STATUTORY INSTRUMENT NO. ___ OF 2026

MEDICINES AND RELATED SUBSTANCES ACT, 2025

(Act No. 29 of 2025)

COMPLEMENTARY MEDICINES (*HUMAN*) REGULATIONS , 2026

(Published on _____, 2026)

ARRANGEMENT OF REGULATIONS

IN EXERCISE of the powers conferred on the Minister of Health by sections 45, 79, 123 and related provisions of the Medicines and Related Substances Act, 2025, and after consultation with the Botswana Medicines Regulatory Authority, the following Regulations are hereby made —

PART I – PRELIMINARY

Citation and commencement

1. (1) These Regulations may be cited as the Complementary 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 ingredients" for a complementary medicine, means an active ingredient, or a kind of active ingredient.

"african pharmacopoeia" means an officially recognized, reference book containing standards, quality specifications, and methods of analysis for pharmaceutical substances and medicinal plant remedies used in

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

"batch" means a defined quantity of a complementary medicine processed in a single process or series of processes so as to ensure homogeneity;

"cannabis" means any plant of the genus *Cannabis*, including any part of the plant, whether growing or not, and any preparation, extract, resin, tincture, isolate, derivative, or product containing cannabinoids.

"cannabinoid" means a naturally occurring, semi-synthetic or synthetic compound that interacts with cannabinoid receptors, including cannabidiol (CBD), tetrahydrocannabinol (THC), and related substances.

"cannabis complementary medicine" means a complementary medicine containing cannabis, cannabis extracts, cannabinoids or cannabinoid preparations intended for therapeutic, wellness, traditional, herbal or health-support purposes

"complementary medicine" means a product falling within one or more of the categories set out in regulation 5, and includes herbal medicines, homeopathic medicines, health supplements, probiotics intended to make health claims, and traditional medicines;

“dosage form” means the physical form in which a finished complementary medicine is presented, including capsule, tablet, liquid, powder, tincture, cream, ointment, tea and any other standardised form;

“established use” means documented use of a herbal medicine or traditional medicine for a defined timeline within a well-established healthcare system, supported by published literature or recognised monographs;

“general Regulations” means the Medicines and Related Substances (General) Regulations, 2026;

Herbal materials Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stirbaking with honey, alcoholic beverages or other materials.

“herbal medicine” means herbs, herbal materials, herbal preparations and finished herbal products, labelled containing as active ingredients aerial or underground parts of plants, or other plant materials, or a combination thereof, whether in crude or processed form, and which may contain conventional excipients; and includes a product based on established traditional use of plants;

“herbal substance” means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):

(a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and

(b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

“health supplement” means a product containing vitamins, minerals, amino acids, essential fatty acids, probiotics or other nutritional substances in a standardised dosage form, intended to supplement the diet and not to diagnose, treat, cure or prevent disease; primary functions include but not limited to include filling nutritional gaps, supporting specific health conditions (like bone or heart health), enhancing physical performance, and boosting general well-being.

“Herbal preparations” are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages

and/or honey, or in other materials.

“Herbs” Herbs include crude plant material such as leaves, flowers, fruit, seed, stems,

wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.

“Homeopathy” Homeopathy is a holistic, health philosophy and practice. People who specialize in homeopathy are called homeopaths, though other complementary health care professionals also use homeopathic philosophy and products in the

treatment of patients. Homeopathy is based on the principle of "The Law of Similars" (also known as "like cures like") meaning that a disease and its symptoms can be cured by a product known to produce similar symptoms. Products are intended to be used in low dosages based on the idea that as a homeopathic product is diluted, its healing effect increases.

"homeopathic medicine" means Homeopathic products that present in many forms such as pellets, oral droplets, syrups, creams and ointments. These products are made up of substances that come from plants, minerals, or animals.

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

"key personnel" has the meaning assigned to it in the Human Medicines Regulations, with appropriate application to complementary medicine manufacturers;

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

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

"marketing authorisation holder" means the person or entity to whom a marketing authorisation has been granted;

"probiotic" means a live microorganism which, when administered in adequate amounts, confers a health benefit on the host, when presented in a pharmaceutical dosage form with a health claim;

"risk category" means the risk classification assigned to a complementary medicine under regulation 6;

"traditional medicine" means a medicine based on indigenous knowledge and practices used in Botswana as provided for in section 45 of the Act, including plant-based, animal-based and mineral-based preparations used in traditional healing practices;

"traditional practitioner" means a person who practises traditional medicine in accordance with traditional knowledge, customs and beliefs, and who may be a member of a recognised traditional medicine practitioners association

"traditional use" means use an active ingredient or product combinationthat:

(a) is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time as set by the Authority; and

(b) accords with well-established procedures of preparation, application and dosage.

3. (1) Matters of general application across all regulated products, including governance, National Quality Control Laboratory, international cooperation, electronic systems, appeals, clinical trials and general offences framework, are governed by the General

Regulations and shall apply to the extent they are not inconsistent with these Regulations.

Application

4. (1) These Regulations apply to all complementary medicines placed on the market in Botswana, including —

(a) herbal medicines;

(b) homeopathic medicines;

(c) health supplements;

(d) probiotics intended to make health claims in a standardised dosage form;

(2) Cannabis-based herbal medicines may be registered under this Part subject to compliance with any additional requirements issued by the Authority.

(3) Complementary medicine shall not be presented as injectables or sterile preparations or any dosage formulation that may be considered beyond the risk profile of a complementary medicine by the Authority.

Regulatory principles

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

(a) apply a science-based risk-based and proportionate approach, recognising that different categories of complementary medicine present different levels of risk;

(b) protect human health, public health and the environment as primary considerations;

(c) calibrate regulatory requirements to the nature of claims made and the risk profile of the product, rather than applying uniform requirements designed for allopathic medicines;

(d) facilitate access to complementary medicines that are safe, appropriately quality-assured and efficacious ;

(e) respect and protect indigenous knowledge and traditional practices while ensuring adequate safety and quality standards;

(f) be transparent and consistent in regulatory decision-making; and

(g) take account of established international standards for complementary medicines, including World Health Organization guidelines and relevant regional guidance.

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

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

PART II – REGISTRABILITY DETERMINATION AND RISK FRAMEWORK

Registrability determination

6. (1) To confirm classification of products an applicant may request a pre-submission classification determination from the Authority before submitting a registration application. The request may be accompanied by the prescribed fee and shall include product details, proposed claims and supporting information.

(2) An applicant who is not satisfied with a classification determination may appeal in writing as per the appeal section of the regulations

Risk categories

7. (1) Within each product category, the Authority shall assign a risk category to each complementary medicine based on —

(a) the nature and extent of claims made;

(b) the ingredients and their safety profile;

(c) the route of administration;

(d) the target population, including whether the product is intended for vulnerable groups;

(e) the potential for adverse interactions with allopathic medicines; and

(f) the potential for misuse or harm.

(g) any other factor that may affect the quality, safety &efficacy of the product

(2) The risk categories shall be —

(a) Category 1 (Very Low Risk (Minimal to no processing)): products making only general wellness or nutritional support claims, with well-established safety profiles, not intended for therapeutic use. Subject to Administrative Notification Pathway registration;

(b) Category 2 (Low Risk (medium-high Processing)): products making only general wellness or nutritional support claims, with well-established safety profiles, not intended for therapeutic use. Subject to Abridged Pathway registration;

(c) Category 3 (Moderate Risk): products making health maintenance, structure-function or traditional use claims, supported by established use evidence. Subject to reliance Registration/comparable Pathway;

(d) Category 4 (Higher Risk): products making specific therapeutic claims, products intended for vulnerable populations, or products with ingredients with a less established safety profile. Subject to Standard Registration Pathway.

(3) Homeopathic medicines prepared in accordance with recognised homeopathic pharmacopoeias at dilutions of 4CH or higher shall generally be classified as Category 1 or Category 2 unless a specific therapeutic claim is made.

(4) The Authority shall publish risk category criteria in the guidelines and shall maintain a product classification list to assist applicants.

(5) Cannabis-containing products shall be classified according to their cannabinoid content, intended use, route of administration, and risk profile as determined by the Authority.

(6) The Authority may assign cannabis-containing complementary medicines to a higher risk category where—

(a) the product contains tetrahydrocannabinol (THC) above limits specified by the Authority;

(b) the product is intended for vulnerable populations;

(c) the route of administration presents increased safety concerns; or

(d) there is insufficient evidence regarding safety, quality or efficacy.

PART III – MARKET AUTHORISATION

Requirement for Registration or Market Authorization

8. (1) No complementary medicine shall be placed on the market in Botswana unless it is registered with the Authority or is otherwise exempted under these Regulations.

(2) For the avoidance of doubt, complementary medicines shall not be exempted from registration solely by reason of being "natural", traditional or widely used.

(3) Subregulation (1) does not apply to complementary medicines imported for personal use in accordance with section 64 of the Act or to investigational complementary medicines used in approved clinical trials.

(4) Importing, manufacturing, marketing, distribution, selling, advertising, promotion, storage, possession or dispensing of an unregistered complementary medicine constitutes an offence under Section 35 of the Act.

Registration pathways

9. (1) All complementary medicine not exempt from registration shall apply for registration at a fee prior to market access.

(2) The application shall be submitted through the following pathways as determined by the Authority —

(a) Administrative Notification Pathway/ Listing Pathway , for Category 1 (Low Risk (Minimal processing) products, requiring submission of product and quality information, safety profile and proposed labelling.

Notification screening shall confirm compliance and no unacceptable safety concerns no and unacceptable safety concerns.

(b) Abridged evaluation Pathway, for Category 2 (Low Risk (highly processed) products, requiring submission of product and quality information, safety profile and proposed labelling. Assessment shall confirm compliance and no unacceptable safety concerns.

(c) Reliance pathway/ Comparable Pathway Category 3 (Modirate risk) products, requiring evidence of established use/indication or recognised monograph support, quality documentation and safety information; and

(d) Standard Registration Pathway/ Full Review Pathway, for Category 4 (Higher Risk) products, requiring quality, safety and efficacy data proportionate to the claims made, and a risk management assessment.

(2) The Authority may move an application from one pathway to another where, upon assessment, the product's risk profile warrants a different classification, with written notification to the applicant.

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

Application for registration

10. (1) An application for a marketing authorisation for complementary medicine shall be submitted as determined by the Authority and shall be accompanied by —

(a) the prescribed application fee;

(b) administrative information, including details of the applicant and, where required, a local technical representative;

(c) quality documentation appropriate to the product category and risk category, as set out in the guidelines

(d) safety information appropriate to the risk category;

(e) evidence of efficacy or health claims appropriate to the risk category and the pathway applied for;

(f) proposed labelling and packaging artwork/labeling;

(g) evidence of Good Manufacturing Practice compliance for the manufacturing site;

(h) a risk management and Pharmacovigilance plans where required by the guidelines;

(i) a declaration of conformity;

(j) appointment of an authorized representative or loal technical representative, where applicable; and

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

(2) An applicant who is not resident or incorporated in Botswana shall appoint a local technical representative. The requirements for the appointment of a local technical representative are as set out in the Human Medicines Regulations, with necessary modifications.

(3) Where the applicant relies on established use evidence, documentary evidence of that use shall be provided in accordance with the relevant requirements stipulated on the guidelines.

Local presence requirement

11. (1) In accordance with section 36 of the Act, an applicant for registration of a complementary medicine who is not resident in Botswana shall appoint a local technical representative who shall be resident or incorporated in Botswana.

(2) The local technical representative shall—

(a) be responsible for all communications with the Authority;

(b) monitor complementary medicine on the market and inform the Authority immediately upon the detection of any problem relating to complementary medicine which may endanger public health;

(c) facilitate communication between the applicant and the Authority;

(d) handle complementary medicine recalls; and

(e) provide technical support and services to users of registered or complementary medicines granted market access

(3) The appointment of a local technical representative shall be documented using the prescribed form and as per the guidelines.

Screening and validation

12. (1) The Authority shall, after receipt of the application, acknowledge receipt and assign a unique reference number.

(2) The Authority shall conduct a validation review to determine whether the application is administratively complete and may accept the application for technical assessment or return it with written reasons.

(3) A returned application may be resubmitted within the stipulated date on the guideline or letter without additional fees, provided deficiencies are rectified.

(a) Applications not resubmitted within the specified time shall be deemed withdrawn.

(b) resubmission cycles will be detailed on the guidelines with an applicable fee where necessary

Assessment of applications

13. (1) The Authority shall assess applications having regard to the quality, safety and efficacy of the complementary medicine proportionate to its risk category and the

claims made, the appropriateness of the proposed labelling and claims, the adequacy of manufacturing controls, and the benefit-risk balance for the Botswana context.

(2) The Authority may, during assessment, request additional information from the applicant, consult with external experts or technical committees, require samples for testing, and rely on assessments from recognised regulatory authorities.

(3) Where additional information is requested, the assessment clock shall stop until a complete response is received. Failure to respond within the specified timeframe, shall result in the application being deemed cancelled /withdrawn.

(4)The Authority shall grant an applicant, assessments cycles as per the guideline 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.

(5) The fees for the two processes may be combined and received once.

Granting Marketing Authorisation and Validity

14. (1) The Authority, upon satisfactory completion of the scientific evaluation, shall grant marketing authorisation rights, in form of a registration certificate, to the applicant who at this point becomes the marketing authorisation holder (MAH).

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

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

(4) Product that have been granted marketing authorisation shall be incorporated into the register of complementary medicines, used as reference for subsequent regulatory processes.

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

(6) Marketing authorisation (certificate) shall be 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.

Registration conditions

15. (1) The Authority may impose conditions on a marketing authorisation for a complementary medicine relating to labelling and claims requirements, post-market

safety monitoring, restrictions on target population or sale settings, and such other matters as are necessary to manage identified risks Including but not limited to;

(a) Registration is subject to compliance with labelling requirements, therefore the Botswana registration number, schedule, manufacturer and applicant details should be included in the package insert and label

(b) You are required to submit information to the Authority annually in a prescribed manner accompanied by a prescribed annual retention fee to maintain your products in the register.

(c) An application for variation, accompanied by a prescribed fee, shall be submitted against any change of the product named in the registration certificate to the Authority.

(d) The registration is valid for 5 years and should you wish to retain the product(s) on the register, an application for renewal of registration should be submitted to the Authority at least six months before the marketing authorization expires

(e) This certificate can be revoked, suspended, cancelled or cease to be valid immediately after registration validity period.

(f) Should the risk profile of the product change, the Applicant will be required to comply with applicable requirements including submission of additional information.

(g) The product label(s), package insert, and promotional materials shall have the following statement: 'The product has not been assessed for quality, safety and efficacy by BoMRA.

(h) The registration certificate shall be revoked immediately if the registration contravenes any condition upon which it was issued.

(2) The marketing authorisation holder shall comply with all conditions and shall notify the Authority of any inability to comply.

Renewal of Market Authorization

16. (1) An application for renewal shall be-

(a) submitted at least six months before expiry,

(b) accompanied by the prescribed renewal fee,

(c) submitted according to the renewal guideline which may include but not limited to ; an updated benefit-risk assessment, a pharmacovigilance summary covering the entire authorisation period, confirmation of continued GMP compliance, notification of all variations, updated labelling if changed, any requirements as stipulated in guidelines

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

(3) Where renewal is applied for after expiry or the prescribed time, a late submission fee set out in the Fees regulations shall be payable;

(4) Upon renewal, the Authority may renew unconditionally, renew with amended conditions, require additional data, or refuse renewal with written reasons.

Retention of Marketing Authorization

17. (1) The Marketing Authorisation Holder shall retain the approved product on the complementary medicines register upon payment of **a**nnual retention fees as prescribed in the Fees Regulations and provision of any additional information as may be required by the Authority

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

(3) Where a MAH fails to retain their product in accordance with provision (1) and (2) above, the Authority shall suspend the marketing authorisation in line with regulation 15.

Variation of Registration

18. (1) No change to a registered complementary medicine shall be made without prior approval from the Authority~~,~~

(2) Variations shall be classified as minor using the same framework as set out in the Human Medicines Regulations, with adaptations as specified in the guidelines for complementary medicines.

Suspension of a Registered Complementary Medicine

19. (1) The Authority may suspend a marketing authorisation where —

(a) the product no longer meets registration requirements or conditions;

(b) the benefit-risk balance, taking into account human health, public health and environmental considerations, is no longer safe, efficacious for use;

(c) the holder fails to comply with conditions of registration;

(d) the product poses an unacceptable risk to human health, public health or the environment;

(e) annual retention fees remain unpaid after written notice; or

(f) it is otherwise in the public health or animal health interest.

(2) Before suspending, except in emergencies, the Authority shall notify the holder in writing of the proposed action and reasons and provide an opportunity to make representations within defined timelines as per the guideline.

(3) Where immediate action is required to protect public health, human health or the environment, the Authority may suspend immediately pending full consideration and shall notify the holder immediately, complete its consideration, and either lift the suspension, confirm cancellation, or impose conditions.

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

Cancellation from the register

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

(a) the grounds for suspension are not remedied within the time specified by the Authority;

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

(c) required fees remain unpaid for more than ninety days after anniversary date; or

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

(2) Cancellation procedures shall follow those applicable to suspension under section.. of the Act.

Revocation of the Registration Certificate

21. (1) The Authority may revoke a marketing authorisation where repeated or serious non-compliance is identified, the product can no longer be marketed consistently with the Act and public health interests, or the authorisation was obtained through fraud or material misrepresentation.

(2) Revocation shall be published in the Gazette and on the Authority's website.

Voluntary withdrawal of a Registered Complementary Medicine

22.(1) A marketing authorisation holder may voluntarily withdraw a marketing authorisation by notifying the Authority in writing as soon as reasonably practicable, indicating the date of the last importation, manufacture, or distribution of the authorised product, and the withdrawal shall not relieve the marketing authorisation holder of any obligations relating to product quality, safety monitoring, recalls, or any other obligations arising under these Regulations.

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

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

Maintenance of registers

23. (1) The Authority shall maintain and publish the following registers ;

(a) a register of all complementary medicines registered in Botswana, including applications & registration numbers, product names, marketing

authorisation holders, manufacturers, pack sizes, approved indications, and any conditions;

(b) a register of all manufacturing licences issued; and

(c) a register of all cancelled, suspended, revoked and withdrawn registrations and licences.

(2)The registers shall be available for public use, published on the Authority's website and updated as per new entries or removal or updated information.

Labelling of herbal medicines

24. (1) In addition to the general labelling requirements of Part VIII, the labelling of a herbal medicine shall include —

(a) the botanical name of each plant ingredient, in addition to the common name;

(b) the part of the plant used;

(c) the form of the herbal preparation, such as extract, tincture, powder or dried herb;

(d) a statement that the product is a herbal medicine;

(e) any warnings relating to known adverse effects, contraindications, interactions with other medicines, or special precautions; and

(f) a statement that the product should not replace conventional medical treatment for serious conditions.

(2) The label shall not state or imply that the product can treat, cure or prevent a disease unless such claims are supported by adequate clinical evidence and approved by the Authority.

Exemption from registration of complementary medicines

25. (1) The Authority may, in accordance with section 35(4) of the Act, in such special circumstances as it considers appropriate, exempt in writing complementary medicine from the requirements for registration.

(2) A complementary medicine in relation to which an exemption may be granted includes—

(a) a complementary medicine which has not been registered but was prescribed outside Botswana for a patient’s personal use;

(b) a complementary medicine which is required by a practitioner, dentist or herbalist, for the treatment of a patient or;

(c) a complementary medicine intended for re-export in the form and packaging in which it was imported;

(d) a donated complementary medicine in compliance with section 66 of the Act;

(e) a complementary medicine imported by a wholesaler where there are no registered alternatives;

(f) a complementary medicine imported for research purposes or approved clinical investigations;

(g) a complementary medicine required during a declared public health emergency or in the public interest;

(h) a complementary medicine manufactured locally for registration purposes;

(i) samples for registration purposes;

(j) extemporaneous preparations made by a pharmacist, practitioner, herbalist for a particular patient in Botswana, or

(k) such other circumstances as may be detailed in guidelines.

(3) An application for exemption shall be made as per the guideline and shall be accompanied by the prescribed fee as set out in the Fees Regulations.

(4) The Authority may require a person importing complementary medicines under subregulation (1) to provide evidence of a valid prescription from a practitioner or herbalist or any additional information as evidence of need

(5) An exemption under subregulation (1) shall be subject to such conditions as the Authority shall impose, including requirements for labelling, storage, and distribution.

(6) Where the Authority exempts a complementary medicine, the applicant shall be accountable for its quality, safety and efficacy on the supply chain.

(7) A person may import an unregistered complemantary medicine for personal use without obtaining an exemption under regulation 6 of the General regulations, provided that the quantity imported does not exceed a 3 months supply.

(8) An exemption under subregulation (1) shall be valid for such period as the Authority may determine and shall be subject to such conditions as the Authority may impose.

Registration during public health emergencies

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

(a) operate expedited assessment procedures;

(b) grant conditional or emergency use authorisations;

(c) waive or reduce fees;

(d) rely on emergency use authorisations from recognised authorities; and

(e) accept rolling submissions of data.

(2) Complementary medicines registered under emergency provisions shall be subject to enhanced post market surveillance and review when the emergency ends.

Listing of Complementary medicines

27. (1)The Authority may list and publishes on the website;

(a)products that may be new category fitting the profile of complementary.

(aa) Annual retention fees as set out in the Fees Regulations shall be applicable to listed complementary medicines.

(ab) A listing shall be valid until the complementary medicine is called for registration or for a period of five years, whichever is earlier.

(b)The Authority may List of prohibited complementary ingredients, sources and products and publish on the website.

Prohibition of undesirable substances

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

(a) it poses unacceptable risk to human or animal health; Page 21 Medicines and Related Substances (General) Regulations, 2025

(b) it has no demonstrated therapeutic value;

(c) safer or more effective alternatives are available;

(d) its use is contrary to the public interest; or

(e) it is required by international convention or agreement.

(2) Before prohibiting a substance, except in emergencies, the Authority shall

(a) conduct a risk assessment;

(b) consult with relevant stakeholders; and

(c) publish a draft prohibition for comment for at least thirty days.

(3) Prohibited substances shall be listed in Schedule 3 to the General Regulations, the list is not exhaustive .

(4) The Authority shall periodically review the list of prohibited substances.

(5) The Authority may prescribe maximum permissible limits for tetrahydrocannabinol (THC) in complementary medicines and may prohibit specific cannabinoid substances or preparations where public health concerns exist.

PART IV – TRADITIONAL MEDICINES

Scope and policy

29. (1) In accordance with section 45 of the Act, this Part applies to medicines based on indigenous knowledge and practices used in Botswana, including plant-based, animal-based and mineral-based preparations.

(2) The Authority shall support the development and formalisation of the traditional medicines sector and shall consult with the Ministry responsible for health, indigenous knowledge custodians and traditional practitioner associations in the development of guidelines and policies for traditional medicines.

(3) The Authority shall take into account the importance of protecting indigenous knowledge while promoting safety and quality of traditional medicines on the market.

(4) Traditional medicines containing cannabis and supported by documented traditional use may be considered for registration, subject to safety, quality and risk management requirements established by the Authority.

Application for Market Authorisation

30. (1) An application for registration of a traditional medicine shall include —

(a) evidence of traditional use in accordance with regulation 33;

(b) quality specifications in accordance with regulation 34;

(c) safety information, including any known adverse effects, contraindications, interactions and precautions; and

(d) support from a recognised traditional practitioner association or council, where applicable.

(2)Traditional medicines may be registered through the Simplified Registration Pathway, subject to the evidence requirements outlined in the guidelines

(3)A traditional medicine making specific therapeutic claims beyond those supported by traditional use evidence shall be subject to the Standard Registration Pathway.

Evidence of traditional use

31. (1) Evidence of traditional use shall demonstrate continuous use of the medicine for a minimum period of thirty years, of which at least fifteen years shall be within Botswana or Africa.

(2)Evidence of traditional use may be demonstrated through —

(a) documented use in published ethnobotanical, ethnopharmacological or ethnomedical literature;

(b) recognised pharmacopoeial or monograph references, including the African Pharmacopoeia and the World Health Organization monographs on selected medicinal plants;

(c) statements from recognised traditional practitioner associations or indigenous knowledge holders, duly authenticated; or

(d) a combination of the foregoing.

(3) Where the traditional medicine is a combination product, evidence of traditional use shall be provided for the combination as traditionally used, or for each individual component where the combination is novel.

(4) Evidence of traditional use for cannabis-containing traditional medicines shall include documentation of historical use, preparation methods, dosage practices and safety considerations.

Quality and safety requirements

32. (1) The quality documentation for a traditional medicine shall include —

(a) botanical or biological identification of each ingredient, including taxonomic name, common name and part used;

(b) qualitative and quantitative composition;

(c) specifications for identity, purity and quality, including tests for microbial contamination, heavy metals, pesticide residues and aflatoxins;

(d) Description of the manufacturing process

(e) stability data; and

(f) evidence of Good Manufacturing Practice compliance and Good Agricultural practices.

(2) The Authority may require additional toxicological data where the safety profile of the traditional medicine is not adequately established by evidence of traditional use.

(3) The labelling of a traditional medicine shall clearly state that the product is a traditional medicine and shall include appropriate safety warnings.

Traditional Medicines Advisory Council

33. (1) The Authority may establish or recognise a Traditional Medicines Advisory Council to advise on —

(a) the registration and regulation of traditional medicines;

(b) the protection and documentation of indigenous knowledge;

(c) the development of quality standards and evidence requirements appropriate for traditional medicines; and

(d) such other matters as the Authority may refer to the Council.

(2) The composition and terms of reference of the Traditional Medicines Advisory Council shall be determined by the Authority in consultation with the Ministry responsible for health and traditional medicine stakeholders.

PART V – MANUFACTURING LICENCE

Requirement for manufacturing licence

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

(a) manufacture;

(b) sell or supply;

(c) export or import;

(d) distribute;

(e) dispense; Or

(f) store for commercial purposes,

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

(2) Subregulation (1) does not apply to

(a) an individual purchasing or receiving complementary medicine products for personal use; and

(b) persons exempted by the Authority by notice in the Gazette.

(3) A licence is specific to

(a) the person to whom it is issued;

(b) the premises specified;

(c) the activities authorised; and

(d) the product categories authorised.

Categories of licences

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

(a) manufacturing licences;

(b) import and export licences;

(c) distribution and wholesale licences;

(d) retailing and dispensing licences;

(e) bonded warehouse licences; and

(f) special licences.

Application

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

(a) the prescribed application fee as per Fee Regulations

(b) company registration documents;

(c) facility location and ownership documents;

(d) detailed floor plans and facility layout;

(e) list of products and dosage forms to be manufactured;

(f) pharmaceutical quality system documentation;

(g) list of key personnel for approval; and

(h) such other documents as may be required in the guidelines.

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

(a) medicines manufacturing;

(b) repackaging and relabelling operations, or any other complementary medicine product as the Authority may determine.

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

Key personnel requirements

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

(a) a Production Manager;

(b) a Quality Assurance Manager; and

(c) a Quality Control Manager.

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

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

Current good manufacturing practice compliance

38. (1) No manufacturing licence shall be issued unless the Authority is satisfied that the

manufacturing facility complies with current good manufacturing practices as specified in the guidelines and such other standards as may be specified by the Authority.

(2)Manufacturers of cannabis-containing complementary medicines shall implement additional controls relating to cultivation sources, traceability, extraction processes, cannabinoid standardisation, security measures and prevention of diversion as determined by the Authority.

(3) The Authority shall conduct an inspection to verify good manufacturing practice

compliance before granting a manufacturing licence.

(4) The inspection shall assess compliance with good manufacturing practice requirements as detailed in guidelines published by the Authority. Issuance of a manufacturing licence

39. (1) Where the Authority is satisfied that all requirements are met, it shall issue a

manufacturing licence in the prescribed form specifying

(a) licence number;

(b) licensee name and licensed premises;

(c) manufacturing category;

(d) authorised activities and product types;

(e) names of approved key personnel;

(f) validity period, being one year;

(g) conditions of licence; and

(h) date of issue.

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

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

(b) ensure approved key personnel are present during operations;

(c) manufacture only authorised products at the licensed premises;

(d) maintain records as specified by the guidelines; and

(e) such other conditions as the Authority may impose.

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

Certificate of compliance with good manufacturing practice

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

(2) A certificate issued under this regulation shall

(a) be specific to the manufacturing site, dosage form, product category, and scope of activities inspected or assessed;

(b) state the date of issuance and period of validity; and

(c) be subject to such terms and conditions as the Authority may determine.

(3) The Authority may issue a certificate based on

(a) a routine, pre-licensing, post-licensing, or for-cause inspection conducted by the Authority; or

(b) reliance on, or recognition of, a valid inspection outcome or certificate issued by a recognised regulatory authority, where applicable.

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

(a) three years, where the certificate is issued following a full inspection conducted by the Authority or through regional cooperation bodies or a recognised regulatory authority; or

(b) two years, where the certificate is issued following a risk-based inspection, abridged inspection, or reliance on a recognised regulatory authority.

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

(a) non-compliance with good manufacturing practice is identified;

(b) information submitted in support of the application is false or misleading; or

(c) continued reliance on the certificate may pose a risk to public or animal health.

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

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

PART VI – DISTRIBUTION, RETAIL AND DISPENSING

Application for distribution and wholesale licence

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

(a) the prescribed application fee;

(b) company registration documents;

(c) details of qualified personnel as specified in the guidelines; and

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

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

(a) medicines wholesale;

(b) bonded warehouse; or

(c) combined facility with other regulated products including cosmetics

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

Assessment and inspection of distribution and wholesale operations

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

(a) Good Storage and Distribution Practices as set out in WHO Technical Report

(b) Series No. 1025 (2020) and subsequent revisions;

(c) Good Distribution Practice for Medical Devices, where applicable; and

(d) such other standards as may be specified by the Authority.

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

(a) suitability of premises and storage facilities;

(b) adequacy of quality management systems;

(c) temperature and environmental monitoring capabilities;

(d) qualification and competence of personnel;

(e) documentation and record-keeping systems;

(f) traceability and inventory management systems;

(g) transportation and delivery arrangements;

(h) security measures and access controls; and

(i) such other requirements as may be specified by the Authority.

Application for retailing and dispensing licence

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

(a) the prescribed application fee;

(b) company registration documents;

(c) details of the qualified person or responsible pharmacist;

(d) scope of activities and regulated products applied for; and

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

Categories of retail licences

44. (1) The scope of permitted complementary medicine products under each retail licence category shall be as follows

(a) Stand-alone pharmacies: a licence issued under this category shall authorise the retail sale and dispensing of controlled substances, prescription-only medicines, pharmacy medicines, and over-the-counter medicines for human use, subject to supervision by a registered pharmacist and compliance with good practices, applicable professional and regulatory requirements;

(b) Hospital pharmacies: a licence issued under this category shall authorise the procurement, storage, compounding where applicable, and dispensing of prescription-only medicines, controlled medicines, pharmacy medicines, and overthe-counter medicines, and other medical products required for inpatient and outpatient care, exclusively for use within the licensed health facility;

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

(d) Dispensaries: a licence issued under this category shall authorise the retail sale and supply of prescription-only medicines, controlled medicines, pharmacy medicines, and over-the-counter medicines for animal use or for human use, in accordance with conditions determined by the Authority

and applicable legislation, subject to supervision by a suitably qualified person and compliance with good practices, applicable professional and regulatory requirements;

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

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

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

Assessment and inspection of retailing and dispensing operations

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

(a) conduct documentary assessment; and

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

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

(a) suitability of premises and dispensing facilities;

(b) adequacy of quality management systems;

(c) temperature and environmental monitoring capabilities;

(d) qualification and competence of personnel;

(e) documentation and record-keeping systems;

(f) traceability and inventory management systems;

(g) patient counselling and dispensing areas;

(h) security measures and access controls;

(i) availability of reference materials and medicines information resources;

(j) facilities for compounding, where applicable;

(k) cold chain management systems, where applicable;

(l) prescription handling and verification procedures where applicable;

(m) adverse event reporting systems; and

(n) such other requirements as may be specified by the Authority.

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

(a) facilitate access by inspectors at any reasonable time;

(b) make personnel available for interview;

(c) demonstrate operational readiness. Issuance of licence

(d) provide requested documentation and access to all evidence required; and

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

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

(a) the name and address of the licensee;

(b) the category of licence;

(c) the scope of authorised activities;

(d) the licensed premises address;

(e) the name and registration number of the responsible pharmacist or qualified person;

(f) conditions and restrictions, if any;

(g) the validity period; and

(h) the licence number and date of issue.

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

(a) the premises do not meet good practice requirements;

(b) the applicant lacks a suitably qualified responsible pharmacist or qualified person;

(c) the quality systems are inadequate;

(d) there is evidence of previous serious non-compliance; or

(e) the applicant has provided false or misleading information.

(4) The Authority shall

(a) issue the licence if requirements are met;

(b) issue the licence with conditions;

(c) defer the decision pending rectification of deficiencies; or

(d) refuse the application, stating reasons in writing.

Licensing of bonded warehouses

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

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

(a) particulars of the premises, layout, and storage conditions;

(b) evidence of approval or control by the relevant customs authority;

(c) details of security, access control, and inventory management systems;

(d) particulars of the responsible person and key personnel; and

(e) any other information required by the Authority for risk assessment.

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

(a) sale, distribution, or supply of medical products to the local market; or

(b) any manipulation of complementary medicine products other than activities expressly permitted by the Authority.

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

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

Special licences

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

(a) e-pharmacy licences, authorising the supply of medical products through

(b) electronic or digital platforms, subject to conditions determined by the Authority;

(c) licences for importers, exporters, or handlers of precursor chemicals, authorising the importation, storage, or supply of precursors used in the manufacture of medical products or controlled substances;

(d) mobile pharmacy licences, authorising the provision, dispensing, or supply of medical products from a mobile or temporary unit, vehicle, or outreach facility, under conditions specified by the Authority; and

(e) such other specialised activities relating to medical products as the Authority may specify by notice or guideline.

(2) A special licence issued under this regulation shall

(a) define the scope of authorised activities;

(b) be subject to such terms, conditions, and limitations as the Authority may

determine; and

(c) be valid for a period determined by the Authority using a risk-based assessment.

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

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

General application requirements

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

(a) the prescribed application fee;

(b) proof of company registration in Botswana;

(c) details of premises including floor plans;

(d) description of proposed activities;

(e) details of responsible persons and key personnel;

(f) evidence of qualifications and experience of key personnel;

(g) evidence of appropriate storage facilities and equipment; and

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

(2) The Authority shall

(a) acknowledge receipt within a timeline stipulated on the guideline;

(b) conduct pre-licensing inspection where required; and

(c) make a decision on a complete application within the stipulated timeline on the guideline.

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

Conditions of licence

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

(a) product categories that may be handled;

(b) activities that may be conducted;

(c) personnel requirements;

(d) quality system requirements;

(e) record-keeping requirements;

(f) reporting requirements;

(g) inspection access; and

(h) any other matter relevant to compliance.

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

(3) Conditions may be

(a) imposed at the time of licensing;

(b) added during the licence period following inspection or review;

(c) amended upon application by the licensee; or

(d) removed when no longer necessary.

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

Validity and renewal of licence

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

(a) three years, where the licensee demonstrates sustained compliance with

(b) applicable standards and a low regulatory risk profile; or

(c) two years, where the licensee presents a moderate regulatory risk requiring

(d) enhanced oversight.

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

(a) the suitability of premises and equipment;

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

(c) the effectiveness of the quality management system;

(d) compliance with applicable standards and guidelines;

(e) past regulatory compliance history; and

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

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

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

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

(4) Application for renewal shall be

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

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

(c) accompanied by the prescribed renewal fee.

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

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

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

Change of business ownership

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

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

(a) details of proposed new ownership;

(b) reasons for the change;

(c) confirmation that operational standards will be maintained;

(d) details of any changes to key personnel; and

(e) such other information as the Authority may require.

(3) The Authority may

(a) approve the change;

(b) approve the change with amended conditions;

(c) require additional information; or

(d) refuse approval where public health may be compromised.

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

Suspension and cancellation of licence

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

(a) has contravened or failed to comply with the Act, these Regulations, or any condition of the licence;

(b) has failed to maintain compliance with applicable standards, guidelines, or good regulatory practices;

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

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

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

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

(a) an imminent or serious risk to public or animal health is identified;

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

(c) continued operation of the licensed activity would undermine regulatory control or public confidence.

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

(a) written notice of its intention to suspend or cancel the licence; and

(b) a reasonable opportunity to make representations within the period specified in the notice.

(4) Upon cancellation or suspension, the licensee shall

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

(b) surrender the licence certificate to the Authority within the period directed;

(c) secure, dispose of, or transfer any stock of medical products in accordance with written directions issued by the Authority; and

(d) retain and make available all records relating to the licensed activities for the prescribed retention period or such longer period as the Authority may require.

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

Variation of licence

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

(2) Variations shall be classified as

(a) minor variations, being changes that do not materially affect the risk profile,

(b) scope of licensed activities, or compliance status of the licensee; and

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

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

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

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

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

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

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

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

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

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

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

Post-licensure notifications

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

(2) Post-licensure notifications shall include

(a) temporary or short-term operational disruptions;

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

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

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

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

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

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

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

(a) acknowledge the notification without further action;

(b) require additional information or clarification;

(c) impose additional licence conditions or corrective actions; or

(d) require the licensee to submit an application for variation or take other

(e) regulatory action.

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

Notification of changes for manufacturing licences

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

(a) any change in key personnel;

(b) extended absence of key personnel exceeding thirty days;

(c) temporary closure of facility;

(d) emergencies affecting operations;

(e) product recalls or serious quality defects;

(f) regulatory actions by other authorities; and

(g) such other changes as may be specified by the Authority.

Registers for controlled substances by licensed establishments

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

(2) The registers for controlled substances shall include

(a) a controlled substances stock register, recording quantities received, supplied, dispensed, transferred, destroyed, or otherwise disposed of;

(b) a supplier and recipient register, including licence details and authorisations;

(c) a prescription or order register, where applicable, detailing prescriber or authorising practitioner particulars;

(d) a loss, theft, discrepancy, and incident register, including investigations and corrective actions; and

(e) such other registers as the Authority may prescribe by notice or guideline.

(3) Registers shall be maintained in a manner that ensures full traceability of controlled

substances, including batch numbers, dates, quantities, and balance carried forward after each transaction.

(4) Registers may be maintained in electronic or hard-copy form, provided that

(a) entries are made contemporaneously and are accurate and complete;

(b) records are protected against unauthorised access, alteration, or loss; and

(c) the system allows for audit trails and inspection by the Authority.

(5) Registers relating to controlled substances shall be retained for a minimum period of five years, or for such longer period as the Authority may require, having regard to the nature of the substance and regulatory risk.

(6) A licensed establishment shall make all controlled substances registers available to

inspectors upon request, and failure to maintain, update, or produce such registers shall constitute serious non-compliance under these Regulations.

Maintenance and publication of registers by the Authority

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

(2) The registers maintained by the Authority shall include

(a) a register of licensed establishments, indicating the licence category, scope of authorised activities, validity period, and licence conditions;

(b) a register of suspended licences, indicating the grounds for suspension and duration;

(c) a register of cancelled or revoked licences, indicating the date and grounds for cancellation or revocation; and

(d) an inspection register, recording inspections conducted, inspection type, dates, and regulatory outcomes.

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

(a) the protection of confidential, commercially sensitive, or security-related

(b) information; and

(c) applicable data protection and access-to-information laws.

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

PART VII – IMPORT AND EXPORT

Requirement for Import and export authorisation

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

(2) Authorisation requires

(a) a valid import or export licence for the entity; and

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

(3) The Authority may refuse authorisation where

(a) the product is not registered/listed, unless an exemption applies;

(b) the product is prohibited;

(c) the product is substandard or falsified;

(d) the product has inadequate remaining shelf-life;

(e) the applicant does not hold a valid licence; or

(f) it is otherwise in the public interest.

(4) Import and export permits for complementary medicines shall be applied for and processed in accordance with the requirements set out in regulation 65 of the general regulations of the Human Medicines Regulations, with necessary modifications for complementary medicine categories

Import and export permits

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

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

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

(4) Permits shall specify

(a) permit number;

(b) Details of the importer and exporter

(c) product details and quantity;

(d) authorised route/s;

(e) validity period as set out in in the relevant guidelines

(f) any conditions; and

(g) inspection requirements.

(h) Any other informations that shall be specified in the relevant guidelines

Authorised ports of entry

61. (1) In accordance with section 63 of the Act, complementary medicine products may only be imported or exported through the ports of entry designated in the relevant guidelines and as per the general regulations.

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

(a) maintain import/export control arrangements at designated ports as per the MoU/MoA;

(b) facilitate inspection/verification of consignments;

(c) share information on imports and exports; and

(d) coordinate enforcement activities.

(3) Complementary medicine products shall not be imported through postal services except

(a) small quantities for personal use as approved; or

(b) samples for registration purposes;

Products in transit

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

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

(3) The holder of a transit permit shall

(a) ensure products remain under customs control;

(b) not release products into the domestic market;

(c) not process, repackage, or alter products during transit;

(d) notify the Authority within forty-eight hours of departure from Botswana; and

(e) maintain records of the transit.

(4) Transit permits shall be valid for period as prescribed in the relevant guidelines.

(5) Contravention of transit permit conditions constitutes an offence punishable by a fine not exceeding P1 000 000 or imprisonment for three years, or both

Donated medical products

63. (1) In accordance with section 66 of the Act, donated complementary medicine products require authorisation from the Authority.

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

(3) Donated products shall

(a) meet the same quality standards as commercially imported products;

(b) have adequate remaining shelf-life as specified in the guidelines;

(c) be appropriately labelled in English;

(d) be on the national essential medicines list or otherwise appropriate for the Botswana context;

(e) not be near-expiry products inappropriate for the healthcare setting; and

(f) comply with the Authority's guidelines on donations, which shall align with World Health Organization guidelines.

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

(5) Where donated products do not meet requirements, the Authority may seize, quarantine, confiscate or order re-export at the importers cost.

Personal importation

64. (1) In accordance with section 64 of the Act, a person entering or re entering Botswana may import complementary medicine products for personal treatment without a permit, subject to the following;

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

(b) the product is not prohibited in Botswana;

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

(d) the person declares the product at customs. The quantities of imported products shall be limited to a ninety-day supply.

(2) Personal importation is not permitted for

(a) narcotic drugs;

(b) psychotropic substances;

(c) Schedule 1D medicines;

(d) products prohibited in Botswana;

(e) Precursor chemicals;

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

Import and export of controlled substances

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

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

(a) product details including international non-proprietary name;

(b) quantity;

(c) International Narcotics Control Board certificate where required;

(d) export authorisation from the exporting country;

(e) purpose of import;

(f) importer or end-user details;

(g) storage and security arrangements;

(h) supplier details; and

(i) intended port of entry.

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

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

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

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

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

(8) Permits for controlled substances shall

(a) be product and quantity specific;

(b) specify the authorised route;

(c) be valid for six months;

(d) require return to the Authority after use; and

(e) require reconciliation of quantities imported against quantities utilised.

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

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

(11) Import and export of controlled substances shall be applied for complementary medicines and processed in accordance with the requirements set out in regulation 65 of the Human Medicines Regulations, with necessary modifications for complementary medicine categories.

(12) Importation or exportation of cannabis-containing complementary medicines shall be subject to additional permit requirements determined by the Authority and any applicable international drug control conventions.

(13) The Authority may establish THC thresholds below which cannabis-containing complementary medicines may be regulated under simplified controls.

Records for controlled substances

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

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

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

(b) concerned;

(c) name and business address of the supplier;

(d) date on which the medicine was received;

(e) import permit number in the case of imports;

(f) export permit number in the case of exports;

(g) name and business address of the purchaser;

(h) date of sale of the medicine; and

(i) invoice or reference number of such sale.

(3) Registers kept by dispensers shall contain

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

(b) name and business address of the supplier;

(c) date on which the medicine was received;

(d) name and address of the patient to whom the medicine was dispensed;

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

(f) dispensed;

(g) date of such dispensing; and

(h) name and address of the prescriber.

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

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

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

(7) All records shall be

(a) maintained separately from other records;

(b) in indelible ink or electronic format that cannot be altered;

(c) maintained for a minimum of five years after the last entry; and

(d) available for inspection at all times.

(8) A register shall not be transferable without the Authoritys approval.

(9) A person who keeps a register under the Act shall make corrections to the register by drawing a line through the entry being corrected and shall insert his or her initials on the

corrected entry, and no correction shall be masked or done with correction fluid, and there shall be no overwriting.

(10) Records for controlled substances shall be applied for complementary medicines and processed in accordance with the requirements set out in regulation 65 of the Human Medicines Regulations, with necessary modifications for complementary medicine categories

Sale and use of precursor chemicals

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

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

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

Storage of medical products by prescribers

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

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

Storage of medicines

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

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

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

PART VIII – LABELLING, PACKAGING AND CLAIMS

Product information and labelling requirements

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

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

(a) the product name and, where applicable, the brand name;

(b) the common name and, for herbal and traditional medicines, the botanical name of each active ingredient;

(c) the quantity of each active ingredient per dosage unit;

(d) the dosage form;

(e) the contents of the container;

(f) the name and address of the manufacturer;

(g) the name and address of the marketing authorisation holder;

(h) the registration number issued by the Authority;

(i) the batch number;

(j) the date of manufacture and expiry date;

(k) any special storage conditions that may be necessary or desirable;

(l) dosage instructions and route of administration;

(m) special warnings, contraindications and precautions, including any relevant drug interactions;

(n) Category 1-3 products shall have the following statement “Not assessed for quality, efficacy and safety by BoMRA”

(o) a statement identifying the product category, such as "Herbal Medicine", "Homeopathic Medicine", "Health Supplement", "Probiotic" or "Traditional Medicine"; and

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

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

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

(a) full name of the patient;

(b) date of dispensing;

(c) pack size;

(d) name and signature of the dispenser; and

(e) all information required for the purposes of subregulation (2).

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

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

(8) Cannabis-containing complementary medicines shall additionally include—

(a) quantitative cannabinoid content per dosage unit;

(b) THC content;

(c) warnings regarding impairment, driving or operation of machinery where applicable;

(d) pregnancy and breastfeeding warnings where applicable; and

(e) any additional warnings determined by the Authority.

Claims Classification

71.(1) Claims made for complementary medicines shall be classified as follows —

(a) nutritional and composition claims, relating to the presence or content of a nutrient or other substance;

(b) function claims, relating to the physiological role of a nutrient or other substance in supporting normal health; and

(c) therapeutic claims, relating to the prevention, treatment or cure of a disease or medical condition.

(2) Claims shall be consistent with the risk category of the product and the evidence submitted in support of the registration.

(3) The Authority shall publish an approved claims list in the guidelines, identifying which claims are permitted for each product category and risk category without requiring additional clinical evidence.

Prohibited claims

72(.1) The following claims are prohibited on complementary medicines —

(a) claims to diagnose, treat, cure or prevent a serious disease unless supported by adequate clinical evidence and specifically approved under the Standard Registration Pathway;

(b) claims implying that the product is a substitute for medical treatment;

(c) claims of guaranteed efficacy;

(d) claims that the product has no side effects or adverse reactions;

(e) claims that are misleading, deceptive or exaggerated; and

(f) claims that are inconsistent with the approved registration and product information.

Language requirements

73. (1) The labelling of a complementary medicine shall be in English.

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

(3) For traditional medicines, the Authority may permit labelling in a relevant local language where this aids consumer understanding.

PART VIII – QUALITY CONTROL AND LABORATORY SERVICES

National Quality Control Laboratory

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

(a) analyse and test complementary medicine products for quality, safety and efficacy;

(b) support market surveillance through sampling and testing;

(c) conduct research relevant to quality control;

(d) provide training and capacity building;

(e) maintain and disseminate reference standards; and

(f) provide quality control services to public and private entities.

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

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

Application for laboratory services

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

(2) Applications shall be accompanied by

(a) the prescribed fee;

(b) samples in required quantity and condition;

(c) product information including specifications;

(d) special handling instructions where applicable; and

(e) such other information as may be required.

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

Certificate of analysis

76. (1) In accordance with section 34 of the Act, the Laboratory shall

(a) analyse samples promptly upon receipt;

(b) issue a Certificate of Analysis upon completion;

(c) specify the tests performed and results obtained; and

(d) state whether the sample conforms to specifications.

(2) A Certificate of Analysis shall be signed by the Laboratory head or authorised delegate.

(3) The Certificate of Analysis shall constitute prima facie evidence of the matters stated therein in any legal proceedings.

Use of external laboratories

77. (1) In accordance with section 110 of the Act, the Authority may

(a) subcontract analysis to approved independent laboratories within or outside Botswana;

(b) rely on test results from accredited laboratories; and

(c) utilise Government Laboratories where appropriate.

(2) External laboratories used by the Authority shall

(a) be accredited to ISO/IEC 17025 for relevant methods;

(b) participate in proficiency testing; and

(c) be approved by the Authority.

(3) The Authority shall maintain and publish a list of approved external laboratories.

PART IX – ADVERTISING AND PROMOTION

Requirement for advertising approval

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

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

(a) the proposed advertising materials;

(b) the target audience;

(c) the media to be used;

(d) the duration of the campaign;

(e) references supporting claims made; and

(f) the prescribed fee.

(3) The Authority shall respond to advertising applications within the timeline specified on the guidelines.

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

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

Advertising standards

79. (1) All advertising of complementary medicines shall —

(a) be accurate, truthful and not misleading;

(b) be balanced, presenting both benefits and risks;

(c) be consistent with the approved product information and registered claims;

(d) clearly identify the product category;

(e) not claim efficacy beyond what is supported by the approved registration;

(f) include appropriate safety information where warranted; and

(g) not be targeted at children for products not intended for or safe for use by children.

(h) be appropriate for the target audience; and

(i) comply with the Authority's guidelines on advertising.

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

(3) Advertising to the general public is permitted only for over-the-counter medicines and general sale medicines;

Prohibited advertising practices

80. (1) The following advertising practices are prohibited for complementary medicines —

(a) advertising of unregistered complementary medicines;

(b) claims to treat, cure or prevent serious diseases beyond what is approved;

(c) use of testimonials in a manner that is misleading;

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

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

(f) comparison with competitors products without substantiation;

(g) promotional activities disguised as scientific or educational;

(h) inducements to healthcare professionals that may improperly influence prescribing;

(i) advertising to children for products not indicated for children; and

(j) presentation as a complete substitute for medical treatment;

(k) use of scientific-sounding language that misrepresents the evidence base; and

(l) any other practice prohibited by the Authority in the guidelines.

(2) Contravention of this regulation is an offence punishable by a fine not exceeding P500 000 or imprisonment for two years, or both.

Online sales and advertising

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

(2) Online sales authorisation requires

(a) a valid retail or wholesale licence;

(b) a dedicated online sales permit;

(c) systems to verify customer identity and age;

(d) secure payment and data protection systems;

(e) appropriate storage and distribution arrangements;

(f) a mechanism for receiving and handling complaints; and

(g) compliance with advertising requirements.

(3) Online sellers shall

(a) display their licence number prominently;

(b) display Authority contact information;

(c) provide accurate product information;

(d) verify prescriptions before supplying prescription medicines;

(e) not sell prohibited or restricted products; and

(f) maintain records of all transactions.

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

PART X – VIGILANCE AND POST-MARKET SURVEILLANCE

Vigilance obligations

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

(2) Marketing authorisation holders, importers, and distributors shall

(a) establish and maintain vigilance systems;

(b) appoint a qualified person responsible for vigilance;

(c) report adverse events as required;

(d) conduct signal detection and assessment;

(e) implement risk minimisation measures; and

(f) respond to Authority requests for information.

(3) Healthcare facilities, authrised premises, health practitioners and endusers shall

(a) report suspected adverse events;

(b) cooperate with investigations; and

(c) provide access to relevant records.

(4) The Authority may inspect vigilance systems at reasonable times to ensure compliance.

(5) Marketing authorisation holders of cannabis-containing complementary medicines shall implement enhanced pharmacovigilance measures and submit periodic safety update reports as specified by the Authority.

Reporting of adverse events

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

(a) suspected or unexpected adverse reactions;

(b) lack of expected efficacy;

(c) safety signals;

(d) adverse reactions suggesting unusual frequency or severity;

(e) field safety corrective actions;

(f) quality defects;

(g) regulatory actions in other countries; and

(h) such other matters as specified in the guidelines.

(2) Reporting timelines shall be

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

(b) serious adverse reactions: within seven days;

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

(d) periodic safety reports: as specified in conditions of registration.

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

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

Post-market surveillance

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

(a) sampling and testing of products on the market;

(b) monitoring of vigilance data;

(c) analysis of complaints;

(d) targeted surveillance based on risk;

(e) international collaboration on safety signals; and

(f) periodic benefit-risk reassessment.

(2) Marketing authorisation holders shall

(a) establish post-market surveillance systems;

(b) monitor the performance of their products;

(c) submit annual post-market surveillance reports; and

(d) not supply substandard or falsified products.

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

Product recall

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

(a) the product is non-compliant with specifications;

(b) the product has caused or is likely to cause injury;

(c) the product is defective or mislabelled; or

(d) new safety information warrants recall.

(2) The Authority may order a recall where

(a) the marketing authorisation holder fails to initiate voluntary recall;

(b) the Authority determines a recall is necessary to protect public health; or

(c) investigation reveals safety concerns.

(3) Recall procedures shall follow the Authoritys published guidelines and shall include

(a) classification of recall level based on risk;

(b) notification to the Authority within twenty-four hours of initiating recall;

(c) public notification where appropriate;

(d) strategy for recovering affected products;

(e) effectiveness checks; and

(f) final reconciliation report.

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

Disposal of unfit products

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

(2) Unfit products shall be disposed of

(a) in accordance with Authority guidelines;

(b) using methods that prevent diversion;

(c) using methods that protect the environment and the public; and

(d) with documentation of disposal.

(3) Where a person is unlikely to dispose of unfit products appropriately, the Authority may dispose of the products at the persons cost.

(4) Disposal shall be documented and certificates retained for inspection.

PART XI – INSPECTION

Appointment of Inspectors

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

(2) Inspectors shall

(a) hold appropriate qualifications as specified in the guidelines;

(b) receive training in inspection procedures;

(c) be furnished with certificates specifying their scope of authority;

(d) carry official identification; and

(e) be bound by a code of conduct.

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

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

Powers of inspectors

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

(a) enter and inspect any premises where regulated products(inc complementary medicines) are manufactured,

(b) stored, distributed, sold, dispensed or administered;

(c) stop and inspect vehicles, vessels or aircraft carrying regulated products;

(d) examine activities and question persons;

(e) examine, copy and seize records;

(f) take samples of products, raw materials and environmental samples, without

(g) compensation;

(h) seize, quarantine or detain products suspected or found to be non-compliant;

(i) seal or close premises where there is immediate risk to public health;

(j) investigate alleged offences;

(k) order disposal of non-compliant products; and

(l) issue improvement notices and administrative fines.

(2) Powers under this regulation may be exercised

(a) at any reasonable time;

(b) without notice where there is reason to believe evidence may be concealed or

(c) destroyed; and

(d) with notice where a routine or scheduled inspection is planned.

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

(4) Persons responsible for premises shall

(a) not obstruct inspectors;

(b) provide access to all areas and records;

(c) provide reasonable assistance; and

(d) answer questions truthfully.

Risk-based inspection

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

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

(a) the classification and inherent risk of the medical products handled;

(b) the compliance history and inspection outcomes of the entity;

(c) the type, complexity, and scale of licensed operations;

(d) the time elapsed since the last inspection;

(e) information derived from vigilance systems, adverse event reports, recalls, and complaints;

(f) inspection findings, alerts, or assessments from other regulatory authorities; and

(g) intelligence information or other credible data relevant to regulatory risk.

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

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

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

Inspection procedures

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

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

(3) For routine announced inspections, the Authority shall

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

(b) where applicable, provide an inspection agenda and an indicative list of areas to be covered;

(c) conduct the inspection in a systematic and risk-based manner;

(d) conduct a closing meeting to discuss preliminary findings; and

(e) issue a written inspection report within the number of days specified in the guidelines.

(4) The Authority may conduct unannounced inspections where

(a) there is reason to believe that serious or systemic non-compliance may exist;

(b) advance notice may result in concealment, alteration, or destruction of evidence;

(c) there is an immediate or potential risk to public or animal health; or

(d) the inspection is conducted to verify the implementation of corrective and preventive actions.

(5) Inspection reports shall document observations and classify them as

(a) critical observations, presenting an immediate or significant risk to public or

(b) animal health and requiring immediate regulatory action;

(c) major observations, constituting significant non-compliance requiring

(d) corrective action within a specified timeframe; and

(e) minor observations, representing deviations that should be corrected but pose

(f) limited regulatory risk.

(6) A licensed entity shall submit corrective and preventive action plans in response to

inspection observations within the timeframes specified by the Authority, and shall implement such actions as approved.

(7) The outcome of an inspection shall inform the Authority's compliance assessment and risk profiling of the licensed entity, and may influence inspection frequency, licence conditions, or other regulatory actions.

Termination of inspection

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

(2) An inspection may be aborted where

(a) the licensee or any person acting on its behalf obstructs, interferes with, or fails

(b) to cooperate with the inspection;

(c) access to premises, records, systems, or personnel required for the inspection is

(d) denied or unreasonably restricted;

(e) conditions at the premises pose a risk to the safety or security of inspectors;

(f) evidence relevant to the inspection is suspected to have been concealed, altered,

(g) or destroyed;

(h) essential personnel are unavailable without reasonable justification; or

(i) any other circumstance arises that materially compromises the integrity or objectives of the inspection.

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

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

(b) notify the licensee of the abortion and the grounds thereof; and

(c) Sampling and testing

(d) determine the appropriate regulatory action, which may include rescheduling the

(e) inspection, conducting an unannounced inspection, imposing licence conditions, or initiating enforcement action.

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

Sampling and testing

92. (1) Inspectors may, for the purposes of verifying quality, safety, efficacy, or regulatory

compliance, take samples of regulated products during inspections or other regulatory activities conducted under the Act and these Regulations.

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

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

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

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

PART XII – OFFENCES AND PENALTIES

General offences

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

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

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

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

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

(e) fails to report adverse events as required;

(f) fails to implement a recall when required;

(g) advertises without approval or in contravention of approval;

(h) fails to maintain required records;

(i) fails to comply with conditions of registration or licence;

(j) imports or exports through an unauthorised port;

(k) sells expired, substandard or falsified products; or

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

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

Specific offences and penalties

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

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

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

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

(d) advertising without approval: a fine not exceeding P1 000 000 or imprisonment for three years, or both;

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

(f) failure to report serious adverse event: a fine not exceeding P1 000 000 or imprisonment for three years, or both;

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

(h) transit permit violation: a fine not exceeding P1 000 000 or imprisonment for three years, or both;

(i) controlled substances violation: a fine not exceeding P5 000 000 or imprisonment for seven years, or both; and

(j) false or misleading information: a fine not exceeding P5 000 000 or imprisonment for seven years, or both.

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

(3) The court may order

(a) forfeiture of products;

(b) closure of premises;

(c) disqualification from holding a licence; and

(d) payment of costs of investigation and prosecution.

Corporate liability

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

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

(a) the offence was committed without his or her knowledge or consent; and

(b) he or she exercised all due diligence to prevent the commission of the offence.

Compounding of offences

96. (1) In accordance with section 121 of the Act, where a person admits to an offence in

writing, the Chief Executive Officer may compound the offence before court proceedings are instituted.

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

(3) Compoundable offences are listed in Schedule 5 of the general regulations.

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

(5) Payment of a compound amount shall

(a) be made within thirty days;

(b) constitute a complete defence to any charge for the offence;

(c) not constitute an admission of guilt for any other purpose; and

(d) be recorded by the Authority.

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

Recovery of expenses

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

(a) costs of sampling and testing;

(b) costs of investigation;

(c) costs of seizure and storage; and

(d) costs of disposal.

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

PART XIII – APPEALS

Right of appeal

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

(2) An appeal shall be lodged within thirty days of notification of the decision.

(3) An appeal shall

(a) be in writing;

(b) state the decision appealed against;

(c) state the grounds of appeal;

(d) include supporting evidence; and

(e) be accompanied by the prescribed fee.

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

Appeals Committee procedures

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

(a) be constituted as provided in section 113;

(b) hear appeals on dates and at places determined by the Chairperson;

(c) give both parties opportunity to present their case;

(d) have power to summon witnesses and require production of documents;

(e) make decisions by majority vote; and

(f) issue written decisions within fourteen days of the hearing.

(2) The Appeals Committee may

(a) confirm the Authoritys decision;

(b) set aside the Authoritys decision;

(c) vary the Authoritys decision; or

(d) remit the matter to the Authority for reconsideration.

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

PART XIV – FINAL PROVISIONS

Guidelines

100. (1) In accordance with section 6 of the Act, the Authority may issue guidelines and directives for implementation of these Regulations, including product classification criteria, evidence requirements by category, quality standards, approved claims lists, GMP standards for each complementary medicine category, and advertising standards.

(2) Guidelines shall be

(a) developed with stakeholder consultation;

(b) based on international best practices;

(c) published on the Authority's website;

(d) regularly reviewed and updated; and

(e) made available in accessible formats.

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

Forms

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

(2) The Authority may

(a) approve alternative forms;

(b) accept electronic equivalents;

(c) modify forms from time to time; and

(d) waive form requirements where appropriate.

Transitional provisions

102. (1) Products registered as complementary medicines under the Human Medicines Regulations before the commencement of these Regulations shall be deemed to be registered under these Regulations until their next renewal date.

(2) Marketing authorisation holders of complementary medicines registered before commencement shall, within the period specified in the guidelines, submit reclassification declarations, update labelling in accordance with these Regulations, and establish vigilance systems proportionate to the risk category of their products.

(3) The Authority shall publish a detailed transitional plan specifying deadlines and procedures.

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

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

(6) The Authority may publish additional transitional arrangements as necessary

Savings

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

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

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

Repeal

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

COMPOUNDABLE OFFENCES

(Regulation 67)

Offences that may be compounded include: advertising without approval, failure to notify of changes, minor labelling non-compliance, failure to submit periodic reports within prescribed timeframe, minor claims violations, and such other offences as the Authority may designate by notice. Compounding fees shall be determined by the Authority having regard to the nature and severity of the offence.

Made this _____ day of _____, 2026

_____

MINISTER OF HEALTH

Republic of Botswana

SCHEDULE 1

Designated active ingredients

Item	Ingredient or kind of ingredient
1	an amino acid
2	charcoal
3	a choline salt
4	an essential oil
5	plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
6	a homoeopathic preparation
7	a microorganism, whole or extracted, except a vaccine
8	a mineral including a mineral salt and a naturally occurring mineral
9	a mucopolysaccharide
10	non-human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates
11	a lipid, including an essential fatty acid or phospholipid
12	a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
13	a sugar, polysaccharide or carbohydrate
14	a vitamin or provitamin

SCHEDULE 2

APPLICATION FOR REGISTRATION OF COMPLEMENTARY MEDICINES
SECTION 1: ADMINISTRATIVE:
1.1 Product and Applicant details

Name, Address, Telephone and Fax numbers, and email address of Applicant:	Click or tap here to enter text.

Proprietary name of product:	Click or tap here to enter text.
Authority Application Number:	TO BE ALLOCATED BY AUTHORITY
INN or Botanical Name (e.g. Vitamin D, Gingko Biloba etc):	Click or tap here to enter text.
Presentation, Strength and dosage form:	Click or tap here to enter text.
Pack size(s):	Click or tap here to enter text.
Uses of the final product:	Click or tap here to enter text.
Source (plant, chemical, animal etc)	Click or tap here to enter text.
Name and physical address of Manufacturer (s): (*Attach GMP certificates/ Manufacturing licence/ ISO certificate for manufacturing sites)*	Click or tap here to enter text.
Countries where product is marketed (*attach authorisation letters)*	Click or tap here to enter text.
Type of application: New or Renewal	Click or tap here to enter text.

1.2 Declaration form

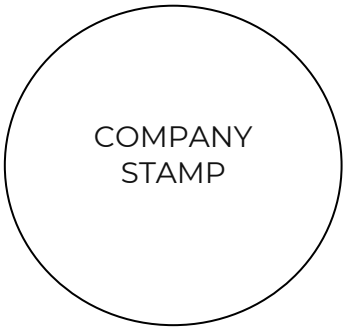
DECLARATION BY THE APPLICANT

1. All information submitted in the application form for registration of complementary medicines is accurate.
2. All uses for this product have been declared on the application form.
3. There are no hidden side effects, cautions, contra indications etc not declared in the application.
4. All promotional material shall be submitted to the Authority for approval before such material is used.
5. Any unwanted/harmful effects shall be reported to the Authority in writing with immediate effect.

Name: Click or tap here to enter text. Position: Click or tap here to enter text.

Signature:Click or tap here to enter text. Date: Click or tap here to enter text.

Qualification: Click or tap here to enter text.



DECLARATION BY MANUFACTURER

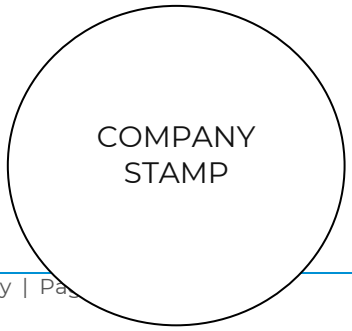
I, the undersigned certify that all the information supplied in this form and all accompanying documentation is correct.

1. This product is not toxic to humans.
2. Any unwanted/harmful effects shall be reported to the Authority in writing with immediate effect.
3. All promotional material shall be submitted to the Authority for approval before such material is used.
4. There are no hidden side effects, cautions, contra indications etc not declared in the package insert/package label.

Name: Click or tap here to enter text. Position: Click or tap here to enter text.

Signature: Click or tap here to enter text. Date: Click or tap here to enter text.

Qualification: Click or tap here to enter text.



PLEASE REFER TO THE COMPLEMENTARY MEDICINE GUIDELINE AS YOU FILL IN THIS FORM

SECTION 2: COMPOSITION

Tabulate the following Schedule of:

- Active ingredients: Give approved name (if known); quantity per unit, specify if active and give the usefulness in the final product.
- Inactive ingredients: Give reason for inclusion (if known), quantity per unit dose, specify if inactive and give the usefulness in the final product.
- Any other raw material used in manufacturing even if not present in final product e.g. water, alcohol.

Ingredients	Unit (mg/ unit)	Purpose for inclusion	Uses for ingredient
e.g Ingredient A		e.g. active	e.g. helps with colds and flu
e.g. Ingredient B		e.g. inactive	e.g. diluent

SECTION 3 PACKAGE INSERT

Package insert shall bear the following:

- Approved name (as it appears on the label)
- Local or common name by which easily known
- Composition
- What it is used for
- Direction of use
- Presentation (powder, mixture, cake etc)
- Contra-indications/Warning /Known symptoms of over-dosage
- Storage information and shelf life
- Manufacturer and or Applicant

The actual copy of the package insert must be attached to the application form.

SECTION 4: PHARMACEUTICAL DOCUMENTATION

Give the listed details as part of your pharmaceutical documentation:

4.1 Comments on Specifications for Excipients

For excipients obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), a letter of attestation with supporting documentation shall be provided confirming that the material is not from a BSE/TSE affected country/area.

4.2 Specifications of the finished product e.g colour expected, consistencies in case of liquid medicines etc. Attach Certificates of Analysis for Final product. The CoA must include Control for Heavy Metals.

4.3 Stability Testing Data – Finished product

Results of stability studies done on product must be submitted and the table of summary of the stability studies must be completed in the template below.

Description of stability study details:

Parameters Monitored:

Container Closure system:

Storage Conditions (°C, % RH)	Batch Number	Batch Size	Completed Time (in months)

Summary and discussion of stability study results:

Proposed storage conditions and shelf life:

4.4 Manufacturing procedures. To be presented in a flow diagram.

4.5 Container closure system

Description of the material of container closure systems, including unit size or volume.

SECTION 5: SAFETY AND QUALITY ASSURANCE of Active Ingredients

Provide information on the following where applicable

5.1 Botanical Authentication of Herbal Components
5.2 Safety and Toxicological information on the product
5.3 General qualitative and quantitative tests of Active Ingredients

5.4 Purity tests of the Active Ingredients

SECTION 6: Evidence of Claim
Provide proof of claim supported by:

a. Clinical data (i.e. including medical indications which are well-established in some countries and which have been validated by clinical trials, the results of which are recorded in the scientific literature);
b. For uses described in pharmacopoeias and other well-recognized documents (i.e. medicinal uses that have been well-established in many countries and are included in official pharmacopoeias or official government monographs
c. For uses described in traditional medicine (i.e. indications described in non-official pharmacopoeias and other forms of literature or purely traditional uses).

SECTION 7: POST-MARKET SURVEILLANCE PLAN
A satisfactory post-market surveillance plan must be provided in the application for registration of a complementary medicine. The plan must include but not limited to: adverse drug reaction form, product defect form. This requirement is applicable to herbal-based substances.

SCHEDULE 3

Registrability application

- Submit form with relevant documentation
- The form and accompanying documents should be emailed to registrability@bomra.co.bw
- Multiple applications can be submitted on the same email
- Content in italics is for guidance purposes only, replace with actual information

Section 1: Applicant Details

Company/Person Name	
Telephone Number(s)	
Email Address	
Physical Address (Companies)	
BRIMS Account Number	

Section 2: Product Details

Brand Name	
Ingredients	*Vitamin C 1000 mg,*
Product Form	*e.g. Capsules, Powder, Tea*
Label Claims and/or Indications	*No therapeutic claims or similar is not permitted. Indicate the claims made on the product*
Pack size(s)	*100g/100 mL*
Product Description	*Round white*
Route of Administration	*Topical, Oral, Injectable, Inhalation*
Manufacturers' Name	
Manufacturers' physical Address	
Countries where product has market authorization	*List countries here, and attach evidence of market authorization*

Section 3: Attachments

Attachment	**Attached?**
Label	Indicate yes or no
Package Insert	
Advertising/Promotional Material	
Instructions for use if not clear on the label	

Section 4: Product Interface Self-Assessment

Indicate which of the following product categories the product may fall under.

Product Category	**Relevant**
Allopathic Medicine	*Indicate Yes where relevant*
Complementary Medicine	
Cosmetic	
Food	
Medical Device	
Veterinary Medical Product	

Section 5: Declaration By The Applicant

I, the undersigned, certify that all the information in this application form including the accompanying documentation concerning determination of classification/registrability of this product is correct and unadulterated. I further confirm that the information referred to in this application file is available for verification by the Authority.

Name : _____
Position : _____
Signature/Initials : _____
Date : _____

Section 6: For Official Use Only
Determination of Registrability
Official 1

Name and Designation	
Classification	
Reasons	
Additional Information Required	
Is yes state what is required	

Official 2

Name and Designation	
Classification	
Reasons	
Additional Information Required	
Is yes state what is required	

Official 3

Name and Designation	
Classification	
Reasons	
Additional Information Required	
Is yes state what is required	

SCHEDULE 4

APPLICATION FORM VARIATIONS

Application details

VARIATION APPLICATION FORM			
Registration Enter Registration No.	Product Name:		
Applicant's Full Name:	Type name in full here.		
Postal Address	Enter Postal address here.		
Contact Person Name	Contact person name.		
Title:	Mr/Ms/Dr/Prof.	Telephone & Fax:	Enter contact number.
Email:	__	Website:	___

NOTIFICATIONS (ANNUAL & IMMEDIATE)

A change can only be submitted as a notification if it complies fully with the conditions and documentation requirements as specified in the Guideline for Variation of Complementary Medicines. The variation number as laid down in the variation guideline should be indicated.

Use the table below to summarize notification variations.

Summary of changes						
Variation number and description	**Pre-change details**	**Post-change details**	**Justification or Background**	**Date of implementation**	**Conditions Fulfilled**	**Documents and Countries where each variation is approved**
				21 August 2021	*Conditions 1, 2, 3, 4, 6, 7 are fulfilled*	*Documentation 1, 2, 3, 4, 5 are submitted*

MINOR & MAJOR VARIATIONS

For Minor and Major variations, kindly populate the below table (do not change the format) with a comment for each condition and documentation applicable to the variation, extracted from the BoMRA variation guideline.

N.B. Generate a new table for each variation in the submission.

Variation category, number and description e.g.,

1. *Minor variation (Vmin), variation number xx as per BoMRA variation guidelines:*

Change inxxx.

Variation type	**Current Details**	**Proposed details**	**Reasons for change**	**Conditions**	**Documents and Countries where each variation is approved**
V Min: 33c	***FPP Batch sizes*** *100 000 tablets*	***FPP Batch sizes*** *100 000 tablets 2 000 000 tablets*	*To meet increased market need*	*Conditions 1, 2, 3, 4, 5, 6, 7 are fulfilled*	*Documentation 1, 2, 3, 4, 5, 6, 7 are submitted*

Conditions:

Populate the applicant's comments for each applicable condition
Condition 1
Applicant's comments:
Condition 2
Applicant's comments:
Condition 3
Applicant's comments:
Condition 4
Applicant's comments:

Documentation:

Populate the applicant's comments for each applicable document	Location in the dossier
1. Document 1	
Applicant's comments:	
2. Document 2	
Applicant's comments:	

Countries where each variation is approved

NB: If approvals from other National Regulatory Agencies (NRA's) are available, applicants are encouraged to attach as part of submission documents to be considered during evaluation.

S/N	**Agency/ Authority where variation approval was obtained**	**Proof of approval**
1.	*TGA (Australia)*	*TGA variation approval provided as annex 2, page 6. Insert Hyperlink* or state location

CERTIFICATION

I hereby submit an application for the concerned product/s to be varied in accord ance with proposal given above. I declare that

- There are no other changes than those identified
- All conditions for the change(s) concerned are fulfilled; and
- The required documents as specified for the change(s) have been submitted.

Name: Name in Full Position: Indicate Job title

Signature: Date:Enter Date