Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By:

Mr. Bathusi Kgosietsile
Director – Product Evaluation and Registration

17/04/2026
Date of Approval (DD/MM/YY)

Table of Contents

Revision status sheet 3
1 Purpose 4
2 Scope 4
3 Definitions and abbreviations 4
3.1 Definitions 4
3.2 Abbreviations 6
4 Guidelines 7
4.1 General Requirements 7
4.2 Possible Access Scenarios 11
4.3 Wholesale-based and Hospital based Exemption Application 11
4.4 Patient-Based Exemption Application 12
4.5 Exemption of donated unregistered medicines 12
5 Turnaround Time and Validity 13

Revision status sheet

Page	Changes made	Issue No	Process Owner (Title)	Initiated By (Name)	Reviewed By (Name)	Date
	List of clauses rephrased and expanded:1, 2, 3, 4.1.11, 4.1.15, 4.1.16, 4.18, 4.2.1 c), 4.16, 5.2	6.0	Team Leader, post-registration		Botshelo Lediretse	18/02/2026
	Clauses added: 2.2.2, 2.2.3, 4.1.3, 4.1.16- 4.1.17, 4.1.28, 4.2.1 b) & d), 4.1.20, 4.31 c-f, 4.1.18.1-4.1.18.2, 4.4					

1 Purpose

1.1 The purpose of these guidelines is to facilitate access to good quality medicines which are not registered and/or where registered alternatives are not available in Botswana and to provide guidance to applicants seeking exemption from medicine registration. Such authorisation is intended to grant access to medicines on an exceptional basis, where conventional therapies have been ruled out, have failed, or are unavailable.

1.2 In accordance with Section 23 (3), (4) and (5) of the Medicines and Related Substances Act, 2013, the Authority may, under special circumstances, grant exemption from registration for a medicine, subject to such conditions as it may determine.

2 Scope

2.1 These guidelines are only applicable to medicine registration exemption applications made for medicines intended for human use only.

2.2 This document does **not** apply to:

2.2.1 Unregistered products that have already been imported into Botswana without prior approval.

2.2.2 Unregistered medicines used in clinical trials. Guidelines that detail authorisation for the use of unregistered medicines as part of a clinical trial can be accessed at BoMRA website: https://www.bomra.co.bw/

2.2.3 The importation of Extemporaneously prepared medicines in premises including compounding facilities authorized or unauthorized in the country of origin to export such medicines.

2.2.4 All Cosmetic products including injectable products for cosmetic and/or aesthetic purposes such as IV nutritional therapy for aesthetic purposes.

2.2.5 Complementary medicines (except in atypical cases)

3 Definitions and abbreviations

3.1 Definitions

For the purpose of this guideline, the following definitions shall apply:

3.1.1 Act- The Medicines and Related Substances Act of 2013 and as subsequently amended.

3.1.2 Applicant - A healthcare professional duly registered with Botswana Health Professions Council submitting the application.

3.1.3 Approved names of active ingredient(s) - Name of the active ingredient (s)

3.1.4 Availability – a registered medicinal product obtainable from normal distribution channels in a reasonable time (up to 21 days) will be considered available for use

3.1.5 Alternative: an equivalent licensed medicinal product

3.1.6 Biologics - are therapeutic substances that are produced through a biological process (often involving biotechnology methods) these include antibody therapies, vaccines, gene therapies, and cell therapies

3.1.7 Biosimilar - A similar biotherapeutic product, a follow-on biologic, subsequent entry biologic is similar (not equivalent) in terms of quality, safety, and efficacy to an already registered reference biopharmaceutical product.

3.1.8 Blue book - medicine register for medicine or related substance registered by BOMRA for use in Botswana.

3.1.9 Brand name -The brand name or trade name of a product.

3.1.10 Dosage Form - The administration form of the completed pharmaceutical product (e.g., tablet, capsule, suspension, injection etc.).

3.1.11 Facility- Any place where a patient goes to seek medical intervention, i.e., pharmacy, clinic, or hospital.

3.1.12 MAH - The entity to whom a market authorization is issued or has been issued

3.1.13 Medicine/drug -This refers to a substance or mixture of substances used or purporting to be suitable for use, manufactured, or sold for use in the alleviation, modification, or prevention of ill health.

3.1.14 Motivation - Justification for exemption.

3.1.15 Name of drug/medicine - The brand name, trade name, and/or generic name.

3.1.16 Patient-based Exemption - An exemption applied for an individual patient.

3.1.17 Public Health Emergency- an extraordinary event which is determined as

a) Constituting a public health risk to other States through the international spread of disease.

b) Potentially requiring a coordinated international response.

c) This definition implies a situation that: is serious, unusual, or unexpected; carries implications for public health beyond the affected State's national border and may require immediate international action.

3.1.18 Purchase Orders- an official document a facility (as defined above) sends to a wholesaler requesting a product(s).

3.1.19 Strength - The amount of active ingredient in a drug/medicine in standard units.

3.1.20 Wholesale-based Exemption - An exemption applied for or granted to a wholesaler (including Central Medical Stores).

3.2 Abbreviations

3.2.1 BOMRA- Botswana Medicines Regulatory Authority

3.2.2 BHPC- Botswana Health Professions Council

3.2.3 BRIMS- BoMRA Regulatory Information Management System

3.2.4 CMS- Central Medical Stores

3.2.5 ICH- The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

3.2.6 OSD- Oral Solid Dosage form

3.2.7 MAH- Marketing Authorization Holder(s)

3.2.8 PIC/S - Pharmaceutical Inspection Cooperation/Scheme.

3.2.9 SmPC - Summary of Product Characteristics

3.2.10 WHO- World Health Organization

4 Guidelines

4.1 General Requirements

4.1.1 Applications for exemptions must be submitted on BRIMS, https://brims.bomra.co.bw/

4.1.2 Exemption from Registration may be applied for only under special circumstances, such as when there is no registered product or, registered alternatives are unavailable, or when registered therapies have been tried without the desired therapeutic outcomes. This does not include justifications such as cost, convenience, or operational needs.

4.1.3 An unlicensed/ unregistered medicinal product may not be applied for where an equivalent licensed/registered medicinal product can meet the defined special clinical needs of the patient, unless in exceptional cases where substitution poses a risk to the intended patient and the prescriber has clearly motivated with the backing of historical medical evidence.

4.1.4 Persons/institutions authorized to apply for exemptions and import unregistered medicines are:

- 4.1.4.1 Licensed Importers
- 4.1.4.2 Licensed Hospital Facilities
- 4.1.4.3 Central Medical Stores or authorized designate

4.1.5 Where there is a registered product or registered alternatives, and for valid reasons they are not available (see definition of availability above) for sale in the Botswana market:

- 4.1.5.1 Evidence of unavailability from the manufacturer(s), MAH, or local distributor(s) of the registered alternative (if available) should be provided.
- 4.1.5.2 Further to this, the authority shall also verify the unavailability of registered alternatives.
- 4.1.5.3 The authority may make use of a medicine shortage database (where available) to establish the availability of a registered medicine.

4.1.6 Exemption from registration may not be applied for, where a product has been denied registration due to unresolved safety, efficacy, and quality reasons.

4.1.7 An application can either be Wholesale based, hospital based, or Patient based.

4.1.8 For applicable fees, applicants should refer to the BoMRA Fees 2019 found on the BOMRA website. The fees are subject for review as and when the need arises.

4.1.9 For a wholesale-based exemption application;

4.1.9.1 The applicant is the local Responsible Pharmacist from a licensed importer/distributor/wholesaler or hospital whose role is to ensure that all the information is included in the application form and all the documents are attached to the application.

4.1.9.2 For subsequent applications, the Authority may request for distribution history (including quantities imported, dispensed, and remaining stock)

4.1.9.3 Applicants must also provide a declaration that the previous order for which authorisation was granted was used for the purpose, in the manner and for the duration for which authorisation was granted.

4.1.10 For requests based on Central Medical Stores orders, CMS should be the applicant, unless CMS specifies otherwise, and this should be supported by evidence of authorization issued by CMS.

4.1.11 Quantity requested should be supported by unsolicited orders emanating from the requesting facilities:

i. Orders from government facilities should be in the form of a Government Purchase Order (GPO). A Letter of Commitment (LOC) will be considered under exceptional cases. Request for Quotation (RFQ) shall never be considered as evidence for an order.
ii. Order requests must not be older than six months. Each order may only be used once.
iii. Quantities not commensurate with orders provided in the application will be rejected.

4.1.12 For a patient-based exemption application; the prescriber is the applicant whose role is to ensure that all the required information is included in the application form.

4.1.12.1 Prescribers will be required to provide details of previous treatment regimens using registered medicines to justify the proposed switch to an unregistered product.

4.1.12.2 Progress reports may be required for subsequent applications involving the same molecule, to substantiate the continued need for the unregistered product.

4.1.12.3 The dispensing pharmacist is to check whether the information provided by the prescriber is correct and complete.

4.1.12.4 Patients **may not** apply for their own exemption.

4.1.13 The prescriber is required to keep patient consent forms detailing that the patient has understood that they have been prescribed an unregistered medicine(s) as well as progress reports for the patient(s) on the unregistered medicine(s). This information should be made

available to the Authority for inspection. In all situations, dispensing pharmacists are required to inform the patient of the status of registration of the medicine before dispensing.

4.1.14 Concerning donations applicants should refer to Guidelines for handling Pharmaceutical Donations - BOMRA/IL/IE/P02/G02. All donated unregistered medicines must be accompanied by the relevant documentation as outlined in clause 4.5 Exemption of donated unregistered medicines. Unregistered medicines that have been deemed unacceptable in the donor country for safety, quality, and efficacy-related reasons will not be eligible for exemption.

4.1.15 Exemption from registration may be applied for where a variation for a registered medicine has been submitted. Applicants must submit proof of the variation submission.

4.1.16 For variation/amendment requests, on Exemption from Registration import permit the following shall apply:

4.1.16.1 If the variation/amendment is due to an error made by the Authority, the applicant may provide a letter or email detailing the nature of the amendment.

4.1.16.2 If the variation/amendment is due to incorrect information submitted by the applicant prior to approval, the applicant may provide a letter or email detailing the nature of the amendment.

4.1.16.3 Post-approval amendments are permitted only are limited to the following details:

a) Product pack size
b) Importer details
c) Supplier details
d) Port of entry

For any other changes, a new Exemption from Registration application must be submitted along with the applicable fees.

4.1.17 Variation/amendment on an expired exemption import permit will not be considered. In this case, Applicants must lodge a new application.

4.1.18 Unregistered medicines may be subjected to pre-distribution inspection by the Authority or designated personnel from other institutions upon their importation. The importers are required to maintain records of distribution including dispensing information to allow traceability of the exempted unregistered medicines to their final destination. This information should be made available to the Authority for inspection at any given time.

4.1.18.1 Unregistered medicines from India imported by licensed importers and authorized importers shall be subjected to pre-shipment inspection as stipulated in the guidelines for Import and Export of medicines-*BOMRA/IL/IE/P02/G01*.

4.1.18.2 Unregistered medicines from other countries may be subjected to pre-shipment inspection by the Authority upon their importation.

4.1.19 Adverse Drug Reactions and Product Defects of exempted medicines must be reported to the Authority within 48 hours, whether confirmed or suspected. The importer of the unregistered medicines shall, in conjunction with the Authority, institute a product recall where a recall is required.

4.1.20 Product information (SmPC, Package insert and outer Label) for exempted medicines should originate from the MAH, FPRR, or FPP manufacturer declared in the application form and be written in English.

4.1.21 The patient-based exemption route may be used by medical practitioners to provide access (upon consultation with the patient) to unapproved investigational medicines to their patients where there are existing/beneficial therapeutic options.

4.1.22 Post-trial access: Participants of clinical trials receiving unregistered medicines may continue to receive the unregistered medicine post the clinical trial via the Patient -Exemption route. Only those participants who derive benefits from the investigational product will be considered (this excludes participants on the standard of care, placebo, and registered medicines)

4.1.23 For chronic medications: resubmission or refill can be sought 60 days before the expiry date of the exemption approval letter.

4.1.24 Advertisement(s), promotion, and sale of exempted medicines for purposes other than those declared on the application is strictly prohibited.

4.1.25 The authority will monitor the frequency and extent of exemption request applications and may recommend that an application for registration be lodged with the Authority for a frequently sought-after unregistered medicine(s).

4.1.26 Notwithstanding the above, the authority may

4.1.26.1 request additional information and documentation

4.1.26.2 impose any additional conditions

4.1.26.3 inspect the site where the unregistered medicine is manufactured, stored or administered; or

4.1.26.4 withdraw the authorisation to treat the patient, if the Authority is of the opinion that the safety of any patient is compromised, that the scientific reasons for administering the unregistered medicine have changed or for any other reason as determined by the Authority.

4.1.27 All documents **must** be in English.

4.2 Possible Access Scenarios

4.3 Wholesale-based and Hospital based Exemption Application

4.3.1 The following documents must be submitted when applying for wholesale-based exemption:

a) Proforma Invoice or Purchase order for each medicine to be imported. The proforma shall state the following:

i. PFI/PO number and date
ii. Name of the supplier
iii. Name of the manufacturer
iv. Trade or proprietary name of the medicine
v. The International Non-Proprietary name (generic name) of the product, its strength and dosage form
vi. The quantity to be imported for each drug, its unit value, total value
vii. Signature and/or stamp of the importer.

b) Unsolicited Orders from facilities received by the wholesaler.

c) Product information (SmPC, Package insert and outer Label) of exempted medicines should be from the FPP manufacturer declared in the application form and should be written in English.

d) Evidence of out-of-stock of the registered product. Evidence must be from the manufacturer(s), MAH, or local distributor(s) of the registered alternative.

e) A Certificate of Analysis (CoA) for the batch(es) to be imported. The tested parameters must be adequate to confirm the quality of the product and should include, but are not limited to: Description, Identification, Related Substances (including specified impurities, individual unknown impurities, and total impurities), Assay, Dissolution (for oral solid dosage forms), and Sterility (for sterile products). If the testing site and the FPP manufacturer are different entities, the relationship between the two sites should be clearly described by the applicant

f) A valid Registration Certificate for the Finished Pharmaceutical Product from the country of origin and from authorities listed in the BoMRA Reliance/ Recognition on Information from Regional and International Bodies guideline- *BOMRA/ER/MD/P04/G07*.

g) A Valid cGMP certificate for the Finished Pharmaceutical Product manufacturing site in line with the Guideline for Good Manufacturing Practice, Document No: BOMRA/IL/IL/P08/G01

4.4 Patient-Based Exemption Application

4.3.1 The following documents are to be submitted when applying for patient-based exemption:

4. Application for Registration Exemption - Patient - ***BOMRA/ER/EX/P02/F01*** completed by the prescriber

5. Valid Prescription from a prescriber registered with BHPC.

6. Patient identity document i.e. Omang/ Passport/ birth certificate

7. Product professional information/ Package insert for the specific product, written in English

8. Proforma Invoice or Purchase order. The proforma invoice or purchase order shall state for each medicine to be imported, the following:

i. PFI/PO number and date
ii. Name of the supplier
iii. Name of the manufacturer
iv. Trade or proprietary name of the medicine OR the International Non-Proprietary name (generic name) of the product, its strength and dosage form
v. The quantity to be imported for each drug, its unit value, total value
vi. Signature and or stamp of the importer

f. For chronic medications: resubmission or refill can be sought 60 days before the expiry date of the exemption approval letter.

4.5 Exemption of donated unregistered medicines

4.5.1 The following documents are to be submitted:

a) Application form for Registration Exemption – ***BOMRA/ER/EX/P02/F02***

b) A donation certificate/letter of donation from donor

c) Acceptance letter from the intended recipient of donation and/or Ministry of Health

d) Product information (SmPC, Package insert and outer Label) of exempted medicines should be from the FPP manufacturer declared in the application form and should be written in English.

e) A Certificate of Analysis (CoA) for the batch(es) to be imported. The tested parameters must be adequate to confirm the quality of the product and should include, but are not limited to:

Description, Identification, Related Substances (including specified impurities, individual unknown impurities, and total impurities), Assay, Dissolution (for oral solid dosage forms), and Sterility (for sterile products). If the testing site and the FPP manufacturer are different entities, the relationship between the two sites should be clearly described by the applicant

f) A valid Registration Certificate for the Finished Pharmaceutical Product from the country of origin and from authorities listed in the BoMRA Reliance/ Recognition on Information from Regional and International Bodies guideline- *BOMRA/ER/MD/P04/G07*.

g) A Valid cGMP certificate for the Finished Pharmaceutical Product manufacturing site in line with the Guideline for Good Manufacturing Practice - *BOMRA/IL/IL/P08/G01*

5 Turnaround Time and Validity

5.1. The Authority will communicate the outcome of an application within 48 working hours. If the application does not meet the Authority's requirements, a regulatory decision will be issued.

5.2. Where an application does not comply with the requirements, application will be rejected and the applicant will be required to submit a new application.

5.3. Where an application is rejected, the Authority will provide the reasons for the rejection. The applicant may resubmit the application after addressing all identified deficiencies and ensuring that all required documentation has been submitted. Any resubmission will be treated as a new application and not as a response to the rejection.

5.4. Exemption approvals are valid for the quantity approved and for 6 months from the date of issue.