STATUTORY INSTRUMENT NO. ___ OF 2026

MEDICINES AND RELATED SUBSTANCES ACT, 2025

(Act No. 29 of 2025)

VETERINARY MEDICINES REGULATIONS, 2026

(Published on _____, 2026)

ARRANGEMENT OF REGULATIONS

IN EXERCISE of the powers conferred on the Minister of Health by sections 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 Minister responsible for agriculture and 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 Veterinary 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 substance" means any substance or mixture of substances intended to be used in the manufacture of a veterinary medicinal product and responsible for its pharmacological activity, that, when used in its production, becomes an active ingredient of that product;

"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

"antimicrobial" means a substance that kills or inhibits the growth of microorganisms, and includes antibiotics, antifungals, antivirals and antiparasitics used in veterinary practice;

"antimicrobial resistance" means the ability of a microorganism to resist the effects of an antimicrobial to which it was previously sensitive, arising from genetic change whether through mutation or acquisition of resistance genes;

"antimicrobial stewardship (AMS)" means coordinated interventions to promote responsible antimicrobial use and minimise antimicrobial resistance;

"applicant" ….means a natural or juristic person who submits, or on whose behalf there is submitted, an application to the Authority under the Act or these Regulations for the registration, renewal, variation, retention, transfer, suspension, reinstatement, withdrawal, exemption, importation, exportation, clinical trial authorisation, special access authorisation, permit, licence, certificate, or any other regulatory approval, authorisation, determination or decision relating to any regulated product, and includes a duly authorised local representative or agent acting on behalf of such person.

"application"… means a request submitted to the Authority by an applicant, in the prescribed form and manner, together with the prescribed information, data, documents, declarations, samples, fees and any other requirements specified by the Authority, for the purpose of obtaining a registration, marketing authorisation, licence, permit, certificate, exemption, approval, variation, renewal, retention, transfer, suspension, reinstatement, revocation, cancellation, special access authorisation, import or export authorisation, clinical trial authorisation, inspection, or any other regulatory decision under the Act or these Regulations.

"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;

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

"autogenous veterinary vaccine" means a veterinary immunological product prepared from pathogens or antigens isolated from animals within a specific epidemiological unit and manufactured under a manufacturing licence, intended for use solely in animals of that same unit;

"batch" has the meaning assigned in the Human Medicines Regulations, 2026;

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

"cancellation" means the regulatory action by which the Authority terminates the validity of a marketing authorisation, registration, licence, permit, certificate or other regulatory approval granted under the Act or these Regulations, resulting in the removal of the affected authorisation from the Register and the cessation of the legal authority to manufacture, import, export, distribute, supply, sell or otherwise deal with the regulated product or conduct the regulated activity.

"cascade" means the hierarchy of options available to a prescribing veterinary surgeon for prescribing a veterinary medicine where no authorised product exists for the species, condition or indication concerned, in the order set out in regulation 53;

"Codex Alimentarius" means the collection of internationally recognised standards, codes of practice, guidelines and other recommendations relating to food, food production and food safety adopted by the Codex Alimentarius Commission established by the Food and Agriculture Organization of the United Nations and the World Health Organization;

"companion animal" means an animal kept primarily for companionship and not intended for food production, and includes cats, dogs, cage birds and ornamental fish;

"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;

"compounded veterinary medical product" means a veterinary medical product prepared by a registered pharmacist, veterinary surgeon or other authorised person pursuant to a prescription for a specific named animal or group of animals where no suitable authorised product is available;

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

"critically important antimicrobial" means an antimicrobial classified as critically important for human medicine in the most current edition of the World Health Organization Critically Important Antimicrobials for Human Medicine list, including fluoroquinolones, third and fourth generation cephalosporins, macrolides, glycopeptides, carbapenems and polymyxins;

"Department of Veterinary Services" means the Department responsible for Veterinary Services in the Ministry responsible for agriculture;

“emergence use” means use required to prevent imminent serious harm to animal health, public health, or the environment;

"Environmental Risk Assessment" means a systematic assessment of the potential risks to the environment that may arise from the use of a veterinary medical product, conducted in accordance with established national and international standards as determined by the Authority ;

"food-producing animal" means an animal whose products, including meat, milk, eggs or honey, may enter the human food chain, and includes aquatic species farmed for food;

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

"Good Distribution Practice for veterinary medicines" means the quality standards governing procurement, receipt, storage, handling, distribution and return of veterinary medicines, aligned with established international standards on Good Storage and Distribution Practices, and as specified in Authority guidelines;

"Good Manufacturing Practice for veterinary medicines" means the quality standards governing manufacture of veterinary medical products, aligned with VICH GL10 and WHO GMP guidelines for pharmaceutical products, and as further specified in Authority guidelines;

"Human Medicines Regulations" means the Human Medicines Regulations, 2026;

"JECFA" means the Joint FAO/WHO Expert Committee on Food Additives, which establishes acceptable daily intakes and maximum residue limits for veterinary drug residues in food;

"key personnel" means a person that,

(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 this includes responsible pharmacists, qualified persons, production managers, quality assurance managers, quality control managers, regulatory affairs officers, and such other persons as may be specified by the Authority.

"local technical representative" means a person resident or incorporated in Botswana appointed by a non-resident applicant to act on their behalf for regulatory purposes;

"marketing authorisation" means a registration certificate issued by the Authority permitting a veterinary 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;

"maximum residue limit or MRL" means the maximum concentration of residue of a pharmacologically active substance and its metabolites, expressed as milligrams per kilogram or micrograms per kilogram of fresh weight, legally permitted in or on a food product of animal origin, established on the basis of a JECFA evaluation, Codex Alimentarius standard or Authority determination;

"medicated feed" means animal feed into which one or more registered medicated premixes have been incorporated in accordance with a veterinary prescription;

"premix" means a registered veterinary medical product prepared for incorporation into animal feed;

"minor species" means an animal species, other than cattle, pigs, poultry, sheep and horses, for which limited authorised veterinary medicines exist due to the limited commercial viability of registration for those species, as determined by the Authority in guidelines;

"minor use"… means the use of a veterinary medicinal product in a major food-producing or companion animal species for the treatment, prevention or control of a disease or condition that occurs infrequently, affects a small portion of the population, or for which the anticipated market size is insufficient to support the full development and authorisation of a veterinary medicinal product under standard regulatory requirements.

"MUMS" means minor use and minor species applications

"named patient use" means use for a specific identified animal or herd under veterinary responsibility.

"notifications" means a formal communication submitted by an MAH to the Authority regarding safety, quality, efficacy, supply, or regulatory status of a veterinary medicinal product; where a "critical notification" means a notification relating to a risk that may result in serious harm to animal health, human health, or the environment

"non-compliance" in the context of these regulations means failure to meet quality, safety, efficacy, legal, or administrative requirements, including conditions of registration.

"off-label use" means the use of a veterinary medicine otherwise than in accordance with its marketing authorisation, including use in a different species, for a different indication,

at a different dose, by a different route of administration, or at a different treatment duration;

"One Health approach" means an integrated and unifying approach that recognises the interconnection between human health, animal health and environmental health and promotes collaborative, multisectoral and transdisciplinary approaches;

"prohibited substance" means any substance listed under these regulations as not permitted for use in food-producing animals.

"Qualified Person" means the person designated in a manufacturing licence who is responsible for certifying that each batch of veterinary medicines has been manufactured, tested and released in accordance with the marketing authorisation and applicable GMP requirements, and who meets the qualifications as prescribed by the relevant professional bodies ;

"qualified person responsible for veterinary pharmacovigilance" means the person designated by a marketing authorisation holder who is responsible for the establishment, maintenance and operation of the veterinary pharmacovigilance system, and who meets the qualifications specified in Authority guidelines;

"recognition" means acceptance by the Authority of a regulatory decision issued by another regulatory authority, subject to conditions determined by the Authority;

"**reference authority"** means a regulatory authority, organisation, or institution recognised by the Authority as meeting established standards of regulatory maturity, competence, and integrity;

"registration" …" means the entry of a regulated product into the Register maintained by the Authority following the grant of a marketing authorisation under the Act, thereby authorising the manufacture, importation, exportation, distribution, supply, sale or use of that regulated product in accordance with the conditions of the marketing authorisation.

"register"… means the official record established and maintained by the Authority under the Act, whether in electronic or other form, containing particulars of regulated products, marketing authorisations, licences, permits, certificates, establishments, persons or any other matter required to be registered under the Act or these Regulations.

"regulated establishment" means 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 the Act and these Regulations;

"Regulated product" means any medicine, veterinary medicinal product, biological product, medical device, in vitro diagnostic medical device, complementary medicine, traditional medicine, cosmetic, active pharmaceutical ingredient, or any other product regulated under the Act or prescribed by the Minister or the Authority in accordance with the Act. For the purposes of these Regulations, the Authority may determine, classify or reclassify any product as a regulated product where, having regard to its composition, intended purpose, mechanism of action, claims, mode of use or potential risk to public health, animal health

or the environment, the Authority considers that such product should be regulated under the Act.

"reliance" means the act whereby the Authority takes into account and gives significant weight to assessments, inspections, decisions, or approvals performed by another trusted authority when reaching its own independent regulatory decision.

"renewal"…. means the regulatory process by which the Authority, upon application by the marketing authorisation holder and following evaluation of compliance with the Act and these Regulations, extends the validity of a marketing authorisation or other regulatory authorisation for a further specified period, subject to such conditions, limitations, or variations as the Authority may determine.

"residues" means pharmacologically active substances, their metabolites, or degradation products remaining in edible tissues, milk, eggs, or honey;

"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.

"retention" means the regulatory process by which the Authority confirms the continued validity of a registration or other regulatory authorisation for a regulated product upon satisfaction of prescribed administrative and compliance requirements, including payment of prescribed fees and submission of prescribed information, without necessarily conducting a full scientific reassessment of the product.

"annual retention fee" means a prescribed fee payable to maintain inclusion of a registered veterinary medicine in the register.

"revoke or revocation" means the formal regulatory action taken by the Authority to withdraw permanently a marketing authorisation, registration, licence, permit, certificate or other regulatory approval granted under the Act or these Regulations, resulting in the immediate cessation of the legal authority to manufacture, import, export, distribute, supply, sell or otherwise deal with the regulated product or activity.

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

"**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;

"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

"special access"… means a regulatory mechanism administered by the Authority that permits, on a case-by-case basis and subject to specified conditions, the importation, supply, prescribing, administration or use of an unregistered or otherwise unauthorised veterinary medicinal product where there is no suitable registered alternative available and where such access is necessary to address an urgent, unmet or exceptional animal health need.

"Substance" means any matter of the following origin: human, animal, vegetable or chemicals

"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" means a temporary regulatory measure imposed by the Authority whereby a marketing authorisation, registration, licence, permit, certificate or other regulatory approval is rendered inactive, in whole or in part, for a specified period or until specified conditions are met, resulting in the immediate prohibition of manufacture, importation, exportation, distribution, supply, sale or use of the affected regulated product or activity.

"target epidemiological unit" means the specific herd, flock, or holding from which the autogenous vaccine source material was derived

"**undesirable substance or product"** means any veterinary medicinal product which—

(a) has been prohibited under these Regulations;

(b) is unsafe;

(c) is ineffective;

(d) is of poor quality;

(e) is falsified;

(f) is substandard;

(g) is contaminated;

(h) has deteriorated beyond acceptable limits; or

(i) has an unfavourable benefit-risk balance.

"Unregistered veterinary medicine or veterinary medicinal product" … means a veterinary medicine or medicinal product not granted marketing authorisation in Botswana

"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

"Variation"….means any amendment, modification or change to the terms, conditions, particulars, specifications, dossier information or approved documentation of a marketing authorisation, registration or other regulatory approval granted under the Act or these Regulations, made after approval by the Authority, and includes changes to quality, safety, efficacy, performance, labelling, manufacturing process, site, formulation, indications, packaging, shelf life, or any other approved aspect of a regulated product. **Where a**

"major variation" means a change with a significant potential impact on the quality, safety, efficacy or performance of a regulated product, and therefore requires prior approval by the Authority following a full scientific assessment before implementation

"minor variation" means a change with moderate or limited potential impact on the quality, safety, efficacy or performance of a regulated product, requiring evaluation by the Authority but not necessarily a full scientific reassessment prior to implementation; and

"notification" means a change with minimal or no impact on the quality, safety, efficacy or performance of a regulated product, which does not require prior approval and may be implemented by the marketing authorisation holder subject to subsequent notification to the Authority within a prescribed period.

"veterinary biological" means a immunological veterinary product, including vaccines, antitoxins, toxoids, and immunosera, intended to induce, stimulate, transfer or evaluate immunity in animals;

"veterinary medicine or veterinary medical product" means any substance or combination of substances presented as having properties for treating, preventing or diagnosing disease

in animals, or which may be administered to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis or euthanasia of animals;

"veterinary pharmacovigilance system master file" means a document providing a detailed description of the pharmacovigilance system used by the marketing authorisation holder for one or more of its veterinary medical products;

"veterinary surgeon" means a person registered as a veterinary surgeon under the Veterinary Surgeons Act;

"voluntary withdrawal" ….means the formal action initiated by an applicant or a marketing authorisation holder to discontinue an application or the marketing, distribution, supply, or availability of a regulated product, or to surrender a marketing authorisation or other regulatory approval, either in whole or in part, subject to acceptance or acknowledgment by the Authority, and without prejudice to the Authority's power to take regulatory action where public health, animal health, food safety or environmental risks exist.

"VICH" means the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical Products, being the trilateral body harmonising veterinary regulatory requirements between the European Union, Japan and the United States, with other jurisdictions as observers;

"withdrawal period" means the minimum period that shall elapse between the last administration of a veterinary medicinal product to a food-producing animal under the approved conditions of use and the production of food derived from that animal, including meat, milk, eggs, honey or any other edible tissue or product, in order to ensure that residues of the veterinary medicinal product do not exceed the applicable maximum residue limits established or recognised by the Authority, is usually expressed in days.

Application of these regulations

3.

(1) These Regulations apply to veterinary medicinal products which are:

(a) presented as tablets, capsules or boluses, powders, lyophilizates, cake or granules, solutions, suspensions or drenches, implants or patches, suppositories, creams, ointments, sprays, drops, pour-on, spot-on, or premixes or any other such formulation e.g., those prepared in a pharmacy or by a person permitted to do so in accordance with a veterinary prescription or in accordance with directions of a pharmacopoeia

(b) administered through an appropriate approved route of administration which includes oral, intranasal, ocular or ophthalmic, Otic or ear, topical, intravenous, intramuscular, subcutaneous, intramammary, intravaginal, intrauterine, intradermal or any other approved route

(c) used in animals which includes livestock, companion animals, poultry and other birds, wildlife & exotic species, aquaculture and bees for prevention, treatment, diagnosis or modification of physiological function or state

(d) commonly grouped or classified as:

i. pharmaceutical or small molecule medicinal products, including anti-infectives, veterinary pesticides or antiparasitic (ecto- and endo-parasiticides), anti-inflammatory and analgesics, anaesthetics and sedatives, hormonal, narcotics, psychotropics, diagnostic agents, euthanasia, antidotes, reproductive, cardiovascular, respiratory, gastrointestinal, metabolic and nutritional, dermatological, ophthalmic, Otic or immunomodulators,

ii. biological or biotechnological products including vaccines, sera, blood products, cell /gene therapies, antitoxins or other immunologicals

iii. medicated premixes or feed additives with therapeutic or pharmacological effects

iv. complementary of supplementary

v. cosmetics and other grooming products with health claims

(2) These Regulations shall be read together with the Act and General Regulations and the fees regulations. Where a conflict arises between the general regulations and these regulations, the provisions of these Regulations shall prevail to the extent of the inconsistency in respect of veterinary medicines.

(3) Matters of general application 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 apply to the extent they are not inconsistent with these Regulations.

(4) Clinical trials involving investigational veterinary medical products are governed by the Clinical Trials Regulations and shall be read together with these Regulations where applicable.

(5) Veterinary medicines that are also controlled substances under the Act shall comply with the controlled substances provisions of the Act and General Regulations and any other applicable regulations in addition to these Regulations.

Regulatory principles

4.

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

(a) apply a science-based, risk-proportionate approach to assessment, registration and ongoing regulatory oversight of veterinary medicines and the supply chain;

(b) protect animal health, public health and the environmental health as primary considerations;

(c) apply and promote antimicrobial stewardship principles consistent with the One - Health approach;

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

(e) take account of food safety including maximum residue limits and withdrawal periods;

(f) cooperate with the Department of Veterinary Services and the Ministry responsible for agriculture;

(g) have regard to VICH guidelines, Codex Alimentarius standards, JECFA evaluations, applicable WHO guidance, and other relevant international standards

(h) implement progressive regulatory system strengthening benchmarked against the established Global Benchmarking Tools.

(2) The Authority shall have regard to regional harmonisation initiatives, including those under the Southern African Development Community, in the exercise of its functions.

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

PART II — MARKETING AUTHORIZATION

Requirement Marketing Authorisation

5.

(1) No person shall import, export, manufacture, distribute, sell, promote, advertise, store or possess for commercial purposes or dispense any veterinary medicine unless it is registered, authorised through listing in the register or specifically exempted from registration by the Authority under the Act and these Regulations.

(2) Any person who wishes to undertake any of the regulated activities listed in sub-regulation (1) above, in relation to the regulated products, shall apply to the Authority for the relevant authorisation in a prescribed form and accompanied with applicable fees.

(3) A person who contravenes the provisions of sub-regulation (1) commits an offence and is liable to the penalties provided under section 35(11) of the Act.

Application for registration

6.

(1) An application for registration shall be submitted in the prescribed form and shall be accompanied by,

(a) the prescribed application fee, as stipulated in the Fees Regulations;

(b) administrative information including proof of appointment of a local technical representative, where applicable;

(c) quality data including the chemistry, manufacturing and control of the active substance, drug substance or bulk antigen, and the finished product;

(d) safety data from appropriately designed laboratory and field studies to demonstrate,

i. target animal safety ;

ii. user safety;

iii. consumer safety, particularly for products intended for use in food-producing animals; and

iv. environmental safety;

(e) efficacy data from appropriately designed laboratory and field studies.

Literature or publications of case studies, clinical trials or other appropriately designed studies, from established peer reviewed journals, may be accepted in support of registration applications as is articulated in the respective guidance documentation.

(f) proposed labelling information which includes a compliant Summary of Product Characteristics, primary and secondary product colour labels, and artwork;

(g) proof of compliance with Good Manufacturing Practice, in form of cGMP certificates and inspection reports from reference national or international regulatory bodies for all manufacturing sites;

(h) a risk management and/or pharmacovigilance plans where required by the guidelines; and

(i) any such other information as may be specified in the guidelines by the Authority

(2) Applications for registration shall follow any of the following procedures:

(a) national procedure, which can either be

i. normal

ii. expedited

iii. reliance based expedited

(b) regional collaborative procedure, and an applicant shall select a pathway of their choice.

(3) The applicant shall be responsible for the accuracy of the information and documentation submitted with respect to their application.

(4) The Authority shall, within stipulated timelines, validate the application and notify the applicant whether all the information and documentation required in accordance with the Act, regulations and relevant guidelines, have been submitted, or request for additional information as determined by the Authority

(5) Where additional information is requested, the assessment clock shall stop until a complete application or dossier is received. Failure to respond with a complete application or dossier and within stipulated timelines shall result in the application being considered for rejection.

(6) Only complete applications shall be considered for scientific assessment.

Specific product requirements

7.

(1) In addition to the requirements defined under regulation 6 above, applications for marketing authorisation of

(a) antimicrobials shall include,

i. data to demonstrate safety on target animals, users, consumers and environment

ii. risk management plans to mitigate antimicrobial resistance development

iii. antimicrobial stewardship considerations, in line with established national and/or international statutory instruments and standards

(b) Veterinary medicinal products intended for food-producing animals shall include or have established MRLs and proposed scientifically justified withdrawal periods

(c) minor use minor species products may include,

i. the reduced data package

ii. safety data from the major species can be adequately extrapolated;

iii. toxicity data to demonstrate an acceptable safety margin; and

iv. the benefit to animal welfare outweighs the data limitations.

(2) The Authority shall from time- to-time waive certain data requirements where scientifically justified and where animal and public health are not compromised.

Assessment of applications

8.

(1) The Authority shall evaluate all applications for registration to determine product quality, safety and efficacy as well as compliance to regulatory and legislative requirements

(2) Subject to the submission pathways under regulation 6 sub-regulation (2) above, the following evaluation pathways shall be considered —

(a) Full Evaluation Pathway, for new veterinary chemical entities, new veterinary biological entities, products for which no prior regulatory approval from any recognised regulatory authority exists, first-in-class products, and novel formulations or delivery systems;

(b) Abridged Evaluation Pathway, for products approved by recognised reference Authorities or approved through recognised regional harmonisation initiatives;

(c) Verification Pathway, for products with unredacted assessment reports from reference regulatory authority

(3) In applying the Abridged Evaluation Pathway, the Authority may rely on the assessments, inspections and decisions of reference regulatory authorities in accordance with section 109 of the Act while retaining full sovereign decision-making authority.

(4) The Authority may, upon written notification to the applicant with reasons given, move an application from one pathway to another where circumstances warrant, without prejudice to the applicant's right to make representations.

(5) Assessment timelines for each pathway shall be set out in the guidelines and are subject to a start-stop clock approach.

(6) Where additional information is requested during assessment, the assessment clock shall stop until a complete response is received. Failure to respond within the stipulated timeline shall result in the application being considered for rejection.

(7) Where additional information is requested during assessment, and the applicant anticipates inability to respond within the stipulated timeline, a request for extension of deadline to submit the additional information for a period not longer than twice the initial timeline, shall be submitted.

(8) The Authority shall grant an applicant, an opportunity, as stipulated in the guidelines, to provide additional information in support of their application for marketing authorisation, after which an application is considered for approval or rejection based on the benefit risk evaluation.

(9) In the case of MUMS products, the data requirements shall be proportionate to the risk posed by the product, species, or intended use.

(10) The Authority shall establish simplified or adaptive authorisation pathways for MUMS products, including,

(a) abridged dossier assessment;

(b) bibliographic evidence-based assessment;

(c) reliance on recognised reference authorities; and

(d) conditional approvals with post-authorisation commitments; recognising limited data availability while ensuring safety, quality, and efficacy.

(11) The applicant may voluntarily withdraw an application from the evaluation pipeline at any stage of assessment

Registration during animal health emergencies

9.

(1) During a declared public health emergency or in cases of animal health emergency, the Authority shall,

(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 may be 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.

Autogenous Vaccines

10.

(1) Autogenous vaccines shall be permitted only where—

(a) a causative pathogen has been identified in a defined epidemiological unit;

(b) no suitable authorised vaccine exists; and,

(c) outbreak control requires targeted immunological intervention.

(2) Applicant shall submit an application for authorisation to the Authority in a prescribed form, accompanied with prescribed fees and in accordance with requirements as may be determined by the Authority.

(3) The following requirements shall apply and the autogenous vaccines shall be,

(a) prepared by an establishment holding a manufacturing licence in the category for autogenous vaccine manufacturing;

(b) manufactured under appropriate Good Manufacturing Practice conditions as specified or determined by the Authority;

(c) comply with minimum quality and sterility standards set by the Authority.

(d) used exclusively in the specific herd, flock or group of animals from which the source pathogen material was isolated, unless otherwise authorised; and

(e) prescribed and used under the direct supervision of a registered veterinary surgeon;

(f) be subject to strict batch traceability.

(4) The Authority, upon satisfactory assessment, shall issue a conditional or temporary authorisation, or a special access (exemption) authorisation.

(5) An autogenous vaccine shall not be —

(a) placed on the market or supplied commercially;

(b) transferred between epidemiological units or used in any animal outside the specific epidemiological unit from which source material was obtained, unless authorised.

(6) Full traceability records linking each batch to the source animal, the pathogen isolate, manufacture and use records shall be maintained and made available to the Authority on request.

(7) Any suspected adverse reactions to autogenous vaccines shall be reported to the Authority

(8) Where strain drift or serious safety concerns arise, the Authority shall restrict or prohibit repeated production or import of the autogenous vaccine.

(9) The Authority shall publish guidelines specifying quality and safety requirements for autogenous vaccines including minimum pathogen characterisation, manufacturing standards and batch release criteria.

(10) Notwithstanding the provisions outlined in (2), (3) and (4) above, and in cases where an autogenous vaccine is manufactured from a pathogen sourced from a different

epidemiological unit, herd or flock, clearance shall be provided from the Director of Veterinary Services prior to authorisation for import and / or use.

Granting Marketing Authorisation and Validity

11.

(1) The Authority, upon satisfactory completion of the scientific evaluation, shall grant marketing authorisation rights, with conditions where applicable, in form of a registration certificate.

(2) At this point, the applicant becomes the marketing authorisation holder (MAH).

(3) Where the application was unsuccessful the Authority shall inform the applicant of the refusal to grant marketing authorisation in writing, stating the reasons thereof.

(4) A summary of assessment reports, approved summary of product characteristics may be published and made available to the public.

(5) A product that has been granted marketing authorisation shall be incorporated into the register of approved veterinary medicines and used as reference for subsequent regulatory processes.

(6) The MAH shall be responsible for the quality, safety, efficacy, and any other regulatory obligations related to their product, post-approval.

(7) Marketing authorisation and /or registration certificate shall remain valid for five years from the date of issue, subject to —

(a) payment of annual retention fees as prescribed in the Fees Regulations;

(b) continued compliance with all conditions of registration as may be determined by the Authority;

(c) timely submission of required pharmacovigilance and post-market surveillance reports; and

(d) no suspension, cancellation or revocation.

Establishment and maintenance of the veterinary medicines register

12.

(1) The Authority shall establish, maintain and publish a Veterinary Medicines Register, which shall include all veterinary medicinal products granted marketing authorisation rights under the Act, and these regulations.

(2) The Authority shall ensure that the register is accurate, current, and updated in real time or within prescribed timelines.

(3) The register shall include at minimum, the —

(a) product name, strength and dosage form;

(b) marketing authorisation number;

(c) name of marketing authorisation holder;

(d) approved manufacturing sites;

(e) species;

(f) route of administration;

(g) indications;

(h) approved pack sizes;

(i) scheduling status;

(j) status of the authorisation (whether active, suspended, cancelled, withdrawn).

(4) The Authority shall update the register to reflect—

(a) approvals of new products;

(b) variations to existing registrations;

(c) suspensions or cancellations;

(d) re-registration or re-instatement; and

(e) changes in product status due to enforcement action.

(5) Updates shall be published in a manner determined by the Authority to ensure transparency and regulatory visibility

Renewal of Marketing Authorization

13.

(1) An application for renewal shall be made and submitted to the Authority at least six months before expiry —

(a) in the prescribed form;

(b) accompanied by the prescribed renewal fee;

(c) with an updated dossier; and,

(d) any other supporting data as may be determined by the Authority in its relevant guidelines

(2) The Authority shall assess the application to determine the quality, safety, and efficacy of the product and if the benefit-risk profile of the product is still favourable or in the interest of animal and public health.

(3) Upon completion of assessment, the Authority may renew unconditionally, renew with amended conditions, or refuse renewal with written reasons and directions on subsequent regulatory actions for the affected products.

(4) Where renewal is applied for within the prescribed timelines, the existing marketing authorisation shall remain valid until a decision is made on the application.

(5) Where renewal is applied for after the lapse but within 90 days of expiry of the preceding marketing authorisation, a late fee shall be payable;

(6) Where renewal is not applied for after the lapse and beyond 90 days of expiry of the preceding marketing authorisation, that marketing authorisation is considered lapsed and an appropriate regulatory action(s) shall be taken by the Authority; unless otherwise an extension had been authorised by the Authority and upon consideration of the animal and public health interest;

(7) Where a holder fails to comply with renewal requirements, the Authority may,

(a) suspend the marketing authorisation or registration of the medicine;

(b) restrict distribution or supply;

(c) order recall of the medicine from the market;

(d) impose administrative penalties as prescribed;

(e) cancel the registration; or

(f) take any other regulatory action necessary to protect public health.

(8) The Authority may publish regulatory actions taken under this Regulation

(9) In the event a marketing authorisation is lapsed in accordance with sub-regulation 6 above, a fresh application for re-registration with full applicable application fees shall be considered.

Retention of Marketing Authorization

14.

(1) A marketing authorisation holder shall be responsible for ensuring that the Marketing Authorisation of each veterinary medicinal product on the register remains valid and the VMP compliant with established standards of quality, safety and efficacy at all times.

(2) The marketing authorisation holder shall retain the approved product on the veterinary medicines register upon payment of annual retention fees as prescribed in the Fees Regulations and provision of any additional information as may be required by the Authority

(3) Applications for retention of products shall be submitted by 31st of March of every year.

(4) Where a MAH fails to retain their product in accordance with provision (2) and (3) above, the Authority shall suspend or cancel the marketing authorisation of the product

(5) A product suspended or cancelled from the veterinary medicines register shall not be manufactured, imported, distributed, sold, stored, possessed, dispensed or supplied for use unless re-registered by the Authority

Variation of registration

15.

(1) No holder of a marketing authorisation for a veterinary medicinal product shall implement any change to the conditions of marketing authorisation of an approved product unless—
(a) the variation has been approved by the Authority; or
(b) the variation is expressly exempted from prior approval by the Authority under its relevant guidelines.

(2) Any unauthorised variation shall render the product non-compliant and subject to regulatory action under the Act and these Regulations.

(3) The Authority shall establish and publish a risk-based classification system for variations, which shall include at minimum—
(a) Minor Variations (Type IA and IB or equivalent categories);
(b) Major Variations (Type II or equivalent categories);
(c) Notifications Variations;

(4) The classification shall be based on the potential impact of the variation on quality, safety, and efficacy of the veterinary medicinal product.

(5) A person who implements a major or minor variation without the required prior approval by the Authority commits an offence.

(6) An application for authority to vary a marketing authorisation of a veterinary medicinal product shall be submitted to the Authority by the MAH, in a prescribed form, accompanied by applicable fees, and supporting documentation as determined by the Authority

(7) The Authority shall evaluate the variation application to determine if the change does not negatively impact the quality, safety, and efficacy of a product as well as its benefit-risk profile.

(8) A start-stop clock approach, reliance and recognition procedures shall be implemented during the assessment of the variation applications to enable improved efficiencies

(9) Upon completion of the assessment, the Authority may approve or reject a change in witing with the reasons thereof and any directions of subsequent regulatory actions for the affected product.

(10) The Authority shall review and publish applicable variation guidelines from time to time to ensure alignment with scientific and international best practice.

Notifications by marketing authorisation holders

16.

(1) A marketing authorisation holder shall notify the Authority of any information that may impact the benefit-risk balance, quality, safety, or efficacy of a veterinary medicinal product

(2) The following shall constitute mandatory notifications—

(a) quality defects, including batch failures or manufacturing deviations;
(b) serious adverse events in target animals or humans;
(c) unexpected lack of efficacy;
(d) emerging risks to public health, animal health, or the environment, including antimicrobial resistance signals;
(e) supply disruptions or shortages affecting availability;
(f) changes in manufacturing sites or critical suppliers not subject to variation approval yet impacting continuity of supply;
(g) regulatory actions taken in other jurisdictions affecting the product; and
(h) voluntary withdrawal from the market.

(3) The holder shall notify the Authority within prescribed timelines of becoming aware of —

(a) any regulatory action taken by another regulatory authority in relation to the product which includes, but not limited to any restriction, suspension, cancelation or withdrawal of the product in another country for any safety, quality or efficacy reason;

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

(c) any change in GMP compliance status of any manufacturing site;

(d) new residue safety information that may affect established MRLs or withdrawal periods, where applicable;

(e) any new antimicrobial resistance data that may affect the benefit-risk balance of an antimicrobial product;

(f) any environmental incident attributable to a product granted MA or approved by the Authority;

(g) any restriction, prohibition, or ban on use in food-producing animals in another jurisdiction;

(h) discontinuation of manufacture and/or marketing in Botswana; and

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

(4) The Authority shall assess notifications to determine the potential impact on —
(a) animal health or safety;
(b) human health and food safety;
(c) environmental safety; and
(d) benefit-risk balance of the product.

(5) As part of its assessment, the Authority may conduct expedited scientific review, request additional data or clarifications from the MAH, conduct inspections or laboratory testing or consult expert committees.

(6) Following evaluation of a notification, the Authority may, depending on potential impact, animal and/or public health interest, national economic priorities, and regulatory priorities —
(a) allow continued marketing of the product without restriction;
(b) impose conditions on continued marketing;
(c) require a variation to the marketing authorisation;
(d) order recall of affected batches;
(e) suspend the marketing authorisation;

(f) cancel or revoke the marketing authorisation; or
(g) impose other risk mitigation measures as may be deemed necessary.

(7) The Authority shall communicate the decision in writing, including the reasons and required corrective actions.

(8) Where a notification reveals a serious or unacceptable risk to animal or public health, the Authority may take immediate action, including—
(a) suspension of the marketing authorisation pending investigation;
(b) restriction of distribution or use; or
(c) emergency recall of the product.

(9) The Authority may act without prior hearing where urgent animal or public health protection is required.

Suspension of Marketing Authorisation

17.

The Authority may suspend a marketing authorisation where immediate action is necessary to protect public, animal or environmental health

(1) Suspension may be imposed where—
(a) there is a suspected or confirmed quality defect;
(b) there is emerging or unacceptable safety risk;
(c) GMP compliance is in doubt;
(d) critical data supporting authorisation is found to be deficient; or
(e) urgent regulatory investigation is required especially in cases where -.
i. the product no longer meets registration requirements or conditions;
ii. the marketing authorisation holder fails to comply with conditions of registration;
(d) the benefit-risk balance, in-terms of animal health, public health and environmental considerations, is no longer favourable; and
(e) the product poses an unacceptable risk to animal health, public health or the environment;
(f) false or misleading information was provided to the Authority
(g) annual retention fees remain unpaid after written notice;
(h) residue levels in food products are found to exceed established MRLs;
(i) it is otherwise in the animal or public health interest.

(2) Prior to implementation of a suspension, except in an emergency, the Authority shall notify the Marketing Authorisation Holder in writing of the proposed action and reasons thereof and provide them an opportunity to make representations within thirty days.

(3) Where immediate action is required to protect animal health, public health, or the environmental health, the Authority shall suspend MA immediately pending full investigation or consideration.

(4) In case of an immediate suspension in accordance with sub-regulation 3 above, the Authority shall notify the MA holder of the immediate suspension in witing with reasons thereof.

(5) Notice of suspension shall be published in the Gazette, in at least one newspaper with wide national circulation, and on the Authority's website.

(6) Upon suspension, the MAH shall cease manufacture, importation, distribution, and sale of the product unless otherwise in accordance with directions by the Authority.

(7) The Authority shall complete its investigations or consideration within sixty days, and either lift the suspension, or impose further conditions on MA or confirm cancellation of MA.

Cancellation of Marketing Authorisation

18.

(1) The Authority may cancel a marketing authorisation where —

(a) the MAH has failed to comply with corrective actions in accordance with regulation 17 above, within prescribed timelines or

(b) the holder provided false or misleading information to obtain the authorisation;

(c) the product is no longer manufactured in accordance with Good Manufacturing Practice and cannot be remedied.

(2) Cancellation procedures shall follow those procedures applicable to suspensions under regulation 17.

Revocation

19.

(1) The Authority shall revoke a marketing authorisation where the product can no longer be marketed consistently with the Act and these Regulations, and the revocation shall be published in the Gazette and on the Authority's website.

(2) The Authority may revoke a marketing authorisation where it determines that—
(a) the authorisation was granted based on false, misleading, or incomplete information;
(b) there is fraud, intentional misrepresentation, or concealment of material facts;
(c) the MAH has engaged in conduct that compromises regulatory integrity; or
(d) continued presence of the product on the market poses unacceptable risk.

(3) Revocation shall take immediate effect and shall not require prior corrective opportunity.

(4) The Authority shall, prior to revocation and except in emergent cases —
(a) notify the MAH of the intended regulatory action;
(b) provide reasons for the proposed action; and
(c) allow the MAH an opportunity to respond within a specified timeframe.

(5) The Authority may waive prior notice where immediate action is necessary to protect health

(6) The Authority shall issue a written decision detailing reasons and conditions of enforcement.

(7) Notwithstanding Regulation 4, the Authority may take immediate recall, or prohibition measures where there is imminent risk to—
(a) animal health;
(b) human health (including food safety); or
(c) environmental safety.

(8) Upon suspension, cancellation, or revocation, the MAH shall immediately—
(a) cease all manufacturing, importation, distribution, and sale;
(b) initiate product recall where instructed;
(c) notify distributors, wholesalers, and retailers; and
(d) provide stock reconciliation reports to the Authority.

(9) The MAH shall cooperate fully with any regulatory investigation or enforcement action.

Voluntary withdrawal

20.

(1) A marketing authorisation holder may voluntarily withdraw a veterinary medicinal product from the market by submitting written notice to the Authority

(2) The MAH shall provide—
(a) reasons for withdrawal;

(b) proposed transition or stock management plans.

(3) The Authority may—
(a) accept the withdrawal;
(b) delay withdrawal or consider alternate ways to enable continued supply for a defined period to prevent critical shortages, where necessary in order to protect animal or public health.

(4) Upon voluntary withdrawal, the Authority shall update the register to reflect the status change for the affected product.

(5) The Authority may require recall of products already placed on the market where public or animal health risks exist.

(6) The list of withdrawn products shall be published within stipulated timelines for public information

(7) Voluntary withdrawal does not limit the Authority's power to investigate any prior regulatory non-compliance.

Exemptions from registration (Special Access) of Veterinary Medicinal Products

21.

(1) The Authority may grant exemptions permitting access to unregistered veterinary medicinal products under strict conditions where—

(a) no registered veterinary medicinal product is suitable or available; or

(b) there is an urgent or unmet animal health need; or

(c) the veterinary medicinal product intended for re-export in the form and packaging that it was imported

(d) extemporaneous preparations or compounded VMPs made or imported by veterinary surgeon for an animal under their care

(e) donated unregistered VMP is intended for use in Botswana

(2) This authorisation shall not constitute a full marketing authorisation and shall not confer general permission to market the product.

(3) The authorisations under sub-regulation (1) above, may be granted under the following categories—

(a) prescription-based exemption for a named animal or herd use;

(b) veterinary hospital for animals under the surgeon's care;

(c) wholesale-based exemption for strategic product supply management;

(d) clinical investigational or field trial supply exemption; and

(e) special dispensation for national animal / public health emergency in cases of zoonotic outbreak;

(4) An application for authorisation through the special access route shall be submitted to the Authority via the electronic submission system by—
(a) a registered veterinarian;
(b) a licensed veterinary institution; or
(c) an authorised importer acting on behalf of a veterinarian or other public health institution.

(5) The application shall include—

(a) justification for use of an unregistered product;

(b) clinical or epidemiological rationale;

(c) product details: brand name and active ingredients composition, strength and dosage form and manufacturer including evidence of cGMP compliance, and evidence of registration from reference authorities where available;

(d) proposed dosage, duration, and administration, where applicable;

(e) product labelling information including SPC, Package insert and primary labels

(f) proposed importation and supply chain details.

(6) The Authority shall assess the applications and may—
(a) approve the application;
(b) approve with conditions;
(c) limit quantity, duration, or scope of use; or
(d) refuse the application with reasons thereof.

(7) The approval shall specify—
(a) authorised user(s);
(b) animal population or herd;
(c) duration of validity;
(d) reporting obligations; and
(e) pharmacovigilance requirements where necessary.

(8) A special access authorisation shall be subject to conditions including—

(a) use strictly under veterinary surgeon supervision;

(b) prohibition of resale or commercial distribution in the case of extemporaneous preparations;

(c) record-keeping of administration and outcomes;

(d) adverse event reporting to the Authority; and

(e) compliance with withdrawal periods where food-producing animals are involved.

(9) The Authority may impose additional conditions as necessary to protect animal and public health.

(10) The veterinarian or institution using a product authorised through the special access route shall report within timelines prescribed by the Authority —
(a) treatment outcomes;
(b) adverse events;
(c) lack of efficacy; and
(d) any other safety concerns.

(11) The Authority may require additional post-use monitoring or studies

(12) Special access authorisation shall automatically terminate upon—
(a) expiry of approved duration;
(b) exhaustion of the quantity authorised or completion of treatment; or
(c) revocation of authorisation by the Authority.

(13) The Authority may revoke authorisation at any time where safety, quality, or compliance concerns arise.

(14) A person shall not use products authorised through special access pathway for—
(a) commercial resale unless otherwise authorised by the Authority;
(b) off-label use beyond the approved scope; or
(c) routine use where registered alternatives exist.

(15) Where conditions of special access are breached, the Authority may—
(a) revoke authorisation immediately and seize or recall remaining stock;
(b) prohibit future access applications by the offender;
(c) impose administrative penalties; or
(d) initiate criminal proceedings under the Act and these regulations.

Prohibition of undesirable substances and products

22.

(1) A person shall not manufacture, import, export, distribute, supply, advertise, prescribe, possess for commercial purposes or administer—
(a) any prohibited veterinary medicinal product;
(b) any veterinary medicinal product containing a prohibited substance;
(c) any veterinary medicinal product declared undesirable by the Authority; or
(d) any veterinary medicinal product prohibited under any written law.

(2) The Authority shall, after scientific evaluation, declare any substance undesirable where it is satisfied that the substance—
(a) presents unacceptable toxicity;
(b) causes carcinogenicity;
(c) causes mutagenicity;
(d) causes reproductive toxicity;
(e) causes developmental toxicity;
(f) causes unacceptable residues in food-producing animals;
(g) contributes significantly to antimicrobial resistance;
(h) presents unacceptable environmental hazards;
(i) threatens biodiversity;
(j) poses occupational hazards; or
(k) presents any other unacceptable public health risk.

(3) The Authority may declare a veterinary medicinal product undesirable where—
(a) new scientific evidence demonstrates unacceptable safety concerns;
(b) efficacy cannot be demonstrated;
(c) quality defects cannot be adequately controlled;
(d) manufacturing deficiencies compromise product quality;
(e) pharmacovigilance demonstrates unacceptable adverse effects;
(f) residue studies demonstrate unacceptable consumer exposure;
(g) the product contains prohibited substances;
(h) the product has been recalled internationally for safety reasons; or
(i) continued marketing is contrary to public interest.
(j) environmental persistence presents unacceptable risks: residues threaten aquatic ecosystems; wildlife species may be harmed; pollinators may be adversely affected, or antimicrobial resistance genes may be propagated.

(4) The Authority shall maintain and publish a list of

(a) prohibited or restricted pharmaceutical substances;

(b) prohibited veterinary medicinal products; and

(c) any substances prohibited for use in food-producing animals.

(5) The list may be amended from time to time by notice published in the Gazette.

(6) Any person who becomes aware of the presence, importation, manufacture, or distribution of a prohibited substance shall report it immediately to the Authority.

(7) Manufacturers, importers, distributors, and veterinary practitioners shall have a duty to report suspected prohibited substances without delay, and failure to report shall constitute an offense.

(8) Unless expressly authorised by the Director of veterinary Services and the Authority, veterinary medicinal products containing hormonal substances for growth promotion in food-producing animals are prohibited in Botswana.

PART III — FOOD-PRODUCING ANIMALS AND PUBLIC HEALTH

Maximum residue limits

23.

(1) A veterinary medicine intended for food-producing animals shall be authorised, imported, manufactured, distributed, prescribed or used when maximum residue limits for its active substances, relevant metabolites and degradation products have been —

(a) established in accordance with requirements as set by the Authority

(b) determined by the Authority with reference to established limits from jurisdictions where the substance is authorised.

(2) Products without established MRLs shall not be used in food-producing animals unless a pharmacologically active substance has been demonstrated to require no MRL, in which case a nil MRL may be established.

(3) The Authority shall refer to international regulations, standards and guidelines during the enforcement of these regulations

Withdrawal periods

24.

(1) A withdrawal period shall be established for each relevant food commodity including meat and offal, milk, eggs, honey, and for aquatic species: the edible portions.

(2) Withdrawal periods shall be calculated using —

(a) residue depletion data from appropriately designed studies conducted in the target species at the proposed dose and route of administration;

(b) the statistical method described in VICH GL48 or an equivalent recognised method;

(c) the established MRL for each relevant food commodity.

(3) Withdrawal periods shall be stated on the label in accordance with this regulation.

(4) A ZERO-withdrawal period may only be established where residue depletion data demonstrate that concentrations in all food commodities at zero days post-treatment do not exceed the established MRL.

(5) No marketing authorisation shall be granted for a product intended for use in food-producing animals without declaration of applicable withdrawal period.

(6) Veterinary surgeons and animal owners shall observe the stated withdrawal period before slaughter.

Residue surveillance programme

25.

(1) The Authority shall, cooperate with the Department of Veterinary Services and the Ministry responsible for agriculture, to establish and maintain a national residue surveillance programme for veterinary medical products in food of animal origin.

(2) The programme shall include —

(a) risk-based sampling of meat, milk, eggs, honey and aquatic species at slaughter, farm and retail levels;

(b) targeted surveillance of products newly registered or with identified residue concerns;

(c) monitoring for prohibited substances in food of animal origin;

(d) use of validated analytical methods suitable for multi-residue detection;

(e) coordination with food safety authorities and export certification requirements; and

(f) annual reporting of surveillance findings.

(3) Where a food product is found to contain residues exceeding the established MRL, the Authority shall investigate the cause, take appropriate regulatory and/or enforcement action, and the relevant authorities responsible for food safety and public health.

(4) Marketing authorisation holders shall cooperate with the national residue committee and support residue surveillance activities as may be required by the Authority and the Department of Veterinary Services.

Antimicrobial stewardship

26.

(1) The Authority shall apply antimicrobial stewardship principles in the registration and oversight of veterinary antimicrobials, adopting a One Health approach

(2) In the registration of veterinary antimicrobials, the Authority shall —

(a) require applicants to assess and justify the clinical indications;

(b) refer to WHO Critically Important Antimicrobials list and list of prohibited substances to prevent authorisation for animal use, those classes of antimicrobials preserved for use in humans;

(c) prohibit registration of veterinary antimicrobials for the sole purpose of growth promotion or feed conversion improvement.

(3) In the ongoing oversight of registered veterinary antimicrobials, the Authority shall —

(a) prohibit use of critically important antimicrobials in food-producing animal groups or flocks as a substitute for good husbandry, hygiene and biosecurity practices;

(b) review information on national antimicrobial resistance trends in veterinary pathogens and zoonotic pathogens

(c) review and amend the conditions of use of veterinary antimicrobials where emerging resistance data indicate unacceptable risk.

PART IV: INTERNATIONAL COLLABORATION, REGULATORY HARMONISATION, RELIANCE AND RECOGNITION

Harmonisation, Collaboration and Information sharing

27.

(1) The Authority may participate in regional, continental, and international regulatory initiatives relating to veterinary medicinal products.

(2) The Authority may enter memoranda of understanding, confidentiality agreements, cooperation agreements, or other arrangements necessary for implementation of this Part.

(3) The Authority may adopt, implement, or align regulatory requirements with regional harmonisation initiatives.

(4) Participation in harmonisation initiatives shall not diminish the Authority's statutory powers.

(5) Such participation may include regulatory work sharing arrangements such as —

(a) joint dossier assessments;

(b) joint inspections;

(c) collaborative pharmacovigilance activities;

(d) information-sharing arrangements;

(e) regulatory capacity-building activities

(f) harmonisation of processes, technical requirements and templates

(6) The Authority may exchange regulatory information with competent authorities, regional bodies, and international organisations.

(7) Information sharing may include—

(a) assessment reports;

(b) inspection reports;

(c) pharmacovigilance information;

(d) quality defect reports;

(e) enforcement actions; and

(f) regulatory decisions.

(8) Information sharing shall be subject to confidentiality and data protection requirements.

Reliance and Recognition

28.

(1) The Authority may rely upon regulatory assessments, inspections, approvals, scientific opinions, or other regulatory decisions issued by a recognised reference authority.

(2) The Authority shall verify any information submitted under a reliance or recognition pathway and may conduct independent scientific review, where necessary.

(3) An applicant or marketing authorisation holder utilising a reliance, recognition, or collaborative pathway shall—

(a) provide complete and accurate information;

(b) disclose all regulatory decisions affecting the product in other jurisdictions which include refusals, suspensions, withdrawals, revocations, restrictions, recalls, or major safety concerns affecting the product; and

(c) promptly notify the Authority of any subsequent regulatory actions taken by reference authorities.

(4) Where an applicant or marketing authorisation holder—

(a) provides false, misleading, or incomplete information;

(b) conceals adverse regulatory decisions;

(c) misrepresents reliance eligibility;

(d) breaches conditions imposed under a reliance or recognition procedure; or

(e) fails to comply with obligations under this Part; the Authority may –

i. suspend/refuse consideration of an application;

ii. reject an application;

iii. suspend, cancel or revoke a marketing authorisation;

iv. order a recall;

v. impose additional regulatory conditions;

vi. prohibit future use of reliance pathways by the offender; or

vii. initiate enforcement proceedings under the Act and these regulations.

(5) The Authority may reject reliance/recognition procedural outcomes where evidence indicates that reliance would compromise public health, animal health, food safety, environmental protection, or regulatory integrity.

Reliance

(6) Reliance procedure shall apply to—

(a) registration of all veterinary medicinal products;

(b) variations;

(c) renewals;

(d) GMP inspections;

(e) pharmacovigilance evaluations;

(f) residue evaluations and MRL determinations; and

(g) any other regulatory activity as may be determined by the Authority.

(7) Reliance shall not prevent the Authority from requesting additional information or conducting supplementary assessments.

(9) The Authority shall retain full responsibility for any regulatory decision taken under a reliance procedure.

Recognition

(10) The Authority shall establish recognition procedures for specified regulatory activities and recognition may be full or partial.

(11) The Authority may refuse recognition where—

(a) local conditions differ significantly from those considered by the reference authority;

(b) Animal health, public health, food safety, environmental safety, or antimicrobial resistance concerns exist;

(c) information provided is incomplete; or

(d) recognition would be inconsistent with the Act or these Regulations.

PART V — LICENSING OF REGULATED ESTABLISHMENTS

Requirement for licence

29. In accordance with section 58 of the Act,

(1) An application for licensing of regulated establishments shall be submitted to the Authority, in Form 8 set out in Schedule 4 accompanied by an application fee set out in Schedule 5.

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

(3) 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.

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

(5) Subject to sub-regulation (4), any change in the person who supervises the premises shall be communicated to the Authority within 30 days.

(6) 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) Sub-regulation (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 licence

30.

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

(a) manufacturing licences;

(b) import and export licences;

(c) distribution and wholesale licences;

(d) retailing and dispensing licences;

(e) special licence

Categories of manufacturing licence

31.

(1) 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

32.

(1) An application for a manufacturing licence under section 58 of the Act shall be made to the Authority and submitted in the prescribed form with —

(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

33.

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

(a) a Qualified Person responsible for batch certification and release;

(b) a Production Manager responsible for production operations;

(c) a Quality Assurance Manager responsible for the pharmaceutical quality system; and

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

(e) any other Key personnel as required by the Authority.

(2) Qualifications, experience and responsibilities of key personnel shall be as specified in Authority guidelines.

(3) The licence holder shall notify the Authority in writing of any change, resignation, removal, or replacement of the appointed key personnel within a timeline specified in the guidelines, and obtain approval for the replacement before any new key personnel assumes responsibilities.

Issuance of manufacturing licence

34.

(1) The Authority shall issue a manufacturing licence specifying —

(a) the licence number, licensee name and premises;

(b) the manufacturing category of licence

(c) the authorised activities and product types

(d) the names of approved key personnel;

(e) the validity period;

(f) any conditions of the licence; and

(g) the date of issue and expiry.

(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

The Authority shall reject an application where key personnel requirements are not met, the applicant has provided false information, or the application is incomplete or otherwise deficient.

(4) The Authority shall not grant a licence where the facility does not meet GMP requirements.

Current good manufacturing practice compliance

35.

(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 current good manufacturing practice requirements as detailed in guidelines published by the Authority.

Certificate of Compliance with current good manufacturing practice

36.

(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, 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

PART VI- DISTRIBUTION, WHOLESALE, RETAIL AND VETERINARY PHARMACY

Application for veterinary distribution and wholesale licence

37.

(1) An application for a licence to operate a veterinary wholesaler shall be made to the Authority in a prescribed Form and shall be accompanied by the prescribed fees.

(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.

(3) The following documents shall be submitted for application for a veterinary wholesaler or distribution licence;

(a) details and of the responsible veterinary surgeon or responsible pharmacist, including registration details;

(b) relevant documents for the veterinary surgeon or responsible pharmacist

(c) scope of activities and product categories applied for; and

(d) such other information as specified in the guidelines.

(4) 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, where applicable.

(5) License issued under sub-regulation (2) 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;

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

(7) 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 Veterinary retail licence

38.

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

(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 prescribed Form.

(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

(4) The following documents shall be submitted for application for a veterinary retail licence —

(a) the prescribed application fee;

(b) details of the responsible veterinary surgeon, veterinary paraprofessional or responsible pharmacist, including registration details;

(c) scope of activities and product categories applied for; and

(d) such other information as specified in the guidelines.

(5) Dispensing, sale or handling of of POM-VS (Prescription Only Medicines — Veterinary Surgeon) Medicines shall only take place under the supervision of a registered veterinary surgeon or registered pharmacist.

(6) Dispensing, sale or handling of GSM (General Sale medicines or over the counter medicines) and POM – VPS shall be done by a register veterinary surgeon, registered pharmacist or veterinary professional registered under the Veterinary Paraprofessional Animal Health (VPP-AH) category.

Assessment, inspection and issuance of licence

39.

(1) Upon receipt of a complete application, the Authority shall conduct a pre-licensing inspection of the premises to verify compliance with the Act, these Regulations, the applicable guidelines, Good Practice and standards for veterinary medicines 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.

40. 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 sub- regulation (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;

(d) record-keeping and reporting requirements;

(e) inspection, monitoring and access to premises;

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

(g) 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

Validity and renewal

41.

(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 using applicable form and 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.

Suspension and cancellation

42. (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) Except in the circumstances specified in sub-regulation (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.

(3) 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.

(4) The suspension, revocation or cancellation of a licence shall not preclude the Authority from taking any other enforcement action available under the Act.

43. Variation of Licences

(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.

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.

44. Post Licensure Notification

(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 VII — IMPORT AND EXPORT

Requirement for authorisation

45.

(1) No person shall import or export any veterinary medicine without a valid licence, and authorisation in form of a valid permit for a specific consignment issued from the Authority

(2) The Authority may refuse authorisation where

(a) the product is not registered unless an exemption applies;
(b) the product is prohibited or substandard;
(c) the remaining shelf life is inadequate;
(d) the applicant does not hold a valid licence;
(e) or it is otherwise in the animal or public health interest.

Import and export permits

46.

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

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

(3) The Authority shall process permit applications within the timelines defined in the guidelines, for routine applications, for expedited applications, and for emergency applications where animal health is at risk.

(4) Permits shall be valid for a maximum period as stipulated in the guidelines and shall specify the permit number, product details, authorised route and any conditions as required by the Authority.

Authorised ports of entry

47. Veterinary medicines may only be imported or exported through the ports of entry designated in the General Regulations and any additional ports designated by notice in the Gazette. At designated ports, the Authority shall ensure regular inspection presence for veterinary consignments.

Products in transit

48. Veterinary medicines in transit through Botswana shall comply with the transit permit requirements in the General Regulations, shall remain under customs control and shall not be released into the domestic market without the required marketing authorisation.

Donated veterinary medicines

49.

(1) Donated veterinary medicines require prior authorisation from the Authority and shall meet the same quality standards as commercially imported products.

(2) Donated products shall have adequate remaining shelf life, be appropriately labelled, and be suitable for use in Botswana's disease context.

(3) Donated products not meeting requirements may be seized, quarantined, confiscated or ordered re-exported at the importer's cost in accordance with section 66(4) of the Act.

Special access (Expand regulation for exemptions)

50.

(1) The Authority may grant special access to an unregistered veterinary medicine on named-patient grounds, for minor species where no suitable registered product exists, or for emergency use where no suitable registered alternative is available, in accordance with the guidelines.

(2) Applications shall be made by a registered veterinary surgeon and shall include clinical justification.

(3) Importation without a permit by Veterinary Surgeon shall be allowed only for animals under their care as per the relevant statute.

PART VIII — PRESCRIPTION, DISPENSING AND USE

Prescription categories and requirements

51.

(1) Veterinary medicines shall be classified into the following categories as set out in Schedule 1 —

(a) Controlled Medicines - which may only be supplied on the written prescription of a registered veterinary surgeon in compliance with the standards and protocols defined by the INCB

(b) Prescription Only Medicines - Veterinary Surgeon (POM-VS), which may only be supplied on the written prescription of a registered veterinary surgeon;

(c) Prescription Only Medicines - Veterinary Paraprofessional (POM-VPS), which may be supplied by a registered veterinary surgeon, or Pharmacist and Veterinary Paraprofessional upon a prescription from a veterinary surgeon.

(d) General Sale Medicines (GSM), which may be sold from authorised premises without a prescription.

(2) A valid veterinary prescription shall contain —

(a) the name and address of the animal holding and species of the animal or group of animals;

(b) sufficient identification of the animal or animals, including for food-producing animals the herd, flock or premises identifier;

(c) the brand name and common scientific names of all active ingredients of the veterinary medicine, strength and dosage form, dose, route of administration, frequency, duration of treatment, and quantity;

(d) the veterinary surgeon or veterinary paraprofessional's name, BVSC registration number, address, signature and the date when the prescription is issued;

(e) the diagnosis or clinical condition to be treated.

(3) A prescription shall be presented for dispensing within 90 days of the date of issue.

(4) Electronic prescriptions are used, the electronic prescribing system must provide an audit trail, linked to the prescribing veterinary surgeon or veterinary paraprofessional, and includes appropriate security measures.

(5) Records of all veterinary prescriptions shall be retained for a minimum of five years and shall be available to the Authority inspection, when required.

Off-label use and the cascade

52.

(1) A veterinary surgeon may prescribe a veterinary medicine off-label under the cascade hierarchy where no authorised product exists for the specific species, condition or indication, in the following sequential order —

(a) a veterinary medicine authorised in Botswana for use in another species or for a different indication;

(b) a human medicine authorised in Botswana containing an active substance included in a veterinary medicine authorised in Botswana; or

(c) a veterinary medicine not authorised in Botswana but authorised in another country with a recognised Authority, imported on a named-patient basis in accordance with regulation 51.

(2) Cascade prescribing is subject to —

(a) the prescribing veterinary surgeon taking personal responsibility for the safety and efficacy of the medicines and welfare of the animal;

(b) a specific documented clinical justification for each animal or group of animals;

(c) specific informed consent of the animal owner or keeper; and

(d) enhanced reporting of adverse events to the Authority.

(e) where a product is prescribed for off label use, this should be reported to the authority with or without an adverse event.

(3) Where cascade products are used in food-producing animals, the prescribing veterinary surgeon shall establish and communicate to the animal owner a specific withdrawal period. Such withdrawal periods shall not be less than the withdrawal period of the innovator veterinary medicinal product containing the same active substances, in each of the animal food products

(4) Cascade use of critically important antimicrobials shall be subject to restriction by the Authority where there is evidence of risk to human health, and the Authority shall publish guidance on the cascade use of each class of critically important antimicrobial.

(5) Cascade use is prohibited for substances that are declared or classified as prohibited for use in animals.

Medicated feed

53.

(1) Medicated feed may only be manufactured using registered medicated premixes and in accordance with a valid prescription issued by a registered veterinary surgeon specifying the target species, disease or condition, the medicated premix and concentration, the duration of administration, and the withdrawal period where applicable.

(2) Medicated feed manufacturers require a licence from the Authority and shall comply with Good Manufacturing Practice requirements for medicated feed as specified in Authority guidelines.

(3) Each batch of medicated feed shall be accompanied by documentation linking it to the authorising prescription, the medicated premix used; including batch number, the calculated dose per animal, and the withdrawal period.

(4) Labels on medicated feed shall indicate the name, batch number and quantity of the medicated premix incorporated, the target species, the dose, the withdrawal period where applicable, the manufacturing date and expiry, and any warnings.

(5) Only antimicrobials for which a therapeutic indication in food-producing animals is registered may be incorporated into medicated feed.

(6) Prophylactic use of antimicrobials in medicated feed for groups of animals without clinical diagnosis is prohibited.

Compounded veterinary medical products

54.

(1) A compounded veterinary medical product may only be prepared —

(a) by a registered pharmacist, a registered veterinary surgeon or a person specifically authorised by the Authority;

(b) pursuant to a valid prescription for a specific named animal or a specific group of animals under the care of the prescribing veterinary surgeon;

(c) where no suitable authorised veterinary or human medicine is available in Botswana that meets the clinical need; and

(d) using active pharmaceutical ingredients registered for veterinary use or sourced from a licensed supplier meeting appropriate pharmaceutical grade standards.

(2) Compounded products shall not be manufactured in advance, stored in bulk, or supplied commercially.

(3) The compounder shall ensure the compounded product is prepared under conditions that maintain sterility where required, correct concentration and homogeneity, and uses suitable excipients or ingredients.

(4) For food-producing animals, the prescribing veterinary surgeon shall establish an appropriate withdrawal period, which shall not be less than the default periods specified for the originator or innovator product.

(5) The prescribing veterinary surgeon and the compounder shall each maintain records of each compounded product for a minimum of five years.

(6) Any suspected adverse events related to compounded products shall be reported to the Authority under Part IX.

Record keeping by prescribers and dispensers

55.

(1) A veterinary surgeon who prescribes or uses veterinary medicines shall maintain records of —

(a) the identity of the animal or group of animals treated, including species, breed, age and ownership details;

(b) the date of examination;

(c) the diagnosis or clinical presentation;

(d) the veterinary medicine prescribed, the dose, route and duration of treatment, and quantity dispensed or administered;

(e) the withdrawal period communicated to the animal owner for food-producing animals;

(f) the batch number of the veterinary medicine used; and

(g) any adverse reactions observed or reported.

(2) Persons dispensing veterinary medicines shall maintain dispensing registers including the particulars of the veterinary medicine including batch number, quantity dispensed, date of dispensing, the animal owner's details, the prescribing veterinary surgeon's details and prescription reference number.

(3) All records shall be retained for a minimum of five years and shall be available to the Authority and the Department of Veterinary Services on request.

PART IX — LABELLING AND PRODUCT INFORMATION

General labelling requirements

56.

(1) The container and outer packaging of every veterinary medicine shall bear a label clearly indicating —

(a) the approved name, being the international non-proprietary name or the approved pharmacopoeial name;

(b) the brand or trade name, if any;

(c) the qualitative and quantitative composition of active substances per dosage unit;

(d) the pharmaceutical form;

(e) the target animal species;

(f) the dosage and route of administration;

(g) the name, address and contact details of the manufacturer and the marketing authorisation holder;

(h) the registration number issued by the Authority;

(i) the batch or lot number;

(j) the date of manufacture and expiry date;

(k) storage conditions, including cold chain requirements where applicable;

(l) necessary warnings and precautions, including user safety information such as hazard pictograms for toxic or ecotoxic products;

(m) the scheduling status or prescription category;

(n) environmental safety information and disposal instructions;

(o) for antimicrobials: a general guiding or warning statements to enable responsible use of antimicrobials in line with antimicrobial stewardship principles; and

(p) such other information as may be required by the conditions of registration or the guidelines.

(2) Immediate containers too small to accommodate full labelling may carry abbreviated labels approved by the Authority, provided the outer packaging carries the full required information.

Labelling for food-producing animals

57.

(1) In addition to regulation 57, the labelling of a veterinary medicine for use in food-producing animals shall clearly state —

(a) the withdrawal period for each relevant food commodity and species, expressed in days, for example "Meat and offal: 28 days; Milk: 7 days"; or

(b) where the product is not intended for use in animals whose products are intended for human consumption, a prominent statement to that effect.

(2) Where a nil withdrawal period applies, the label shall explicitly state "Withdrawal period: None" or "Zero-day withdrawal period" for each relevant commodity.

(3) The withdrawal period label shall be in a font size and position that is clearly legible and prominently displayed.

Summary of product characteristics

58.

(1) Every veterinary medicine registered under these Regulations shall have an approved summary of product characteristics which shall include —

(a) the name of the veterinary medicine;

(b) qualitative and quantitative composition of all active substances and relevant excipients;

(c) pharmaceutical form;

(d) clinical particulars including —

(i) target species;

(ii) indications for use specifying the target species;

(iii) contraindications;

(iv) special warnings for each target species;

(v) special precautions for use including user safety information;

(vi) adverse reactions;

(vii) use during pregnancy, lactation or lay;

(viii) interactions with other medical products;

(ix) administration and dosage;

(x) overdose including symptoms, emergency procedures and antidotes; and

(xi) withdrawal periods for each food commodity and species;

(e) pharmacological properties including pharmacodynamics, pharmacokinetics and relevant antimicrobial resistance information;

(f) pharmaceutical particulars including incompatibilities, shelf life, storage conditions, container type and disposal of unused product;

(g) environmental safety information summarising the conclusions of the environmental risk assessment; and

(h) marketing authorisation details including holder, registration number and date of first authorisation.

(2) The summary of product characteristics shall be approved by the Authority as part of the marketing authorisation, shall not be modified without Authority approval, and may be published on the Authority's website.

Language requirements

59.

(1) Labelling and the summary of product characteristics shall be in English.

(2) The Authority may require or permit additional labelling in Setswana or another language, provided the English text remains authoritative.

PART X — PHARMACOVIGILANCE

Veterinary pharmacovigilance system

60.

(1) In accordance with section 71 of the Act, the Authority shall establish and maintain a veterinary pharmacovigilance programme covering —

(a) spontaneous adverse event reporting from veterinary surgeons, animal owners and marketing authorisation holders;

(b) signal detection and assessment;

(c) environmental safety monitoring including persistence and ecotoxicity surveillance;

(d) antimicrobial resistance surveillance in veterinary pathogens, zoonotic pathogens and environmental microorganisms;

(e) consumer safety monitoring including food residue surveillance in coordination with the residue surveillance programme under regulation 22;

(f) user safety monitoring for persons handling and administering veterinary medicines; and

(g) coordination with the Department of Veterinary Services, the national public health pharmacovigilance programme, and international veterinary pharmacovigilance systems and relevant international databases.

(2) The Authority shall designate a veterinary pharmacovigilance function responsible for operational management of the programme and shall publish guidelines on its operation.

Obligations of Manufacturers, marketing authorisation holders and distributors

61.

(1) Every marketing authorisation holder shall —

(a) Every manufacturer, marketing authorisation holder or distributors shall plan, establish, implement, monitor and maintain an updated pharmacovigilance system

(b) designate a qualified person responsible for veterinary pharmacovigilance meeting the requirements specified in Authority guidelines;

(c) maintain a veterinary pharmacovigilance system master file describing the system, organisation, data sources, standard operating procedures and quality system;

(d) collect, assess and report all adverse events in accordance with regulation 63;

(e) submit periodic safety update reports in accordance with regulation 67;

(f) implement and maintain a risk management plan;

(g) conduct post-authorisation safety studies where required by conditions of registration or directed by the Authority;

(h) implement urgent safety measures directed by the Authority within the required timeframes; and

(i) cooperate with the Authority in all pharmacovigilance activities and provide information on request within seven working days.

(2) 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, the QPPV shall; -

a) be appropriately qualified in a animal health science or life science discipline,

b) has adequate training and experience in pharmacovigilance,

c) is always contactable,

d) is authorised to act on pharmacovigilance matters, including urgent safety restrictions.

e) 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.

(Pursuant to regulations section 62 (2), in the case where the QPPV is based outside Botswana, the marketing authorisation holder shall appoint a local technical representative

Adverse event reporting

62.

(1) Marketing authorisation holders, distributors, veterinary surgeons, pharmacist, farmers and animal owners shall report to the Authority —

(a) fatal or life-threatening adverse events in target animals within seven calendar days of awareness, with a follow-up report within a further eight days;

(b) serious non-fatal adverse events in target animals within fifteen calendar days;

(c) adverse events in humans, including veterinary surgeons, farmers and animal handlers, within fifteen calendar days of awareness;

(d) lack of expected efficacy for products used in serious or life-threatening conditions within thirty calendar days;

(e) environmental incidents attributable to the product within fifteen calendar days; and

(f) any regulatory action taken by another regulatory authority for safety reasons within fifteen calendar days.

(2) Veterinary surgeons and other persons involved in the use of veterinary medicines shall report suspected adverse events to the Authority or to the marketing authorisation holder within the time stipulated in the Guidelines.

(3) Animal owners and the public may report suspected adverse events directly to the Authority.

(4) Report formats and submission requirements are set out in Authority guidelines.

Environmental safety monitoring

63.

(1) Marketing authorisation holders shall continuously monitor the environmental safety profile of their products, including —

(a) persistence or accumulation of active substances and metabolites in soil, sediment, water and manure;

(b) impact on non-target organisms including wild mammals, birds, invertebrates particularly dung insects, bees, earthworms, and aquatic species;

(c) potential for antimicrobial resistance in environmental microorganisms; and

(d) impact on nitrogen cycling and soil microbial diversity for soil-applied products.

(2) Any new information indicating an unacceptable environmental risk shall be reported to the Authority within fifteen calendar days of awareness, together with proposed risk management measures.

(3) The Authority may require additional environmental monitoring studies as a condition of registration for products with significant persistence or ecotoxicity potential.

User safety monitoring

64. Marketing authorisation holders shall monitor and report risks to users who handle, prepare or administer veterinary medicines, including dermal, ocular, inhalation and accidental systemic exposure risks, and shall update product information, revise personal protective equipment requirements and implement risk mitigation measures where new user safety concerns are identified.

Consumer and food safety monitoring

65.

(1) Marketing authorisation holders shall monitor residue safety data, new toxicological findings and food safety signals for products used in food-producing animals and shall report any new information that may affect established MRLs or withdrawal periods to the Authority within fifteen calendar days of awareness, together with a proposed remedial action plan.

Medication Errors

66.

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

(2) The Authority shall, in collaboration with the department of veterinary services and or Ministry responsible for animal 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 veterinary practitioners, farmers and the public

Periodic safety reporting

67.

(1) Marketing authorisation holders shall submit periodic safety update reports to the Authority at intervals specified in conditions of registration or guidelines, covering —

(a) an integrated analysis of all safety data accumulated since the previous report;

(b) a benefit-risk assessment taking into account target animal, user, consumer and environmental safety;

(c) antimicrobial resistance surveillance data for antimicrobial products;

(d) residue surveillance data for products used in food-producing animals;

(e) an assessment of the effectiveness of risk management measures; and

(f) proposals for any changes to the marketing authorisation, labelling or conditions of use.

(2) The format and timelines of periodic safety update reports shall align with the guidelines for veterinary pharmacovigilance reporting and Authority guidelines.

Risk Management Plan

68.

(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 theA risk management plan and associated risk minimisation documents shall include a safety specification, a pharmacovigilance plan, a risk minimisation plan, and a summary suitable for suitable public accessdisclosure.

(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

69.

(1) The Authority shall establish a system for detection, assessment and management of safety signals from veterinary pharmacovigilance data through statistical and qualitative analysis of adverse event reports, literature review, assessment of information from other regulatory authorities, and environmental monitoring data.

(2) Where a signal is validated, the Authority may request further investigation by the marketing authorisation holder within a specified timeframe, require amendments to the summary of product characteristics or labelling, impose additional risk minimisation measures, restrict the conditions of use, or suspend the marketing authorisation.

Urgent safety measures

70.

(1) In accordance with Section 72 (1) (f) and (g) of the case, where new safety information necessitates urgent action and in cases where new safety information necessitates urgent action, the marketing authorisation holder decides to implement, or is directed by another NRA, to shall immediately implement any urgent safety restriction, they shall and 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

71.

(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 animal health.

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

Post Authorisation Safety Studies

72.

(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 Practice Inspections

73.

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.

PART XI — POST-MARKET SURVEILLANCE

Post-market surveillance programme

74.

(1) The Authority shall conduct a risk-based post-market surveillance programme for veterinary medicines including —

(a) market surveillance sampling and testing for quality, safety and efficacy compliance;

(b) monitoring of pharmacovigilance data and environmental safety reports;

(c) analysis of complaints and quality defect reports;

(d) targeted surveillance based on risk assessment;

(e) antimicrobial resistance monitoring in veterinary pathogens and environmental samples;

(f) residue surveillance in coordination with the programme under regulation 22; and

(g) international collaboration on safety signals, quality alerts and antimicrobial resistance data.

(2) Marketing authorisation holders shall establish and maintain post-market surveillance systems, monitor product performance, submit annual surveillance reports, and not supply substandard or falsified products.

Market surveillance sampling and testing

75.

(1) The Authority shall, through the National Quality Control Laboratory or approved laboratories, conduct risk-based sampling and testing of veterinary medicines on the market.

(2) Sampling shall target newly registered products, products with known quality concerns, products from manufacturers with compliance history issues, products identified through complaints or pharmacovigilance signals, and products selected through random surveillance.

(3) Where a product is found non-compliant, the Authority shall take appropriate action including recall, suspension or enforcement action.

Product recalls

76.

(1) A marketing authorisation holder shall voluntarily recall a veterinary medicine that is non-compliant with specifications, has caused or is likely to cause harm to animals, humans or the environment, or for which new safety information warrants recall.

(2) 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 from the supply chain, effectiveness checks, and a final reconciliation report submitted to the Authority within thirty days of completion.

(3) Failure to comply with recall requirements constitutes an offence under these Regulations.

PART XII — ADVERTISING AND PROMOTION

Requirement for advertising approval

77.

(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.

within fourteen working days for straightforward applications, and twenty-eight working days where additional review is required.

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

Advertising standards

78.

(1) All advertising of veterinary medicines shall be accurate, truthful and not misleading presenting consistent information with the approved summary of product characteristics; not contain claims not supported by evidence; appropriate for the target audience; and not compare products unfairly.

(2) POM veterinary medicines shall only be advertised to registered veterinary surgeons and pharmacists.

(3) Advertising shall not promote the use of critically important antimicrobials or encourage use beyond the registered indications.

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

Prohibited advertising practices

79.

(1) The following advertising practices are prohibited —

(a) advertising of unregistered veterinary medicines;

(b) claims that a product has no adverse effects or withdrawal period unless the authorised withdrawal period is nil;

(c) advertising of antimicrobials in a manner that encourages their use without veterinary prescription or as growth promoters;

(d) advertising of prohibited substances

(e) promotional activities disguised as scientific or educational programmes; and

(f) any advertising contrary to the guidelines.

(2) A person who contravenes this regulation commits an offence and is liable to a fine not exceeding P500 000 or imprisonment for two years, or both.

PART XIII — INSPECTION

Appointment of inspectors

80.

(2) The Authority may collaborate with the Department of Veterinary Services in the inspection of veterinary premises, farms and livestock facilities, and may develop joint inspection protocols where appropriate.

Powers of inspectors

81.

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

(a) enter and inspect any premises where veterinary medicines are manufactured, stored, distributed, sold, dispensed or used;

(b) examine activities and question persons;

(c) examine, copy and seize records and data, including electronic records;

(d) take samples of products without compensation;

(e) seize, quarantine or detain products suspected of non-compliance;

(f) seal or close premises where there is immediate risk to public health, animal health or the environment; and

(g) investigate alleged offences and institute or recommend administrative proceedings.

(2) Persons responsible for premises shall not obstruct inspectors, shall provide access to all areas and records, shall provide reasonable assistance, and shall answer questions truthfully.

(3) Where entry is refused, an inspector may apply to a Magistrate for a warrant in accordance with section 78(2) of the Act.

Risk-based inspection

82.

(1) The Authority shall apply a risk-based approach to the planning and execution of inspections, considering the classification and inherent risk of veterinary medicines handled, compliance history, type and complexity of operations, time elapsed since the last inspection, and information from pharmacovigilance, antimicrobial resistance surveillance, residue surveillance and complaints.

(2) Manufacturing facilities for biologicals and sterile products shall be inspected at intervals not exceeding two years. Other manufacturing facilities shall be inspected at intervals not exceeding three years. High-risk distribution and retail establishments shall be inspected at least annually.

(3) Nothing in this regulation limits the Authority's power to conduct unannounced or for-cause inspections at any time.

Inspection procedures

83.

(1) Inspections shall be planned and executed in accordance with documented procedures approved by the Authority.

(2) Inspection reports shall classify observations as critical observations presenting an immediate or significant risk to animal health, public health or the environment and requiring immediate regulatory action; major observations constituting significant non-compliance requiring corrective action within a specified timeframe; and minor observations representing deviations that should be corrected but pose limited risk.

(3) A licensed entity shall submit corrective and preventive action plans in response to inspection observations within timeframes specified by the Authority.

Termination of inspection

84.

(1) The Authority may abort, suspend or terminate an inspection where the licensee obstructs the inspection, access to premises or records is denied, conditions pose a risk to the safety

of inspectors, evidence relevant to the inspection is suspected to have been concealed or destroyed, or any other circumstance arises that materially compromises the integrity of the inspection.

(2) Where an inspection is aborted due to the conduct or omission of the licensee, the Authority may require the licensee to bear costs of any subsequent inspection.

Sampling and testing

85.

(1) Inspectors may take samples of veterinary medicines during inspections or other regulatory activities to verify quality, safety, efficacy or regulatory compliance.

(2) Sampling shall be conducted in accordance with documented procedures, and a certificate of sampling shall be issued to the person from whom the sample was taken.

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

PART XIV — OFFENCES AND PENALTIES

General offences

86.

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

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

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

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

(d) fails to comply with a lawful direction of the Authority;

(e) fails to report adverse events as required under Part IX;

(f) fails to initiate or comply with a recall when required;

(g) advertises a veterinary medicine without required approval or in contravention of approval;

(h) uses a veterinary medicine in food-producing animals without observing the required withdrawal period;

(i) uses or supplies a prohibited substance;

(j) fails to maintain required records; or

(k) contravenes any provision of these Regulations for which no specific penalty is provided.

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

Specific offences and penalties

87.

(1) The following specific offences and penalties apply under these Regulations —

(a) manufacturing without a manufacturing licence: a fine not exceeding P5 000 000 or imprisonment for seven years, or both;

(b) import, export or manufacture of substandard or falsified veterinary medicines: a fine not exceeding P10 000 000 or imprisonment for ten years, or both;

(c) selling expired veterinary medicines: a fine not exceeding P5 000 000 or imprisonment for seven years, or both;

(d) advertising a veterinary medicine without approval or in contravention of approval: a fine not exceeding P500 000 or imprisonment for two years, or both;

(e) obstruction of an inspector: a fine not exceeding P500 000 or imprisonment for two years, or both;

(f) failure to observe the withdrawal period for food-producing animals: a fine not exceeding P2 000 000 or imprisonment for five years, or both;

(g) use of a prohibited substance in a food-producing animal: a fine not exceeding P5 000 000 or imprisonment for seven years, or both;

(h) failure to report a serious or fatal adverse event within the required timeline: a fine not exceeding P1 000 000 or imprisonment for three years, or both; and

(i) providing false or misleading information to the Authority: a fine not exceeding P5 000 000 or imprisonment for seven years, or both.

(2) The court may impose both a fine and imprisonment and may additionally order forfeiture of the veterinary medicines concerned, closure of premises, and payment of the Authority's investigation and prosecution costs.

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 or approved the commission of the offence shall also be liable.

(2) It shall be a defence for such a person to prove that the offence was committed without their knowledge and that all reasonable steps were taken to prevent its commission.

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 and to comply with such remedial and corrective measures as the Authority may specify.

(2) Compounding of an offence does not affect the Authority's power to take other regulatory action.

PART XV — 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 notification of the decision, in writing setting out the grounds of appeal, the decision appealed against, and the relief sought.

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

Appeals Committee procedures

91. The Appeals Committee shall conduct proceedings in accordance with the Act, affording the appellant and the Authority an opportunity to be heard. The Committee may confirm, vary or set aside the decision of the Authority and may make such order as it considers appropriate. Further appeal shall lie to the High Court on a question of law.

PART XVI — FINAL PROVISIONS

Guidelines

92.

(1) The Authority shall issue guidelines on all matters requiring detailed specification under these Regulations, including registration requirements by product category, GMP standards for veterinary products, prescription category substance lists, cascade use requirements, withdrawal period calculation methodology, MRL standards, pharmacovigilance requirements, environmental risk assessment requirements, antimicrobial stewardship standards, and Good Storage and Distribution Practice for veterinary medicines.

(2) Guidelines shall be developed with meaningful stakeholder consultation including veterinary surgeons, the pharmaceutical industry, farmers' associations and academic institutions; shall be based on VICH guidelines, WHO guidance or international best practices; shall be published on the Authority's website; and shall be reviewed at intervals not exceeding five years.

(3) Guidelines do not create obligations beyond those established by the Act and these Regulations but provide interpretive guidance and technical detail for implementation.

Coordination with Ministry responsible for agriculture

93.

(1) The Authority shall coordinate with the Department of Veterinary Services and the Ministry responsible for agriculture in —

(a) the registration and ongoing oversight of veterinary medicines;

(b) antimicrobial stewardship and One Health antimicrobial resistance monitoring;

(c) food safety, residue surveillance and MRL setting;

(d) animal health emergency responses;

(e) regulation of medicated feed and related products;

(f) inspections of farms and livestock premises; and

(g) international reporting obligations under the OIE and relevant international conventions.

(2) The Authority and the Department of Veterinary Services shall develop, within one year of commencement of these Regulations, a memorandum of understanding formalising coordination arrangements, joint inspection protocols and data-sharing arrangements.

Transitional provisions

94.

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

(2) Applications for registration 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 summaries of product characteristics in compliance with regulation 59;

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

(c) establish veterinary pharmacovigilance systems in accordance with Part IX.

(4) Manufacturing licences issued before commencement shall remain valid until their next renewal, at which time full compliance with these Regulations shall be required.

(5) The Authority shall publish a detailed transitional plan within ninety days of commencement specifying implementation deadlines for each requirement.

Repeal

95. These Regulations supersede all previous regulatory provisions specifically relating to veterinary medicines under the Medicines and Related Substances (General) Regulations, to the extent of any inconsistency. Subsidiary legislation made under the repealed provisions and not inconsistent with these Regulations shall continue in force until revoked or replaced.

SCHEDULES

SCHEDULE 1

1. PRESCRIPTION CATEGORIES FOR VETERINARY MEDICINES

Category	Full Name	Description	Examples
Controlled Substances	**Controlled substances**	May only be supplied on the written prescription of a registered veterinary surgeon. May only be	All Narcotics, psychotropics and Precursors

		dispensed by a pharmacist or veterinary surgeon.	
POM-VS	Prescription Only Medicine – Veterinary Surgeon	May only be supplied on the written prescription of a registered veterinary surgeon. May only be dispensed by a pharmacist or veterinary surgeon.	All antimicrobials; vaccines requiring cold chain; injectable general anaesthetics; controlled veterinary medicines; cytotoxic; hormonal products; products for notifiable disease treatment; any product designated by the Authority.
POM-VPS	Prescription Only Medicines - Veterinary Paraprofessional	May be supplied by a registered pharmacist or veterinary surgeon without a prescription but under professional oversight and with dispensing records maintained.	Certain oral antiparasitics for companion animals; non-prescription analgesics with safety concerns in certain species; products requiring professional guidance on dose.
GSM	General Sale — Veterinary	May be sold from authorised premises without a prescription.	Minor OTC ectoparasiticides for companion animals; basic wound care preparations; oral rehydration salts for animals; products specifically designated by the Authority.

Detailed substance lists for each category shall be published in guidelines and in the Gazette.

Made this _____ day of _____, 2026.

_____

MINISTER OF HEALTH

Republic of Botswana