) the risk classification of the product;
- (c) the appropriateness of the proposed indications or intended use;
- (d) the adequacy of manufacturing controls;
- (e) the appropriateness of proposed labelling and packaging;
- (f) compliance with relevant standards and guidelines; and
- (g) the benefit-risk balance for the Botswana context.

(2) The Authority may

- (a) request additional information from the applicant;
- (b) conduct or commission inspections of manufacturing sites;
- (c) require testing of samples by the National Quality Control Laboratory or approved laboratories;
- (d) consult with external experts or technical committees;
- (e) rely on assessments by recognised regulatory authorities; and
- (f) apply abridged or verification-only pathways where appropriate.

(3) Where additional information is requested

- (a) the request shall be in writing, specifying the information required and the timeframe for response;
- (b) the assessment clock shall stop until a complete response is received;

- (c) the applicant shall respond within the specified timeframe, which shall not exceed ninety days; and
- (d) failure to respond within the timeframe shall result in the application being deemed withdrawn.

(4) The Authority shall, within the prescribed assessment timeframes

- (a) register the product;
- (b) register the product with conditions;
- (c) request additional information; or
- (d) refuse registration, stating reasons in writing.

### **Registration pathways**

13. (1) The Authority shall operate the following registration pathways, where applicable

- (a) Full Evaluation Pathway, for new chemical entities, products not approved by any recognised authority, first-in-class products, and products with novel delivery systems or formulations;
- (b) Abridged Evaluation Pathway, for products approved by a Stringent Regulatory Authority as defined in the guidelines, World Health Organization Prequalified products, products approved through regional harmonisation initiatives, and generic products where the reference product is registered in Botswana;
- (c) Verification Pathway, for products approved by two or more Stringent Regulatory Authorities, products with extensive post-market history demonstrating safety, and products on the World Health Organization Essential Medicines List approved by recognised authorities; and
- (d) Notification Pathway, for low-risk medical devices meeting Class A criteria, general sale cosmetics meeting notification requirements, and other low-risk products specified in the guidelines.

(2) The target assessment timelines shall be

- (a) Full Evaluation Pathway: two hundred and seventy working days;
- (b) Abridged Evaluation Pathway: one hundred and eighty working days;
- (c) Verification Pathway: ninety working days; and
- (d) Notification Pathway: thirty working days.

(3) The Authority shall publish criteria for pathway allocation in the guidelines.

(4) The Authority may move an application to a different pathway where circumstances warrant, with written notification to the applicant.

#### **Registration during public health emergencies**

14. (1) In accordance with section 38 of the Act, during a declared public health emergency, the Authority may

- (a) operate expedited assessment procedures;
- (b) grant conditional or emergency use authorisations;
- (c) waive or reduce fees for products addressing the emergency;
- (d) rely on emergency use authorisations from recognised authorities; and
- (e) accept rolling submissions of data.

(2) Emergency registration procedures shall be

- (a) published in the Gazette;
- (b) notified through newspapers with wide circulation; and
- (c) made available on the Authority's website.

(3) Products registered under emergency provisions shall be subject to

- (a) enhanced post-market surveillance;
- (b) additional conditions as specified;
- (c) review when the emergency ends; and
- (d) requirements for transition to normal registration.

(4) Emergency authorisations shall automatically expire

- (a) when the public health emergency is declared over;
- (b) at such time as specified in the authorisation; or
- (c) when replaced by normal registration.

#### **Validity and renewal of registration**

15. (1) A marketing authorisation shall be valid for five years from the date of issue, subject to

- (a) payment of annual retention fees;
- (b) continued compliance with conditions of registration;
- (c) timely submission of required reports and notifications; and
- (d) no suspension or cancellation.

- (2) An application for renewal shall be
- (a) made in Form GEN-04 set out in Schedule 1;
  - (b) submitted at least six months before expiry; and
  - (c) accompanied by the prescribed renewal fee, an updated benefit-risk assessment, a summary of pharmacovigilance data, confirmation of continued good manufacturing practice compliance, notification of any variations since registration, and updated labelling if changed.
- (3) Where renewal is applied for within the prescribed time, the existing registration shall remain valid until a decision is made.
- (4) Where renewal is applied for after the prescribed time
- (a) a late submission fee shall be payable;
  - (b) the registration may lapse if application is not made within ninety days after expiry; and
  - (c) a lapsed registration shall require a new application.
- (5) Upon renewal, the Authority may
- (a) renew unconditionally;
  - (b) renew with amended conditions;
  - (c) require submission of additional data; or
  - (d) refuse renewal, stating reasons in writing.

#### **Variation of registration**

16. (1) In accordance with section 40 of the Act, no change to a registered product shall be made without prior approval from the Authority, except for notifiable changes.

- (2) Variations shall be classified as
- (a) major variations, being changes that could have significant effects on quality, safety or efficacy, including changes to the active substance or its specification, changes to the therapeutic indication or target population, significant changes to the manufacturing process, changes to the dosage form or route of administration, changes to the manufacturing site for sterile products, and changes to container closure systems affecting product stability;

(b) minor variations, being changes that may have minor effects on quality, safety or efficacy, including changes to batch size within approved limits, minor changes to specifications, changes to in-process controls, changes to testing laboratories, and addition of alternative suppliers of excipients; and

(c) notifications, being changes that have minimal or no effect on quality, safety or efficacy, including administrative changes to marketing authorisation holder details, changes to local representative, minor changes to labelling or package leaflet, and changes to shelf-life based on approved stability data.

(3) Applications for variations shall be made in Form GEN-05 set out in Schedule 1 and shall be accompanied by

- (a) the prescribed fee;
- (b) justification for the change;
- (c) supporting data as appropriate; and
- (d) updated documentation as affected.

(4) Assessment timelines shall be

- (a) major variations: ninety working days;
- (b) minor variations: sixty working days; and
- (c) notifications: thirty working days, no prior approval being required, but the Authority may object within that period.

(5) Implementing a variation without approval, where approval is required, constitutes an offence under these Regulations.

#### **Notifications**

17. (1) The marketing authorisation holder shall notify the Authority of the following within thirty days of occurrence

- (a) any restriction, suspension or withdrawal of the product in any other country;
- (b) any new safety information that may affect the benefit-risk balance;
- (c) any regulatory action taken by another authority;
- (d) any change in good manufacturing practice status of the manufacturing site;
- (e) discontinuation of marketing or manufacture; and
- (f) any other matters specified in the guidelines.

- (2) Notifications shall be made in Form GEN-06 set out in Schedule 1.
- (3) Failure to notify as required constitutes an offence under these Regulations.

**Cancellation, suspension and withdrawal**

18. (1) In accordance with section 41 of the Act, the Authority may cancel, suspend or withdraw a marketing authorisation where

- (a) the product no longer meets registration requirements;
- (b) the benefit-risk balance is no longer favourable;
- (c) the marketing authorisation holder has provided false or misleading information;
- (d) the marketing authorisation holder fails to comply with conditions of registration;
- (e) the product is no longer manufactured in accordance with good manufacturing practice;
- (f) the marketing authorisation holder fails to pay required fees;
- (g) the marketing authorisation holder requests withdrawal; or
- (h) it is otherwise in the public health interest.

(2) Before cancelling, suspending or withdrawing a registration, except in emergencies, the Authority shall

- (a) notify the marketing authorisation holder in writing of the proposed action and reasons;
- (b) provide an opportunity for the holder to make representations within thirty days; and
- (c) consider any representations made.

(3) Where immediate action is required to protect public health, the Authority may immediately suspend a registration pending full consideration, and shall

- (a) notify the holder immediately of the suspension and reasons;
- (b) complete the full consideration process within sixty days; and
- (c) either lift the suspension, confirm cancellation, or impose conditions.

(4) The Authority shall publish notice of cancellations, suspensions and withdrawals in

- (a) the Gazette;
- (b) at least one newspaper with wide national circulation; and

(c) on the Authority's website.

#### **Maintenance of registers**

19. (1) In accordance with section 42 of the Act, the Authority shall maintain registers of

- (a) all registered regulated products;
- (b) cancelled, suspended and withdrawn products;
- (c) applications under consideration;
- (d) licensed operators;
- (e) regulated products that are not required to be registered; and
- (f) such other matters as may be required.

(2) The registers may include

- (a) the registration number;
- (b) product name and description;
- (c) active substance or substances and strength;
- (d) dosage form and route of administration;
- (e) marketing authorisation holder;
- (f) manufacturer or manufacturers and manufacturing site or sites;
- (g) date of registration and expiry;
- (h) any conditions or restrictions;
- (i) variation history; and
- (j) registration status.

(3) The registers shall be

- (a) available for public inspection during normal business hours;
- (b) published on the Authority's website;
- (c) updated at least bi-monthly; and
- (d) maintained in a format facilitating searchability.

#### **Prohibition of undesirable substances**

20. (1) In accordance with section 43 of the Act, the Authority may prohibit any substance or product by notice in the Gazette where

- (a) it poses unacceptable risk to human or animal health;

- (b) it has no demonstrated therapeutic value;
  - (c) safer or more effective alternatives are available;
  - (d) its use is contrary to the public interest; or
  - (e) it is required by international convention or agreement.
- (2) Before prohibiting a substance, except in emergencies, the Authority shall
- (a) conduct a risk assessment;
  - (b) consult with relevant stakeholders; and
  - (c) publish a draft prohibition for comment for at least thirty days.
- (3) Prohibited substances shall be listed in Schedule 3 to these Regulations.
- (4) The Authority shall periodically review the list of prohibited substances.

#### ***PART IV - LICENSING OF REGULATED ESTABLISHMENTS***

##### **Requirement for licence**

21. (1) In accordance with section 58 of the Act, no person shall

- (a) manufacture;
- (b) sell or supply;
- (c) export or import;
- (d) distribute;
- (e) dispense; or
- (f) store for commercial purposes,

any regulated product unless that person holds a valid licence or authorisation issued by the Authority for that purpose.

(2) Subregulation (1) does not apply to

- (a) an individual purchasing or receiving regulated products for personal use; and
- (b) persons exempted by the Authority by notice in the Gazette.

(3) A licence is specific to

- (a) the person to whom it is issued;
- (b) the premises specified;
- (c) the activities authorised; and
- (d) the product categories authorised.

**Categories of licences**

22. (1) The following categories of licences shall be issued under these Regulations

- (a) manufacturing licences;
- (b) import and export licences;
- (c) distribution and wholesale licences;
- (d) retailing and dispensing licences;
- (e) bonded warehouse licences; and
- (f) special licences.

**Application for manufacturing licence**

23. (1) An application for a manufacturing licence under section 58 of the Act shall be made to the Authority in the prescribed form and shall be accompanied by

- (a) the prescribed application fee as per Fee Regulations
- (b) company registration documents;
- (c) facility location and ownership documents;
- (d) detailed floor plans and facility layout;
- (e) list of products and dosage forms to be manufactured;
- (f) pharmaceutical quality system documentation;
- (g) list of key personnel for approval; and
- (h) such other documents as may be required in the guidelines.

(2) The Authority shall issue manufacturing licences in the following categories

- (a) medicines manufacturing;
- (b) medical devices manufacturing;
- (c) biologicals manufacturing;
- (d) blood establishment operations;
- (e) cosmetics manufacturing; and
- (f) repackaging and relabelling operations,

or any other regulated product as the Authority may determine.

(3) A manufacturer may apply for multiple category licences for the same premises subject to demonstration of adequate segregation and contamination control measures.

**Key personnel requirements**

24. (1) Every manufacturing licence application shall designate the following key personnel

- (a) a Production Manager;
- (b) a Quality Assurance Manager; and
- (c) a Quality Control Manager.

(2) Qualifications, experience, and responsibilities for key personnel shall be as specified and detailed in guidelines published by the Authority.

(3) The Authority may set out conditions or requirements for key personnel.

**Current good manufacturing practice compliance**

25. (1) No manufacturing licence shall be issued unless the Authority is satisfied that the manufacturing facility complies with current good manufacturing practices as specified in the guidelines and such other standards as may be specified by the Authority.

(2) The Authority shall conduct an inspection to verify good manufacturing practice compliance before granting a manufacturing licence.

(3) The inspection shall assess compliance with good manufacturing practice requirements as detailed in guidelines published by the Authority.

**Issuance of manufacturing licence**

26. (1) Where the Authority is satisfied that all requirements are met, it shall issue a manufacturing licence in the prescribed form specifying

- (a) licence number;
- (b) licensee name and licensed premises;
- (c) manufacturing category;
- (d) authorised activities and product types;
- (e) names of approved key personnel;
- (f) validity period, being one year;
- (g) conditions of licence; and
- (h) date of issue.

(2) Every manufacturing licence is subject to the following standard conditions

- (a) maintain good manufacturing practice compliance at all times;

- (b) ensure approved key personnel are present during operations;
- (c) manufacture only authorised products at the licensed premises;
- (d) maintain records as specified by the guidelines; and
- (e) such other conditions as the Authority may impose.

(3) The licensee shall display the manufacturing licence prominently at the licensed premises.

#### **Certificate of compliance with good manufacturing practice**

27. (1) The Authority may issue a Certificate of Compliance with Good Manufacturing Practice to a manufacturer of medical products where, following inspection or assessment conducted in accordance with the Act and applicable guidelines, the Authority is satisfied that the manufacturing site complies with the prescribed standards of good manufacturing practice.

(2) A certificate issued under this regulation shall

- (a) be specific to the manufacturing site, dosage form, product category, and scope of activities inspected or assessed;
- (b) state the date of issuance and period of validity; and
- (c) be subject to such terms and conditions as the Authority may determine.

(3) The Authority may issue a certificate based on

- (a) a routine, pre-licensing, post-licensing, or for-cause inspection conducted by the Authority; or
- (b) reliance on, or recognition of, a valid inspection outcome or certificate issued by a recognised regulatory authority, where applicable.

(4) A certificate shall be valid for a period not exceeding

- (a) three years, where the certificate is issued following a full inspection conducted by the Authority or through regional cooperation bodies or a recognised regulatory authority; or
- (b) two years, where the certificate is issued following a risk-based inspection, abridged inspection, or reliance on a recognised regulatory authority.

(5) The Authority may suspend, vary or revoke a certificate where

- (a) non-compliance with good manufacturing practice is identified;
- (b) information submitted in support of the application is false or misleading; or
- (c) continued reliance on the certificate may pose a risk to public or animal health.

(6) A manufacturer shall apply for renewal of a certificate not later than six months prior to its expiry, in the manner and form determined by the Authority.

(7) The issuance of a certificate shall not exempt a manufacturer from ongoing regulatory oversight, including inspections, compliance verification, or post-market surveillance as provided for under the Act.

#### **Application for distribution and wholesale licence**

28. (1) A person who intends to operate distribution or wholesale operations for regulated products shall apply to the Authority for a licence in the prescribed form, accompanied by

- (a) the prescribed application fee;
- (b) company registration documents;
- (c) details of qualified personnel as specified in the guidelines; and
- (d) such other information as may be specified in the guidelines.

(2) Applications under subregulation (1) shall specify the category of licence sought, which shall include

- (a) medicines wholesale;
- (b) medical devices distribution;
- (c) cosmetics distribution;
- (d) bonded warehouse; or
- (e) combined facility for any of the above scope.

(3) A licensee shall not stock, sell, dispense or supply any medical product outside the scope of the licence category issued, and any contravention of this regulation shall constitute grounds for regulatory action under the Act.

#### **Assessment and inspection of distribution and wholesale operations**

29. (1) Upon receipt of a complete application, the Authority shall conduct inspection of the premises to verify compliance with

- (a) Good Storage and Distribution Practices as set out in WHO Technical Report Series No. 1025 (2020) and subsequent revisions;
- (b) Good Distribution Practice for Medical Devices, where applicable; and
- (c) such other standards as may be specified by the Authority.

(2) The inspection under subregulation (1) shall verify

- (a) suitability of premises and storage facilities;
- (b) adequacy of quality management systems;
- (c) temperature and environmental monitoring capabilities;
- (d) qualification and competence of personnel;
- (e) documentation and record-keeping systems;
- (f) traceability and inventory management systems;
- (g) transportation and delivery arrangements;
- (h) security measures and access controls; and
- (i) such other requirements as may be specified by the Authority.

**Application for retailing and dispensing licence**

30. (1) A person who intends to operate retailing or dispensing operations for regulated products shall apply to the Authority for a licence in the prescribed form, accompanied by

- (a) the prescribed application fee;
- (b) company registration documents;
- (c) details of the qualified person or responsible pharmacist;
- (d) scope of activities and regulated products applied for; and
- (e) such other information as may be specified in the guidelines.

**Categories of retail licences**

31. (1) The scope of permitted medical products under each retail licence category shall be as follows

- (a) Stand-alone pharmacies: a licence issued under this category shall authorise the retail sale and dispensing of controlled substances, prescription-only medicines, pharmacy medicines, and over-the-counter medicines for human use, subject to supervision by a registered pharmacist and compliance with good practices, applicable professional and regulatory requirements;
- (b) Hospital pharmacies: a licence issued under this category shall authorise the procurement, storage, compounding where applicable, and dispensing of prescription-only medicines, controlled medicines, pharmacy medicines, and over-the-counter medicines, and other medical products required for inpatient and outpatient care, exclusively for use within the licensed health facility;

(c) Veterinary retailers: a licence issued under this category shall authorise the retail sale and supply of veterinary prescription medicines and veterinary over-the-counter medicines, for animal use only, in accordance with conditions determined by the Authority and applicable veterinary legislation, subject to supervision by an authorised person and compliance with good practices, applicable professional and regulatory requirements;

(d) Dispensaries: a licence issued under this category shall authorise the retail sale and supply of prescription-only medicines, controlled medicines, pharmacy medicines, and over-the-counter medicines for animal use or for human use, in accordance with conditions determined by the Authority and applicable legislation, subject to supervision by a suitably qualified person and compliance with good practices, applicable professional and regulatory requirements;

(e) Authorised premises: a licence issued under this category shall authorise the sale or supply of specified categories of over-the-counter medicines or other medical products expressly approved by the Authority, for defined purposes and under conditions specified in the licence; and

(f) Combined facility: a licence issued under this category shall authorise any combination of the activities described in paragraphs (a) to (e).

(2) A licensee shall not stock, sell, dispense or supply any medical product outside the scope of the licence category issued, and any contravention of this regulation shall constitute grounds for regulatory action under the Act.

#### **Assessment and inspection of retailing and dispensing operations**

32. (1) Upon receipt of a complete application, the Authority shall

(a) conduct documentary assessment; and

(b) conduct inspection of the premises to verify compliance with Good Practice as set out in World Health Organization and international standards and specified guidelines, Good Distribution Practice for Medical Devices where applicable, Good Pharmacy Practice Standards for human medicines retailers, Veterinary Pharmacy Practice Standards for veterinary retailers, and such other standards as may be specified by the Authority.

(2) The inspection under subregulation (1)(b) shall verify

(a) suitability of premises and dispensing facilities;

- (b) adequacy of quality management systems;
- (c) temperature and environmental monitoring capabilities;
- (d) qualification and competence of personnel;
- (e) documentation and record-keeping systems;
- (f) traceability and inventory management systems;
- (g) patient counselling and dispensing areas;
- (h) security measures and access controls;
- (i) availability of reference materials and medicines information resources;
- (j) facilities for compounding, where applicable;
- (k) cold chain management systems, where applicable;
- (l) prescription handling and verification procedures;
- (m) adverse event reporting systems; and
- (n) such other requirements as may be specified by the Authority.

(3) Where an inspection is required, the applicant shall

- (a) facilitate access by inspectors at any reasonable time;
- (b) make personnel available for interview;
- (c) provide requested documentation and access to all evidence required; and
- (d) demonstrate operational readiness.

#### **Issuance of licence**

33. (1) Where the Authority is satisfied that the applicant meets the prescribed requirements and good practice standards, it shall issue a licence in the prescribed form.

(2) The licence issued under subregulation (1) shall specify

- (a) the name and address of the licensee;
- (b) the category of licence;
- (c) the scope of authorised activities;
- (d) the licensed premises address;
- (e) the name and registration number of the responsible pharmacist or qualified person;
- (f) conditions and restrictions, if any;
- (g) the validity period; and

(h) the licence number and date of issue.

(3) The Authority may refuse to issue a licence where

- (a) the premises do not meet good practice requirements;
- (b) the applicant lacks a suitably qualified responsible pharmacist or qualified person;
- (c) the quality systems are inadequate;
- (d) there is evidence of previous serious non-compliance; or
- (e) the applicant has provided false or misleading information.

(4) The Authority shall

- (a) issue the licence if requirements are met;
- (b) issue the licence with conditions;
- (c) defer the decision pending rectification of deficiencies; or
- (d) refuse the application, stating reasons in writing.

#### **Licensing of bonded warehouses**

34. (1) A person shall not operate a bonded warehouse for the storage of medical products unless licensed by the Authority in accordance with the Act and these Regulations.

(2) An application for a bonded warehouse licence shall be made in the form and manner determined by the Authority, and shall include

- (a) particulars of the premises, layout, and storage conditions;
- (b) evidence of approval or control by the relevant customs authority;
- (c) details of security, access control, and inventory management systems;
- (d) particulars of the responsible person and key personnel; and
- (e) any other information required by the Authority for risk assessment.

(3) A bonded warehouse licence shall authorise the licensee to receive, store, and release medical products under customs control, strictly in accordance with the scope and conditions specified in the licence, and shall not authorise

- (a) sale, distribution, or supply of medical products to the local market; or
- (b) any manipulation of medical products other than activities expressly permitted by the Authority.

(4) A bonded warehouse licence shall be valid for a period determined by the Authority using a risk-based assessment, and shall be subject to suspension or cancellation in accordance with these Regulations.

(5) The licensee shall notify the Authority in writing of any material change to the premises, operations, ownership, or customs authorisation affecting the bonded warehouse.

### **Special licences**

35. (1) The Authority may issue special licences for regulated activities that require enhanced or distinct regulatory controls, including

- (a) e-pharmacy licences, authorising the supply of medical products through electronic or digital platforms, subject to conditions determined by the Authority;
- (b) licences for importers, exporters, or handlers of precursor chemicals, authorising the importation, storage, or supply of precursors used in the manufacture of medical products or controlled substances;
- (c) mobile pharmacy licences, authorising the provision, dispensing, or supply of medical products from a mobile or temporary unit, vehicle, or outreach facility, under conditions specified by the Authority; and
- (d) such other specialised activities relating to medical products as the Authority may specify by notice or guideline.

(2) A special licence issued under this regulation shall

- (a) define the scope of authorised activities;
- (b) be subject to such terms, conditions, and limitations as the Authority may determine; and
- (c) be valid for a period determined by the Authority using a risk-based assessment.

(3) Specific requirements applicable to each category of special licence shall be prescribed in product-specific regulations, guidelines, or licence conditions issued by the Authority.

(4) A person shall not conduct any activity requiring a special licence unless authorised under this regulation, and any contravention shall constitute a breach of the Act.

### **General application requirements**

36. (1) An application for a licence shall be made in Form GEN-07 set out in Schedule 1 and shall be accompanied by

- (a) the prescribed application fee;
- (b) proof of company registration in Botswana;
- (c) details of premises including floor plans;
- (d) description of proposed activities;
- (e) details of responsible persons and key personnel;
- (f) evidence of qualifications and experience of key personnel;
- (g) evidence of appropriate storage facilities and equipment; and
- (h) such other information as may be specified in the guidelines.

(2) The Authority shall

- (a) acknowledge receipt within five working days;
- (b) conduct pre-licensing inspection where required; and
- (c) make a decision within ninety working days of a complete application.

(3) The Authority may request additional information or clarification, which shall stop the assessment timeline until a complete response is received.

#### **Conditions of licence**

37. (1) The Authority may impose conditions on any licence relating to

- (a) product categories that may be handled;
- (b) activities that may be conducted;
- (c) personnel requirements;
- (d) quality system requirements;
- (e) record-keeping requirements;
- (f) reporting requirements;
- (g) inspection access; and
- (h) any other matter relevant to compliance.

(2) Standard conditions shall be published in the guidelines.

(3) Conditions may be

- (a) imposed at the time of licensing;
- (b) added during the licence period following inspection or review;
- (c) amended upon application by the licensee; or

(d) removed when no longer necessary.

(4) Variation of conditions shall follow the process in regulation 41 with necessary modifications.

#### **Validity and renewal of licence**

38. (1) A licence granted under these Regulations shall be valid for a period determined by the Authority using a risk-based assessment, and shall not exceed

(a) three years, where the licensee demonstrates sustained compliance with applicable standards and a low regulatory risk profile; or

(b) two years, where the licensee presents a moderate regulatory risk requiring enhanced oversight.

(2) In determining the validity period of a licence, the Authority shall take into account

(a) the suitability of premises and equipment;

(b) the qualifications, competence, and adequacy of personnel;

(c) the effectiveness of the quality management system;

(d) compliance with applicable standards and guidelines;

(e) past regulatory compliance history; and

(f) any other factor relevant to the protection of public or animal health.

(3) Where significant deficiencies, unresolved corrective actions, or heightened public health risks are identified, the Authority may

(a) grant a licence with a reduced validity period not exceeding one year; or

(b) impose specific licence conditions, including enhanced inspection frequency or reporting obligations.

(4) Application for renewal shall be

(a) made in Form GEN-08 set out in Schedule 1;

(b) submitted at least three months before expiry; and

(c) accompanied by the prescribed renewal fee.

(5) The Authority may conduct an inspection as part of the renewal process.

(6) Where renewal is applied for within the prescribed time, the existing licence shall remain valid until a decision is made.

(7) Late renewal applications shall be subject to late payment penalties as provided in the Fees Regulations.

#### **Change of business ownership**

39. (1) In accordance with section 59 of the Act, a licensee shall apply for Authority approval before any change of business ownership.

(2) An application for approval of change of ownership shall be made in Form GEN-09 set out in Schedule 1 and shall include

- (a) details of proposed new ownership;
- (b) reasons for the change;
- (c) confirmation that operational standards will be maintained;
- (d) details of any changes to key personnel; and
- (e) such other information as the Authority may require.

(3) The Authority may

- (a) approve the change;
- (b) approve the change with amended conditions;
- (c) require additional information; or
- (d) refuse approval where public health may be compromised.

(4) A change of ownership without approval constitutes an offence and may result in suspension or cancellation of the licence.

#### **Suspension and cancellation of licence**

40. (1) The Authority may suspend or cancel a licence issued under these Regulations where it is satisfied, on reasonable grounds, that the licensee

- (a) has contravened or failed to comply with the Act, these Regulations, or any condition of the licence;
- (b) has failed to maintain compliance with applicable standards, guidelines, or good regulatory practices;
- (c) has provided false, misleading, or incomplete information in connection with an application or regulatory submission;
- (d) poses, or is likely to pose, a risk to public health, animal health, or safety; or

(e) has failed to implement corrective and preventive actions within the timeframe specified by the Authority.

(2) The Authority may suspend a licence with immediate effect where

- (a) an imminent or serious risk to public or animal health is identified;
- (b) regulated products are suspected to be falsified, substandard, unsafe, or unlawfully supplied; or
- (c) continued operation of the licensed activity would undermine regulatory control or public confidence.

(3) Except in cases of immediate suspension under subregulation (2), the Authority shall give the licensee

- (a) written notice of its intention to suspend or cancel the licence; and
- (b) a reasonable opportunity to make representations within the period specified in the notice.

(4) Upon cancellation or suspension, the licensee shall

- (a) immediately cease the licensed activities to the extent specified by the Authority;
- (b) surrender the licence certificate to the Authority within the period directed;
- (c) secure, dispose of, or transfer any stock of medical products in accordance with written directions issued by the Authority; and
- (d) retain and make available all records relating to the licensed activities for the prescribed retention period or such longer period as the Authority may require.

(5) The suspension or cancellation of a licence shall not preclude the Authority from taking any other enforcement action available under the Act, including prosecution or seizure of products.

#### **Variation of licence**

41. (1) A licensee may apply to the Authority for a variation of a valid licence where there is a proposed change to the particulars, scope, premises, operations, or conditions of the licensed activity.

(2) Variations shall be classified as

- (a) minor variations, being changes that do not materially affect the risk profile, scope of licensed activities, or compliance status of the licensee; and

(b) major variations, being changes that may materially affect regulatory risk, public or animal health, or the scope or nature of licensed activities.

(3) An application for variation shall be made in the form and manner determined by the Authority, accompanied by

(a) the prescribed variation fee, determined according to whether the variation is minor or major; and

(b) such supporting information as the Authority may require.

(4) In assessing an application for variation, the Authority shall apply a risk-based assessment, and may

(a) approve the variation, with or without conditions;

(b) require additional information, inspection, or verification; or

(c) refuse the variation, giving reasons in writing.

(5) The Authority may reclassify a proposed minor variation as a major variation where, upon assessment, the change is found to have a material regulatory or public health impact.

(6) An approved variation shall not extend the validity period of the licence, unless expressly determined by the Authority.

(7) A licensee shall not implement a proposed variation until written approval is granted by the Authority, except where the Authority authorises phased or conditional implementation.

#### **Post-licensure notifications**

42. (1) A licensee shall notify the Authority in writing of any change or occurrence affecting the licensed activity after the grant of a licence, in accordance with this regulation.

(2) Post-licensure notifications shall include

(a) temporary or short-term operational disruptions;

(b) changes in key personnel where qualifications remain equivalent;

(c) minor equipment replacement or maintenance not affecting capacity or compliance;

(d) security incidents, theft, or loss of regulated products;

(e) significant deviations, quality incidents, or product integrity concerns; and

(f) any other matter specified by the Authority by notice or guideline.

(3) A notification under this regulation shall be submitted within the period prescribed by the Authority, or where no period is prescribed, within fourteen days of the occurrence or awareness of the change or event.

(4) Upon receipt of a post-licensure notification, the Authority may

- (a) acknowledge the notification without further action;
- (b) require additional information or clarification;
- (c) impose additional licence conditions or corrective actions; or
- (d) require the licensee to submit an application for variation or take other regulatory action.

(5) Failure to submit a required post-licensure notification within the prescribed timeframe shall constitute non-compliance and may result in regulatory action.

#### **Notification of changes for manufacturing licences**

43. (1) The licensee shall notify the Authority in writing within seven working days of

- (a) any change in key personnel;
- (b) extended absence of key personnel exceeding thirty days;
- (c) temporary closure of facility;
- (d) emergencies affecting operations;
- (e) product recalls or serious quality defects;
- (f) regulatory actions by other authorities; and
- (g) such other changes as may be specified by the Authority.

#### **Registers for controlled substances by licensed establishments**

44. (1) Every licensed establishment authorised to manufacture, import, export, distribute, dispense, or otherwise handle controlled substances shall establish, maintain, and keep up-to-date registers of all controlled substances handled in accordance with the Act and these Regulations.

(2) The registers for controlled substances shall include

- (a) a controlled substances stock register, recording quantities received, supplied, dispensed, transferred, destroyed, or otherwise disposed of;
- (b) a supplier and recipient register, including licence details and authorisations;

- (c) a prescription or order register, where applicable, detailing prescriber or authorising practitioner particulars;
  - (d) a loss, theft, discrepancy, and incident register, including investigations and corrective actions; and
  - (e) such other registers as the Authority may prescribe by notice or guideline.
- (3) Registers shall be maintained in a manner that ensures full traceability of controlled substances, including batch numbers, dates, quantities, and balance carried forward after each transaction.
- (4) Registers may be maintained in electronic or hard-copy form, provided that
- (a) entries are made contemporaneously and are accurate and complete;
  - (b) records are protected against unauthorised access, alteration, or loss; and
  - (c) the system allows for audit trails and inspection by the Authority.
- (5) Registers relating to controlled substances shall be retained for a minimum period of five years, or for such longer period as the Authority may require, having regard to the nature of the substance and regulatory risk.
- (6) A licensed establishment shall make all controlled substances registers available to inspectors upon request, and failure to maintain, update, or produce such registers shall constitute serious non-compliance under these Regulations.

#### **Maintenance and publication of registers by the Authority**

45. (1) The Authority shall establish, maintain, and keep up to date official registers for the purpose of regulatory oversight, transparency, and enforcement in relation to licensed establishments and inspections conducted under the Act and these Regulations.

- (2) The registers maintained by the Authority shall include
- (a) a register of licensed establishments, indicating the licence category, scope of authorised activities, validity period, and licence conditions;
  - (b) a register of suspended licences, indicating the grounds for suspension and duration;
  - (c) a register of cancelled or revoked licences, indicating the date and grounds for cancellation or revocation; and
  - (d) an inspection register, recording inspections conducted, inspection type, dates, and regulatory outcomes.

(3) The Authority may publish or make accessible to the public such registers, or parts thereof, as it considers appropriate, subject to

- (a) the protection of confidential, commercially sensitive, or security-related information; and
- (b) applicable data protection and access-to-information laws.

(4) The Authority may publish abridged inspection reports or inspection outcome summaries for specified categories of inspections where such publication supports regulatory transparency and public confidence, does not compromise enforcement actions or confidentiality obligations, and is consistent with guidelines issued by the Authority.

### ***PART V - IMPORT AND EXPORT CONTROL***

#### **Requirement for import and export authorisation**

46. (1) In accordance with section 62 of the Act, no person shall import or export any regulated product without authorisation from the Authority.

(2) Authorisation requires

- (a) a valid import or export licence for the entity; and
- (b) a valid import, export or transit permit for the specific consignment.

(3) The Authority may refuse authorisation where

- (a) the product is not registered/listed, unless an exemption applies;
- (b) the product is prohibited;
- (c) the product is substandard or falsified;
- (d) the product has inadequate remaining shelf-life;
- (e) the applicant does not hold a valid licence; or
- (f) it is otherwise in the public interest.

#### **Import and export permits**

47. (1) A holder of a valid import or export licence may apply for permits for specific consignments.

(2) An application for a import/exportpermits shall be made in forms set out in relevant guidelines.

(4) The Authority shall process permit applications within set turnaround times in the relevant guidelines.

(5) Permits shall specify

- a) permit number;
- b) Details of the importer and exporter
- c) product details and quantity;
- d) authorised route/s;
- e) validity period as set out in in the relevant guidelines
- f) any conditions; and
- g) inspection requirements.
- h) Any other informations that shall be specified in the relevant guidelines

#### **Authorised ports of entry**

48. (1) In accordance with section 63 of the Act, regulated products may only be imported or exported through the ports of entry designated in the relevant guidelines.

(3) The Authority shall liaise with the strategic partners to

- (a) maintain import/export control arrangements at designated ports as per the MoU/MoA;
- (b) facilitate inspection/verification of consignments;
- (c) share information on imports and exports; and
- (d) coordinate enforcement activities.

(5) Regulated products shall not be imported through postal services except

- (a) small quantities for personal use as approved;
- (b) samples for registration purposes; and
- (c) diagnostic specimens as authorised.

#### **Products in transit**

49. (1) In accordance with section 70 of the Act, regulated products in transit through Botswana require a transit permit from the Authority.

(2) An application for a transit permit shall be made in a form as prescribed by the relevant guidelines.

- (3) The holder of a transit permit shall
- (a) ensure products remain under customs control;
  - (b) not release products into the domestic market;
  - (c) not process, repackage, or alter products during transit;
  - (d) notify the Authority within forty-eight hours of departure from Botswana; and
  - (e) maintain records of the transit.
- (4) Transit permits shall be valid for period as prescribed in the relevant **guidelines**.
- (5) Contravention of transit permit conditions constitutes an offence punishable by a fine not exceeding P1 000 000 or imprisonment for three years, or both.

**Commented [MM1]:** @Nonofa Thipe is it fine for them to be prescribed in the guidelines or they have to be stated here?

#### **Donated medical products**

50. (1) In accordance with section 66 of the Act, donated regulated products require authorisation from the Authority.
- (2) An application for a donation permit shall be made in a form as prescribed in the relevant guidelines.
- (3) Donated products shall
- (a) meet the same quality standards as commercially imported products;
  - (b) have adequate remaining shelf-life as specified in the guidelines;
  - (c) be appropriately labelled in English;
  - (d) be on the national essential medicines list or otherwise appropriate for the Botswana context;
  - (e) not be **near-expiry** products inappropriate for the healthcare setting; and
  - (f) comply with the Authority's guidelines on donations, which shall align with World Health Organization guidelines.
- (4) The Authority may waive or reduce fees for donated products intended for humanitarian purposes.
- (5) Where donated products do not meet requirements, the Authority may seize, quarantine, confiscate or order re-export at the importers cost.

**Commented [MM2]:** Minimum shelf-life to be specified

#### **Personal importation**

- a) 51. (1) In accordance with section 64 of the Act, a person entering or re-entering Botswana may import regulated products for personal treatment

without a permit, subject to the following the product is accompanied by a prescription or medical documentation;

- b) the product is not prohibited in Botswana;
- c) the product is for the personal use of the person importing or a person in his or her care; and
- d) the person declares the product at customs.

The quantities of imported products shall be limited to a ninety-day supply.

(2) Personal importation is not permitted for

- a) narcotic drugs;
- b) psychotropic substances;
- c) Schedule 1D medicines;
- d) products prohibited in Botswana;
- e) Precursor chemicals;
- f) Class D medical devices
- g) In-vitro diagnostics

**Commented [MM3]:** Even when the person has a prescription for such?

(3) The Authority may establish specific authorisation procedures for patients requiring ongoing supply of medicines not available in Botswana.

### **Import and export of controlled substances**

52. (1) In accordance with section 67 of the Act, the import or export of narcotic drugs, psychotropic substances, or precursor chemicals requires a separate permit for each consignment.

(2) An application for a controlled substances import permit shall be made to the Authority by the responsible person, being a pharmacist or veterinary surgeon, in Form GEN-14 set out in Schedule 1 and shall include

- (a) product details including international non-proprietary name;
- (b) quantity;
- (c) International Narcotics Control Board certificate where required;
- (d) export authorisation from the exporting country;
- (e) purpose of import;
- (f) importer or end-user details;

- (g) storage and security arrangements;
- (h) supplier details; and
- (i) intended port of entry.

(3) Upon assessment, the Authority shall issue an import permit to the applicant, which permit shall be valid for six months.

(4) After receipt of the medicines, the pharmacist shall notify the Authority and submit an acknowledgement and a copy of the export permit from the relevant country within seven days.

(5) An application for a controlled substances export permit shall be made to the Authority by the responsible person, being a pharmacist or veterinary surgeon, in the prescribed form and shall include the information specified in subregulation (2), with such modifications as are necessary for exports.

(6) Upon assessment, the Authority shall issue an export permit valid for six months prior to exportation of the medicines.

(7) After dispatch of the medicines, the pharmacist shall notify the Authority and submit an acknowledgement within seven days.

(8) Permits for controlled substances shall

- (a) be product and quantity specific;
- (b) specify the authorised route;
- (c) be valid for six months;
- (d) require return to the Authority after use; and
- (e) require reconciliation of quantities imported against quantities utilised.

(9) All importers of controlled substances shall submit estimates of requirements for narcotics, psychotropics and precursors annually to the Authority.

(10) Contravention of this regulation is an offence punishable by a fine not exceeding P5 000 000 or imprisonment for seven years, or both.

#### **Records for controlled substances**

53. (1) Separate registers of controlled substances shall be kept by each manufacturer, seller, importer, exporter, distributor, or dispenser of such medicines.

(2) Registers kept by manufacturers, sellers, importers, exporters or distributors shall contain

- (a) quantities received, issued, spoiled, disposed of and the balance of the medicine concerned;
- (b) name and business address of the supplier;
- (c) date on which the medicine was received;
- (d) import permit number in the case of imports;
- (e) export permit number in the case of exports;
- (f) name and business address of the purchaser;
- (g) date of sale of the medicine; and
- (h) invoice or reference number of such sale.

(3) Registers kept by dispensers shall contain

- (a) quantities received, issued, spoiled, disposed of and the balance of the medicines concerned;
- (b) name and business address of the supplier;
- (c) date on which the medicine was received;
- (d) name and address of the patient to whom the medicine was dispensed;
- (e) prescription number or reference number upon which the medicine was dispensed;
- (f) date of such dispensing; and
- (g) name and address of the prescriber.

(4) All invoices for the purchase or supply of Schedule 1A, 1B, 1C medicines or precursor chemicals shall be kept for a minimum of five years.

(5) All registers or records required to be kept under this regulation shall be retained for a period of five years after the date of the last relevant entry, and shall be kept available for inspection by authorised officers.

(6) All registers and records required to be kept under these Regulations shall be balanced within thirty days and all entries shall be made within seven days.

(7) All records shall be

- (a) maintained separately from other records;
- (b) in indelible ink or electronic format that cannot be altered;
- (c) maintained for a minimum of five years after the last entry; and

(d) available for inspection at all times.

(8) A register shall not be transferable without the Authority's approval.

(9) A person who keeps a register under the Act shall make corrections to the register by drawing a line through the entry being corrected and shall insert his or her initials on the corrected entry, and no correction shall be masked or done with correction fluid, and there shall be no overwriting.

#### **Dispensing of controlled substances**

54. (1) Schedule 1A, 1B and 1C medicines may only be dispensed by a pharmacist upon a written prescription by a medical practitioner or dentist, presented for dispensing within thirty days of the date of its issue, and for the supply of a quantity not greater than the quantity indicated on the prescription, which shall not exceed thirty days supply.

(2) The prescription shall be retained in the pharmacy for a period of five years after the date it was dispensed.

(3) The dispenser of Schedule 1A, 1B and 1C medicines shall enter a record of such dispensing and the register shall be kept for a period of five years after the last entry.

(4) Separate registers shall be kept for Schedule 1A, 1B and 1C medicines.

(5) Except when being administered to a patient, every Schedule 1A, 1B and 1C medicine shall be kept under safe custody in a lockable cabinet or in a safe securely fixed.

#### **Emergency dispensing of Schedule 1A, 1B and 1C medicines**

55. (1) Emergency dispensing of Schedule 1A, 1B and 1C medicines may be done where

(a) there is a repeat prescription for a patient known by both the prescriber and pharmacist;

(b) the pharmacist has contacted the prescriber and the prescriber is confirmed as being a medical practitioner or dentist; and

(c) the pharmacist is satisfied that it is impossible or impracticable to obtain a written prescription.

(2) The prescription may be made by telephone, email or facsimile, in quantities not exceeding those stated in regulation 54(1), on condition that a written prescription shall be provided within forty-eight hours.

#### **Sale and use of precursor chemicals**

56. (1) Precursor chemicals listed in Schedule 2 of these Regulations shall be sold by authorised dealers.

(2) The use of precursor chemicals that require import permits shall be authorised by the Authority.

(3) Registers of the sale and use of chemicals shall be maintained by the authorised dealers and the registers shall capture information as determined by the Authority.

## ***PART VI SCHEDULING AND CLASSIFICATION OF MEDICINES***

### **Classification and description of medicines**

57. (1) The Authority shall carry out a risk-based review of the classification of medicines in consultation with relevant stakeholders.

(2) For purposes of the Act and these Regulations, medicines shall be classified in accordance with the lists set out in Schedule 1 and the lists shall be published in the Gazette.

### **Prescription of medicines**

58. (1) Prescriptions of medicines shall be written in generic or approved international non-proprietary names, except when a particular brand of medicine is preferred and clinically acceptable reasons for such preference are communicated to the dispenser.

(2) The Minister shall draw guidelines on dispensing and prescription of medicines in terms of section 38(3) and section 39(2) of the Act.

### **Contents of prescriptions**

59. (1) A valid prescription shall contain the following information

- (a) particulars of the patient including name, age and gender;
- (b) name of the medicine, dosage form, dosage strength, directions for use, duration of treatment or quantity;
- (c) name, qualifications, address and signature of the prescriber;
- (d) date of prescription;
- (e) if issued by a dentist, the words for dental treatment only, and if for topical application, the words for external use only; and
- (f) the facility stamp.

(2) For Schedule 1A, 1B and 1C medicines, the quantity shall be written in words and figures.

(3) A prescriber shall keep a copy of each prescription issued for a period of one year.

#### **General dispensing**

60. (1) A person shall not dispense medicine of a quantity greater than the amount and the stated duration of treatment in the prescription.

(2) A person dispensing medicine shall endorse on the prescription the date when the medicine is dispensed, the quantity dispensed, and shall append his or her signature thereto.

(3) A repeat prescription may be dispensed for a maximum of six times from the date of issue.

#### **Dispensing of Schedule 2 medicines**

61. Schedule 2 medicines may be dispensed in

(a) referral hospitals, district hospitals, primary hospitals, mission hospitals, mine hospitals or private hospitals, by a pharmacist or an intern pharmacist, a pharmacy technician under the supervision of a pharmacist, or by any authorised dispenser upon a written prescription issued by a medical practitioner or a dentist;

(b) a retail pharmacy, by a pharmacist, a pharmacy technician under the supervision of a pharmacist or by any authorised dispenser upon a written prescription issued by a medical practitioner or a dentist;

(c) a Government clinic, by a pharmacy technician under the supervision of a pharmacist upon a written prescription issued by an authorised prescriber; or

(d) a private health facility, by an authorised dispenser.

#### **Dispensing of Schedule 1D and 3 medicines**

62. Schedule 1D and 3 medicines shall only be dispensed by a pharmacist or any authorised dispenser upon a prescription.

#### **Emergency supply of medicines by pharmacist**

63. (1) Notwithstanding regulation 61, in an emergency, Schedule medicines may be supplied or dispensed without a prescription by a pharmacist, where

(a) there is an immediate need for the medicine requested to be supplied and it is impractical in the circumstances to obtain a prescription; or

(b) the treatment with the medicine has on a previous occasion been prescribed for the person requesting it.

(2) The quantity of the medicine to be supplied in accordance with subregulation (1) shall not exceed five days treatment, provided that

(a) where the medicine is an ointment, a cream or an aerosol for the relief of asthma, which has been made up for sale in a container elsewhere than at a place of supply, the dispenser may supply the smallest pack available;

(b) where the medicine is an oral contraceptive, the dispenser may supply a sufficient quantity for a full cycle; or

(c) where the medicine required is in such a package that it is impractical to split the package, the whole package may be supplied.

#### **Dispensing by healthcare providers other than pharmacists**

64. (1) A healthcare provider shall apply to his/her professional body for an authorisation to dispense medical products.

(2) An authorization shall be given to a healthcare provider on condition that he or she has competency in dispensing medical products.

(3) A dispensary, clinic, health post and mobile clinic shall meet standards set out in the guidelines.

#### **Storage of medical products by prescribers**

65. (1) A prescriber may, in line with the guidelines, store some medical products to administer to his or her patients.

(2) Subject to subregulation (1), the type and quantities of the medical products administered shall be determined by the scope of the prescribers practice and the prescriber shall fulfil other requirements set out in the guidelines.

#### **Storage of medicines**

66. (1) Medicines shall be stored in secure, well-ventilated rooms, with adequate lighting and controlled temperatures.

(2) Schedule 1 medicines shall be kept in bolted locked steel cabinets or rooms with controlled access.

(3) The storage facilities shall be protected from pests, harsh weather and shall meet building codes.

(4) The guidelines relating to the storage of medicines shall be updated as the Authority may determine.

**Product information and labelling**

67. (1) Any product information shall be provided in line with the guidelines.

(2) The container of every medicine imported, manufactured, processed or packed in Botswana shall bear a label written in English, with the following information clearly indicated thereon

- (a) either the approved name of the medicine as used in official pharmacopoeias or formularies, or the international non-proprietary name;
- (b) the brand name, if any;
- (c) the contents of the container;
- (d) the quantity of active ingredients per dosage unit;
- (e) the name of the manufacturer or applicant;
- (f) the batch identification;
- (g) the expiry date;
- (h) any special storage conditions that may be necessary or desirable;
- (i) any warnings or precautions that may be necessary or desirable;
- (j) any directions for use if sold without prescription;
- (k) any appropriate statutory or restrictive direction or label;
- (l) any conditions of registration stipulated by the Authority during registration; and
- (m) manufacture date.

(3) In any special circumstances the Authority may exempt any particular consignment of medicines from the requirements of subregulation (2).

(4) The container of every medicine dispensed to a patient shall have a label bearing the following information

- (a) full name of the patient;
- (b) date of dispensing;
- (c) pack size;
- (d) name and signature of the dispenser; and
- (e) all information required for the purposes of subregulation (2).

(5) The containers of pre-packed medicines shall bear a label with the name, strength and quantity of the medicine, batch number, date of manufacture, expiry date, and manufacturer.

(6) If the medicine contains any ingredient that is known to cause any allergic reaction, there shall be a warning to that effect.

(7) For medicines which require caution, such medicine shall bear a label giving information and instructions in accordance with the guidelines issued by the Authority.

## ***PART VII QUALITY CONTROL AND LABORATORY SERVICES***

### **National Quality Control Laboratory**

68. (1) In accordance with section 31 of the Act, the National Quality Control Laboratory shall

- (a) analyse and test regulated products for quality, safety and efficacy;
- (b) conduct batch release testing for vaccines and biologicals;
- (c) support market surveillance through sampling and testing;
- (d) conduct research relevant to quality control;
- (e) provide training and capacity building;
- (f) maintain and disseminate reference standards; and
- (g) provide quality control services to public and private entities.

(2) The Laboratory shall maintain accreditation to ISO/IEC 17025 for relevant testing methods.

(3) The Laboratory shall participate in proficiency testing programmes and international inter-laboratory comparisons.

### **Application for laboratory services**

69. (1) In accordance with section 33 of the Act, applications for laboratory services shall be made to the Authority in Form GEN-15 set out in Schedule 1.

(2) Applications shall be accompanied by

- (a) the prescribed fee;
- (b) samples in required quantity and condition;
- (c) product information including specifications;
- (d) special handling instructions where applicable; and
- (e) such other information as may be required.

(3) The Laboratory shall provide estimated timelines for testing upon receipt of samples.

**Certificate of analysis**

70. (1) In accordance with section 34 of the Act, the Laboratory shall
- (a) analyse samples promptly upon receipt;
  - (b) issue a Certificate of Analysis upon completion;
  - (c) specify the tests performed and results obtained; and
  - (d) state whether the sample conforms to specifications.
- (2) A Certificate of Analysis shall be signed by the Laboratory head or authorised delegate.
- (3) The Certificate of Analysis shall constitute prima facie evidence of the matters stated therein in any legal proceedings.

**Use of external laboratories**

71. (1) In accordance with section 110 of the Act, the Authority may
- (a) subcontract analysis to approved independent laboratories within or outside Botswana;
  - (b) rely on test results from accredited laboratories; and
  - (c) utilise Government Laboratories where appropriate.
- (2) External laboratories used by the Authority shall
- (a) be accredited to ISO/IEC 17025 for relevant methods;
  - (b) participate in proficiency testing; and
  - (c) be approved by the Authority.
- (3) The Authority shall maintain and publish a list of approved external laboratories.

***PART VIII VIGILANCE AND POST-MARKET SURVEILLANCE***

**National vigilance programme**

72. (1) In accordance with section 71 of the Act, the Authority shall establish and maintain a national vigilance programme covering
- (a) pharmacovigilance for medicines;
  - (b) materiovigilance for medical devices;
  - (c) haemovigilance for blood and blood products; and
  - (d) cosmetovigilance for cosmetics.

- (2) Marketing authorisation holders, importers, and distributors shall
- (a) establish and maintain vigilance systems;
  - (b) appoint a qualified person responsible for vigilance;
  - (c) report adverse events as required;
  - (d) conduct signal detection and assessment;
  - (e) implement risk minimisation measures; and
  - (f) respond to Authority requests for information.
- (3) Healthcare facilities and health practitioners shall
- (a) report suspected adverse events;
  - (b) cooperate with investigations; and
  - (c) provide access to relevant records.
- (4) The Authority may inspect vigilance systems at reasonable times to ensure compliance.

**Reporting of adverse events**

73. (1) In accordance with section 72 of the Act, the following shall be reported to the Authority

- (a) suspected or unexpected adverse reactions;
- (b) adverse reactions from medication errors;
- (c) adverse reactions suggesting unusual frequency or severity;
- (d) lack of expected efficacy;
- (e) field safety corrective actions;
- (f) safety signals;
- (g) quality defects;
- (h) regulatory actions in other countries; and
- (i) such other matters as specified in the guidelines.

(2) Reporting timelines shall be

- (a) fatal or life-threatening reactions: within twenty-four hours;
- (b) serious adverse reactions: within seven days;
- (c) non-serious adverse reactions: within thirty days; and
- (d) periodic safety reports: as specified in conditions of registration.

(3) Reports shall be made using Form GEN-16 set out in Schedule 1 or through the Authority's electronic reporting system.

(4) For cannabis products, adverse events shall be reported to both the Authority and the cannabis control authority.

#### **Haemovigilance system**

74. (1) In accordance with section 73 of the Act, blood establishments shall

- (a) establish haemovigilance systems;
- (b) ensure compliance with Good Haemovigilance Practice;
- (c) report adverse reactions and quality defects;
- (d) conduct look-back investigations; and
- (e) submit data to the national haemovigilance system.

(2) Healthcare facilities providing transfusion services shall

- (a) report transfusion reactions;
- (b) maintain transfusion records;
- (c) participate in traceability requirements; and
- (d) implement patient blood management programmes.

(3) Reporting timelines and requirements shall be as specified in the Blood and Blood Products Regulations.

#### **Post-market surveillance**

75. (1) In accordance with section 74 of the Act, the Authority shall conduct post-market surveillance including

- (a) sampling and testing of products on the market;
- (b) monitoring of vigilance data;
- (c) analysis of complaints;
- (d) targeted surveillance based on risk;
- (e) international collaboration on safety signals; and
- (f) periodic benefit-risk reassessment.

(2) Marketing authorisation holders shall

- (a) establish post-market surveillance systems;

- (b) monitor the performance of their products;
- (c) submit annual post-market surveillance reports; and
- (d) not supply substandard or falsified products.

(3) The Authority shall publish annual reports on post-market surveillance activities and findings.

#### **Product recall**

76. (1) In accordance with section 75 of the Act, a marketing authorisation holder shall voluntarily recall a product where

- (a) the product is non-compliant with specifications;
- (b) the product has caused or is likely to cause injury;
- (c) the product is defective or mislabelled; or
- (d) new safety information warrants recall.

(2) The Authority may order a recall where

- (a) the marketing authorisation holder fails to initiate voluntary recall;
- (b) the Authority determines a recall is necessary to protect public health; or
- (c) investigation reveals safety concerns.

(3) Recall procedures shall follow the Authority's published guidelines and shall include

- (a) classification of recall level based on risk;
- (b) notification to the Authority within twenty-four hours of initiating recall;
- (c) public notification where appropriate;
- (d) strategy for recovering affected products;
- (e) effectiveness checks; and
- (f) final reconciliation report.

(4) Failure to comply with recall requirements constitutes an offence.

#### **Disposal of unfit products**

77. (1) In accordance with section 76 of the Act, no person shall sell, supply or offer unfit products.

(2) Unfit products shall be disposed of

- (a) in accordance with Authority guidelines;

- (b) using methods that prevent diversion;
  - (c) using methods that protect the environment and the public; and
  - (d) with documentation of disposal.
- (3) Where a person is unlikely to dispose of unfit products appropriately, the Authority may dispose of the products at the persons cost.
- (4) Disposal shall be documented and certificates retained for inspection.

### ***PART IX ADVERTISING AND PROMOTION***

#### **Requirement for advertising approval**

78. (1) In accordance with section 83 of the Act, no person shall advertise or promote any regulated product without prior approval from the Authority.

(2) An application for advertising approval shall be made in Form GEN-17 set out in Schedule 1 and shall include

- (a) the proposed advertising materials;
- (b) the target audience;
- (c) the media to be used;
- (d) the duration of the campaign;
- (e) references supporting claims made; and
- (f) the prescribed fee.

(3) The Authority shall respond to advertising applications within

- (a) fourteen working days for straightforward applications; and
- (b) twenty-eight working days where additional review is required.

(4) Approval may be granted, granted with modifications, refused with reasons, or deferred pending additional information.

(5) Approved advertisements shall display the approval reference number.

#### **Advertising standards**

79. (1) All advertising of regulated products shall

- (a) be accurate, truthful and not misleading;
- (b) be balanced, presenting both benefits and risks;

- (c) be consistent with the approved product information;
  - (d) not contain claims not supported by evidence;
  - (e) not compare products unfairly;
  - (f) not include offensive content;
  - (g) be appropriate for the target audience; and
  - (h) comply with the Authority's guidelines on advertising.
- (2) Prescription-only medicines and high-risk medical devices shall only be advertised to healthcare professionals.
- (3) Advertising to the general public is permitted only for
- (a) over-the-counter medicines and general sale medicines;
  - (b) low-risk medical devices;
  - (c) general-use cosmetics; and
  - (d) disease awareness campaigns that do not promote specific products.
- (4) All advertising materials shall be retained by the marketing authorisation holder for at least three years after last use.

#### **Prohibited advertising practices**

80. (1) The following advertising practices are prohibited
- (a) advertising of unregistered products;
  - (b) advertising of prescription medicines to the public;
  - (c) use of testimonials for prescription medicines;
  - (d) claims of cure for serious conditions without evidence;
  - (e) claims that a product has no side effects;
  - (f) comparison with competitors products without substantiation;
  - (g) promotional activities disguised as scientific or educational;
  - (h) inducements to healthcare professionals that may improperly influence prescribing;
  - (i) advertising to children for products not indicated for children; and
  - (j) any advertising contrary to the guidelines.
- (2) Contravention of this regulation is an offence punishable by a fine not exceeding P1 000 000 or imprisonment for three years, or both.

### **Online sales and advertising**

81. (1) In accordance with section 61 of the Act, no person shall sell regulated products online without Authority authorisation.

(2) Online sales authorisation requires

- (a) a valid retail or wholesale licence;
- (b) a dedicated online sales permit;
- (c) systems to verify prescriptions for prescription products;
- (d) systems to verify customer identity and age;
- (e) secure payment and data protection systems;
- (f) appropriate storage and distribution arrangements;
- (g) a mechanism for receiving and handling complaints; and
- (h) compliance with advertising requirements.

(3) Online sellers shall

- (a) display their licence number prominently;
- (b) display Authority contact information;
- (c) provide accurate product information;
- (d) verify prescriptions before supplying prescription medicines;
- (e) not sell prohibited or restricted products; and
- (f) maintain records of all transactions.

(4) The Authority may take down or block websites operating in contravention of these Regulations.

## ***PART X INSPECTION AND ENFORCEMENT***

### **Appointment of inspectors**

82. (1) In accordance with section 77 of the Act, the Chief Executive Officer shall appoint qualified inspectors.

(2) Inspectors shall

- (a) hold appropriate qualifications as specified in the guidelines;
- (b) receive training in inspection procedures;
- (c) be furnished with certificates specifying their scope of authority;

- (d) carry official identification; and
- (e) be bound by a code of conduct.

(3) Inspectors shall declare any conflicts of interest and shall not inspect entities with which they have personal or financial connections.

(4) For cannabis-related inspections, the Authority shall coordinate with the cannabis control authority.

#### **Powers of inspectors**

83. (1) In accordance with section 78 of the Act, inspectors may

- (a) enter and inspect any premises where regulated products are manufactured, stored, distributed, sold, dispensed or administered;
- (b) stop and inspect vehicles, vessels or aircraft carrying regulated products;
- (c) examine activities and question persons;
- (d) examine, copy and seize records;
- (e) take samples of products, raw materials and environmental samples, without compensation;
- (f) seize, quarantine or detain products suspected or found to be non-compliant;
- (g) seal or close premises where there is immediate risk to public health;
- (h) investigate alleged offences;
- (i) order disposal of non-compliant products; and
- (j) issue improvement notices and administrative fines.

(2) Powers under this regulation may be exercised

- (a) at any reasonable time;
- (b) without notice where there is reason to believe evidence may be concealed or destroyed; and
- (c) with notice where a routine or scheduled inspection is planned.

(3) Where entry is refused, an inspector may apply to a Magistrate for a warrant.

(4) Persons responsible for premises shall

- (a) not obstruct inspectors;
- (b) provide access to all areas and records;
- (c) provide reasonable assistance; and

(d) answer questions truthfully.

#### **Risk-based inspection**

84. (1) The Authority shall apply a risk-based approach to the planning, scheduling, and execution of inspections of licensed entities under the Act and these Regulations.

(2) In determining inspection priority, scope, and frequency, the Authority shall consider relevant risk factors, including

- (a) the classification and inherent risk of the medical products handled;
- (b) the compliance history and inspection outcomes of the entity;
- (c) the type, complexity, and scale of licensed operations;
- (d) the time elapsed since the last inspection;
- (e) information derived from vigilance systems, adverse event reports, recalls, and complaints;
- (f) inspection findings, alerts, or assessments from other regulatory authorities; and
- (g) intelligence information or other credible data relevant to regulatory risk.

(3) The Authority shall publish, by notice or guideline, indicative inspection frequencies applicable to different categories of licensed entities, which may be adjusted based on risk assessment.

(4) Licensed entities assessed as high risk shall be inspected at least once every twelve months, while entities assessed as lower risk may be inspected at longer intervals, as determined by the Authority through risk assessment.

(5) Nothing in this regulation shall limit the Authority's power to conduct inspections at any time, including unannounced or for-cause inspections, where necessary to protect public or animal health or to ensure regulatory compliance.

#### **Inspection procedures**

85. (1) Inspections conducted under the Act and these Regulations shall be planned and executed in accordance with documented inspection procedures approved by the Authority.

(2) Inspections may be conducted as announced or unannounced inspections, depending on the purpose, risk profile, and regulatory context.

(3) For routine announced inspections, the Authority shall

- (a) notify the licensed entity prior to the inspection as defined in the guidelines;

- (b) where applicable, provide an inspection agenda and an indicative list of areas to be covered;
  - (c) conduct the inspection in a systematic and risk-based manner;
  - (d) conduct a closing meeting to discuss preliminary findings; and
  - (e) issue a written inspection report within the number of days specified in the guidelines.
- (4) The Authority may conduct unannounced inspections where
- (a) there is reason to believe that serious or systemic non-compliance may exist;
  - (b) advance notice may result in concealment, alteration, or destruction of evidence;
  - (c) there is an immediate or potential risk to public or animal health; or
  - (d) the inspection is conducted to verify the implementation of corrective and preventive actions.
- (5) Inspection reports shall document observations and classify them as
- (a) critical observations, presenting an immediate or significant risk to public or animal health and requiring immediate regulatory action;
  - (b) major observations, constituting significant non-compliance requiring corrective action within a specified timeframe; and
  - (c) minor observations, representing deviations that should be corrected but pose limited regulatory risk.
- (6) A licensed entity shall submit corrective and preventive action plans in response to inspection observations within the timeframes specified by the Authority, and shall implement such actions as approved.
- (7) The outcome of an inspection shall inform the Authority's compliance assessment and risk profiling of the licensed entity, and may influence inspection frequency, licence conditions, or other regulatory actions.

#### **Termination of inspection**

86. (1) The Authority may abort, suspend, or terminate an inspection, in whole or in part, where circumstances arise that prevent the inspection from being conducted effectively, safely, or lawfully.

(2) An inspection may be aborted where

- (a) the licensee or any person acting on its behalf obstructs, interferes with, or fails to cooperate with the inspection;
- (b) access to premises, records, systems, or personnel required for the inspection is denied or unreasonably restricted;
- (c) conditions at the premises pose a risk to the safety or security of inspectors;
- (d) evidence relevant to the inspection is suspected to have been concealed, altered, or destroyed;
- (e) essential personnel are unavailable without reasonable justification; or
- (f) any other circumstance arises that materially compromises the integrity or objectives of the inspection.

(3) Where an inspection is aborted, the Authority shall

- (a) record the reasons for the abortion in writing;
- (b) notify the licensee of the abortion and the grounds thereof; and
- (c) determine the appropriate regulatory action, which may include rescheduling the inspection, conducting an unannounced inspection, imposing licence conditions, or initiating enforcement action.

(4) Where an inspection is aborted due to the conduct or omission of the licensee, the Authority may require the licensee to bear the costs of any subsequent inspection and treat the abortion as an adverse inspection outcome for the purposes of compliance and risk profiling.

### **Sampling and testing**

87. (1) Inspectors may, for the purposes of verifying quality, safety, efficacy, or regulatory compliance, take samples of regulated products during inspections or other regulatory activities conducted under the Act and these Regulations.

(2) Sampling shall be conducted in accordance with documented guidelines or procedures approved by the Authority, including procedures relating to sample size, handling, sealing, storage, and chain of custody.

(3) Where a sample is taken, the inspector shall issue a certificate of sampling to the person from whom the sample was taken.

(4) The certificate of sampling shall be in Form GEN-18 set out in Schedule 1, and shall contain such particulars as may be prescribed.

(5) The Authority may require the owner, manufacturer, importer, distributor, or licensee to provide samples free of charge for the purposes of testing, analysis, or investigation.

## ***PART XI INTERNATIONAL COOPERATION***

### **International cooperation agreements**

88. (1) In accordance with section 108 of the Act, the Authority may

- (a) enter into cooperation agreements with other regulatory authorities;
- (b) participate in regional and international harmonisation initiatives;
- (c) participate in joint assessment programmes;
- (d) participate in collaborative inspection programmes; and
- (e) participate in information sharing arrangements.

(2) Cooperation agreements may cover

- (a) information sharing;
- (b) joint assessments;
- (c) mutual recognition of inspections;
- (d) work sharing;
- (e) capacity building; and
- (f) emergency response coordination.

(3) The Authority shall maintain a register of cooperation agreements on its website.

### **Recognition and reliance**

89. (1) In accordance with section 109 of the Act, the Authority may

- (a) rely on assessments, inspections or decisions of recognised regulatory authorities;
- (b) accept reports from approved inspection programmes;
- (c) recognise certifications from approved certification bodies; and
- (d) enter into mutual recognition agreements.

(2) The Authority retains sovereign decision-making authority and may

- (a) conduct additional review where appropriate;
- (b) impose additional conditions relevant to Botswana;

- (c) reject assessments where there are concerns; and
- (d) withdraw recognition of authorities where standards decline.

(3) The Authority shall publish and maintain a list of recognised authorities and assessment programmes.

### **Regulatory harmonisation**

90. (1) In accordance with section 111 of the Act, the Authority shall participate in regulatory harmonisation initiatives including

- (a) the Southern African Development Community Medicines Regulatory Harmonisation Programme;
- (b) the African Medicines Regulatory Harmonisation Initiative;
- (c) the World Health Organization Prequalification Programme;
- (d) the International Medical Device Regulators Forum; and
- (e) other relevant international initiatives.

(2) The Authority shall

- (a) align technical requirements with regional and international standards where appropriate;
- (b) adopt common technical documents and guidelines;
- (c) participate in joint assessments;
- (d) recognise harmonised assessment outcomes; and
- (e) contribute to the development of harmonised standards.

### **Information sharing**

91. (1) The Authority may share information with other regulatory authorities subject to

- (a) confidentiality agreements;
- (b) data protection requirements;
- (c) commercial confidentiality considerations; and
- (d) public interest considerations.

(2) Information that may be shared includes

- (a) inspection findings;
- (b) vigilance data;

- (c) quality defects;
- (d) regulatory actions taken;
- (e) compliance history; and
- (f) product assessments where authorised.

(3) The Authority shall participate in international rapid alert systems for

- (a) substandard and falsified products;
- (b) serious safety signals;
- (c) quality defects; and
- (d) enforcement actions.

## ***PART XII ELECTRONIC SYSTEMS***

### **Electronic submissions**

92. (1) In accordance with section 122 of the Act, the Authority shall accept electronic submissions for any application, notification, or report.

(2) Electronic submissions shall

- (a) have the same legal validity as paper submissions;
- (b) be made through channels specified by the Authority;
- (c) use formats specified in the guidelines; and
- (d) include appropriate authentication.

(3) The Authority shall publish guidance on electronic submission formats, technical requirements, authentication requirements, and procedures for electronic signatures.

(4) Where electronic systems are unavailable, paper submissions shall be accepted.

### **Integrated electronic platform**

93. (1) The Authority may establish a comprehensive electronic regulatory system providing

- (a) online submission portals for all product categories;
- (b) online licensing and permit applications;
- (c) automated workflow management;
- (d) real-time tracking of application status;
- (e) electronic payment processing;

- (f) document management;
- (g) adverse event reporting; and
- (h) public access to registers and information.

(2) Where implemented, the electronic system shall include connectivity to

- (a) World Health Organization Prequalification databases;
- (b) International Council for Harmonisation electronic Common Technical Document submission gateways;
- (c) WHO VigiBase for pharmacovigilance;
- (d) regional harmonisation portals; and
- (e) other international regulatory information systems.

(3) Manual processes shall remain valid where electronic systems are not implemented or are unavailable.

#### **Data protection and security**

94. (1) The Authority shall ensure

- (a) data security and confidentiality;
- (b) system reliability and availability;
- (c) regular backup and disaster recovery;
- (d) user access controls;
- (e) audit trails; and
- (f) compliance with data protection requirements.

(2) Personal data shall be processed in accordance with applicable data protection laws.

(3) Commercial confidential information shall be protected from unauthorised disclosure.

### ***PART XIII OFFENCES AND PENALTIES***

#### **General offences**

95. (1) A person commits an offence under these Regulations who

- (a) manufactures, imports, exports, distributes, sells, stores, possess or supplies a regulated product without the required registration or licence;
- (b) provides false or misleading information to the Authority;

- (c) obstructs an inspector in the performance of duties;
- (d) fails to comply with a lawful direction of the Authority;
- (e) fails to report adverse events as required;
- (f) fails to implement a recall when required;
- (g) advertises without approval or in contravention of approval;
- (h) fails to maintain required records;
- (i) fails to comply with conditions of registration or licence;
- (j) imports or exports through an unauthorised port;
- (k) sells expired, substandard or falsified products; or
- (l) contravenes any provision of these Regulations for which no specific penalty is provided.

(2) A person who commits an offence under subregulation (1) is liable to the penalties provided under section 119 of the Act.

#### **Specific offences and penalties**

96. (1) The following specific offences and penalties apply

- (a) manufacturing without licence: a fine not exceeding P5 000 000 or imprisonment for seven years, or both;
- (b) import or export of substandard or falsified products: a fine not exceeding P10 000 000 or imprisonment for ten years, or both;
- (c) selling expired products: a fine not exceeding P5 000 000 or imprisonment for seven years, or both;
- (d) advertising without approval: a fine not exceeding P1 000 000 or imprisonment for three years, or both;
- (e) obstruction of inspector: a fine not exceeding P500 000 or imprisonment for two years, or both;
- (f) failure to report serious adverse event: a fine not exceeding P1 000 000 or imprisonment for three years, or both;
- (g) operating without licence: a fine not exceeding P5 000 000 or imprisonment for seven years, or both;
- (h) transit permit violation: a fine not exceeding P1 000 000 or imprisonment for three years, or both;

- (i) controlled substances violation: a fine not exceeding P5 000 000 or imprisonment for seven years, or both; and
- (j) false or misleading information: a fine not exceeding P5 000 000 or imprisonment for seven years, or both.

(2) The court may impose both a fine and imprisonment.

(3) The court may order

- (a) forfeiture of products;
- (b) closure of premises;
- (c) disqualification from holding a licence; and
- (d) payment of costs of investigation and prosecution.

#### **Corporate liability**

97. (1) Where an offence is committed by a body corporate, every director, manager, secretary, or other officer who knowingly participated in the commission of the offence shall also be liable.

(2) It shall be a defence for a person charged under subregulation (1) to prove that

- (a) the offence was committed without his or her knowledge or consent; and
- (b) he or she exercised all due diligence to prevent the commission of the offence.

#### **Compounding of offences**

98. (1) In accordance with section 121 of the Act, where a person admits to an offence in writing, the Chief Executive Officer may compound the offence before court proceedings are instituted.

(2) The compound amount shall not exceed fifty per cent of the maximum fine for the offence.

(3) Compoundable offences are listed in Schedule 5.

(4) An application to compound an offence shall be made in Form GEN-19 set out in Schedule 1.

(5) Payment of a compound amount shall

- (a) be made within thirty days;
- (b) constitute a complete defence to any charge for the offence;
- (c) not constitute an admission of guilt for any other purpose; and

(d) be recorded by the Authority.

(6) Failure to pay within thirty days shall result in court proceedings.

**Recovery of expenses**

99. (1) In accordance with section 120 of the Act, the court may order a person convicted of an offence to pay to the Authority

- (a) costs of sampling and testing;
- (b) costs of investigation;
- (c) costs of seizure and storage; and
- (d) costs of disposal.

(2) Amounts ordered shall be recovered as a civil debt if not paid.

***PART XIV APPEALS***

**Right of appeal**

100. (1) In accordance with section 112 of the Act, a person aggrieved by a decision of the Authority may appeal to the Appeals Committee.

(2) An appeal shall be lodged within thirty days of notification of the decision by filing Form GEN-20 set out in Schedule 1.

(3) An appeal shall

- (a) be in writing;
- (b) state the decision appealed against;
- (c) state the grounds of appeal;
- (d) include supporting evidence; and
- (e) be accompanied by the prescribed fee.

(4) The lodging of an appeal shall not suspend the decision appealed against unless the Appeals Committee or Authority so orders.

**Appeals Committee procedures**

101. (1) In accordance with sections 113 to 115 of the Act, the Appeals Committee shall

- (a) be constituted as provided in section 113;
- (b) hear appeals on dates and at places determined by the Chairperson;

- (c) give both parties opportunity to present their case;
- (d) have power to summon witnesses and require production of documents;
- (e) make decisions by majority vote; and
- (f) issue written decisions within fourteen days of the hearing.

(2) The Appeals Committee may

- (a) confirm the Authority's decision;
- (b) set aside the Authority's decision;
- (c) vary the Authority's decision; or
- (d) remit the matter to the Authority for reconsideration.

(3) A person aggrieved by the decision of the Appeals Committee may appeal to the High Court on a point of law within thirty days.

## ***PART XV MISCELLANEOUS PROVISIONS***

### **Guidelines and directives**

102. (1) In accordance with section 6 of the Act, the Authority may issue guidelines and directives for implementation of these Regulations.

(2) Guidelines shall be

- (a) developed with stakeholder consultation;
- (b) based on international best practices;
- (c) published on the Authority's website;
- (d) regularly reviewed and updated; and
- (e) made available in accessible formats.

(3) Guidelines shall not create obligations beyond those established by the Act and these Regulations but shall provide interpretive guidance.

### **Forms**

103. (1) The forms set out in Schedule 1 shall be used for the purposes indicated.

(2) The Authority may

- (a) approve alternative forms;
- (b) accept electronic equivalents;

- (c) modify forms from time to time; and
- (d) waive form requirements where appropriate.

**Service of documents**

104. (1) Any document required to be served under these Regulations may be served by

- (a) personal delivery;
- (b) registered post;
- (c) email to an address provided by the person;
- (d) courier service with tracking; or
- (e) such other method as may be approved.

(2) Service shall be deemed complete

- (a) for personal delivery, at the time of delivery;
- (b) for registered post, seven days after posting;
- (c) for email, when confirmation of delivery is received; and
- (d) for courier, when delivery is confirmed.

**Transitional provisions**

105. (1) The transitional periods in Schedule 6 shall apply.

(2) Applications submitted before commencement shall be processed under the regulations in force at the time of submission.

(3) Registrations and licences valid at commencement shall remain valid for their unexpired term.

(4) The Authority may publish additional transitional arrangements as necessary.

**Savings**

106. (1) All actions taken, decisions made, licences issued, and registrations granted under the repealed regulations shall continue in force as if made under these Regulations.

(2) All pending investigations, proceedings, and appeals shall continue under the regulations in force when they were commenced.

(3) Any reference in any law or document to the repealed regulations shall be read as a reference to the corresponding provisions of these Regulations.

**Repeal**

107. The Medicines and Related Substances Regulations, 2019, are hereby repealed.

***SCHEDULES***

**SCHEDULE 1 FORMS**

[Detailed forms to be prescribed by the Authority]

**SCHEDULE 2 RISK CLASSIFICATION FRAMEWORK**

[Risk classification framework as set out in the guidelines]

**SCHEDULE 3 PROHIBITED SUBSTANCES**

[To be prescribed based on international conventions, World Health Organization recommendations, and national public health considerations]

**SCHEDULE 4 DESIGNATED PORTS OF ENTRY**

1. Kazungula Border Post
2. Mamuno Border Post
3. Pioneer Border Post
4. Ramokgwebana Border Post
5. Sir Seretse Khama International Airport
6. Tlokweng Border Post

**SCHEDULE 5 COMPOUNDABLE OFFENCES**

[Compoundable offences and maximum compound amounts as prescribed]

**SCHEDULE 6 TRANSITIONAL PERIODS**

[Transitional periods for existing registrations, licences, pending applications, good manufacturing practice compliance, electronic submission capability, and local representative appointment as prescribed]

Made this \_\_\_\_ day of \_\_\_\_\_, 2025

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**MINISTER OF HEALTH**

DRAFT

## SCHEDULE 1

### FORMS

(Regulation 103)

The following forms are prescribed for the purposes of these Regulations. The Authority may approve alternative forms, accept electronic equivalents, and modify forms from time to time.

#### BOTSWANA MEDICINES REGULATORY AUTHORITY

#### FORM GEN-01

#### DECLARATION OF INTEREST AND COMMITMENT

Medicines and Related Substances (General) Regulations, 2025 — reg. 5

#### INSTRUCTIONS

This form must be completed by every Board member and committee member within thirty (30) days of appointment.

Declarations must be updated annually and within fourteen (14) days of any material change.

Submit the completed form to the Secretary of the Board.

#### PART A: PERSONAL PARTICULARS

|                            |  |
|----------------------------|--|
| Full Name                  |  |
| National ID / Passport No. |  |
| Position / Title           |  |
| Board / Committee Name     |  |
| Date of Appointment        |  |
| Contact Telephone          |  |
| Email Address              |  |

#### PART B: DECLARATION OF INTERESTS

B1. Do you, or any immediate family member, hold any financial, professional, or personal interest that may conflict with your duties on this Board / Committee?

Yes  No

If yes, provide full details below:

| No. | Nature of Interest | Entity / Organisation | Relationship | Period |
|-----|--------------------|-----------------------|--------------|--------|
| 1.  |                    |                       |              |        |
| 2.  |                    |                       |              |        |
| 3.  |                    |                       |              |        |
| 4.  |                    |                       |              |        |

B2. Do you hold shares, directorships, consultancies, or advisory roles in any entity that is regulated by, does business with, or seeks to do business with BoMRA?

Yes  No

If yes, provide details:

---

---

### PART C: COMMITMENTS AND UNDERTAKINGS

I, the undersigned, hereby declare and undertake as follows: (a) The information provided in this declaration is true, complete, and correct to the best of my knowledge. (b) I commit to scientific independence and evidence-based decision-making in the discharge of my duties. (c) I acknowledge and accept the confidentiality requirements under section 23 of the Medicines and Related Substances Act, 2025. (d) I commit to good regulatory practices and international cooperation principles. (e) I shall update this declaration annually and within fourteen (14) days of any material change in circumstances. (f) I shall disclose any new interest before participation in any decision where such interest may exist. (g) I understand that non-compliance may result in the voiding of decisions and other regulatory consequences.

Name:

---

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

| FOR OFFICIAL USE ONLY        |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-02**

**APPLICATION FOR REGISTRATION OF A REGULATED PRODUCT**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 10*

**INSTRUCTIONS**

Complete all sections applicable to the product category. Attach all required supporting documentation.

Ensure the prescribed application fee is paid before submission.

Incomplete applications will be returned within thirty (30) working days.

Applications returned for incompleteness may be resubmitted within ninety (90) days without additional fees.

**PART A: APPLICANT DETAILS**

|                               |  |
|-------------------------------|--|
| Company / Entity Name         |  |
| Company Registration No.      |  |
| Physical Address              |  |
| Postal Address                |  |
| Telephone                     |  |
| Email Address                 |  |
| Contact Person (Name & Title) |  |

**PART B: LOCAL TECHNICAL REPRESENTATIVE (IF APPLICANT NOT RESIDENT IN BOTSWANA)**

|                         |  |
|-------------------------|--|
| Name of Representative  |  |
| Company (if applicable) |  |

Medicines and Related Substances (General) Regulations, 2025

|                              |                                                                                       |
|------------------------------|---------------------------------------------------------------------------------------|
| Physical Address in Botswana |                                                                                       |
| Telephone                    |                                                                                       |
| Email Address                |                                                                                       |
| Form GEN-03 Attached?        | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

**PART C: PRODUCT DETAILS**

|                                                        |                                                                                                                                                                                                                                         |
|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Category                                       | <input type="checkbox"/> Medicine <input type="checkbox"/> Medical Device <input type="checkbox"/> Vaccine/Biological <input type="checkbox"/> Cosmetic <input type="checkbox"/><br>Traditional Medicine <input type="checkbox"/> Other |
| Proprietary / Brand Name                               |                                                                                                                                                                                                                                         |
| International Non-Proprietary Name (INN) / Common Name |                                                                                                                                                                                                                                         |
| Active Ingredient(s) & Strength(s)                     |                                                                                                                                                                                                                                         |
| Dosage Form                                            |                                                                                                                                                                                                                                         |
| Route of Administration                                |                                                                                                                                                                                                                                         |
| Pack Size(s)                                           |                                                                                                                                                                                                                                         |
| Shelf Life (months)                                    |                                                                                                                                                                                                                                         |
| Storage Conditions                                     |                                                                                                                                                                                                                                         |
| Therapeutic Classification (ATC Code)                  |                                                                                                                                                                                                                                         |
| Proposed Indication(s) / Intended Use                  |                                                                                                                                                                                                                                         |
| Scheduling / Classification                            |                                                                                                                                                                                                                                         |

**PART D: MANUFACTURING INFORMATION**

|                               |  |
|-------------------------------|--|
| Finished Product Manufacturer |  |
|-------------------------------|--|

|                                         |  |
|-----------------------------------------|--|
| Manufacturing Site Address              |  |
| Country of Manufacture                  |  |
| GMP Certificate No. & Issuing Authority |  |
| GMP Expiry Date                         |  |
| API Manufacturer (if different)         |  |
| API Manufacturing Site Address          |  |

#### PART E: REGISTRATION PATHWAY REQUESTED

Select the applicable pathway (the Authority may reassign based on assessment):

- Full Evaluation Pathway (new chemical entities, novel products, first-in-class)
- Abridged Evaluation Pathway (SRA-approved, WHO-prequalified, SADC harmonised, generic with local reference)
- Verification Pathway (approved by 2+ SRAs, extensive post-market history, WHO EML products)
- Notification Pathway (low-risk Class A medical devices, general sale cosmetics)

#### PART F: REGULATORY STATUS IN OTHER COUNTRIES

| No. | Country | Regulatory Authority | Approval Date | Status | Reg. No. |
|-----|---------|----------------------|---------------|--------|----------|
| 1.  |         |                      |               |        |          |
| 2.  |         |                      |               |        |          |
| 3.  |         |                      |               |        |          |
| 4.  |         |                      |               |        |          |
| 5.  |         |                      |               |        |          |

#### PART G: CHECKLIST OF ATTACHMENTS

- Proof of payment of prescribed application fee
- Technical documentation (Common Technical Document format where applicable)

- Quality data (Module 3 / equivalent)
- Non-clinical data (Module 4 / equivalent, where applicable)
- Clinical data (Module 5 / equivalent, where applicable)
- Product samples (as required)
- GMP Certificate for manufacturing site
- Certificate of Pharmaceutical Product (CPP) or equivalent
- Labelling and packaging artwork
- Summary of Product Characteristics / Product Information
- Patient Information Leaflet
- Appointment of Local Technical Representative (Form GEN-03, if applicable)
- Proof of registration in other countries (where applicable)
- Stability data
- Bioequivalence study report (for generics, where applicable)

#### PART H: DECLARATION

I/We, the undersigned, declare that: (a) The information provided in this application and all accompanying documentation is true, complete, and correct. (b) The product meets the quality, safety, and efficacy requirements as applicable. (c) I/We undertake to comply with all conditions of registration and regulatory requirements. (d) I/We shall notify the Authority of any changes affecting the registration as required by the Regulations. (e) I/We acknowledge that providing false or misleading information is an offence under the Act.

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

#### FOR OFFICIAL USE ONLY

Application Reference No.

\_\_\_\_\_

Date Received

\_\_\_\_\_

Assessment Officer

\_\_\_\_\_

*Medicines and Related Substances (General) Regulations, 2025*

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-03**

**APPOINTMENT OF LOCAL TECHNICAL REPRESENTATIVE**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 11*

**INSTRUCTIONS**

This form must be completed by a non-resident applicant appointing a local technical representative in Botswana.  
Both the appointing entity and the representative must sign this form.  
File with the Authority before or with the registration application.

**PART A: APPOINTING ENTITY DETAILS**

|                               |  |
|-------------------------------|--|
| Name of Appointing Entity     |  |
| Country of Incorporation      |  |
| Registration Number           |  |
| Physical Address              |  |
| Telephone                     |  |
| Email Address                 |  |
| Contact Person (Name & Title) |  |

**PART B: LOCAL TECHNICAL REPRESENTATIVE DETAILS**

|                                           |  |
|-------------------------------------------|--|
| Full Name / Company Name                  |  |
| National ID / Passport / Company Reg. No. |  |
| Physical Address in Botswana              |  |

|                                            |  |
|--------------------------------------------|--|
| Postal Address                             |  |
| Telephone                                  |  |
| Email Address                              |  |
| Qualifications / Professional Registration |  |

**PART C: SCOPE OF APPOINTMENT**

The Local Technical Representative is hereby appointed and authorised to:

- Act as the communication point with BoMRA on all regulatory matters
- Ensure compliance with regulatory requirements on behalf of the appointing entity
- Receive and process safety reports and complaints
- Facilitate inspections and information requests
- Maintain required records in Botswana
- Act on behalf of the marketing authorisation holder in regulatory matters

|                               |  |
|-------------------------------|--|
| Product(s) Covered            |  |
| Effective Date of Appointment |  |
| Duration of Appointment       |  |

**PART D: DECLARATION AND SIGNATURES**

We, the undersigned, confirm that the above appointment is made in good faith and that the Local Technical Representative has the authority to act on behalf of the appointing entity in all regulatory matters with the Authority.

**Appointing Entity:**

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Local Technical Representative:**

**Name:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

| FOR OFFICIAL USE ONLY        |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-04**

**APPLICATION FOR RENEWAL OF MARKETING AUTHORISATION**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 15*

**INSTRUCTIONS**

Submit at least six (6) months before expiry of the current marketing authorisation.

Late submissions attract a late submission fee. Applications not made within ninety (90) days after expiry require a new application.

**PART A: CURRENT REGISTRATION DETAILS**

|                                    |  |
|------------------------------------|--|
| Registration Number                |  |
| Product Name (Proprietary)         |  |
| INN / Common Name                  |  |
| Active Ingredient(s) & Strength(s) |  |
| Dosage Form                        |  |
| Marketing Authorisation Holder     |  |
| Date of Current Registration       |  |
| Date of Expiry                     |  |

**PART B: BENEFIT-RISK ASSESSMENT UPDATE**

B1. Have there been any changes to the benefit-risk profile since registration or last renewal?

Yes    No

If yes, provide a summary:

---

**PART C: PHARMACOVIGILANCE SUMMARY**

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Total adverse event reports received    |                                                                                       |
| Serious adverse events reported         |                                                                                       |
| Any new safety signals identified?      | <input type="checkbox"/> Yes <input type="checkbox"/> No                              |
| Any recalls during the period?          | <input type="checkbox"/> Yes <input type="checkbox"/> No                              |
| Periodic Safety Update Report attached? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

**PART D: MANUFACTURING AND COMPLIANCE**

|                                             |                                                          |
|---------------------------------------------|----------------------------------------------------------|
| Current Manufacturer                        |                                                          |
| GMP Certificate Valid?                      | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| GMP Certificate Expiry Date                 |                                                          |
| Any changes to manufacturing site?          | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Any approved variations since registration? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

**PART E: CHECKLIST OF ATTACHMENTS**

- Proof of payment of prescribed renewal fee
- Updated benefit-risk assessment
- Summary of pharmacovigilance data / Periodic Safety Update Report
- Current GMP Certificate

- List of approved variations since registration / last renewal
- Updated labelling (if changed)
- Confirmation of continued compliance with conditions of registration

**PART F: DECLARATION**

I/We, the undersigned, declare that the information provided is true and correct, and that the product continues to meet the requirements for registration. I/We undertake to comply with all conditions of registration.

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

**Signature:**

\_\_\_\_\_

\_\_\_\_\_

**Date:**

---

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-05**

**APPLICATION FOR VARIATION OF MARKETING AUTHORISATION**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 16*

**INSTRUCTIONS**

No change to a registered product shall be implemented without prior approval, except notifiable changes.

Assessment timelines: Major — 90 working days; Minor — 60 working days; Notification — 30 working days.

**PART A: PRODUCT IDENTIFICATION**

|                                |  |
|--------------------------------|--|
| Registration Number            |  |
| Product Name (Proprietary)     |  |
| INN / Common Name              |  |
| Marketing Authorisation Holder |  |

**PART B: VARIATION CLASSIFICATION**

**Type of variation (select one):**

- Major Variation (significant effect on quality, safety, or efficacy)
- Minor Variation (minor effect on quality, safety, or efficacy)
- Notification (minimal or no effect)

**PART C: DESCRIPTION OF PROPOSED CHANGE**

Category of change (tick all that apply):

- Active substance or specification
- Therapeutic indication or target population
- Manufacturing process

- Dosage form or route of administration
- Manufacturing site
- Container closure system
- Batch size
- Specifications or in-process controls
- Testing laboratory
- Excipient supplier
- Administrative details (MAH address, name change)
- Local representative change
- Labelling or package leaflet
- Shelf-life based on stability data
- Other (specify below)

**Detailed description of the proposed variation:**

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**Justification for the change:**

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**PART D: CHECKLIST OF ATTACHMENTS**

- Proof of payment of prescribed variation fee

- Comparative data (before and after the change)
- Supporting study data (stability, bioequivalence, etc.)
- Updated product documentation (as affected)
- Updated labelling / artwork (where applicable)
- Risk assessment of the proposed change

**PART E: DECLARATION**

I/We, the undersigned, declare that the information provided is true and correct. I/We understand that implementing a variation without required approval constitutes an offence under the Regulations.

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

\_\_\_\_\_

**Signature:**

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**Date:**

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DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-06**

**NOTIFICATION FORM**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 17*

**INSTRUCTIONS**

Submit within thirty (30) days of the occurrence of the notifiable event.

Failure to notify as required constitutes an offence under the Regulations.

**PART A: NOTIFIER DETAILS**

|                                           |  |
|-------------------------------------------|--|
| Marketing Authorisation Holder / Licensee |  |
| Registration / Licence Number             |  |
| Product Name(s) Affected                  |  |
| Contact Person (Name & Title)             |  |
| Telephone                                 |  |
| Email Address                             |  |

**PART B: TYPE OF NOTIFICATION**

Select the applicable category:

- Restriction, suspension, or withdrawal of the product in another country
- New safety information affecting benefit-risk balance
- Regulatory action taken by another authority
- Change in GMP status of manufacturing site
- Discontinuation of marketing or manufacture
- Other (specify below)

**PART C: DETAILS OF NOTIFICATION**

|                                              |  |
|----------------------------------------------|--|
| Date of Occurrence / Awareness               |  |
| Country / Authority Involved (if applicable) |  |

**Detailed description of the event or change:**

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**Impact assessment and actions taken or proposed:**

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**PART D: ATTACHMENTS**

- Regulatory authority communication / notice (if applicable)
- Safety assessment report
- Corrective action plan
- Other supporting documentation (specify)

**PART E: DECLARATION**

I/We, the undersigned, declare that the information provided herein is true and correct to the best of my/our knowledge.

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-07**

**APPLICATION FOR LICENCE**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 36*

**INSTRUCTIONS**

This is the general licence application form. Complete all applicable sections.

The Authority shall make a decision within ninety (90) working days of a complete application.

Separate sections cover manufacturing, distribution/wholesale, retail/dispensing, bonded warehouse, and special licences.

**PART A: APPLICANT DETAILS**

|                                     |  |
|-------------------------------------|--|
| Company / Entity Name               |  |
| Company Registration No.            |  |
| Physical Address (Principal Office) |  |
| Postal Address                      |  |
| Telephone                           |  |
| Email Address                       |  |
| Contact Person (Name & Title)       |  |

**PART B: LICENCE CATEGORY APPLIED FOR**

- Manufacturing Licence (medicines, medical devices, biologicals, blood, cosmetics, repackaging)
- Import and Export Licence
- Distribution and Wholesale Licence (medicines, medical devices, cosmetics, combined)
- Retailing and Dispensing Licence (stand-alone pharmacy, hospital pharmacy, veterinary retailer, dispensary, authorised premises, combined)
- Bonded Warehouse Licence
- Special Licence (e-pharmacy, precursor chemicals, mobile pharmacy, other)

|                                       |  |
|---------------------------------------|--|
| Specific Sub-Category (if applicable) |  |
| Scope of Activities                   |  |
| Product Categories                    |  |

### PART C: PREMISES DETAILS

|                              |                                                                                                         |
|------------------------------|---------------------------------------------------------------------------------------------------------|
| Physical Address of Premises |                                                                                                         |
| Plot No. / Stand No.         |                                                                                                         |
| Ownership of Premises        | <input type="checkbox"/> Owned <input type="checkbox"/> Leased <input type="checkbox"/> Other (specify) |
| Total Floor Area (sq. m)     |                                                                                                         |
| Floor plans attached?        | <input type="checkbox"/> Yes <input type="checkbox"/> No                                                |

### PART D: KEY PERSONNEL

| No. | Name | Designation | Qualifications | Reg. No. |
|-----|------|-------------|----------------|----------|
| 1.  |      |             |                |          |
| 2.  |      |             |                |          |
| 3.  |      |             |                |          |
| 4.  |      |             |                |          |
| 5.  |      |             |                |          |

### PART E: QUALITY MANAGEMENT SYSTEM

Applicable good practice standards (tick all that apply):

- Good Manufacturing Practice (GMP)
- Good Storage and Distribution Practice (GSDP)

- Good Distribution Practice for Medical Devices
- Good Pharmacy Practice (GPP)
- Veterinary Pharmacy Practice Standards
- Other (specify)

|                                         |                                                          |
|-----------------------------------------|----------------------------------------------------------|
| Quality Management System documented?   | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Temperature monitoring system in place? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Traceability system in place?           | <input type="checkbox"/> Yes <input type="checkbox"/> No |

#### PART F: CHECKLIST OF ATTACHMENTS

- Proof of payment of prescribed application fee
- Company registration documents
- Premises floor plans and layout drawings
- Proof of premises ownership or lease agreement
- CVs and qualification certificates for key personnel
- Professional registration certificates for key personnel
- Quality management system documentation (site master file or equivalent)
- Equipment list (where applicable)
- Product list (where applicable)
- GMP Certificate (for manufacturing licence applicants)
- Security plan (where applicable)

#### PART G: DECLARATION

I/We, the undersigned, declare that: (a) The information provided in this application is true, complete, and correct. (b) I/We undertake to comply with the Act, Regulations, and all conditions of the licence. (c) I/We shall facilitate access by inspectors at any reasonable time. (d) I/We acknowledge that operating without a valid licence is an offence under the Act.

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

| FOR OFFICIAL USE ONLY        |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

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**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-08**

**APPLICATION FOR RENEWAL OF LICENCE**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 38*

**INSTRUCTIONS**

Submit at least three (3) months before expiry of the current licence.

Late renewal applications attract late payment penalties.

**PART A: CURRENT LICENCE DETAILS**

|                           |  |
|---------------------------|--|
| Licence Number            |  |
| Licence Category          |  |
| Licensee Name             |  |
| Licensed Premises Address |  |
| Date of Current Licence   |  |
| Expiry Date               |  |

**PART B: CHANGES SINCE LAST LICENCE / RENEWAL**

Have there been any changes to the following since the licence was issued or last renewed?

|                           |                                                                                   |
|---------------------------|-----------------------------------------------------------------------------------|
| Premises                  | <input type="checkbox"/> Yes <input type="checkbox"/> No (if yes, attach details) |
| Key Personnel             | <input type="checkbox"/> Yes <input type="checkbox"/> No (if yes, attach details) |
| Scope of Activities       | <input type="checkbox"/> Yes <input type="checkbox"/> No (if yes, attach details) |
| Quality Management System | <input type="checkbox"/> Yes <input type="checkbox"/> No (if yes, attach details) |
| Equipment                 | <input type="checkbox"/> Yes <input type="checkbox"/> No (if yes, attach details) |

|                   |                                                                                   |
|-------------------|-----------------------------------------------------------------------------------|
| Compliance status | <input type="checkbox"/> Yes <input type="checkbox"/> No (if yes, attach details) |
|-------------------|-----------------------------------------------------------------------------------|

### PART C: COMPLIANCE SUMMARY

|                                                      |                                                          |
|------------------------------------------------------|----------------------------------------------------------|
| Any regulatory actions during licence period?        | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Outstanding corrective actions from last inspection? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Any product recalls during the period?               | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Any adverse events reported?                         | <input type="checkbox"/> Yes <input type="checkbox"/> No |

### PART D: CHECKLIST

- Proof of payment of prescribed renewal fee
- Updated key personnel details (if changed)
- Current professional registration certificates for key personnel
- Confirmation of continued compliance with good practice standards
- Summary of changes since last licence/renewal

### PART E: DECLARATION

I/We, the undersigned, declare that the information provided is true and correct, and that the licensed establishment continues to meet the requirements for licensing.

Name:

Signature:

Date:

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**FOR OFFICIAL USE ONLY**

*Medicines and Related Substances (General) Regulations, 2025*

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-09**

**APPLICATION FOR APPROVAL OF CHANGE OF BUSINESS OWNERSHIP**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 39*

**INSTRUCTIONS**

Authority approval must be obtained BEFORE any change of business ownership takes effect.

A change of ownership without approval constitutes an offence and may result in suspension or cancellation of the licence.

**PART A: CURRENT LICENCE DETAILS**

|                               |  |
|-------------------------------|--|
| Licence Number                |  |
| Licence Category              |  |
| Current Licensee / Owner Name |  |
| Licensed Premises Address     |  |

**PART B: PROPOSED NEW OWNERSHIP**

|                                  |  |
|----------------------------------|--|
| Proposed New Owner / Entity Name |  |
| Company Registration No.         |  |
| Physical Address                 |  |
| Telephone                        |  |
| Email Address                    |  |
| Contact Person (Name & Title)    |  |

**Reason for Change of Ownership:**

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**PART C: CONTINUITY ASSURANCE**

|                                           |                                                          |
|-------------------------------------------|----------------------------------------------------------|
| Will operational standards be maintained? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Any changes to key personnel?             | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Any changes to premises?                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Any changes to scope of activities?       | <input type="checkbox"/> Yes <input type="checkbox"/> No |

**PART D: CHECKLIST**

- New owner company registration documents
- Details of proposed changes to key personnel (if any)
- Confirmation of maintenance of operational standards
- Sale/transfer agreement (relevant sections)
- New owner qualifications and experience

**PART E: DECLARATIONS**

**Current Owner:**

I confirm that the information provided regarding the current licence and proposed change is true and correct.

**Name:**

---

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

Proposed New Owner:

I/We undertake to maintain compliance with all applicable laws, regulations, and conditions of the licence.

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-10**

**APPLICATION FOR IMPORT PERMIT**

Medicines and Related Substances (General) Regulations, 2025 — reg. 47

**INSTRUCTIONS**

A valid import licence must be held before applying for consignment-specific import permits.

Processing times: Routine — 5 working days; Expedited — 2 working days (additional fee); Emergency — 1 working day.

Permits are valid for a maximum of ninety (90) days.

**PART A: IMPORTER DETAILS**

|                       |  |
|-----------------------|--|
| Import Licence Number |  |
| Importer Name         |  |
| Physical Address      |  |
| Contact Person        |  |
| Telephone / Email     |  |

**PART B: CONSIGNMENT DETAILS**

| No. | Product Name | Reg. No. | Qty | Batch No. | Expiry | Mfr. | Origin |
|-----|--------------|----------|-----|-----------|--------|------|--------|
| 1.  |              |          |     |           |        |      |        |
| 2.  |              |          |     |           |        |      |        |
| 3.  |              |          |     |           |        |      |        |
| 4.  |              |          |     |           |        |      |        |
| 5.  |              |          |     |           |        |      |        |

**PART C: SHIPPING AND LOGISTICS**

|                          |                                                                                                                                                                                                            |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Supplier Name & Address  |                                                                                                                                                                                                            |
| Intended Port of Entry   | <input type="checkbox"/> Kazungula <input type="checkbox"/> Mamuno <input type="checkbox"/> Pioneer <input type="checkbox"/> Ramokgwebana <input type="checkbox"/> SSKIA <input type="checkbox"/> Tlokweng |
| Expected Date of Arrival |                                                                                                                                                                                                            |
| Mode of Transport        |                                                                                                                                                                                                            |
| Cold Chain Required?     | <input type="checkbox"/> Yes <input type="checkbox"/> No                                                                                                                                                   |
| End-User (if required)   |                                                                                                                                                                                                            |

Processing type requested:

- Routine (5 working days)  Expedited (2 working days)  Emergency (1 working day)

**PART D: DECLARATION**

I/We declare that the products to be imported are registered with BoMRA (or exempted), meet applicable quality standards, and will be stored and distributed in compliance with the Act and Regulations.

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                           |  |
|---------------------------|--|
| Application Reference No. |  |
| Date Received             |  |
| Assessment Officer        |  |

*Medicines and Related Substances (General) Regulations, 2025*

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-11**

**APPLICATION FOR EXPORT PERMIT**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 47*

**INSTRUCTIONS**

A valid export licence must be held before applying for consignment-specific export permits.

An import authorisation from the destination country may be required.

**PART A: EXPORTER DETAILS**

|                       |  |
|-----------------------|--|
| Export Licence Number |  |
| Exporter Name         |  |
| Physical Address      |  |
| Contact Person        |  |
| Telephone / Email     |  |

**PART B: CONSIGNMENT DETAILS**

| No. | Product Name & Description | Reg. No. | Quantity | Batch No. | Expiry Date |
|-----|----------------------------|----------|----------|-----------|-------------|
| 1.  |                            |          |          |           |             |
| 2.  |                            |          |          |           |             |
| 3.  |                            |          |          |           |             |
| 4.  |                            |          |          |           |             |
| 5.  |                            |          |          |           |             |

**PART C: DESTINATION AND LOGISTICS**

|                                                   |                                                                                       |
|---------------------------------------------------|---------------------------------------------------------------------------------------|
| Destination Country                               |                                                                                       |
| Consignee Name & Address                          |                                                                                       |
| Intended Port of Exit                             |                                                                                       |
| Import Authorisation from Destination (attached?) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

**PART D: DECLARATION**

I/We declare that the products to be exported meet applicable quality standards and that the export complies with all applicable laws and regulations.

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |

|         |  |
|---------|--|
| Remarks |  |
|---------|--|

**Name:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-12**

**APPLICATION FOR TRANSIT PERMIT**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 49*

**INSTRUCTIONS**

Transit permits are valid for a maximum of fourteen (14) days.

Violation of transit permit conditions is an offence punishable by a fine up to P1,000,000 or imprisonment for 3 years, or both.

**PART A: APPLICANT DETAILS**

|                                |  |
|--------------------------------|--|
| Company / Entity Name          |  |
| Local Agent / Transporter Name |  |
| Contact Telephone              |  |
| Email Address                  |  |

**PART B: CONSIGNMENT DETAILS**

|                               |  |
|-------------------------------|--|
| Product Name(s) & Description |  |
| Quantities                    |  |
| Country of Origin             |  |
| Final Destination Country     |  |
| Entry Port in Botswana        |  |
| Exit Port in Botswana         |  |
| Expected Transit Period       |  |

**PART C: AUTHORISATIONS**

|                                                    |                                                          |
|----------------------------------------------------|----------------------------------------------------------|
| BURS Transit Authority Attached?                   | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Destination Country Import Authorisation Attached? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

**PART D: DECLARATION AND UNDERTAKING**

I/We undertake that the products shall remain under customs control, shall not be released into the domestic market, shall not be processed, repackaged, or altered during transit, and that the Authority shall be notified within 48 hours of departure from Botswana.

Name:

Signature:

Date:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

---

**Signature:**

---

**Date:**

---

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-13**

**APPLICATION FOR AUTHORISATION OF DONATED MEDICAL PRODUCTS**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 50*

**INSTRUCTIONS**

Donated products must meet the same quality standards as commercially imported products.  
Products must be labelled in English and have adequate remaining shelf-life.  
Fees may be waived or reduced for humanitarian donations.

**PART A: DONOR DETAILS**

|                         |  |
|-------------------------|--|
| Donor Organisation Name |  |
| Country                 |  |
| Contact Person          |  |
| Telephone / Email       |  |

**PART B: RECIPIENT DETAILS**

|                              |  |
|------------------------------|--|
| Recipient Organisation Name  |  |
| Physical Address in Botswana |  |
| Contact Person               |  |
| Telephone / Email            |  |

**PART C: PRODUCT DETAILS**

| No. | Product Name | Strength | Qty | Batch | Expiry | Manufacturer |
|-----|--------------|----------|-----|-------|--------|--------------|
|-----|--------------|----------|-----|-------|--------|--------------|

|    |  |  |  |  |  |  |
|----|--|--|--|--|--|--|
| 1. |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |
| 4. |  |  |  |  |  |  |
| 5. |  |  |  |  |  |  |

**PART D: COMPLIANCE**

Confirm that the donated products:

- Meet the same quality standards as commercially imported products
- Have adequate remaining shelf-life as per BoMRA guidelines
- Are labelled in English
- Are on the national essential medicines list or appropriate for the Botswana context
- Are NOT near-expiry products inappropriate for the intended healthcare setting
- Comply with WHO Guidelines for Medicine Donations

Intended Use and Distribution Plan

Fee Waiver Requested?

Yes  No

**PART E: DECLARATION**

I/We declare that the information provided is true and correct and that the donated products meet all applicable quality requirements.

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

| FOR OFFICIAL USE ONLY        |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

Name:

Signature:

Date:

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-14**

**APPLICATION FOR CONTROLLED SUBSTANCES IMPORT/EXPORT PERMIT**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 52*

**INSTRUCTIONS**

A separate permit is required for each consignment of narcotic drugs, psychotropic substances, or precursor chemicals.  
Applications must be submitted by the responsible person (pharmacist or veterinary surgeon).  
Permits are valid for six (6) months. Acknowledgement must be submitted within seven (7) days of receipt/dispatch.  
Contravention is an offence punishable by a fine up to P5,000,000 or imprisonment for 7 years, or both.

**PART A: APPLICATION TYPE**

Import Permit     Export Permit

**PART B: APPLICANT DETAILS**

|                               |                                                                                 |
|-------------------------------|---------------------------------------------------------------------------------|
| Responsible Person (Name)     |                                                                                 |
| Professional Qualification    | <input type="checkbox"/> Pharmacist <input type="checkbox"/> Veterinary Surgeon |
| Professional Registration No. |                                                                                 |
| Licensed Establishment Name   |                                                                                 |
| Licence Number                |                                                                                 |
| Physical Address              |                                                                                 |
| Telephone / Email             |                                                                                 |

**PART C: SUBSTANCE DETAILS**

Medicines and Related Substances (General) Regulations, 2025

| No. | INN / Name | Schedule | Form | Strength | Quantity | Purpose |
|-----|------------|----------|------|----------|----------|---------|
| 1.  |            |          |      |          |          |         |
| 2.  |            |          |      |          |          |         |
| 3.  |            |          |      |          |          |         |
| 4.  |            |          |      |          |          |         |

**PART D: SUPPLIER / CONSIGNEE AND LOGISTICS**

|                                                          |                                                                                       |
|----------------------------------------------------------|---------------------------------------------------------------------------------------|
| Supplier / Consignee Name & Address                      |                                                                                       |
| Country                                                  |                                                                                       |
| INCB Certificate Attached? (if required)                 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| Export/Import Authorisation from Other Country Attached? | <input type="checkbox"/> Yes <input type="checkbox"/> No                              |
| Intended Port of Entry / Exit                            |                                                                                       |
| Storage and Security Arrangements                        |                                                                                       |

**PART E: DECLARATION**

I, the undersigned responsible person, declare that the information provided is true and correct. I undertake to maintain records, provide acknowledgement within seven (7) days of receipt/dispatch, and reconcile quantities as required by the Regulations.

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

| FOR OFFICIAL USE ONLY        |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

Name:

Signature:

Date:

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-15**

**APPLICATION FOR LABORATORY SERVICES**

Medicines and Related Substances (General) Regulations, 2025 — reg. 69

**PART A: APPLICANT DETAILS**

|                                            |  |
|--------------------------------------------|--|
| Applicant Name / Organisation              |  |
| Physical Address                           |  |
| Contact Person                             |  |
| Telephone / Email                          |  |
| Licence / Registration No. (if applicable) |  |

**PART B: SAMPLE DETAILS**

| No. | Product Name | Batch No. | Qty | Mfr. | Expiry | Tests Requested |
|-----|--------------|-----------|-----|------|--------|-----------------|
| 1.  |              |           |     |      |        |                 |
| 2.  |              |           |     |      |        |                 |
| 3.  |              |           |     |      |        |                 |

|                                  |                                                                                                                                                                                                     |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Specifications Provided? | <input type="checkbox"/> Yes <input type="checkbox"/> No                                                                                                                                            |
| Special Handling Instructions    |                                                                                                                                                                                                     |
| Purpose of Testing               | <input type="checkbox"/> Registration <input type="checkbox"/> Market Surveillance <input type="checkbox"/> Quality Complaint <input type="checkbox"/> Batch Release <input type="checkbox"/> Other |

**PART C: DECLARATION**

I/We declare that the samples submitted are representative and have been handled and stored appropriately. I/We accept the prescribed fees and testing timelines.

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

**Signature:**

**Date:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-16**

**ADVERSE EVENT / SAFETY REPORT FORM**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 73*

**INSTRUCTIONS**

Reporting timelines: Fatal/life-threatening — 24 hours; Serious — 7 days; Non-serious — 30 days.

This form may be submitted electronically through the Authority's vigilance system.

**PART A: REPORTER INFORMATION**

|                                |  |
|--------------------------------|--|
| Reporter Name                  |  |
| Designation / Profession       |  |
| Health Facility / Organisation |  |
| Telephone / Email              |  |
| Date of Report                 |  |

**PART B: PATIENT INFORMATION**

|                          |                                                                                              |
|--------------------------|----------------------------------------------------------------------------------------------|
| Patient Initials         |                                                                                              |
| Age / Date of Birth      |                                                                                              |
| Gender                   | <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other |
| Weight (kg)              |                                                                                              |
| Relevant Medical History |                                                                                              |

**PART C: SUSPECTED PRODUCT(S)**

| No. | Product Name | Dose | Route | Start Date | Stop Date | Indication |
|-----|--------------|------|-------|------------|-----------|------------|
| 1.  |              |      |       |            |           |            |
| 2.  |              |      |       |            |           |            |
| 3.  |              |      |       |            |           |            |

**PART D: ADVERSE EVENT DETAILS**

Date of Onset

Date of Resolution (if applicable)

Seriousness (tick all that apply):

- Death (date: .....)
- Life-threatening
- Hospitalisation (or prolonged)
- Significant disability or incapacity
- Congenital anomaly
- Other medically important event
- Non-serious

**Description of adverse event:**

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Outcome:

Recovered  Recovering  Not recovered  Fatal  Unknown

Causality assessment (reporter's opinion):

Certain  Probable  Possible  Unlikely  Unassessable

**PART E: CONCOMITANT MEDICATIONS**

List all other medicines taken concurrently:

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**PART F: ADDITIONAL INFORMATION**

Any additional relevant information, laboratory results, or investigations:

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Name:

---

Signature:

---

Date:

\_\_\_\_\_

| FOR OFFICIAL USE ONLY        |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-17**

**APPLICATION FOR ADVERTISING APPROVAL**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 78*

**INSTRUCTIONS**

Processing times: Straightforward — 14 working days; Complex — 28 working days.

Approved advertisements must display the approval reference number.

Advertising without approval is an offence punishable by a fine up to P1,000,000 or imprisonment for 3 years, or both.

**PART A: APPLICANT DETAILS**

|                                            |  |
|--------------------------------------------|--|
| Marketing Authorisation Holder / Applicant |  |
| Registration / Licence Number              |  |
| Contact Person                             |  |
| Telephone / Email                          |  |

**PART B: PRODUCT DETAILS**

|                             |  |
|-----------------------------|--|
| Product Name                |  |
| Registration Number         |  |
| Product Category            |  |
| Scheduling / Classification |  |

**PART C: ADVERTISEMENT DETAILS**

|                                 |                                                                                                                                                                                                                                 |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Target Audience                 | <input type="checkbox"/> Healthcare Professionals Only <input type="checkbox"/> General Public <input type="checkbox"/> Both                                                                                                    |
| Media Channel(s)                | <input type="checkbox"/> Print <input type="checkbox"/> TV <input type="checkbox"/> Radio <input type="checkbox"/> Online <input type="checkbox"/> Social Media <input type="checkbox"/> Outdoor <input type="checkbox"/> Other |
| Campaign Duration (Start - End) |                                                                                                                                                                                                                                 |

**Key claims made in the advertisement:**

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**References supporting claims:**

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**PART D: CHECKLIST**

- Prescribed application fee paid
- Proposed advertising materials (all formats) attached
- References supporting all claims attached
- Advertisement is accurate, truthful, and not misleading
- Advertisement is balanced, presenting benefits and risks
- Advertisement is consistent with approved product information
- No prohibited advertising practices (per reg. 80)

**PART E: DECLARATION**

I/We declare that the proposed advertisement complies with the advertising standards set out in the Regulations and that all claims are supported by evidence.

**Name:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-18**

**CERTIFICATE OF SAMPLING**

Medicines and Related Substances (General) Regulations, 2025 — reg. 87

**PART A: INSPECTOR DETAILS**

|                                |  |
|--------------------------------|--|
| Inspector Name                 |  |
| Inspector ID / Certificate No. |  |
| Date of Sampling               |  |
| Time of Sampling               |  |

**PART B: PREMISES FROM WHICH SAMPLE TAKEN**

|                                   |  |
|-----------------------------------|--|
| Name of Establishment             |  |
| Licence Number                    |  |
| Physical Address                  |  |
| Person from Whom Sample Was Taken |  |
| Designation                       |  |

**PART C: SAMPLE DETAILS**

| No. | Product Name | Batch No. | Qty | Mfr. | Expiry | Storage Conditions |
|-----|--------------|-----------|-----|------|--------|--------------------|
| 1.  |              |           |     |      |        |                    |

Medicines and Related Substances (General) Regulations, 2025

|    |  |  |  |  |  |  |
|----|--|--|--|--|--|--|
| 2. |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |

|                              |                                                                                                                                                                                 |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reason for Sampling          | <input type="checkbox"/> Routine <input type="checkbox"/> Complaint <input type="checkbox"/> Surveillance <input type="checkbox"/> Investigation <input type="checkbox"/> Other |
| Sampling Method Used         |                                                                                                                                                                                 |
| Chain of Custody Maintained? | <input type="checkbox"/> Yes <input type="checkbox"/> No                                                                                                                        |

**PART D: ACKNOWLEDGEMENT**

I acknowledge that the above samples have been taken from my premises in my presence.

**Person from Whom Sample Was Taken:**

Name:

Signature:

Date:

**Sampling Inspector:**

Name:

Signature:

Date:

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-19**

**APPLICATION TO COMPOUND AN OFFENCE**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 98*

**INSTRUCTIONS**

Compounding must occur before court proceedings are instituted.

The compound amount shall not exceed 50% of the maximum fine for the offence.

Payment must be made within thirty (30) days. Failure to pay results in court proceedings.

**PART A: OFFENDER DETAILS**

|                                            |  |
|--------------------------------------------|--|
| Full Name / Company Name                   |  |
| National ID / Company Reg. No.             |  |
| Physical Address                           |  |
| Telephone / Email                          |  |
| Licence / Registration No. (if applicable) |  |

**PART B: OFFENCE DETAILS**

|                                  |  |
|----------------------------------|--|
| Date of Offence                  |  |
| Regulation / Section Contravened |  |
| Schedule 5 Reference             |  |
| Maximum Fine for Offence         |  |

**Description of Offence:**

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**PART C: ADMISSION AND APPLICATION**

I, the undersigned, hereby admit to the commission of the offence described above and apply for the offence to be compounded in accordance with section 121 of the Act and regulation 98 of the Regulations. I understand that: (a) Payment of the compound amount constitutes a complete defence to any charge for the offence. (b) Payment does not constitute an admission of guilt for any other purpose. (c) Failure to pay within thirty (30) days shall result in court proceedings.

**Name:**

---

**Signature:**

---

**Date:**

---

**FOR OFFICIAL USE ONLY**

|                              |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |

|         |  |
|---------|--|
| Remarks |  |
|---------|--|

**Name:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

DRAFT

**BOTSWANA MEDICINES REGULATORY AUTHORITY**

**FORM GEN-20**

**NOTICE OF APPEAL**

*Medicines and Related Substances (General) Regulations, 2025 — reg. 100*

**INSTRUCTIONS**

An appeal must be lodged within thirty (30) days of notification of the decision.

Filing an appeal does not automatically suspend the decision appealed against.

A person aggrieved by the Appeals Committee decision may appeal to the High Court on a point of law within thirty (30) days.

**PART A: APPELLANT DETAILS**

|                               |  |
|-------------------------------|--|
| Full Name / Company Name      |  |
| Physical Address              |  |
| Postal Address                |  |
| Telephone / Email             |  |
| Legal Representative (if any) |  |

**PART B: DECISION APPEALED AGAINST**

|                                  |  |
|----------------------------------|--|
| Reference Number of Decision     |  |
| Date of Notification of Decision |  |
| Nature of Decision               |  |
| Decision-Maker                   |  |

**Summary of the Decision:**

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Do you request suspension of the decision pending appeal?

- Yes    No

**If yes, state reasons:**

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**PART E: CHECKLIST**

- Prescribed appeal fee paid
- Copy of the decision being appealed
- Supporting evidence and documents
- Written submissions / legal arguments
- Authority to act (if lodged by representative)

**PART F: DECLARATION**

I/We, the undersigned, declare that the information provided in this appeal is true and correct. I/We understand that this appeal will be heard by the Appeals Committee constituted under section 113 of the Act.

*Medicines and Related Substances (General) Regulations, 2025*

**Name:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

| FOR OFFICIAL USE ONLY        |                                                                                                                                                        |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application Reference No.    |                                                                                                                                                        |
| Date Received                |                                                                                                                                                        |
| Assessment Officer           |                                                                                                                                                        |
| Validation Outcome           | <input type="checkbox"/> Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Returned                                                |
| Decision                     | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Deferred <input type="checkbox"/> Refused |
| Reference/Licence No. Issued |                                                                                                                                                        |
| Validity Period              |                                                                                                                                                        |
| Remarks                      |                                                                                                                                                        |

**Name:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

## SCHEDULE 2

### RISK CLASSIFICATION FRAMEWORK

(Regulation 4(2))

#### 1. Purpose

This Schedule establishes the risk classification framework for the application of risk-based regulatory oversight by the Authority. The framework aligns with WHO Global Benchmarking Tool indicators for Maturity Level 3 and above, and supports proportionate allocation of regulatory resources based on the level of risk to public or animal health.

#### 2. Risk Classification of Regulated Products

##### 2.1 Medicines

| Level | Risk Class | Description                                                                  | Examples                                                 | Reg. Approach                 |
|-------|------------|------------------------------------------------------------------------------|----------------------------------------------------------|-------------------------------|
| 1     | Very High  | Sterile products, biologicals, blood products, novel entities                | Vaccines, monoclonal antibodies, blood derivatives, NCEs | Full evaluation, enhanced PMS |
| 2     | High       | Prescription-only medicines, controlled substances, narrow therapeutic index | Warfarin, opioids, antiepileptics, cytotoxics            | Full or abridged evaluation   |
| 3     | Moderate   | Pharmacy medicines, generics of established products                         | NSAIDs, antibiotics (generics), oral contraceptives      | Abridged or verification      |
| 4     | Low        | OTC medicines, established traditional medicines                             | Paracetamol, antacids, cough preparations                | Verification or notification  |

##### 2.2 Medical Devices

| Level | GHTF Class | Description                                                          | Examples                                               | Reg. Approach                  |
|-------|------------|----------------------------------------------------------------------|--------------------------------------------------------|--------------------------------|
| 1     | Class D    | Life-sustaining/supporting, implantable, direct contact with CNS/CVS | Heart valves, pacemakers, implantable defibrillators   | Full evaluation or abridged    |
| 2     | Class C    | Surgically invasive long-term, active therapeutic devices            | Joint prostheses, haemodialysis equipment, ventilators | Full or abridged               |
| 3     | Class B    | Surgically invasive short-term, active diagnostic devices            | Surgical instruments, ultrasound probes, catheters     | Full, Abridged or verification |
| 4     | Class A    | Non-invasive, no direct patient contact, general purpose             | Wheelchairs, hospital beds, stethoscopes, bandages     | Notification                   |

##### 2.3 Cosmetics

| Level | Risk Class | Description                                                                                                     | Examples                                                                                       |
|-------|------------|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| 1     | High       | Products with systemic absorption potential, products for children under 3, products near eyes/mucous membranes | Hair dyes with oxidative chemicals, skin-lightening agents, sunscreens with active ingredients |
| 2     | Moderate   | Leave-on products, products with active ingredients                                                             | Anti-ageing creams, anti-acne formulations, deodorants with active ingredients                 |

|   |     |                                               |                                                  |
|---|-----|-----------------------------------------------|--------------------------------------------------|
| 3 | Low | Rinse-off products, general purpose cosmetics | Shampoo, soap, general moisturisers, nail polish |
|---|-----|-----------------------------------------------|--------------------------------------------------|

### 3. Risk Classification of Licensed Establishments

The Authority shall classify licensed establishments using the following risk factors to determine inspection frequency, licence validity, and regulatory intensity:

| Risk Factor                | High Risk                                            | Moderate Risk                                | Low Risk                         |
|----------------------------|------------------------------------------------------|----------------------------------------------|----------------------------------|
| Product types handled      | Controlled substances, sterile products, biologicals | Prescription medicines, Class B/C devices    | OTC, low-risk devices, cosmetics |
| Compliance history         | Previous critical/major findings, regulatory actions | Minor findings, corrective actions completed | Clean compliance record          |
| Complexity of operations   | Manufacturing, compounding, repackaging              | Wholesale, distribution, hospital pharmacy   | Retail-only, simple storage      |
| Time since last inspection | > 24 months                                          | 12–24 months                                 | < 12 months                      |
| Vigilance signals          | Recalls, serious AEs, quality complaints             | Minor quality issues                         | No signals                       |
| International alerts       | WHO alerts, SFCC notifications                       | Monitoring advisories                        | None                             |

### 4. Application of Risk Framework

The risk classification framework shall inform: registration pathway allocation and assessment timelines; inspection planning, frequency, and scope; licence validity periods; post-market surveillance intensity; resource allocation and prioritisation; and enforcement and compliance monitoring.

The Authority shall periodically review and update this framework to reflect emerging risks, international best practices, and lessons learned from regulatory experience.

### SCHEDULE 3 PROHIBITED SUBSTANCES

(Regulation 20)

1. The following substances are prohibited for manufacture, importation, distribution, sale, supply, or use in Botswana as regulated products, except where expressly authorised by the Authority for approved research purposes:

| No. | Substance / Category                                                             | Basis for Prohibition              | Convention / Reference    |
|-----|----------------------------------------------------------------------------------|------------------------------------|---------------------------|
| 1.  | Thalidomide (for use in women of childbearing potential without REMS equivalent) | Teratogenicity — unacceptable risk | WHO restrictions          |
| 2.  | Phenylpropanolamine (PPA) in OTC preparations                                    | Haemorrhagic stroke risk           | WHO/FDA advisory          |
| 3.  | Rofecoxib (Vioxx)                                                                | Cardiovascular risk                | Global withdrawal 2004    |
| 4.  | Phenacetin                                                                       | Nephropathy, carcinogenicity       | IARC Group 1 carcinogen   |
| 5.  | Chloroform in oral preparations                                                  | Hepatotoxicity, carcinogenicity    | International conventions |
| 6.  | Diethylstilbestrol (DES) for human use                                           | Carcinogenicity, teratogenicity    | Global withdrawal         |
| 7.  | Cosmetic products containing mercury compounds                                   | Neurotoxicity, nephrotoxicity      | Minamata Convention       |
| 8.  | Cosmetic products containing hydroquinone above 2%                               | Ochronosis, carcinogenicity risk   | WHO/regional guidance     |
| 9.  | Lead and lead compounds in cosmetics                                             | Neurotoxicity, systemic toxicity   | International consensus   |
| 10. | Products containing asbestos                                                     | Mesothelioma, asbestosis           | Rotterdam Convention      |
| 11. | Such other substances as the Minister may prescribe by notice in the Gazette     | As determined by risk assessment   |                           |

2. The Authority shall periodically review this Schedule and may recommend additions or removals to the Minister, following risk assessment and stakeholder consultation.

3. Amendments to this Schedule shall be published in the Gazette.

**SCHEDULE 4**  
**DESIGNATED PORTS OF ENTRY**

*(Regulations 48 and 63 of the Act)*

The following ports of entry are designated for the importation and exportation of regulated products:

| No. | Port of Entry                           | Type | Location / Bordering Country          |
|-----|-----------------------------------------|------|---------------------------------------|
| 1.  | Kazungula Border Post                   | Land | Northern Botswana / Zambia & Zimbabwe |
| 2.  | Mamuno Border Post                      | Land | Western Botswana / Namibia            |
| 3.  | Pioneer Border Post                     | Land | Eastern Botswana / South Africa       |
| 4.  | Ramokgwebana Border Post                | Land | North-Eastern Botswana / Zimbabwe     |
| 5.  | Sir Seretse Khama International Airport | Air  | Gaborone                              |
| 6.  | Tlokweng Border Post                    | Land | South-Eastern Botswana / South Africa |

*The Minister may, by notice in the Gazette, designate additional ports of entry or remove designated ports.*

The Authority shall liaise with the Botswana Unified Revenue Service (BURS) to maintain inspection arrangements at designated ports.

## SCHEDULE 5 COMPOUNDABLE OFFENCES

(Regulation 98)

The following offences may be compounded before court proceedings are instituted. The compound amount shall not exceed 50% of the maximum fine for the offence.

| No. | Offence Description                                                        | Regulation    | Max Fine | Max Compound |
|-----|----------------------------------------------------------------------------|---------------|----------|--------------|
| 1.  | Failure to maintain required records                                       | reg. 95(1)(h) | P500,000 | P250,000     |
| 2.  | Failure to report adverse events (non-serious)                             | reg. 95(1)(e) | P500,000 | P250,000     |
| 3.  | Failure to display licence prominently                                     | reg. 26(3)    | P100,000 | P50,000      |
| 4.  | Late renewal of registration or licence                                    | regs. 15, 38  | P200,000 | P100,000     |
| 5.  | Failure to notify changes within prescribed time                           | reg. 17       | P500,000 | P250,000     |
| 6.  | Failure to update declaration of interest                                  | reg. 5(2)     | P200,000 | P100,000     |
| 7.  | Minor labelling non-compliance                                             | reg. 67       | P500,000 | P250,000     |
| 8.  | Failure to retain advertising materials                                    | reg. 79(4)    | P200,000 | P100,000     |
| 9.  | Failure to maintain controlled substances register (minor discrepancy)     | reg. 44       | P500,000 | P250,000     |
| 10. | Minor storage non-compliance                                               | reg. 66       | P500,000 | P250,000     |
| 11. | Operating with expired licence (within 30 days of expiry, renewal pending) | reg. 38       | P200,000 | P100,000     |
| 12. | Advertising without displaying approval reference number                   | reg. 78(5)    | P200,000 | P100,000     |

**Notes:**

- (a) The CEO may decline to compound an offence where the circumstances warrant prosecution.
- (b) Repeat offences within 24 months shall not be eligible for compounding.
- (c) Serious offences involving falsified products, controlled substances violations, or risk to life are NOT compoundable.

**SCHEDULE 6**  
**TRANSITIONAL PERIODS**  
*(Regulation 105)*

The following transitional periods shall apply from the date of commencement of these Regulations:

| No. | Matter                                                                       | Transitional Period                  | From Date    | Conditions                                |
|-----|------------------------------------------------------------------------------|--------------------------------------|--------------|-------------------------------------------|
| 1.  | Existing product registrations granted under the repealed Regulations        | Valid until expiry date              | Commencement | Renewal under new Regulations             |
| 2.  | Existing licences granted under the repealed Regulations                     | Valid until expiry date              | Commencement | Renewal under new Regulations             |
| 3.  | Pending registration applications submitted before commencement              | Processed under previous regulations | Commencement | Applicant may elect new Regulations       |
| 4.  | Pending licence applications submitted before commencement                   | Processed under previous regulations | Commencement | Applicant may elect new Regulations       |
| 5.  | Compliance with GMP standards under new Regulations                          | 24 months                            | Commencement | Progressive compliance plan required      |
| 6.  | Implementation of electronic submission systems                              | 18 months                            | Commencement | Paper accepted during transition          |
| 7.  | Appointment of local technical representatives by existing MAHs              | 12 months                            | Commencement | Must apply within period                  |
| 8.  | Compliance with new labelling requirements                                   | 24 months                            | Commencement | Existing stock may be sold until expiry   |
| 9.  | Establishment of vigilance systems by MAHs                                   | 12 months                            | Commencement | Serious AE reporting from day one         |
| 10. | Risk-based inspection programme fully operational                            | 18 months                            | Commencement | Current inspection programme continues    |
| 11. | Compliance with new advertising requirements                                 | 6 months                             | Commencement | Existing approved ads may run to term     |
| 12. | Compliance with controlled substances register requirements under new format | 6 months                             | Commencement | Current registers valid during transition |

The Authority may publish additional transitional arrangements as necessary to ensure orderly transition and continued public health protection.