STATUTORY INSTRUMENT NO. ___ OF 2026

MEDICINES AND RELATED SUBSTANCES ACT, 2025

(Act No. 29 of 2025)

HUMAN MEDICINES REGULATIONS, 2026

(Published on _____, 2026)

ARRANGEMENT OF REGULATIONS

Commented [KM1]: Update list here after finalising added sections,

IN EXERCISE of the powers conferred on the Minister of Health by sections 32, 79, 123 and all other enabling provisions of the Medicines and Related Substances Act, 2025 (Act No. 29 of 2025), and after consultation with the Botswana Medicines Regulatory Authority, the following Regulations are hereby made —

PART I — PRELIMINARY

Citation and commencement

1. (1) These Regulations may be cited as the Human Medicines Regulations, 2026.

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

(3) Different dates may be appointed for different provisions of these Regulations.

Interpretation

2. In these Regulations, unless the context otherwise requires —

"Act" means the Medicines and Related Substances Act, 2025;

"active pharmaceutical ingredient" means any substance or mixture of substances used in a finished pharmaceutical product intended to furnish pharmacological activity or to otherwise have a direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have a direct effect in restoring, correcting or modifying physiological functions in humans, and includes API;

"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 regulated product as defined in the Act, whether or not related to the regulated product.

"Authority" means the Botswana Medicines Regulatory Authority continued under section 5 of the Act;

"batch" means a defined quantity of starting material, packaging material or product processed in a single process or series of processes so as to ensure homogeneity, and in the case of continuous manufacture, a defined fraction of the production characterised by its intended homogeneity, and includes lot;

"benefit-risk balance" means an evaluation of the positive therapeutic effects of a medicine in relation to the risks relating to its quality, safety and efficacy for any use for which it is authorised;

"bioequivalence" means the absence of a significant difference in the rate and extent of absorption of the active substance between two pharmaceutical equivalents or pharmaceutical alternatives when administered at the same molar dose under similar conditions;

"biological medicine" means a medicine whose active substance is produced by or extracted from a biological source, and which requires a combination of physico-chemical-biological testing together with the production process and its control for characterisation and determination of quality;

"Biopharmaceutics Classification System" means the scientific framework for classifying drug substances based on their aqueous solubility and intestinal permeability, and includes BCS;

"biosimilar" means a biological medicine that is highly similar to an already registered reference biological medicine in terms of quality characteristics, biological activity, safety and efficacy, notwithstanding natural variability inherent to the biological source;

“Cancellation”- the removal of an application from the registration process before a decision is made either as requested by the applicant or for reasons as determined by the authority

"Common Technical Document" means the internationally harmonised format for the organisation of documentation for marketing authorisation applications, comprising the five modules adopted by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and includes CTD;

"controlled medicine" means a medicine containing substances controlled under the Act, the Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, or international conventions to which Botswana is a party;

"dosage form" means the physical form in which a finished pharmaceutical product is presented for administration, including tablet, capsule, solution, suspension, emulsion, ointment, cream, suppository, injection, patch and inhalation form;

"essential medicines list" means the list of medicines maintained by the Ministry responsible for health that satisfies the priority healthcare needs of the population of Botswana;

"fixed-dose combination" means a medicine containing two or more active pharmaceutical ingredients in a fixed ratio of doses in a single dosage form;

"General Regulations" means the Medicines and Related Substances (General) Regulations, 2026;

"generic medicine" means a pharmaceutical product that has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as a reference medicine, and whose bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies or otherwise justified;

"Good Clinical Practice" means the international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials, as defined by the International Council for Harmonisation, and includes GCP;

"Good Distribution Practice" means the standards governing the procurement, receipt, storage, handling, distribution and return of regulated products to ensure their quality and integrity throughout the supply chain, as specified in World Health Organization Technical Report Series No. 1025 and subsequent revisions, and includes GDP;

"Good Manufacturing Practice" means the standards governing the manufacture of medicinal products to ensure they are consistently produced and controlled according to quality standards appropriate to their intended use and as required by the marketing authorisation or product specification, as specified in guidelines issued by the Authority, and includes GMP;

"interchangeable medicine" means a medicine that is therapeutically equivalent to a reference medicine and may be substituted for the reference medicine in clinical practice;

"key personnel" means any person who performs critical functions in the manufacture, quality assurance, quality control, distribution or dispensing of human medicines, holds the qualifications and competencies required by the Authority for the designated role, is specifically designated in the licence or approved by the Authority, and exercises professional judgment that directly affects product quality, safety or regulatory compliance, and includes a Responsible Pharmacist, Qualified Person, Production Manager, Quality Assurance Manager and Quality Control Manager;

"local technical representative" means a person resident or incorporated in Botswana appointed by a non-resident applicant to act on his or her behalf for the purposes of these Regulations;

"marketing authorisation" means a registration certificate issued by the Authority permitting a human medicine to be placed on the market in Botswana, and includes registration;

"marketing authorisation holder" means the person or entity to whom a marketing authorisation has been granted, and includes the holder of a registration certificate;

"medication error" means any unintended failure in the treatment process that leads to, or has the potential to lead to, harm to the patient, including errors in prescribing, dispensing, preparation, administration and monitoring;

"medicine" has the meaning assigned to it in section 2 of the Act;

"new chemical entity" These are **novel molecules**, or formulations **including** all biological medicines. For these, detailed pharmaceutical, pharmacological and clinical documentation shall be submitted.;

"orphan medicine" means a medicine intended for the diagnosis, prevention or treatment of a rare disease as provided for in section 44 of the Act;

"patient information leaflet" means the written information accompanying a medicine that is intended for the patient or end user;

"Periodic Benefit-Risk Evaluation Report" means a report providing an evaluation of the benefit-risk balance of a medicine at defined time points in the post-marketing period;

"pharmaceutical equivalents" means products that contain the same amount of the same active substance in the same dosage form and route of administration that meet the same or comparable standards;

"Qualified Person" means a person who has the qualifications and experience required by the Authority to certify batches of medicines for release, in accordance with the Act and the guidelines, and includes QP;

"qualified person responsible for pharmacovigilance" means a person designated by a marketing authorisation holder who is responsible for the establishment and maintenance of the pharmacovigilance system and who has the required qualifications and experience, and includes QPPV;

"rare disease" means a disease or condition affecting not more than five in ten thousand of the population of Botswana;

"reference medicine" means a medicine against which a generic or biosimilar medicine is compared;

“Reinstatement”- the restoration of a marketing authorisation that was previously suspended or ceased to be valid due to specific regulatory actions

“Rescind” - a change in any regulatory decision made by the authority

"responsible pharmacist" means a registered pharmacist designated in a licence as having overall responsibility for the pharmaceutical operations of a licensed establishment;

“Revoke”- the permanent discontinuation of MA when a registered medical products’ benefits no longer outweigh its risks, or when a MAH fails to comply with regulatory obligations

"risk management plan" means a detailed description of the risk management system for a particular medicine, and includes RMP;

"shelf life" means the period during which the quality of a product remains acceptable for its intended use when stored under the conditions stated on the label, established on the basis of stability studies;

"signal" means information arising from one or more sources suggesting a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, judged to be of sufficient likelihood to justify verificatory action;

"Stringent Regulatory Authority" means has the meaning determined by the Authority in guidelines, having regard to the World Health Organization definition, and includes SRA;

"summary of product characteristics" means the document providing the essential scientific information needed for the safe and effective use of a medicine by healthcare professionals, and includes SmPC.

"Suspension"- a temporary discontinuation of MA when a registered medical products' benefits no longer outweigh its risks, or when a MAH fails to comply with regulatory obligations

"urgent safety restriction" means Urgent regulatory action triggered by the marketing authorisation holder or a national regulatory authority in the event of, or to prevent, a risk to human health or to the environment

"Withdrawal"- the request for permanent discontinuation of a medical product's authorization by the MAH, often for commercial, administrative, or safety reasons.

Application

3. (1) These Regulations apply to all medicines for human use placed on the market in Botswana, including —

(a) allopathic medicines, being new chemical entities, generic medicines, biological medicines, biosimilars and fixed-dose combinations;

(b) controlled medicines;

(c) orphan medicines; and

(d) such other categories of medicines for human use as the Authority may determine by notice in the Gazette.

(2) These Regulations do not apply to complementary medicines, traditional medicines or homeopathic medicines, which are governed by the Complementary Medicines Regulations.

(3) Matters of general application across all regulated products, including governance and administration of the Authority, the National Quality Control Laboratory, international cooperation, electronic regulatory systems and the general offences framework, are governed by the General Regulations and shall apply to the extent they are not inconsistent with these Regulations.

(4) Where there is any conflict between these Regulations and the General Regulations, these Regulations shall prevail to the extent of the inconsistency in respect of human medicines.

(5) Clinical trials involving investigational medicinal products for human use are governed by the Clinical Trials Regulations and shall be read together with these Regulations where applicable.

Regulatory principles

4. (1) In exercising its functions under these Regulations, the Authority shall —

(a) apply a risk-based approach to the assessment, registration and ongoing oversight of human medicines;

(b) facilitate timely access to safe, effective and quality-assured medicines;

(c) promote the rational use of medicines and the containment of antimicrobial resistance;

(d) support regulatory reliance and recognition in accordance with section 109 of the Act;

(e) encourage the development, local manufacture and use of essential medicines;

(f) safeguard the integrity and transparency of the medicines regulatory system;

(g) protect patient safety as the paramount consideration; and

(h) progressively implement regulatory system strengthening benchmarked against the World Health Organization Global Benchmarking Tool maturity levels.

(2) The Authority shall have regard to the guidance and standards of the World Health Organization, the International Council for Harmonisation, the Pharmaceutical Inspection Co-operation Scheme, and the Southern African Development Community Medicines Regulatory Harmonisation Programme in the exercise of its functions and any other as prescribed.

(3) Detailed requirements and procedures shall be set out in guidelines issued by the Authority, which may be amended without amendment to these Regulations.

PART II — MARKETING AUTHORISATION

Requirement for marketing authorisation

5. (1) In accordance with section 35 of the Act, no human medicine shall be placed on the market, imported, manufactured, distributed, sold, promoted, advertised, stored for commercial purposes or dispensed unless it holds a valid marketing authorisation issued by the Authority.

(2) Sub regulation (1) does not apply to —

(a) investigational products used in clinical trials approved by the Authority in accordance with the Clinical Trials Regulations;

(b) medicines imported for personal use by a person entering or re-entering Botswana, subject to regulation 69;

(c) medicines supplied under the provision for exemption from registration in accordance with the Act;

(d) medicines imported under emergency provisions during a declared public health emergency in accordance with the provisions of the Act; and

(e) extemporaneous preparations made by a pharmacist for a particular patient in accordance with a prescription.

(3) A person who contravenes subregulation (1) commits an offence and is liable to the penalties provided in the Act.

Registration pathways

6. (1) The Authority shall operate the following registration pathways for human medicines —

(a) Normal Evaluation Pathway as defined by the standard fees as stipulated in schedule 4 of the MRS Fees and Levies Regulations;

(b) as defined by the expedited fees as stipulated in schedule 4 of the MRS Fees and Levies Regulations;

(d) (2) Notwithstanding the provisions of regulation 6 (1) above, the same standards of quality, safety, and efficacy required registration shall be maintained.

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

Application for marketing authorisation

7. (1) An application for a marketing authorisation shall be made in the prescribed form and shall be accompanied by —

(a) the prescribed application fee as set out in the Fees Regulations;

Common Technical Document as per the ICH M4Q guideline;

(b) samples, if requested by the Authority; and

(c) such other information as may be specified in the guidelines.

(2) An applicant who is not resident or incorporated in Botswana shall appoint a local technical representative who —

(a) is a natural person ordinarily resident in Botswana or a company incorporated in Botswana;

(b) is responsible for all communications with the Authority;

(c) ensures compliance with regulatory requirements;

(d) receives and processes safety reports and complaints;

(e) facilitates inspections and information requests; and

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

(3) The appointment of a local technical representative shall be in writing, signed by both parties, filed with the Authority before or with the application, and updated within fourteen days of any change.

Assessment of applications

8. (1) The Authority shall assess applications having regard to —

(a) the quality, safety and efficacy of the medicine;

(b) the risk classification of the medicine;

(c) the appropriateness of the proposed labelling, summary of product characteristics and patient information leaflet;

(d) compliance with relevant standards and guidelines;

(e) the benefit-risk balance for the Botswana context; and

(f) the adequacy of the risk management plan and pharmacovigilance arrangements.

(2) The Authority may, during the assessment —

(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 external laboratories;

(d) consult with external experts or technical committees;

(e) rely on assessments by recognised regulatory authorities; and

(f) request a meeting with the applicant.

(3) Where additional information is requested —

(a) the request shall be in writing, specifying the information required and a reasonable timeframe as prescribed in applicable guidelines;

(b)

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

(4) The Authority shall, within the applicable assessment timeline —

(a) grant the marketing authorisation where an application to register medicines is successful;

(b) refuse the marketing authorisation, stating reasons in writing.

(5) The Authority shall, before making a decision to refuse a marketing authorisation, give the applicant an opportunity to make representations within applicable timelines.

Registration conditions

9. (1) The Authority shall specify conditions for registration for a particular medicine or group of medicines and may –

(a) amend any conditions for registration at any time where new information warrants;

(b) specify product labelling requirements; or

(c) determine what is to be described in the label or packages of medicines.

; and

(d) such other matters as the Authority considers necessary to protect public health.

(2) The marketing authorisation holder shall comply with all conditions imposed and shall be responsible for the importation, advertising and promotion of the medicine(s).

Maintenance of registers

10 (1) The Authority shall maintain and publish a register of all human medicines registered in Botswana, including registration numbers, product names, marketing authorisation holders, schedules, validity periods and any conditions;

(2) The Registers shall be publicly available, published on the Authority's website.

Publications

11. The authority may publish summaries of technical assessment reports for approved and rejected registration.

Validity and renewal of marketing authorisation

12. (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 reporting of any post approval changes; and

(d) no active suspension or cancellation.

(2) An application for renewal shall be —

(a) made in the prescribed form;

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

(c) accompanied by the prescribed renewal fee, and in line with the prescribed guideline.

d) Notwithstanding (c), the Authority may require submission of additional data

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

(4) a lapsed marketing authorisation shall require a new application with full fees.

(5) The Authority may, renew with amended conditions, or refuse renewal, stating reasons in writing.

Variations to marketing authorisation

13. (1) In accordance with section 40 of the Act, no change to a registered medicine 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 minor effects on quality, safety or efficacy; and

(c) notifications, being changes that have minimal or no effect on quality, safety or efficacy. Such notifications do not require prior approval but must be notified to the authority immediately after implementation (immediate notification (IN), or within 12 months following implementation (annual notification (AN)) of the change. Additional documentation may be requested by the Authority to fully support the notification.

(4) A person who contravenes subregulation (1) commits an offence and is liable to the penalties provided under section 40(3) of the Act.

Notifications by marketing authorisation holders

14. (1) A marketing authorisation holder shall notify the Authority within thirty days of the occurrence of —

(a) any restriction, suspension or withdrawal of the medicine in any other country;

(b) any new safety information that may affect the benefit-risk balance;

(c) any regulatory action taken by another regulatory authority in relation to the medicine;

(d) any change in Good Manufacturing Practice status of the manufacturing site;

(e) discontinuation of marketing or manufacture; and

(f) such other matters as may be specified in the guidelines.

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

Suspension, cancellation/revocation and withdrawal

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

(a) the medicine no longer meets registration requirements and conditions;

(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 medicine is no longer manufactured in accordance with Good Manufacturing Practice;

(f) the marketing authorisation holder fails to pay required fees; or

(g) it is not in the public health interest.

(2) Before suspending, cancelling or revoking a marketing authorisation, except in emergencies, the Authority shall notify the marketing authorisation holder in writing of the proposed action and reasons, and provide an opportunity to make representations within the prescribed timelines.

(3) Where immediate action is required to protect public health, the Authority may immediately suspend a marketing authorisation pending full consideration and shall notify the holder immediately, complete the consideration process within the prescribed time, and either lift the suspension, confirm cancellation, or impose conditions.

(4) The Authority shall publish notice of suspensions, and cancellations in the Gazette, in at least one newspaper with wide national circulation, and on the Authority's website.

(15) Withdrawal of Marketing Authorisation

A marketing authorisation holder who wishes to withdraw his or her medicines from the market shall provide the Authority with —

(a) information on the decision to withdraw;
(b) the effective date of withdrawal;
(c) reasons for withdrawal; and
(d) the plan of communication to prescribers and dispensers.

Data protection

16. (1) Data submitted in support of the registration shall be protected against unfair commercial use, having regard to the provisions of the Act and international agreements to which Botswana is a party.

(2) Data protection shall not prevent the Authority from —

(a) relying on published literature and publicly available information;

(b) granting marketing authorisations on the basis of independent data; or

(c) taking regulatory action in the interest of public health.

PART III — CONTROLLED MEDICINES

Classification of controlled medicines

17. (1) Controlled medicines are classified in the schedules set out in Schedule 2 to these Regulations, aligned with the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and the Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act.

(2) The Authority may, by notice in the Gazette and after consultation with the Minister, amend Schedule 2 to add, remove or reclassify substances.

(3) The Authority shall maintain and publish the substance lists for each schedule in the guidelines.

Additional requirements for controlled medicines

18. (1) In addition to the requirements for marketing authorisation under Part II, controlled medicines are subject to the following —

(a) secure storage in accordance with regulation 34 and the guidelines;

(b) prescription by an authorised prescriber in accordance with regulation 32;

(c) record keeping in separate controlled medicines registers in accordance with regulation 35;

(d) reporting to the Authority, including annual estimates of requirements for narcotics, psychotropics and precursors;

(e) import and export permit requirements in accordance with regulation 36;

(f) reconciliation of quantities imported against quantities utilised; and

(g) disposal by methods approved by the Authority in the presence of an inspector or designated officer.

Prescription and dispensing of controlled medicines

19. (1) Schedule 1A, 1B and 1C medicines may only be prescribed by a medical practitioner or dentist.

(2) A prescription for a Schedule 1A, 1B or 1C medicine shall —

(a) be in writing, signed by the prescriber and dated;

(b) state the quantity of the medicine in both words and figures;

(c) not prescribe a quantity exceeding thirty days' supply;

(d) be presented for dispensing within thirty days of the date of issue; and

(e) be retained by the dispenser for a period of five years.

(3) Schedule 1A, 1B and 1C medicines may only be dispensed by a registered pharmacist.

(4) Every Schedule 1A, 1B and 1C medicine shall, except when being administered to a patient, be kept under safe custody in a lockable cabinet or safe that is securely fixed.

Emergency dispensing of controlled medicines

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

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

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

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

(2) Where a medicine is dispensed under subregulation (1), a written prescription shall be provided by the prescriber within forty-eight hours.

(3) The quantity dispensed shall not exceed the quantity stated in the most recent valid prescription and shall not exceed thirty days' supply.

Storage of controlled medicines

21. (1) Every establishment handling Schedule 1A, 1B and 1C medicines shall store them in —

(a) a fixed, lockable, steel safe or cabinet of adequate construction meeting the specifications in the guidelines; or

(b) a dedicated, locked room with controlled access, where the volume of stock warrants.

(2) Access to the storage area shall be limited to authorised personnel.

(3) Schedule 2 and 3 medicines shall be stored under security conditions appropriate to their risk classification, as specified in the guidelines.

Records for controlled medicines

22. (1) Every establishment authorised to handle controlled medicines shall maintain separate registers for each schedule, recording —

(a) quantities received, issued, spoiled, disposed of and the balance of the medicine concerned;

(b) name and business address of the supplier;

(c) date on which the medicine was received;

(d) name and address of the person to whom the medicine was dispensed or supplied;

(e) prescription number or order reference upon which the medicine was dispensed;

(f) date of dispensing or supply; and

(g) name and address of the prescriber.

(2) Registers shall be maintained in indelible ink or in an electronic system with a secure audit trail, balanced within thirty days, retained for a minimum of five years, and available for inspection at all times.

(3) A person who fails to comply with this regulation commits an offence and is liable to the penalties provided under section 68(5) of the Act.

Import and export of controlled medicines

23. (1) In accordance with sections 67 and 68 of the Act, controlled medicines may only be imported or exported under a valid import or export permit issued by the Authority for each consignment.

(2) Applications for import or export permits shall be accompanied by —

(a) a description of the controlled medicine and the quantity in metric units;

(b) the name, address and status of the consignee;

(c) the name of the country of final destination; and

(d) where applicable, the name of the country of transit and confirmation that transit is authorised.

(3) The Authority shall provide annual estimates of national requirements for narcotic drugs and psychotropic substances to the International Narcotics Control Board in accordance with international treaty obligations.

PART IV — MANUFACTURING

Requirement for manufacturing licence

24. (1) In accordance with section 58 of the Act, no person shall manufacture a human medicine unless authorised by the Authority through a valid manufacturing licence.

(2) This regulation applies to all stages of manufacture, including primary manufacture, secondary manufacture, packaging, labelling, testing, and contract manufacture.

Categories of manufacturing licence

25. (1) The Authority shall issue manufacturing licences in the following categories —

(a) full manufacturing licence, for manufacturers who carry out all stages of manufacture including release testing;

(b) secondary manufacturing licence, for manufacturers engaged in secondary processing, packaging or labelling only; and

(c) contract manufacturing licence, for manufacturers providing manufacturing services to a marketing authorisation holder.

Application for manufacturing licence

26. (1) An application for a manufacturing licence shall be made in the prescribed form and shall include —

(a) details of the manufacturing site, including site master file;

(b) details of key personnel in accordance with regulation 40;

(c) description of products to be manufactured and dosage forms;

(d) description of manufacturing and quality control operations;

(e) a declaration of compliance with Good Manufacturing Practice; and

(f) the prescribed fee.

(2) The Authority shall, before issuing a manufacturing licence, conduct an inspection of the manufacturing premises for Good Manufacturing Practice compliance.

Key personnel requirements

27. (1) Every manufacturing licence holder shall designate the following key personnel —

(a) a Qualified Person, who shall be responsible for batch certification and release;

(b) a Production Manager, who shall be responsible for production operations; and

(c) a Quality Control Manager, who shall be responsible for quality control operations, and who shall be independent of the Production Manager.

(2) Key personnel shall hold the qualifications and experience specified in the guidelines and shall be approved by the Authority.

(3) The licence holder shall notify the Authority within fourteen days of any change in key personnel.

Good manufacturing practice compliance

28. (1) Every manufacturing licence holder shall comply with Good Manufacturing Practice requirements as specified in the guidelines and as assessed through regular inspection by the Authority.

(2) The standards of Good Manufacturing Practice shall be aligned with the World Health Organization recommendations and applicable regional harmonisation standards.

Issuance of manufacturing licence

29. (1) The Authority shall, following a satisfactory inspection, issue a manufacturing licence specifying the licence holder, the licensed site, the categories of products and dosage forms authorised, the key personnel approved, and the date of issue and expiry.

(2) A manufacturing licence shall not be transferred or used at premises other than those specified in the licence.

GMP certificate of compliance

30. (1) The Authority may, following a satisfactory Good Manufacturing Practice inspection, issue a certificate of Good Manufacturing Practice compliance for use in applications to other regulatory authorities or for the purposes of a marketing authorisation application.

Contract manufacturing

31. (1) A marketing authorisation holder who uses a contract manufacturer shall —

(a) enter into a written technical agreement with the contract manufacturer;

(b) ensure the contract manufacturer holds the appropriate manufacturing licence; and

(c) ensure Good Manufacturing Practice compliance is maintained throughout the contract.

Local manufacturing incentives

32. (1) In order to promote local manufacturing capacity, the Authority may provide priority application review for locally manufactured essential medicines, fee reductions or waivers for locally manufactured products as specified in the Fees Regulations, and technical assistance for manufacturers seeking Good Manufacturing Practice compliance.

Conditions, variation and renewal of manufacturing licence

33. (1) The Authority may impose conditions on a manufacturing licence, and such conditions shall be complied with by the licence holder.

(2) A licence holder who wishes to vary the scope of a manufacturing licence shall apply in the prescribed form, with the prescribed fee.

(3) Manufacturing licences shall be renewed annually, with application in the prescribed form and payment of the prescribed fee.

Suspension and cancellation of manufacturing licence

34. (1) The Authority may suspend or cancel a manufacturing licence where the licence holder —

(a) ceases to comply with Good Manufacturing Practice requirements;

(b) fails to comply with conditions of the licence;

(c) manufactures products not covered by the licence;

(d) provides false information to the Authority; or

(e) fails to pay required fees.

(2) Before suspending or cancelling a manufacturing licence, except in emergencies, the Authority shall give the licence holder an opportunity to make representations within thirty days.

Notification of changes affecting manufacturing licence

35. (1) A manufacturing licence holder shall notify the Authority within thirty days of —

(a) any change to the manufacturing site, including structural modifications;

(b) any change in key personnel;

(c) any change in manufacturing processes or equipment that may affect product quality;

(d) any recall, quality defect or serious Good Manufacturing Practice deviation; and

(e) cessation of manufacturing.

PART V — DISTRIBUTION, WHOLESALE, RETAIL AND DISPENSING

Requirement for licence

36. (1) In accordance with section 58 of the Act, no person shall distribute, wholesale, retail or dispense human medicines without a valid licence issued by the Authority.

Categories of licence

37. (1) The Authority shall issue licences in the following categories —

(a) distribution licence, for wholesale distributors supplying to authorised premises;

(b) wholesale licence, for wholesalers dealing in human medicines;

(c) retail pharmacy licence, for licensed pharmacies dispensing medicines to the public; and

(d) dispensary licence, for health facilities authorised to dispense medicines.

Application for distribution and wholesale licence

38. (1) An application for a distribution or wholesale licence shall be made in the prescribed form and shall include site details, key personnel particulars including the responsible pharmacist, a description of storage facilities and temperature controls, a description of the distribution system and vehicle fleet, Good Distribution Practice compliance evidence, and the prescribed fee.

Application for retail and dispensing licence

39. (1) An application for a retail pharmacy or dispensary licence shall include site details, details of the responsible pharmacist, a description of the premises including storage and dispensing areas, and the prescribed fee.

(2) A retail pharmacy or dispensary shall be under the continuous supervision of a registered pharmacist or, in the case of a dispensary in a health facility, an authorised healthcare provider.

Assessment and inspection of distribution and wholesale premises

40. (1) The Authority shall inspect distribution and wholesale premises prior to issuing a licence and at intervals determined by risk assessment thereafter, to verify compliance with Good Distribution Practice requirements.

Assessment and inspection of retail and dispensing premises

41. (1) The Authority shall inspect retail and dispensing premises prior to issuing a licence and periodically thereafter to verify compliance with applicable standards.

Issuance of licence

42. (1) Where the Authority is satisfied that an applicant meets all requirements, it shall issue the licence specifying the licence holder, the licensed premises, the categories of activities authorised, and the date of issue and expiry.

Conditions of licence

43. (1) Every licence holder shall comply with the conditions attached to the licence, maintain premises and equipment in accordance with applicable standards, comply with applicable Good Distribution Practice requirements, permit inspection by authorised inspectors at all times, report any quality defects or safety issues to the Authority, and not supply or receive medicines from or to persons who are not appropriately licensed.

Validity and renewal of licence

44.

(1) A licence issued under this Part shall be valid for one year from the date of issue.

(2) An application for renewal shall be submitted at least sixty days before expiry in the prescribed form and with the prescribed fee.

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

Suspension and cancellation of licence

45.

(1) The Authority may suspend or cancel a licence issued under this Part on the same grounds and in accordance with the same procedures as set out in regulation 47, with necessary modifications.

Prescription requirements

46.

(1) A prescription shall be issued by a person authorised by his or her professional body to prescribe medicines, and shall include the name and address of the prescriber, the prescriber's professional registration number, the date of issue, the name and address of the patient, the name and quantity of the medicine, directions for use, and the signature of the prescriber.

(2) Electronic prescriptions are permitted where the electronic system has been approved by the Authority and appropriate security and authentication measures are in place.

General dispensing

47.

(1) A person dispensing a human medicine shall verify the authenticity of the prescription and the identity of the prescriber, check for potential drug interactions or contraindications based on available information, provide the patient with adequate counselling on the correct use of the medicine, label the dispensed medicine in accordance with regulation 73(2), and record the dispensing in the dispensing register.

(2) A person shall not dispense a prescription-only medicine without a valid prescription.

(3) A prescription shall not be refilled more than the number of times indicated by the prescriber and shall not be dispensed after the validity period has expired.

Dispensing by healthcare providers other than pharmacists

48.

(1) A healthcare provider other than a pharmacist who wishes to dispense medicines shall obtain authorisation from his or her professional body, which shall be granted on condition that the healthcare provider has demonstrated competency in dispensing.

(2) A dispensary, clinic, health post or mobile clinic operated by an authorised healthcare provider shall meet the standards set out in the guidelines.

(3) Schedule 1A, 1B and 1C medicines shall not be dispensed by healthcare providers other than registered pharmacists except in the emergency circumstances provided in regulation 33.

Online pharmacy

49.

(1) In accordance with section 61 of the Act, the sale or supply of human medicines through online platforms requires a valid retail pharmacy licence, a dedicated online pharmacy permit issued by the Authority, operation under the supervision of a registered pharmacist, systems to verify prescriptions before dispensing prescription-only medicines, systems to verify patient identity, appropriate storage and distribution arrangements, prominent display of the licence number and the Authority's verification mark, and compliance with advertising requirements under Part XVI.

(2) Controlled medicines, prohibited products and restricted products shall not be sold or supplied through an online platform.

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

Record keeping for dispensing

50.

(1) Every person dispensing human medicines shall maintain dispensing records that include the information required under these Regulations.

(2) Records relating to controlled medicines shall be maintained as separate registers in accordance with regulation 35 and retained for a minimum period of five years.

(3) Dispensing records for prescription-only medicines shall be retained for a minimum period of two years.

(4) All dispensing records shall be available for inspection by inspectors at all times.

PART VI — IMPORT AND EXPORT

Requirement for import and export authorisation

51.

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

(2) Authorisation requires a valid import or export licence for the entity, and a valid import or export permit for the specific consignment.

(3) The Authority may refuse authorisation where the medicine is not registered unless an exemption applies, the product is prohibited or substandard, the remaining shelf life is inadequate, the applicant does not hold a valid licence, or it is otherwise in the public interest.

Import and export permits

52.

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

(2) An application for an import permit shall include product details including registration number, quantity and batch information, manufacturer and country of origin, supplier details, intended port of entry, expected date of arrival, and end-user information where required.

(3) The Authority shall process permit applications within five working days for routine applications, two working days for expedited applications, and one working day for emergency applications where public health is at risk.

(4) Permits shall specify the permit number, product details, authorised route, validity period not exceeding ninety days, and any conditions or inspection requirements.

Authorised ports of entry

53.

(1) Human medicines may only be imported or exported through the ports of entry designated under section 63 of the Act and as specified in the General Regulations.

Products in transit

54.

(1) Regulated products in transit through Botswana shall comply with the transit permit requirements set out in section 70 of the Act and the General Regulations, and the holder of a transit permit shall ensure the medicines remain under customs control and are not released into the domestic market.

Donated human medicines

55.

(1) In accordance with section 66 of the Act, donated human medicines require authorisation from the Authority, and an application for a donation permit shall include donor and recipient details, product details and quantities, evidence of quality requirements, remaining shelf life information, and an intended use and distribution plan.

(2) Donated medicines shall meet the same quality standards as commercially imported products, have adequate remaining shelf life, be appropriately labelled in English, and be on the national essential medicines list or otherwise appropriate for the Botswana context.

(3) The Authority may waive or reduce fees for donated products intended for humanitarian purposes.

(4) Where donated products do not meet requirements, the Authority may seize, quarantine, confiscate or order re-export at the importer's cost, in accordance with section 66(4) of the Act.

Personal importation

56.

(1) In accordance with section 64 of the Act, a person entering or re-entering Botswana may import human medicines for personal treatment without a permit, subject to the quantity being limited to a ninety-day supply, the product being accompanied by a prescription or medical documentation, the product not being prohibited in Botswana, the product being for the personal use of the person importing or a person in his or her care, and the person declaring the product at customs.

(2) Personal importation is not permitted for narcotic drugs, psychotropic substances, Schedule 1D medicines or products prohibited in Botswana, in accordance with section 64(3) of the Act.

Exemption from Registration

57. Exemption from registration of medicines for individual patient

(1) In accordance with section 35(4) of the Act, the Authority may grant access to unregistered medicines for individual patients on compassionate grounds or where no suitable registered alternative exists, through the special access scheme.

(2) An application for Exemption from registration shall be made by a registered medical practitioner on behalf of the patient and shall include medical justification for use of the unregistered medicine, evidence of efficacy and safety, information on the product and its source, and patient consent.

58. Subject to subregulation (2), the application shall comply with the guidelines and shall be signed by an importing pharmacist residing in Botswana.

(1) Special access shall be granted on a named-patient or per-patient basis and shall not constitute a general exemption from the registration requirement.

(2) Adverse events occurring in patients under special access shall be reported to the Authority in accordance with Part XIV.

(3) The validity period of the exemption from registration shall not exceed 6 months from the date of issue.

Exemption from registration of medicines for wholesale

59 (1) An applicant may apply to the Authority to exempt the registration of medicines for wholesale from outside Botswana under special circumstances as determined by the Authority.

(2) The application shall –

(a) comply with the guidelines; and

(b) be accompanied by the application fee in a prescribed **Form** set out in Schedule 1.

(3) The applicant may be required to pay for the inspection of the manufacturing site prior to authorization.

60 Exemption of donated unregistered medicines

A person may apply to the Authority for exemption from registration of Exemption of donated medicines in a prescribed Form set out in Schedule 1 and he or she shall meet donated unregistered medicines the requirements of the guidelines on donation.

PART VII — SCHEDULING AND CLASSIFICATION

Classification of human medicines

61.

(1) In accordance with section 79 of the Act and schedule 1 of the regulations, medicines for human use shall be classified into the following prescription categories —

(a) Prescription Only Medicines, which may only be supplied on the prescription of an authorised prescriber this includes schedules 1 & 2 medicines;

(b) Pharmacy Medicines, which may be sold from a licensed pharmacy without a prescription but under the supervision of a pharmacist this includes schedule 3 medicines; and

(c) General Sale List medicines, which may be sold from authorised premises without a prescription and without pharmacist supervision this includes schedule 4 medicines.

(2) The classification of a medicine shall be determined by the Authority at the time of granting a marketing authorisation, having regard to the safety profile, risk of misuse or abuse, need for medical diagnosis or monitoring, route of administration, potential for adverse interactions, novelty, and international classification practices.

(3) The Authority shall issue and maintain detailed substance lists for each prescription category in the guidelines, published in the Gazette.

Reclassification

62.

(1) The Authority may reclassify a medicine from one prescription category to another where sufficient post-market safety data support a change, there is a change in the benefit-risk balance, there is a public health need for wider or more restricted availability, or international practice supports reclassification.

(2) Before reclassifying a medicine, the Authority shall conduct a risk assessment, consult with relevant stakeholders, and publish the proposed reclassification for comment for at least thirty days.

(3) A reclassification shall be published by notice in the Gazette and on the Authority's website.

PART XIV — PHARMACOVIGILANCE

National pharmacovigilance programme

63.

(1) In accordance with section 71 of the Act, the Authority shall establish and maintain a national pharmacovigilance programme for human medicines and vaccines which shall include spontaneous adverse event reporting, signal detection, assessment and management, risk assessment and management, communication of safety information to stakeholders including healthcare professionals and the public, coordination with international pharmacovigilance systems including the World Health Organization Programme for International Drug Monitoring, and capacity building and training for healthcare professionals.

(2) The Authority shall designate a pharmacovigilance centre responsible for the operational management of the national pharmacovigilance programme.

Obligations of manufacturers, marketing authorisation holders and distributors

64.

(1) Every manufacturer, marketing authorisation holder or distributors shall plan, establish, implement, monitor and maintain an updated pharmacovigilance system, appoint a qualified person responsible for pharmacovigilance, maintain a pharmacovigilance system master file, collect, report and analyse adverse events, submit periodic benefit-risk evaluation reports, implement and maintain a risk management system, conduct post-authorisation safety and efficacy studies where required, implement any urgent safety restriction directed by the Authority, ensure product information is kept up to date with current scientific knowledge implement systems for communication of vigilance information including crisis prevention and management, and cooperate with the Authority in all pharmacovigilance activities.

Qualified person responsible for pharmacovigilance

65.

(1) Every marketing authorisation holder and distributors shall designate a qualified person responsible for pharmacovigilance who resides and operates within Botswana or within the SADC region, is appropriately qualified in a health science or life science discipline, has adequate training and experience in pharmacovigilance, is contactable at all times, and is authorised by the marketing authorisation holder to take action on pharmacovigilance matters, including urgent safety restrictions.

(2) The name and contact details of the qualified person responsible for pharmacovigilance shall be notified to the Authority and updated within fourteen days of any change.

(3) Pursuant to regulations section 7 (2), in the case where the QPPV is based outside Botswana, the marketing authorisation holder shall appoint a local technical representative who is appropriately qualified in a health science or life science discipline, has adequate training and experience in pharmacovigilance, is contactable at all times, perform pharmacovigilance activities as authorised by the marketing authorisation holder.

Pharmacovigilance system master file

66.

(1) Every marketing authorisation holder and distributor shall maintain a pharmacovigilance system master file (PSMF) providing a detailed description of the pharmacovigilance system, including the organisational structure, the qualified person responsible for pharmacovigilance, sources of safety data, standard operating procedures, databases and record-keeping systems, contractual arrangements for delegated activities, quality system documentation, and audit schedules and findings.

(2) The PSMF format shall be as prescribed in the guidelines.

(3) The pharmacovigilance system master file shall be maintained at the location of main pharmacovigilance activities and made available to the Authority upon request within seven working days.

Obligations of marketing for Public Health Programmes

67

(1) Health facilities and Public Health Programmes shall have the responsibility of monitoring the safety of regulated products distributed within their programs

(2) In accordance to section 71(5) of the Act, public health programmes shall establish a pharmacovigilance system;

a. identify focal persons to coordinate pharmacovigilance activities;

b. collaborate with the Authority to distribute reporting forms, collect safety reports, and submit reports to the Authority

c. collaborate with the Authority in implementing active surveillance or cohort event monitoring for products of interest where necessary

d. 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;

e. promote rational and safe use of products by health care providers;

f. maintain and implement a risk management system including communication of risks and effectiveness of products to relevant stakeholders

Adverse event reporting by healthcare professionals

68.

(1) In accordance with section 72 of the Act, every healthcare professional shall report to the Authority any suspected adverse events related to medicines or vaccines.

(2) Reportable adverse events include all suspected non-serious and serious adverse events, unusual frequency or severity, suspected medication errors, abuse, misuse, off-label use, and lack of expected efficacy.

(3) Reports shall be submitted using the prescribed form or through the Authority's electronic reporting system, and patients and consumers may also report suspected adverse events directly to the Authority.

(4) Reporting timelines for Adverse drug reactions shall be

(a) fatal or life-threatening reactions: within twenty-four hours;

(b) serious adverse reactions: within seven days; and

(c) non-serious adverse reactions: within thirty days;

Adverse event reporting by marketing authorisation holders and distributors

69.

(1) A marketing authorisation holder and distributor shall report adverse events, safety signals, and safety-related regulatory actions locally and internationally within timelines in schedule 4 and procedures specified in guidelines issued by the Authority.

(2) Individual case safety reports shall be submitted in any format as prescribed in the guidelines.

(3) Marketing authorisation holders shall maintain records of all adverse events for a minimum period of ten years.

Medication errors

70.

(1) Medication errors associated with human medicines shall be reported to the Authority and assessed as part of the pharmacovigilance system.

(2) The Authority shall, in collaboration with the Ministry or Ministries responsible for health, promote measures to prevent medication errors, including assessment of medication error risk during the marketing authorisation process, requiring changes to labelling, packaging or nomenclature where a risk is identified, and communicating information on medication errors to healthcare professionals and the public.

Periodic benefit-risk evaluation reports

71.

(1) Marketing authorisation holders shall submit Periodic Benefit-Risk Evaluation Reports at intervals specified in the conditions of registration and in the guidelines.

(2) A Periodic Benefit-Risk Evaluation Report shall provide a comprehensive analysis of cumulative safety data, evaluate the benefit-risk balance, include an assessment of the effectiveness of risk minimisation measures, and propose any warranted changes to the marketing authorisation. It shall also include "zero" events (i.e., situations where no events are reported).

(3) The format shall be consistent with the ICH E2C(R2) guideline or as otherwise specified by the Authority.

Risk management plans

72.

(1) A risk management plan shall be submitted as part of the marketing authorisation application for new active substances, biosimilar medicines, generic medicines where specific safety concerns are identified, products with significant identified or potential risks, and such other products as the Authority may determine.

(2) The Authority may prepare and publish a summary of the risk management plan and associated risk minimisation documents for suitable public access.

(3) The risk management plan shall be updated throughout the product lifecycle as new safety information becomes available.

(4) The RMP format shall be submitted as per specified by the Authority in the guidelines.

Signal detection and assessment

73.

(1) The Authority shall establish and maintain a system for the detection, assessment and management of safety signals through statistical and qualitative analysis of adverse event reports, review of published literature, assessment of information from other regulatory authorities, and periodic review of cumulative safety profiles.

(2) The Marketing Authorisation holder shall be required as part of their pharmacovigilance system mechanisms for conducting signal detection, investigation and management.

(3) Where a signal is validated, the Authority may request further investigation by the marketing authorisation holder, the MAH must submit a report to the Authority containing;

a) the methods and conclusions of the MAH's investigation

b) any preventive action or corrective action the manufacturer has taken or intends to take.

(4) The Authority may further require amendments to product information, impose additional risk minimisation measures, suspend or cancel the marketing authorisation, or issue a public safety communication or any other regulatory action the Authority deems appropriate to ensure public health.

Urgent safety restrictions

74.

(1) In accordance with Section 72 (1) (f) and (g), where new safety information necessitates urgent action and the marketing authorisation holder decides to implement, or is directed by another NRA to implement an urgent safety restriction, they shall notify the Authority immediately or within 72 hours.

(2) The Authority may direct a marketing authorisation holder to implement an urgent safety restriction, including suspension of supply, recall of specific batches, amendment of product information, restriction of indications or patient populations, and imposition of additional risk minimisation measures.

(3) Failure to implement an urgent safety restriction directed by the Authority constitutes an offence under section 119 of the Act.

Risk communication

75.

(1) The Authority shall communicate safety information to healthcare professionals and the public through direct healthcare professional communications, public safety alerts and advisories, the Authority's website, the Gazette where required, and coordination with the Ministries responsible for health.

(2) The Authority may require a marketing authorisation holder to prepare and disseminate safety information to healthcare professionals and the public, subject to prior approval of the content.

Post Authorisation Safety Studies

76.

(1) The Authority may impose on the marketing authorization holder the obligation to conduct post-authorization studies on safety and on efficacy as a condition at the time of the granting of the marketing authorization or at a later time whilst the product's registration is valid.

(2) The post-authorisation study shall be registered in accordance with the regulations for Control of Clinical Trials in force.

(3) The conduct and reporting of the results of the studies shall be communicated with the Authority in a manner and timelines as prescribed in the guidelines.

Good Vigilance Practices Inspections

77.

a) The Authority may inspect any marketing authorisation holders or distributors to ensure the effectiveness of their pharmacovigilance systems and ensure compliance to Good

Vigilance Practices, the Medicines and Related Substances Act, the General Regulations, these regulations and guidelines thereof.

b) The nature and conduct of the inspection will be communicated to the Inspectee as prescribed in the guidelines.

Eco vigilance

78. ***Environmental safety***

(1) The Authority may require Manufacturers, marketing authorisation holders, distributors or public health programmes to conduct post-market environmental monitoring for regulated products where the environmental risk assessment identifies potential safety concerns.

PART VIII — POST-MARKET SURVEILLANCE

Post-market surveillance programme

79.

(1) In accordance with section 74 of the Act, the Authority shall conduct a risk-based post-market surveillance programme for human medicines, including market surveillance sampling and testing, monitoring of pharmacovigilance data, analysis of complaints and quality defect reports, targeted surveillance based on risk assessment, international collaboration on safety signals and quality alerts, and periodic benefit-risk reassessment.

(2) Marketing authorisation holders shall establish and maintain post-market surveillance systems, monitor the performance of their products on the market, submit annual post-market surveillance reports as specified in the guidelines, and not supply substandard or falsified products.

Market surveillance sampling and testing

80.

(1) The Authority shall, through the National Quality Control Laboratory established under section 31 of the Act or approved external laboratories, conduct sampling and testing of human medicines on the market to verify compliance with registered specifications.

(2) Sampling shall be risk-based and shall target newly registered products, products with known quality concerns, products from manufacturers with a history of non-compliance, products identified through complaints or pharmacovigilance signals, and products selected through random surveillance.

(3) Where a product is found to be non-compliant, the Authority shall take appropriate action, which may include recall, suspension of the marketing authorisation, or enforcement action.

Product recalls

81.

(1) In accordance with section 75 of the Act, a marketing authorisation holder shall voluntarily recall a human medicine where the product is non-compliant with specifications, has caused or is likely to cause injury, is defective or mislabelled, or new safety information warrants recall.

(2) The Authority may order a recall where the marketing authorisation holder fails to initiate a voluntary recall, or the Authority determines a recall is necessary to protect public health.

(3) Recall procedures shall include classification of recall level based on risk, notification to the Authority within twenty-four hours of initiating recall, public notification where appropriate, a strategy for recovering affected products, effectiveness checks, and a final reconciliation report.

(4) Failure to comply with recall requirements constitutes an offence under regulation 102.

PART IX — ADVERTISING AND PROMOTION

Requirement for advertising approval

82.

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

(2) An application for advertising approval shall be submitted in the prescribed form and shall include the proposed advertising materials, the target audience, the media to be used, the duration of the campaign, references supporting any claims made, and the prescribed fee.

(3) The Authority shall respond to advertising applications as specified in guidelines.

(4) Approved advertisements shall display the approval reference number or any other appropriate labelling as prescribed by the Authority

Advertising standards

83.

(1) All advertising of human medicines shall be accurate, truthful and not misleading; balanced, consistent with the approved product information; not contain claims not supported by evidence; not compare products unfairly; not include offensive content; and be appropriate for the target audience.

(2) Only Schedule 1, 2 and 3 medicines shall be advertised to healthcare professionals.

(3) Advertising to the general public is permitted only for Schedule 4 medicines and complementary medicines, and disease awareness campaigns that do not promote specific products.

(4) All advertising materials shall be retained by the marketing authorisation holder for at least three years after last use.

Prohibited advertising practices

84.

(1) The following advertising practices are prohibited —

(a) advertising of unregistered human medicines;

(b) advertising of prescription medicines to the general public;

(c) use of testimonials for prescription medicines;

(d) claims of cure for serious conditions without adequate evidence;

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

(f) promotional activities disguised as scientific or educational; and

(g) inducements to healthcare professionals that may improperly influence prescribing.

(2) A person who contravenes this regulation commits an offence and is liable to a fine not exceeding P1 000 000 or imprisonment for three years, or both.

Online sales and advertising

85.

(1) Online sale and advertising of human medicines shall comply with the requirements of regulation 62 and the online advertising requirements of the General Regulations, and the Authority may take down or block websites operating in contravention of these Regulations.

PART X — OFFENCES AND PENALTIES

General offences

86.

(1) A person commits an offence under these Regulations who manufactures, imports, exports, distributes, sells or supplies a human medicine without the required registration or licence; provides false or misleading information to the Authority; obstructs an inspector in the performance of duties; fails to comply with a lawful direction of the Authority; fails to report adverse events as required; fails to implement a recall when required; advertises without approval or in contravention of approval; fails to maintain required records; fails to comply with conditions of registration or licence; imports or exports through an unauthorised port; sells expired, substandard or falsified human medicines; or 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

87.

(1) The specific offences and penalties set out in the Act apply in respect of human medicines, and the Authority may institute administrative proceedings, including the imposition of fines, in accordance with sections 119 and 121 of the Act.

Corporate liability

88.

(1) Where an offence under these Regulations 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 the offence was committed without his or her knowledge and that all reasonable steps were taken to prevent the commission of the offence.

Compounding of offences

89.

(1) The Authority may, in accordance with section 121 of the Act, compound an offence under these Regulations where the offender agrees to pay a compounding fee as set out in Schedule 5 and to comply with such remedial or corrective measures as the Authority may specify.

(2) Compounding of an offence does not affect the Authority's power to take other regulatory action, including suspension or cancellation of a licence or registration.

PART XI — APPEALS

Right of appeal

90.

(1) In accordance with sections 112 to 115 of the Act, a person aggrieved by a decision of the Authority under these Regulations may appeal to the Appeals Committee established under the Act.

(2) An appeal shall be lodged within thirty days of the date of notification of the decision appealed against, or such longer period as the Appeals Committee may allow on good cause shown.

(3) An appeal shall be in writing and shall state the grounds of appeal, the decision appealed against, and the relief sought.

(4) The lodging of an appeal does not suspend the operation of the decision appealed against, unless the Appeals Committee so orders on application.

Appeals Committee procedures

91.

(1) The Appeals Committee shall conduct proceedings in accordance with the Act and shall afford the appellant and the Authority an opportunity to be heard.

(2) The Appeals Committee may confirm, vary or set aside the decision of the Authority, and may make such order as it considers appropriate in the circumstances.

(3) Further appeal shall lie to the High Court on a question of law.

PART XII — FINAL PROVISIONS

Guidelines

92.

(1) The Authority shall issue guidelines on all matters requiring detailed specification under these Regulations.

(2) Guidelines shall be developed with stakeholder consultation, based on international best practices and WHO guidance, published on the Authority's website, regularly reviewed and updated, and 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 and technical detail for implementation.

Transitional provisions

93.

(1) Medicines registered before the commencement of these Regulations shall remain valid until their next renewal date.

(2) Applications submitted before commencement shall be processed under the requirements in force at the time of submission, unless the applicant elects to be assessed under these Regulations.

(3) Marketing authorisation holders shall, within the period specified in the guidelines —

(a) submit a summary of product characteristics and patient information leaflet in compliance with these Regulations;

(b) designate a qualified person responsible for pharmacovigilance; and

(c) establish a pharmacovigilance system in accordance with Part XIV.

(4) The Authority shall publish a detailed transitional plan specifying deadlines and procedures for compliance.

Repeal

94.

(1) The provisions of the General Regulations relating to human medicines, to the extent that they are inconsistent with or duplicated by these Regulations, are hereby superseded by these Regulations.

SCHEDULES

SCHEDULE 1

PART A — PRESCRIPTION CATEGORIES

Category	Description	Applicable Schedule
POM	Prescription Only Medicines: May only be supplied on the prescription of an authorised prescriber.	Schedule 1 & 2
P	Pharmacy Medicines: May be sold from a licensed pharmacy under the supervision of a pharmacist without a prescription.	Schedule 3
GSL	General Sale List: May be sold from authorised premises without a prescription or pharmacist supervision.	Schedule 4

SCHEDULE 2

CONTROLLED MEDICINES SCHEDULES

Schedule	Description	Control Level	Examples
1A	Narcotic drugs with no accepted medical use and high abuse potential.	Prohibited except for authorised research.	Heroin, cannabis resin (subject to Cannabis Control Act).
1B	Narcotic drugs with accepted medical use and high abuse potential.	Highest control; prescription by medical practitioner or dentist only.	Morphine, pethidine, fentanyl, methadone, oxycodone.
1C	Psychotropic substances with high abuse potential.	Highest control; prescription by medical practitioner or dentist only.	Amphetamine, methylphenidate, secobarbital, flunitrazepam.
1D	Precursor chemicals used in illicit manufacture.	Controlled manufacture and supply.	Ephedrine, pseudoephedrine, acetic anhydride.

Schedule	Description	Control Level	Examples
2	Medicines with moderate to high abuse potential.	High control; prescription required.	Codeine combinations, benzodiazepines, tramadol, ketamine.
3	Medicines with lower abuse potential.	Standard control; no prescription required.	Barbiturate combinations, certain anticonvulsants.

Substance lists shall be published in the guidelines, aligned with the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and the Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act.

SCHEDULE 4

ADVERSE EVENT REPORTING TIMELINES

Event Type	Timeline	
Marketing authorisation holders and distributors		
Fatal or life-threatening AE (domestic)	As soon as possible, no later than 15 days	
Other serious adverse events (domestic)	As soon as possible, no later than 15 days	
Non-serious adverse events (domestic)	Within 30 calendar days of initial receipt.	

Made this _____ day of _____, 2026.

MINISTER OF HEALTH

Republic of Botswana