STATUTORY INSTRUMENT NO. ___ OF 2026

MEDICINES AND RELATED SUBSTANCES ACT, 2025

(Act No. ___ of 2025)

MEDICINES AND RELATED SUBSTANCES (GENERAL) REGULATIONS, 2026

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ARRANGEMENT OF REGULATIONS

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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.

PART I - PRELIMINARY

Citation and commencement

1. 1.1 These Regulations may be cited as the Medicines and Related Substances General Regulations, 2025.

   1.2 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;

"adverse drug reaction" means a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. Adverse drug reactions (ADRs) may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure. Conditions of use outside the marketing authorisation include off-label use, overdose, misuse, abuse and medication errors.

"adverse event" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a cosmetic and regulated product as defined in the Act, whether or not related to the cosmetic and regulated product.

"advertisement and promotional material" are used interchangeably and include any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any medicinal product. It encompasses written or spoken words and refers to all informational and persuasive activities by stakeholders, the effect of which is intended to induce and encourage the prescription or supply, purchase and/or use of medicines by means of highlighting qualities of medicines (product claims). Point of sale material, information leaflet, booklets and other promotional material which include specific product claims, and which are supplied separately from the product may also be considered "advertisement". Words

forming part of a soundtrack or video recording are within the definition of advertisement as is a spoken word.

"**authorised person**" in relation to a regulated establishment, means:

- *(i)* a person designated in the license or authorization as having overall responsibility for the operations of the regulated establishment;
- *(ii)* holds qualifications and experience appropriate to the activities authorized;
- *(iii)* is accountable to the Authority for compliance with this Act and conditions of the licence and or authorization; and
- *(iv)* has authority to bind the licensee in regulatory matters; or

(b) any **key personnel** means:

- *(i)* performs critical functions in the manufacture, quality assurance, quality control, distribution, storage, or dispensing of regulated products;
- *(ii)* holds qualifications and competencies required by the Authority for their designated role;
- *(iii)* is specifically designated in the licence or approved by the Authority; and
- *(iv)* 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.

"blood establishment" means any facility performing collection, testing, processing, storage, release, or distribution of human blood or blood components for transfusion or manufacturing;

"cannabis product" means any regulated product containing cannabis or cannabis derivatives subject to coordinated assessment with the cannabis control authority;

"Chief Executive Officer" means the Chief Executive Officer of the Authority appointed under section 24 of the Act;

"complementary medicine" means a labelled substance or mixture of substances manufactured, sold or represented for use as adjuvants to conventional therapy, originating from plant, mineral, animal including microorganisms, homeopathic preparations, or nutritional substances in accepted pharmaceutical dosage forms;

"controlled substance" means a prohibited substance or medicine listed in Schedules 1A, 1B, 1C or 1D to the Act or a precursor chemical;

"cosmetic" means a substance or mixture intended for external application to the human body for cleansing, beautifying, protecting, or correcting body odour, excluding products with therapeutic claims;

falsified medical product" means a product with false representation of its identity, packaging, labelling, composition, source, or history;

"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, such as good laboratory practices (GLP), good clinical practices (GCP), current good manufacturing practices (GMP), good pharmacy practice (GPP), good storage and distribution practices (GS/DP) and other good practices..

"guidelines" means documents issued by the Authority outlining regulatory requirements and procedures;

"inspection" means a systematic regulatory process carried out by competent authorities to assess whether any part of the pharmaceutical supply chain—including manufacturing, marketing authorisation holders, wholesale, and community pharmacy operations—complies with applicable laws, Good Pharmacy Practice (GPP), Good Distribution Practice (GDP), Good Manufacturing Practice (GMP), Good Vigilance Practice (GVP), Good Clinical Practice (GCP) and other relevant quality and safety standards. In the context of community pharmacy, inspections verify that medicines are procured, stored, dispensed, and documented in a manner that ensures their safety, quality, and efficacy, protects public health, and prevents the circulation of falsified or substandard products

"import permit" means a permit issued for a specific consignment of regulated products to be imported;

"**license"** means a licence, in any of the categories set out in regulation 22, issued by the Authority under the Act and these Regulations, authorising a person to carry out one or more regulated activities, and includes a licence as varied or renewed under these Regulations, but does not include a permit, certificate, or other authorisation issued for a specific consignment, product, or transaction;

"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;

"medical product" means medicine, complementary medicine, vaccines, in-vitro diagnostics and medical devices;

"precursor chemical" has the same meaning as in the Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act;

"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" any premises, facility, structure, body, organization, or undertaking that:

- (i) manufactures, imports, exports, distributes, stores, sells, dispenses, repackages, relabels, or otherwise handles regulated products; or
- (iii) provides laboratory services for testing, analysis, or quality control of regulated products; or
- (iv) operates as a vaccines and biologics establishment; or
- (v) carries out any other activity in relation to regulated products,

- (vi) any other premises designated by the Authority as requiring oversight;

and which is required to be authorized, licensed, or registered by the Authority under this Act;

"**Regulated products**" "regulated product" means medical products, blood and blood products, traditional medicines, food and related substances;

"Retailer" means an establishment licensed by the Authority to sell or supply regulated products directly to the end user or consumer for personal, medical, veterinary or household use, and who is not authorised to engage in wholesale distribution.

"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.

"Wholesaler" means the premise procuring, purchasing, holding, storing, selling, supplying, importing, exporting or movement of medical products, excluding premises dispensing or providing medical products directly to a patient or his or her agent and licensed as such under these regulations.

Within Group Practice pharmacy – authorised to procure, store, compound where applicable, dispense and supply medicines and other medical products exclusively for use within a licensed health facility for inpatient and outpatient care and licensed as such.

Application

3. (1) These Regulations apply to

(a) cosmetics and 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 regulated establishments where regulated products are manufactured, imported, exported, handled, tested, 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.

(4) 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 – MARKET AUTHORISATION OF REGULATED PRODUCTS

Requirements for marketing authorisation

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

(b) products for which a special access scheme applies under product-specific regulations;

(c) products in transit in accordance with regulation 52;

(d) products imported for personal use in accordance with regulation 54;

(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) Authorisation 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 the prescribed form in the specific regulations 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, conduct a validation review to determine whether the application is complete and may

(a) accept the application for evaluation; or

(b) Reject the application if incomplete

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 and;

(c) filed with the Authority before or with the application;

(4) A change of local technical representative shall be subject to sub regulation (3) above.

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; and

(e) rely on assessments by recognised regulatory authorities;

(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; and

(d) failure to respond within the timeframe shall result in the application being refused.

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

(b) register the product with conditions; 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 where no prior approval from reference National Regulatory Authority;

(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) 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.

(3) The Authority shall publish criteria for the pathway in sub regulation 13(1) in the guidelines.

(4) The Authority may move an application to a different pathway where circumstances warrant.

Market Authorisation during public health emergencies

14. (1) During a declared public health emergency or in cases of animal health emergency, the Authority shall in accordance to section 38 of the Act,

(a) operate expedited assessment procedures in accordance with applicable guidelines;

(b) grant conditional or emergency use authorisations with enhanced post-marketing conditions;

(c) accept rolling data submissions where necessary;

(d) waive or reduce applicable fees;

(e) rely on emergency use authorisations from reference Authorities

(2)Emergency use authorisations shall be,

(a) subject to enhanced surveillance, mandatory adverse event reporting and additional conditions as specified by the Authority;

(b) reviewed when the declared emergency ends; and

(c) subject to conversion to a full marketing authorisation or withdrawal, as determined by the Authority.

(3)The Authority shall issue guidelines on emergency use authorisation procedures that shall be reviewed from time to time in accordance with the Act and these Regulations.

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 set out in specific product regulations ;

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

(c) accompanied by the prescribed renewal fee, an updated dossier and any other documents as specified in the relevant guidelines.

(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 completion of assessement, the Authority may

(a) renew unconditionally;

(b) renew with amended conditions; or

(c) refuse renewal, stating reasons in writing and any subsequent regulatory actions

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;

(b) minor variations, being changes that may have moderate to minimal effects on quality, safety or efficacy; and

(c) notifications, being changes that have minimal or no effect on quality, safety or efficacy(3) Applications for variations shall be submitted to the Authority in the prescribed form and shall be accompanied by prescribed fees

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

(5) Upon completion of assessment, the Authority may

(a) approve unconditionally;

(b) with amended conditions; or

(c) refuse the change, stating reasons and any subsequent regulatory actions in writing

Notifications

17. (1) The marketing authorisation holder shall notify the Authority within specified timelines 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 specified timelines; 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 stipulated timelines; 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 Authoritys 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 Authoritys 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,

(i) An application for licensing of regulated establishments shall be submitted to the Authority, in a prescribed form accompanied by an application fee set out by the authority.

(ii) The Authority may, having considered the application, grant the applicant an authorisation or licence in a prescribed form, and the Authority may attach conditions thereto as it may consider necessary.

(iii) The Authority shall inform an unsuccessful applicant in writing, of the decision not to licence the premises and the reasons ,in line with the guidelines.

(iv) Where premises are licensed, the premises shall be under the supervision of a qualified person in line with the guidelines.

(v) Subject to subregulation (4), any change in the person who supervises the premises shall be communicated to the Authority within 30 days.

(vi) The Authority shall keep a database of all licenced manufacturing facilities, pharmacies and pharmaceutical wholesalers

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;

(c) distribution and wholesale licences;

(d) retailing and dispensing licences;

(e)

(f) special authorisation/licences.

Categories of manufacturing licence

Manufacturing licences shall be issued in the following categories —

(a) full manufacturing licence, including dosage form manufacture, in-process testing, finished product release testing and batch certification;
(b) secondary manufacturing and packaging licence;
(c) biological medicines manufacturing licence, including vaccines, immunosera and immunological products;
(d) autogenous veterinary vaccine manufacturing licence;
(e) repackaging and relabelling licence; and
(f) Quality Control Laboratory operations licence.

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

(e) list of products and dosage forms to be manufactured;(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) medical products manufacturing;(e) cosmetics manufacturing; or any other regulated product as the Authority may determine.

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.

(d) any other Key personnel as required by the Authority

(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.

The manufacturer shall notify the Authority in writing of any resignation, removal, replacement, or change in the particulars of the appointed key personnel within a timeline specified in the guidelines.

Issuance of manufacturing licence

25. (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;

(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.

26 Current good manufacturing practice compliance

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

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

Certificate of compliance with current good manufacturing practice

27. (1) The Authority may issue a Certificate of Compliance with Good Manufacturing Practice to a manufacturer 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, block, 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 validity period of a cGMP certificate shall be determined by the Authority on the basis of a quality risk assessment conducted in accordance with its determined guidelines.

(4) Notwithstanding the validity period specified in the certificate, the Authority may conduct announced or unannounced inspections, require additional information, or vary, suspend or revoke the certificate where there is evidence of non-compliance with GMP requirements or where such action is necessary to protect public or animal health.

(5) The issuance of a cGMP certificate shall not relieve the manufacturer of its obligation to maintain continuous compliance with applicable GMP requirements throughout the period of validity of the certificate.(6) A manufacturer shall apply for renewal of a certificate not later than six (6) months prior to its expiry, in the manner and form determined by the Authority.

Application for distribution and wholesale licence

28. (1) An application for a licence to operate a pharmaceutical wholesaler shall be made to the Authority in a form prescribed, and shall be accompanied by the prescribed fee set.

(2) Where the Authority is satisfied that the applicant has submitted the prescribed application form, paid the applicable fee, and submitted all documents and information required the Authority shall issue a licence.

(3) A licence issued under subregulation (2) shall be subject to the licensee's continued compliance with the requirements of the Act, these Regulations, the applicable guidelines, and the principles of Good Practices, where applicable.

(4) License issued under subregulation (1) shall specify the category of licence sought, which shall include

(a) Medicines wholesaler;

(b) medical devices wholesaler;

(c) cosmetics wholesaler;

(d) bonded warehouse; or

(e) combined facility for any of the above scope.

(f) any other premises designated by the Authority as requiring oversight;

(5) A licensee shall not stock, sell, distribute, supply or otherwise deal in any medical product that falls outside the scope of the licence category issued by the Authority.

(6) Any contravention of this regulation shall constitute a breach of the licence conditions and may result in suspension, variation, revocation of the licence, or any other regulatory action under the Act.

Application for retailing and dispensing licence

29. **(1)** An application for a licence to operate a retailer or dispensing facility for regulated products shall be made to the Authority in and shall be accompanied by the prescribed fee set out.

(2) Where the Authority is satisfied that the applicant has submitted the prescribed application form, paid the applicable fee, and submitted all documents and information required, the Authority shall issue a licence in a prescribed form and manner.

(3) A licence issued under sub regulation (2) shall be subject to the licensee's continued compliance with the requirements of the Act, these Regulations, the applicable guidelines, and the principles of Good Practices.

30. **Categories of Retailers**

A retailer may be licensed under one of the following categories—

(a) Stand-alone pharmacy

(b) Hospital pharmacy .

(c) Veterinary retailer

(d) Dispensary

(e) Authorised premises

(f) Combined facility:a licence issued under this category shall authorise an establishment to handle any combination of regulated scope of products as per the regulations .

(g) any other premises designated by the Authority as requiring oversight;

(3) A licensee shall not store, sell, distribute, supply or otherwise handle in any medical product that falls outside the scope of the licence category issued by the Authority.

(4) Any contravention of this regulation shall constitute a breach of the licence conditions and may result in suspension, revocation of the licence, or any other regulatory action under the Act.

Licensing of bonded warehouses

31. An application for a licence to operate a bonded warehouse for the storage of medical products shall be made to the Authority in a prescribed form and shall be accompanied by the prescribed fee set.

(2) Where the Authority is satisfied that the applicant has submitted the prescribed application form, paid the applicable fee, and submitted all required documents and information, the Authority shall issue a licence.

(3) A licence issued under subregulation (2) shall authorise the licensee to receive, store and release medical products under Botswana Unified Revenue Service's control in accordance with the scope and conditions specified in the licence.

(4) A licence issued under subregulation (2) shall be subject to the licensee's continued compliance with the requirements of the Act, these Regulations, the applicable guidelines, the principles of Good Practices, where applicable, and any conditions specified in the licence.

(5) A bonded warehouse licensee shall not sell, distribute, supply, relabel, repackage, or otherwise deal in medical products except as authorised under the Act, these Regulations, the licence, and any applicable Botswana Unified Revenue Service's legislation.

(6) The validity period of a bonded warehouse licence shall be determined by the Authority based on a quality risk assessment and may be suspended, varied or revoked in accordance with the Act and these Regulations.

Special licences

32. **1)** An application for a special licence to conduct a regulated activity shall be made to the Authority in the prescribed form and shall be accompanied by the prescribed fee

(2) The Authority may issue a special licence for regulated activities requiring enhanced or distinct regulatory controls, including—

(a) e-pharmacy operations;

(b) the importation, exportation, storage, handling or supply of precursor chemicals;

(c) mobile operations; and

(d) any other specialised regulated activity determined by the Authority.

(3) Where the Authority is satisfied that the applicant has submitted the prescribed application form, paid the applicable fee, and submitted all required documents and information, the Authority shall issue a special licence in the prescribed form.

(4) A special licence issued under subregulation (3) shall specify the scope of authorised activities and shall be subject to the licensee's continued compliance with the requirements of the Act, these Regulations, the applicable guidelines, the principles of Good Practices, where applicable, and any conditions specified in the licence.

(5) A person shall not conduct a regulated activity requiring a special licence unless authorised by the Authority under these Regulations.

33. General application requirements

(1) An application for a licence under these Regulations shall be made to the Authority and shall be accompanied by the prescribed fee.

(2) An application under subregulation (1) shall be accompanied by all documents and information required under the Act, these Regulations and the applicable guidelines, including—

(a) proof of company registration in Botswana;

(f) evidence of appropriate premises, storage facilities, equipment and utilities, where applicable; and

(g) such other documents or information as the Authority may require.

(3) The Authority may conduct a pre-licensing inspection or any other assessment it considers necessary to verify compliance with the Act, these Regulations and the applicable guidelines.

(4) The Authority shall determine an application within prescribed timelines after receipt of a complete application.

34. Assessment, inspection and issuance of licence

(1) Upon receipt of a complete application, the Authority shall conduct a documentary assessment and, where applicable, a pre-licensing inspection to verify the applicant's compliance with the Act, these Regulations, the applicable guidelines, and the relevant Good Practices and standards recognised by the Authority.

(2) The applicant shall facilitate the inspection by providing the Authority with reasonable

access to the premises, personnel, records and any other information or evidence required to assess compliance.

(3) Where the Authority is satisfied that the applicant complies with the requirements of the Act, these Regulations, the applicable guidelines and the relevant Good Practices, the Authority shall issue a licence in the prescribed form.

(4) Where the Authority is not satisfied that the applicant complies with the prescribed requirements, the Authority may—

(a) issue the licence subject to conditions;

(b) defer its decision pending the correction of identified deficiencies; or

(c) refuse the application and provide the applicant with written reasons for the decision.

35. Conditions of licence

(1) The Authority may impose such conditions on a licence as it considers necessary to ensure compliance with the Act, these Regulations, the applicable guidelines, and the relevant Good Practices.

(2) Without limiting subregulation (1), licence conditions may relate to—

(a) the categories of regulated products that may be handled;

(b) the scope of authorised activities;

(c) the qualifications and availability of responsible persons or other personnel;

(e) record-keeping and reporting requirements;

(f) inspection, monitoring and access to premises;

(g) storage, distribution, dispensing or handling requirements, where applicable; and

(h) any other matter the Authority considers necessary to ensure compliance.

(3) The Authority may impose, vary, suspend or remove licence conditions at the time of issuing the licence or at any time during the period of validity of the licence.

(4) A licensee shall comply with all conditions attached to the licence.

(5) The Authority may publish standard licence conditions in the applicable guidelines.

36. Validity and renewal of licence

(1) A licence issued under these Regulations shall be valid for such period as may be determined by the Authority based on a quality risk assessment and shall not exceed three (3) years.

(2) Where the Authority identifies significant deficiencies or determines that enhanced regulatory oversight is required, it may—
(a) issue or renew a licence for a shorter period;
(b) impose or vary licence conditions; or
(c) require additional inspections or reporting during the period of validity.

(3) An application for renewal of a licence shall be made in a prescribed form, accompanied by the prescribed renewal fee, and shall be submitted at least three (3) months before the expiry of the licence.

(4) The Authority may conduct an inspection or any other assessment it considers necessary before renewing a licence.

(5) Where an application for renewal is submitted three (3) months before the expiry of the licence, the existing licence shall remain in force until the Authority has made a decision on the application.

(6) All applications submitted after license expiry shall be subjected prescribed late payment penalty.

37. Change of business ownership

(1) A licensee shall not transfer, assign or otherwise effect a change in the ownership of a regulated establishment without the prior written approval of the Authority in accordance with section 59 of the Act.

(2) An application for approval of a change of ownership shall be made and shall be accompanied by the prescribed fee and such documents and information as may be required by the Authority.

(3) The Authority may conduct such assessment or inspection as it considers necessary to determine whether the proposed change of ownership complies with the Act, these Regulations and the applicable guidelines.

(4) Where the Authority is satisfied that the proposed change of ownership complies with the Act, these Regulations and the applicable guidelines, it may approve the application and amend the licence where necessary.

(5) A change of ownership effected without the prior written approval of the Authority shall constitute a contravention of these Regulations and may result in suspension, variation or revocation of the licence or any other regulatory action under the Act.

38. Suspension, revocation and cancellation of licence

(1) The Authority may suspend, revoke 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, any applicable guidelines, or any condition of the licence;

(b) has failed to maintain compliance with the applicable Good Practices or other standards recognised by the Authority;

(c) has provided false, misleading or incomplete information in connection with an application or any regulatory submission;

(d) poses, or is likely to pose, a risk to public health, animal health; or

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

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

(a) an imminent or serious risk to public health, animal health has been identified;

(b) regulated products are suspected to be falsified, substandard, unsafe or unlawfully supplied; or

(c) continued operation of the licensed activity is likely to compromise regulatory control or public confidence.

(3) Except in the circumstances specified in subregulation (2), the Authority shall, before suspending, revoking or cancelling a licence, give the licensee written notice of the proposed action and a reasonable opportunity to make representations within the period specified in the notice.

(4) Where a licence has been suspended, revoked or cancelled, the licensee shall comply with any directions issued by the Authority, including—

(a) ceasing the licensed activities to the extent specified by the Authority;

(b) surrendering the licence to the Authority within the period specified;

(c) securing, transferring, recalling or disposing of regulated products in accordance with the written directions of the Authority; and

(d) retaining and making 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, revocation or cancellation of a licence shall not preclude the Authority from taking any other enforcement action available under the Act.

39. Variation of licence

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

(2) An application for variation shall be made in the prescribed form and shall be accompanied by the prescribed fee and such documents and information as the Authority may require.(3) An application shall not be made where the license validity has less than three (3) months.

(3) The Authority may conduct such assessment or inspection as it considers necessary to determine whether the proposed variation complies with the Act, these Regulations, the applicable guidelines and the relevant Good Practices.

(4) Where the Authority is satisfied that the proposed variation complies with the requirements of the Act, these Regulations and the applicable guidelines, it may approve the variation subject to such conditions as it considers appropriate.

(5) A licensee shall not implement a proposed variation until it has received the written approval of the Authority.

(6) The approval of a variation shall not extend the validity period of the licence unless otherwise determined by the Authority.

40. Types of variation

(1) A variation to a licence shall be classified by the Authority as either—

(a) a **minor variation**, being a change that has no significant effect on the safety, efficacy, quality of medicinal products, regulatory risk profile, or scope of licensed activities; or

(b) a **major variation**, being a change that has a significant effect on the safety, efficacy, or quality of medicinal products, or that materially affects the regulatory risk profile, scope, or nature of licensed activities.

(2) In determining whether a proposed variation is minor or major, the Authority shall apply a quality risk assessment, taking into account the nature, complexity and potential impact of the proposed change.

(3) The Authority may reclassify a proposed variation where, upon assessment, it determines that the variation presents a greater or lesser regulatory risk than that declared by the applicant.

(4) The Authority may publish guidelines specifying the categories of minor and major variations and the applicable requirements for each category.

41. Post-licensure notifications

41. (1) A licensee shall notify the Authority in writing of any change or occurrence that may affect the licensed activity, compliance with the Act, these Regulations, the applicable guidelines, or the conditions of the licence.

(2) A notification under this regulation shall be submitted within the period specified by the Authority or, where no period is specified, within thirty (30) calendar days after the occurrence of, or becoming aware of, the event.

(3) Upon receipt of a notification, the Authority may—

(a) acknowledge the notification;

(b) require additional information or an inspection;

(d) require the submission of an application for variation of the licence; or

(e) take any other regulatory action authorised under the Act**.**

PART V– CONTROLLED SUBSTANCES

42. **Import and export permits for controlled substances**

(1) A person shall not import or export a narcotic drug, psychotropic substance or precursor chemical unless authorised by an import or export permit issued by the Authority for each consignment.

(2) An application for an import or export permit shall be made to the Authority in the prescribed form and shall be accompanied by the prescribed fee and such documents and information as the Authority may require.

(3) Where the Authority is satisfied that the application complies with the Act, these Regulations, applicable international obligations and applicable guidelines, it may issue an import or export permit subject to such terms and conditions as it considers appropriate.

(4) An import or export permit issued under this regulation shall—
(a) relate to a specific consignment;
(b) specify the authorised controlled substance or precursor chemical, quantity, consignee or consignor, as applicable;
(c) be subject to such conditions as the Authority may determine; and
(d) remain valid for a period of six (6) months, unless otherwise specified by the Authority.

(5) A holder of an import or export permit shall comply with any reporting, reconciliation, notification and record-keeping requirements imposed by the Authority or as a condition of the permit.

43. Registers and records for controlled substances

(1) A person authorised to manufacture, import, export, distribute, sell, dispense, store or otherwise handle a narcotic drug, psychotropic substance or precursor chemical shall establish,

maintain and keep separate registers and records for each category of controlled substance or precursor chemical handled.

(2) The registers referred to in subregulation (1) shall accurately record all transactions relating to the receipt, manufacture, importation, exportation, storage, distribution, dispensing, transfer, destruction and disposal of controlled substances or precursor chemicals, as applicable, and shall ensure full traceability and accountability.

(3) Registers may be maintained in electronic or hard-copy form, provided that they are accurate, complete, secure, readily retrievable and available for inspection by the Authority.

(4) Every transaction involving a controlled substance or precursor chemical shall be entered into the appropriate register within twenty-four (24) hours of the transaction.

(5) Registers shall be reconciled and balanced at least once every calendar month, and any discrepancy identified during reconciliation shall be investigated, documented and reported to the Authority without undue delay.

(6) Registers and supporting records maintained under this regulation shall be retained for a minimum period of five (5) years after the date of the last entry or for such longer period as the Authority may determine.

(7) Any correction to a register shall preserve the original entry, be clearly identifiable, dated and attributable to the person making the correction. No entry shall be erased, overwritten or obscured.

(8) The Authority may determine the format, content, manner of maintenance, reconciliation and correction of registers by guideline or other regulatory instrument.

44. Dispensing of controlled substances

(1) A Schedule 1A, 1B or 1C controlled substance shall only be dispensed by a pharmacist or veterinary surgeon upon a valid prescription issued by an authorised prescriber in accordance with the Act and these Regulations.

(2) A person dispensing a controlled substance shall ensure that—
(a) the prescription complies with the requirements of the Act and these Regulations;
(b) the quantity supplied does not exceed that authorised by the prescriber or which shall be

presented for dispensing within thirty (30) 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 30days'supply.

(c) every dispensing transaction is recorded in the register maintained under regulation 47; and

(d) prescriptions and dispensing records are retained for a minimum period of five (5) years.

(3) Schedule 1 medicines shall be stored under secure custody in a locked cabinet, safe or secure room with controlled access, in accordance with the Act, these Regulations and any applicable guidelines issued by the Authority.

45. Emergency dispensing of controlled substances

(1) A pharmacist may dispense a Schedule 1A, 1B or 1C medicine in an emergency where—

(a) the medicine is required for the immediate treatment of a patient who has a repeat prescription and is known to both the prescriber and the pharmacist;

(b) the pharmacist has confirmed with the prescriber that the medicine is required and that the prescriber is authorised to prescribe the medicine; and

(c) the pharmacist is satisfied that it is not reasonably practicable to obtain a written prescription before dispensing.

(2) Where a medicine is dispensed under subregulation (1), the prescription may be communicated by telephone, electronic mail or other electronic means, provided that the quantity dispensed does not exceed the maximum quantity prescribed under Regulation 48(2)b and the original written prescription is submitted to the pharmacist within forty-eight (48) hours.

46. Sale and use of precursor chemicals

(1) A person shall not manufacture, import, export, possess, sell, supply or use a precursor chemical except in accordance with Regulation 46.

(2) A precursor chemical specified by the Authority shall only be manufactured, imported, exported, sold, supplied or used by a person authorised by the Authority.

(3) An authorised person who manufactures, imports, exports, sells, supplies or uses a precursor chemical shall maintain the registers and records required under regulation 47.

(4) A person authorised to handle precursor chemicals shall comply with such security, storage, reporting and record-keeping requirements as may be determined by the Authority.

47. Submission of returns and annual estimates

(1) A person authorised to manufacture, import, export, distribute, sell, dispense or otherwise handle narcotic drugs, psychotropic substances or precursor chemicals shall submit to the Authority such returns, reports, annual estimates and assessments of requirements as the Authority may require, in form and within the period specified by the Authority.

(2) The returns referred to in subregulation (1) shall contain such information relating to the receipt, manufacture, importation, exportation, distribution, dispensing, sale, use, stock balances, disposal and estimated annual requirements for controlled substances as the Authority may require.

(3) A person who fails to submit a return, report, annual estimate or assessment of requirements within the prescribed period, or who submits false, misleading or incomplete information, commits an offence and is liable to the penalties prescribed under the Act.

48. Non-compliance

A person who contravenes this provision commits an offence and is liable to the penalties prescribed under the Act.

PART VI - IMPORT AND EXPORT CONTROL

49. Requirement for import and export authorisation

(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 licence for the entity; and

(b) a valid import or export permit for the specific consignment.

(3) The Authority may refuse authorisation where

(a) the product is not registered, 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.

50. Import and export permits

(1) A holder of a valid licence or other authorisation may apply to the Authority for an import or export permit for each specific consignment in the prescribed form with payment of applicable fee.

(2) An application for an import permit shall be made in Form GEN-10 set out in Schedule 1 and shall include

(a) product details including registration number;

(b) quantity;

(c) manufacturer and country of origin;

(d) supplier details;

(e) intended port of entry;

(f) expected date of arrival;

(g) batch numbers and expiry dates; and

(h) end-user information where required.

(3) An application for an export permit shall be made in Form GEN-11 set out in Schedule 1 and shall include

(a) product details;

(b) quantity;

(c) destination country;

(d) consignee details;

(e) intended port of exit; and

(f) import authorisation from the destination country where required.

(4) The Authority shall process permit applications within

(a) five working days for routine applications;

(b) two working days for expedited applications, with an additional fee; and

(c) one working day for emergency applications where public health is at risk.

(5) Permits shall specify

(a) permit number;

(b) product details and quantity;

(c) authorised route;

(d) validity period, being a maximum of ninety days;

(e) any conditions; and

(f) inspection requirements.

51. Authorised ports of entry

(1) In accordance with section 63 of the Act, regulated products may only be imported or exported through the ports of entry designated in Schedule 4.

(2) The designated ports of entry are

(a) Kazungula Road Border;

Kazungula Bridge Border

(b) Mamuno Border;

(c) Pioneer Border;

(d) Ramokgwebana Border;

(e) Sir Seretse Khama International Airport; and

(f) Tlokweng Border.

(g) Martin's drift

(h) Francistown Airport

(i) Maun Airport

(j) Ramatlabama Border

(3) The Authority shall liaise with the Botswana Unified Revenue Service to

(a) maintain arrangements at designated ports;

(b) facilitate inspection of consignments;

(c) share information on imports and exports; and

(d) coordinate enforcement activities.

(4) The Minister may, by notice in the Gazette, designate additional ports of entry or remove designated ports.

(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.

52. Products in transit

(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 Form GEN-12 set out in Schedule 1 and shall include

(a) product details and quantities;

(b) country of origin and final destination;

(c) entry and exit ports in Botswana;

(d) proof of authority from the Botswana Unified Revenue Service;

(e) authorisation from the destination country authority;

(f) expected transit period; and

(g) name and contact of local agent or transporter.

(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 a maximum of fourteen days.

(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.

53. Donated medical products

(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 Form GEN-13 set out in Schedule 1 and shall include

(a) donor details and contact information;

(b) recipient organisation details;

(c) product details including quantities;

(d) evidence that products meet quality requirements;

(e) remaining shelf-life information;

(f) statement of conformity with the Authority's donation guidelines; and

(g) intended use and distribution plan.

(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 Authoritys 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.

54. Personal importation

(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

(a) the quantity is limited to a ninety-day supply;

(b) the product is accompanied by a prescription or medical documentation;

(c) the product is not prohibited in Botswana;

(d) the product is for the personal use of the person importing or a person in his or her care; and

(e) the person declares the product at customs.

(2) Personal importation is not permitted for

(a) narcotic drugs;

(b) psychotropic substances;

(c) Schedule 1D medicines; and

(d) products prohibited in Botswana.

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

PART VII SCHEDULING AND CLASSIFICATION OF MEDICINES

Classification and description of medicines

55. (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

56. (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

57. (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;

(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

58. (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

59. 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

60. 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

61. (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

62. (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

63. (1) A prescriber may store medical products for administration to patients in the course of his or her professional practice, in accordance with the Act, these Regulations and the applicable guidelines.

(2) The types and quantities of medical products stored by a prescriber shall be appropriate to the scope of the prescriber's practice and shall comply with any requirements determined by the Authority.

Storage of medical products

64. (1) A person authorised under the Act to store, manufacture; sell or supply; export or import; distribute; dispense regulated products shall ensure that the products are stored under conditions that maintain their quality, safety and efficacy and prevent unauthorised access, loss, damage, deterioration or contamination.

(2) Controlled substances shall be stored under secure custody in accordance with the Act, these Regulations and any applicable guidelines.

(3) Storage facilities shall be suitable for the products stored and shall comply with the applicable Good Practices, relevant standards and any guidelines issued by the Authority.

(4) The Authority may determine requirements for the storage, handling, security and environmental conditions of medical products by guideline or other regulatory instrument.

Product information and labelling

65. (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) All products shall contain a product or professional information and/or patient information leaflet (PIL), which shall be approved and published by the Authority.

66. **Labelling of dispensed medicines**

(1) A person who dispenses a medicine shall ensure that the container is clearly and legibly labelled with sufficient information to enable the safe and appropriate use of the medicine.

(2) Without limiting subregulation (1), the label shall include—

(a) the name of the patient;

(b) the date of dispensing;

(c) the name, strength and quantity of the medicine;

(d) the directions for use;

(e) the name or identification of the dispenser; and

(f) such other information as may be required by the Authority.

(3) A pre-packed medicine shall bear the information required under the Act, these Regulations and any applicable labelling requirements, including the name of the medicine, strength, batch number, date of manufacture, expiry date and the name of the manufacturer.

(4) Where a medicine requires special warnings, precautions, storage conditions or cautionary statements, the label shall include such information in accordance with the Act, these Regulations and any applicable guidelines issued by the Authority.

PART VII QUALITY CONTROL AND LABORATORY SERVICES

National Quality Control Laboratory

67. (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

68. (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

69. (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

70. (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 IX VIGILANCE AND POST-MARKET SURVEILLANCE

National vigilance programme

71. (1) In accordance with section 71 of the Act, the Authority shall establish and maintain a national vigilance programme covering

(a) pharmacovigilance for medicines and vaccines;

(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) plan, establish, implement, monitor and maintain an updated pharmacovigilance system

(b) appoint a qualified person responsible for vigilance;

(c) collect, report and analyse adverse events as required;

(d) conduct signal detection, assessment and management;

(e) implement any urgent safety restriction directed by the Authority

(f) carry out investigations and conduct corrective and preventative actions

(g) develop and implement a system for assessing the benefit-risk profile of regulated products including submission of periodic safety update reports as prescribed in the guidelines,

(h) implement and maintain risk management system, including development, submission and implementation of Risk Management Plans and risk minimisation measures;

(i) establish and maintain a Pharmacovigilance System Master File (PSMF)

(j) conduct post-authorisation safety and efficacy studies where required,

(k) submit safety labelling variations as per section 16 on these regulations

(j) implement systems for communication of vigilance information including crisis prevention and management, where applicable

(k) respond to Authority requests for information as prescribed in the guidelines

(l) submission of adverse event reporting timelines as prescribed in the specific product regulations and guidelines.

(3) Public health programmes shall

(a) establish and maintain a pharmacovigilance system of regulated products distributed within their programs;

(b) identify focal persons to coordinate pharmacovigilance activities;

(c) collaborate with the Authority to distribute reporting forms, collect safety reports, and submit reports to the Authority

(d) collaborate with the Authority in implementing active surveillance or cohort event monitoring for products of interest where necessary

(e) collaborate with Authority in implementing pharmacovigilance activities including training of health care providers on pharmacovigilance and investigation of serious or cluster adverse events where necessary;

(f) promote rational and safe use of products by health care providers;

(g) maintain and implement a risk management system including communication of risks and effectiveness of products to relevant stakeholders

(4) Healthcare facilities and health practitioners shall

(a) report suspected adverse events;

(b) cooperate with investigations; and

(c) provide access to relevant records.

(5) Reporting timelines for adverse events following immunisation.

(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.

(6) Reporting timelines for adverse drug reactions associated with human medicines;

(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) submission of adverse event reports for all other regulated products shall be as prescribed in the specific product regulations and guidelines.

(7) In accordance with section 72 (3) of the Act, a patient or a consumer may report adverse event outlined in section 73 of these regulations associated with the use of a regulated product immediately to the nearest to the nearest health facility, healthcare provider or directly to the Authority.

Reporting of adverse events

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

(a) all suspected or unexpected adverse events;

(b) medication errors associated with and without adverse events

(d) adverse events suggesting unusual frequency or severity;

(e) off-label use

(f) abuse and misuse

(g) lack of expected efficacy;

(h) field safety notifications and corrective actions;

(i) safety signals;

(j) quality defects;

(k) regulatory actions in other countries; and

(l) such other matters as specified in the relevant guidelines.

(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

73. (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 events 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 and guidelines.

Good Vigilance Practice Inspections

74.

(1) In accordance with section 71 (4) of the Act, the Authority shall conduct inspections vigilance systems at reasonable times to ensure compliance for all regulated products for the purpose of ensuring compliance to established standards.

(2) GVP inspection regulation shall in accordance to sections 84 and 85 of these regulations unless otherwise specified in the pharmacovigilance guidelines.

Eco vigilance

75. ***Environmental safety***

(1) The Authority may require MAHs, distributors or public health programmes to conduct post-market environmental safety monitoring for registered medical products where the environmental risk assessment identifies potential safety concerns.

Post-market surveillance

77. (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 medical product quality;

(c) analysis of medical product quality complaints;

(d) risk-based targeted surveillance;

(f) international collaboration on safety signals

(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.

77. Tracebility

(Pursuant to Section 117 of the Act, the Authority shall prescribe Traceability and verification of regulated products

The Authority will provide guidelines for the standards of implementation of a track and trace system.

Product recall

78. (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 and its type based on level of 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

79. (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 X ADVERTISING AND PROMOTION

Requirement for advertising approval

80. (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 through the electronic regulatory management system, Form GEN-17 set out in Schedule 1 or other forms as prescribed by guidelines and product specific guidelines.

An application shall include;

(a) the proposed advertising materials;

(b) the target audience;

(c) the media to be used;

(d) references supporting claims made; and

(e) the prescribed fee.

(3) The Authority shall respond to advertising applications within turnaround timelines as prescribed in the guidelines.

(4) The response to the application may be

a) approved

b) deferred pending additional information or modifications,

c) rejected

(5) Approved advertisements shall display the approval reference number or any other means as prescribed by the Authority.

Advertising standards

81. (1) All advertising of regulated products shall

(a) be accurate, truthful and not misleading;

(b) be consistent with the approved product information;

(c) not contain claims not supported by evidence;

(d) not contain any statement(s) which either explicitly or by implication disparages another product;

(e) not include offensive content;

(f) be appropriate for the target audience; and

(g) comply with the Authority's guidelines on promotional materials and advertising.

(2) Prescription-only medicines and high-risk medical devices shall only be advertised to healthcare professionals notwithstanding the provisions of this section, the Authority may, where it considers it necessary in the interest of public health, patient safety or effective risk management, authorise the advertisement of a high-risk product to the public, subject to such conditions as the Authority may determine.

(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 a prescribed duration as per the guidelines. least three years after last use.

Prohibited advertising practices

82. (1) The following advertising practices are prohibited

(a) advertising of unregistered products;

(b) claims that a product has no side effects;

(c) promotional activities disguised as scientific or educational;

(d) promotional activities disguised as scientific or educational;

(e) any advertising contrary to the guidelines.

(2) As per section 119 of the MRSA and 63 of the regulations 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

83. (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 as prescribed in the guidelines.

(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 medical products;

(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 XI INSPECTION AND ENFORCEMENT

Appointment of inspectors

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

(2) Inspectors shall

(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.

Inspections of Establishment

85. **(1)** The Authority may, in accordance with the Act, conduct inspections of any licensed establishment or any premises where regulated activities are conducted to determine compliance with the Act, these Regulations, the applicable guidelines and the relevant Good Practices.

(2) The Authority shall conduct inspections using a risk-based approach in accordance with guidelines issued by the Authority.

(3) The Authority may conduct pre-licensing, pre-Authorisation, post Authorisation, routine, renewal, follow-up, for-cause, remote, announced or unannounced inspections, as it considers necessary.

(4) The establishment shall provide authorised inspectors with access to the premises, regulated products, records, equipment, personnel and any other information required by the Authority to verify compliance with the Act and these Regulations.

(5) Following an inspection, the Authority may issue observations, require corrective and preventive actions, impose licence and marketing authorisation conditions, or take any other regulatory action authorised under the Act.

(6) The Authority may issue guidelines prescribing the risk-based inspection framework, inspection procedures, inspection frequency, inspection classifications and any other matters necessary for the implementation of this regulation.

(7) 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.

(8) 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.

(9) 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.

(10) Inspections may be conducted as announced or unannounced inspections, depending on the purpose, risk profile, and regulatory context as determined in the applicable guidelines.

(11) 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.

(12) 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.

(13) 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 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 terminated 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 terminated, the Authority shall

(a) record the reasons for the termination in writing;

(b) notify the licensee of the termination 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 terminated 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 termination as an adverse inspection outcome for the purposes of compliance and risk profiling.

Sampling and testing

87. (1 **(1)** An authorised officer may, in the exercise of his or her powers under the Act, take samples of any regulated product, raw material, packaging material, substance or other article from any licensed establishment or any premises where regulated activities are conducted for the purpose of examination, testing, analysis or investigation.

(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 documented evidence of sampling to the person from whom the sample was taken.(4) The evidence of sampling shall be in prescribed form 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.

(6) The Authority may issue guidelines prescribing the procedures for the collection, handling, transportation, storage, analysis and disposal of samples taken under this regulation.

PART XII CONTROL OF CLINICAL TRIALS

88. Clinical Trials

(1) The applicant shall apply to the Authority in a prescribed Form accompanied by a fee set out.

(2) The Authority shall issue an applicant a written approval for use of medicines regulated under the Act.

(3) The Authority shall keep registers of —

(a) medicines and sites approved for clinical trials; and

(b) all authorised and rejected clinical trials.

(3) the clinical trials shall be conducted according to the set standards and guideline.

(4) The Authority shall inspect clinical trial sites for readiness and Inspection and compliance with good clinical practices

(5) 58. (1) The Authority may suspend or terminate an approval to conduct clinical trials where the Authority determines that the use of the medicines under trial is not safe or the anticipated benefits cannot be realised

(6) (2) The trials may also be suspended or terminated if the conduct is not according to the approval issued under these Regulations

(7) the Authority shall publish a list of all approved and rejected CT applications, as well as summary evaluation reports and shall be updated periodically.

PART XIII INTERNATIONAL COOPERATION

International cooperation agreements

89. (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

90. (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.

(4) The Authority may issue guidelines prescribing the procedures for the purposes of this regulation.

Regulatory harmonisation

91. (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

92. (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 surveillance monitoring systems such as Global Surveillance Monitoring System and the Rapid Alert System for;

(a) substandard and falsified products;

(b) serious safety signals;

(c) quality defects; and

(d) enforcement actions.

PART XIV ELECTRONIC SYSTEMS

Electronic submissions

93. (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

94. (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

95. (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 XV OFFENCES AND PENALTIES

General offences

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

(a) manufactures, imports, exports, distributes, sells or supplies a regulated product without the required registration or licence;

(b) provides false or misleading information to the Authority or relevant body;

(c) obstructs an inspector in the performance of duties;

(d) fails to comply with a lawful directive/instruction 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

97. (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

98. (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

99. (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

100. (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 XVI APPEALS

Right of appeal

101. (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

102. (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 Authoritys decision;

(b) set aside the Authoritys decision;

(c) vary the Authoritys 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 XVII MISCELLANEOUS PROVISIONS

Guidelines and directives

103. (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 Authoritys 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

104. (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

105. (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

106. (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

107. (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

108. 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

_____

MINISTER OF HEALTH

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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ 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)	

Physical Address in Botswana	
Telephone	
Email Address	
Form GEN-03 Attached?	☐ Yes ☐ No ☐ N/A

PART C: PRODUCT DETAILS

Product Category	☐ Human Medicine Device ☐ Vaccine/Biological ☐ Veterinary Medicine ☐ Medical device ☐ in-vitro device ☐ Cosmetic ☐ Traditional Medicine ☐ 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)

☐ 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

☐ Risk Management Plan

☐ 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	
Validation Outcome	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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.

Submit to the Authority before or with the registration application and during any post-authorisation Local Technical Representative (LTR) updates or appointments.

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

☐Other,Specify_____

_____

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

PART D.. ADDITIONAL COMMENTS BY MARKET AUTHORISATION HOLDERS

PART E: 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ 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?~~	☐ ~~Yes~~ ☐ ~~No~~
~~Any recalls during the period?~~	☐ ~~Yes~~ ☐ ~~No~~
Periodic Safety Update Report attached?	☐ Yes ☐ No ☐ N/A

PART D: MANUFACTURING AND COMPLIANCE

Current Manufacturer	
GMP Certificate Valid?	☐ Yes ☐ No
GMP Certificate Expiry Date	
Any changes to manufacturing site?	☐ Yes ☐ No
Any approved variations since registration?	☐ Yes ☐ No

PART E: CHECKLIST OF ATTACHMENTS

☐ Proof of payment of prescribed renewal fee

☐ Updated benefit-risk assessment

☐ Summary of pharmacovigilance data and Periodic Safety Update Report

☐ Updated Risk Management Plan

☐ 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date:

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.

.

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:

Justification for the change:

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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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:

Impact assessment and actions taken or proposed:

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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ 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	☐ Owned ☐ Leased ☐ Other (specify)
Total Floor Area (sq. m)	
Floor plans attached?	☐ Yes ☐ 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?	☐ Yes ☐ No
Temperature monitoring system in place?	☐ Yes ☐ No
Traceability system in place?	☐ Yes ☐ 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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	☐ Yes ☐ No (if yes, attach details)
Key Personnel	☐ Yes ☐ No (if yes, attach details)
Scope of Activities	☐ Yes ☐ No (if yes, attach details)
Quality Management System	☐ Yes ☐ No (if yes, attach details)
Equipment	☐ Yes ☐ No (if yes, attach details)

Compliance status	☐ Yes ☐ No (if yes, attach details)

PART C: COMPLIANCE SUMMARY

Any regulatory actions during licence period?	☐ Yes ☐ No
Outstanding corrective actions from last inspection?	☐ Yes ☐ No
Any product recalls during the period?	☐ Yes ☐ No
Any adverse events reported?	☐ Yes ☐ 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: _____

FOR OFFICIAL USE ONLY

Application Reference No.	
Date Received	
Assessment Officer	
Validation Outcome	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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:

PART C: CONTINUITY ASSURANCE

Will operational standards be maintained?	☐ Yes ☐ No
Any changes to key personnel?	☐ Yes ☐ No
Any changes to premises?	☐ Yes ☐ No
Any changes to scope of activities?	☐ Yes ☐ 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ 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	☐ Kazungula ☐ Mamuno ☐ Pioneer ☐ Ramokgwebana ☐ SSKIA ☐ Tlokweng
Expected Date of Arrival	
Mode of Transport	
Cold Chain Required?	☐ Yes ☐ 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	

Validation Outcome	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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?)	☐ Yes ☐ No ☐ 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	

Remarks	

Name: _____

Signature: _____

Date: _____

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?	☐ Yes ☐ No
Destination Country Import Authorisation Attached?	☐ Yes ☐ 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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	☐ Pharmacist ☐ Veterinary Surgeon
Professional Registration No.	
Licensed Establishment Name	
Licence Number	
Physical Address	
Telephone / Email	

PART C: SUBSTANCE DETAILS

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)	☐ Yes ☐ No ☐ N/A
Export/Import Authorisation from Other Country Attached?	☐ Yes ☐ 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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?	☐ Yes ☐ No
Special Handling Instructions	
Purpose of Testing	☐ Registration ☐ Market Surveillance ☐ Quality Complaint ☐ Batch Release ☐ 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

Z

BOTSWANA MEDICINES REGULATORY AUTHORITY

FORM GEN-16

HUMAN MEDICINES ADVERSE DRUG REACTION/ADVERSE EVENT REPORTING FORM

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

INSTRUCTIONS

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

Submission of adverse event reports for all other regulated products shall be as prescribed in the specific product regulations and guidelines.

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	☐ Male ☐ Female ~~☐ 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:

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:

PART F: ADDITIONAL INFORMATION

Any additional relevant information, laboratory results, or investigations:

Name:

Signature:

Date: _____

FOR OFFICIAL USE ONLY	
Application Reference No.	
Date Received	
Assessment Officer	
Validation Outcome	☐ Complete ☐ Incomplete ~~☐ Returned~~
Decision	~~☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused~~
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

BOTSWANA MEDICINES REGULATORY AUTHORITY

FORM GEN-17

APPLICATION FOR ADVERTISING APPROVAL

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

INSTRUCTIONS

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	☐ Healthcare Professionals Only ☐ General Public ☐ Both
	☐ Print ☐ Electronic
~~Media Channel(s)~~	~~☐ Print ☐ TV ☐ Radio ☐ Online ☐ Social Media ☐ Outdoor ☐ Other~~
~~Campaign Duration (Start - End)~~	

Key claims made in the advertisement:

References supporting claims:

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 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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Deferred ☐ Rejected
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.						

2.						
3.						

Reason for Sampling	☐ Routine ☐ Complaint ☐ Surveillance ☐ Investigation ☐ Other
Sampling Method Used	
Chain of Custody Maintained?	☐ Yes ☐ 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:

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	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	

Remarks	

Name: _____

Signature: _____

Date: _____

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:

PART C: GROUNDS OF APPEAL

State the grounds upon which the appeal is based:

PART D: RELIEF SOUGHT

State the relief or order sought from the Appeals Committee:

Do you request suspension of the decision pending appeal?

☐ Yes ☐ No

If yes, state reasons:

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.

Name: _____

Signature: _____

Date: _____

FOR OFFICIAL USE ONLY	
Application Reference No.	
Date Received	
Assessment Officer	
Validation Outcome	☐ Complete ☐ Incomplete ☐ Returned
Decision	☐ Approved ☐ Approved with Conditions ☐ Deferred ☐ Refused
Reference/Licence No. Issued	
Validity Period	
Remarks	

Name: _____

Signature: _____

Date: _____

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	12 months	Commencement	Serious Adverse event 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