



**Botswana Medicines Regulatory  
Authority**

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## Botswana Medicines Regulatory Authority



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## 1 Preamble

1.1 The Botswana Medicines Regulatory Authority (BoMRA) was established through an Act of parliament; the Medicines and Related Substances Act of 2013. The act provides for the regulation of medicines, medical devices, and cosmetics in Botswana in order to promote human and animal health by providing guarantees for quality, safety and efficacy of medicines and medicinal products throughout the supply chain. In order to achieve this goal, the Authority has undertaken to develop a set of guidelines and procedures to guide the regulation of pharmaceutical products.

## 2 Purpose

2.1 The purpose of this guideline is to provide guidance to stakeholders on how remote inspections will be conducted.

## 3 Laws, Policies, Regulations & relevant Guidelines

### 3.1 General

3.1.1 The guidelines were developed using principles from the following;


- a) Medicines and Related Substances Act, 2013, (MRSA)
- b) Medicines and Related Substances Regulations, 2019
- c) WHO Technical Report Series, No. 1025, 2020 Annex 7

3.1.2 This guideline applies to the applications for licensing of all pharmaceutical operations (veterinary retail, Pharmacies, Distributors and manufacturing pharmaceutical operations) received through the BoMRA Regulatory Information Management system (BRIMS).

### 3.2 Legal Considerations

3.2.1 The importation and exportation of Medicines in Botswana shall be through a licensed wholesaler authorised by BOMRA.

- a) No person shall import, export, distribute or sell medicines except in accordance with a license issued for the import, export, distribution or sale of medicines. (Sec 28(1) of the MRSA, 2013)
- b) A person who wishes to import, export, distribute or sell medicines shall apply to the Authority, in the prescribed form accompanied by such fee as may be prescribed and such information as the authority may require (Sec 28 (2) of the MRSA, 2013)
- c) The person referred to in subsection (2) shall be resident in Botswana (Sec 28 (3) of the MRSA, 2013)

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- d) The import, export, distribution or sale of medicines in terms of this section shall be under the continuous supervisory control of a pharmacist, or veterinary surgeon (Sec 28 (4) of the MRSA, 2013)
- e) A person authorised in terms of this act to import, export, distribute, or sell medicines shall not import, export, distribute, sell, or keep in storage contrary to such conditions as may be prescribed, any medicine after the date of expiry indicated on the package of the medicine (Sec 28 (4) of the MRSA, 2013)
- f) The Authority shall therefore ensure that all premises are inspected to assess compliance with the guidelines set.

#### 4 Scope

- 4.1 This guideline is applicable to the inspection of all types of pharmaceutical operations.

#### 5 Definitions and Abbreviations

##### 5.1 Definitions


The following definitions shall apply:

- 5.1.1 **Authority** - means Botswana Medicines Regulatory Authority established under section 3 of MRSA 2013.
- 5.1.2 **Information and communication technology** - the use of technology for gathering, storing, retrieving, processing, analysing and transmitting information. e.g. software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others.
- 5.1.3 **Remote inspection** – inspection performed off-site through the use of information and communication technology to gather information, interview the applicant, etc (Synonyms: e-Inspection, virtual inspection)

##### 5.2 Abbreviations

The following abbreviations shall apply:

- 5.2.1 **BOMRA** - Botswana Medicines Regulatory Authority
- 5.2.2 **ICT** - Information and communication technology
- 5.2.3 **BRIMS**- BOMRA Regulatory Information Management System

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## 6 General considerations

- 6.1 In the event that it is not possible or desirable for on-site inspection to be conducted, inspectors may perform remote inspections as an alternative method of inspection.
- 6.2 Reasons for conducting remote inspection of premises may include the following;
- a) Safety constraints
  - b) Pandemics
  - c) Travel restrictions
  - d) Risk rating as determined by BOMRA
- 6.3 Remote inspection provides advantages including increased flexibility and shorter set-up times. To realize the benefits of this method, all interested parties should be aware of their role in the process, their inputs, expected outputs, and the risks and opportunities which are relevant to the achievement of the inspection and inspection program objectives.
- 6.4 The use of ICT may be appropriate for inspections both locally and remotely. Examples include but are not limited to;
- a) Meetings; by means of teleconference facilities, including audio, video and data sharing
  - b) Audit/assessment of documents and records by means of remote access, either synchronously (in real time) or asynchronously (when applicable)
  - c) Recording of information and evidence by means of still video, video or audio recordings
  - d) Providing visual/audio access to remote or potentially hazardous locations
  - e) Documentation should be submitted in text-searchable PDF format.


## 7 Remote Inspection Structure

### 7.1 Preparation

#### 7.1.1 Feasibility

Suitability of ICT for remote inspection shall be assessed prior to the decision on whether or not the method should be used. The choice of technology shall take into consideration the following steps;

- a) Availability of suitable technology.
- b) Online connection quality - A weak bandwidth or limited hardware capability may slow down the process to the point of inefficiency. The inspection process may be

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affected by the speed at which the inspectee accesses and shows evidence by video, or through a tablet or computer.

- c) The Inspectee must agree to the remote inspection as well as the proposed ICT tools
- d) Confidentiality, security and data protection shall be ensured for all data shared during the inspection. This may require specific agreements between the inspectee and BoMRA for the use of recordings etc.
- e) Risk assessment shall be done to identify areas (people, activities, sites) that cannot be adequately assessed by remote inspection alone.

### 7.1.2 Confidentiality, Security and Data Protection (CSDP)

- a) Confidentiality and security issues, as well as data protection, are critical to the use of ICT.
- b) BoMRA requires for anyone handling (collecting, storing, analysing) data related to the inspection process to have adequate security practices in place to maintain the integrity, access permissions, and confidentiality of the data in accordance with their data governance policy.
- c) If part of the inspection will be recorded, the inspectee shall be given the opportunity to appropriately inform any personnel who may appear in such video footage in accordance with the relevant local legislation.

## 7.2 Performing the Inspection


The remote inspection consists of the four elements below.

### 7.2.1 Scoping:

- a) The inspector shall first have a scoping call with the inspectee. During that call they will test connectivity and agree on the online meeting tool to use for the live interaction.
- b) Any challenges and questions regarding the accessibility and transfer of documentation as well as the sharing of pictures and videos shall be discussed during this call.
- c) Both inspectee and inspector should agree on who is assigned as facilitator to ensure that the remote interviews and site tours can be conducted smoothly during the live interaction. Furthermore, the date for the live interaction is fixed.

### 7.2.2 Document Collection

- a) Documentation provided by the inspectee prior to the inspection forms an essential part of the remote inspection

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- b) The documentation package shall contain all documents as per the inspection preparation checklist [BOMRA/IL/IL/P18/F01](#) and it is to be submitted to [inspections@bomra.co.bw](mailto:inspections@bomra.co.bw) within three (3) working days. (from date of contacting the inspectee).
- c) For manufacturers, the documentation package shall contain all documents as per the tentative inspection plan [BOMRA/IL/IL/P06/F02](#).
- d) Non-submission of the required documents may lead to cancellation of the planned inspection

### 7.2.3 Desktop review


- a) Once the documentation has been submitted, the inspector will review all documents the inspectee has provided.
- b) The inspector might reach out to the inspectee asking for additional or outstanding information or to clarify any questions

### 7.2.4 Live interaction:

- a) On the agreed date and time for the live interaction, the inspectee will connect with the inspector via the online meeting tool.
- b) The inspection will start with a formal opening meeting where the Inspector introduces the inspection proceeding.
- c) The inspector will highlight findings from the desktop review through remote interviews and remote site tours, if applicable, and check the remaining requirements from the inspection checklist.
- d) At the end of the inspection, the inspector will explain the inspection findings in closing.
- e) Once the inspection has been concluded, the inspector sends an email to the inspectee attaching the signature page of the inspection checklist to be signed and returned by the inspectee immediately.

## 8 Technical Requirements

- 8.1 In order to fully benefit from the advantages of remote inspection, certain technical conditions must be ensured. Communication devices – like laptop, desktop computer or tablet, mobile phone equipped with microphone, camera, loudspeaker and stable internet connection - must be available to ensure both video and audio communication of adequate quality.
- 8.2 In general, the inspected party should suggest the conference tool, organize the digital video conference and the respective internet connection. The conferencing tool used for the remote inspection must comply with the following minimum requirements:

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- a) It must allow the possibility to share screens and files during the remote inspection.
- b) It must allow all people involved in the remote inspection to join when necessary (can be multiple people on the inspector's side at the same time) without the inspector having to purchase extra licenses.
- c) If needed, e.g. where internet connection is a challenge, a combination of different tools can be used simultaneously - such as image transmission via conferencing tool and audio transmission via phone.

## 9 Online communication platforms

- 9.1 Microsoft Teams
- 9.2 Zoom
- 9.3 Cisco Webex Meetings
- 9.4 Google meet
- 9.5 WhatsApp

## 10 References

- 10.1 Medicines and Related Substance Act 2013
- 10.2 Medicines and Related Substances Regulations, 2019
- 10.3 WHO Good Storage and Distribution Practices (Technical Report Series. 1025 No, 2020 Annex 7)

