

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



GUIDANCE FOR ONSITE INSPECTIONS / VISITS DURING COVID-19 LOCKDOWN

This document has been prepared to serve as a guidance for interactions during site visits or onsite inspections during emergencies/disasters including the COVID-19 pandemic. It represents the South African Health Products Regulatory Authority's current thinking on this subject. This guidance should be read in conjunction with:

- the SA Guidelines for Good Manufacturing/Clinical/Wholesale Practices.
- Guidance on Good Practice (GxP) inspections during the Pandemic
- Disaster Management Act: Consolidated Coronavirus COVID-19 Direction on Occupational Health and Safety Measures in Certain Workplaces (04 June 2020)
- DPSA Circular 27 of 2020

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GUIDANCE FOR ONSITE INSPECTIONS / VISITS DURING COVID-19 LOCKDOWN

Table of Contents

1. Introduction..... 3

2. Purpose..... 4

3. Scope 4

4. GxP Inspections 5

4.1 Virtual vs Onsite Inspections 5

4.2 Planning for onsite inspection 5

4.3 Conduct during onsite inspection..... 6

4.4 Contact tracing in the event of a COVID-19 infection 7

5. Onsite inspections for law enforcement activities..... 7

6. Definitions 8

1. Introduction

- 1.1 As per Section 2B of the Medicines and Related Substance Act, Act 101 of 1965 (as amended) the Authority must, in order to achieve its objects, ensure that existing legislation is promoted and controlled through a process of active inspection and investigation.
- 1.2 Further to the above, under section 28 of the Medicines and Related Substance Act, Act 101 of 1965 (as amended), inspectors appointed by SAHPRA, may enter any place or premises for the purposes of inspection or investigation.
- 1.3 Considering the COVID-19 pandemic and subsequent lockdown, SAHPRA developed the Guidance on Good Practice (GxP) Inspections During Emergencies/Disasters Including the COVID-19 Pandemic to facilitate virtual inspections, however, SAHPRA has the authority to conduct onsite inspections. In the case of law enforcement activities, onsite inspections are a necessity.
- 1.4 This document has been written to facilitate and provide guidance to conducting onsite inspection activities during the COVID-19 pandemic lockdown, ensuring that COVID-19 risks detected, assessed, defined and mitigations implemented during onsite inspections.

2. Purpose

The purpose of this guide is to stipulate SAHPRA's approach to onsite inspections during the COVID-19 Lockdown in South Africa. It provides for guidance on the measures to be taken by inspectors to mitigate risk of spread of COVID-19 during onsite inspections and outlines SAHPRA's expectations of sites undergoing physical inspection. This guide does not replace nor seeks to lessen the requirements of the site's policies and procedures related to management of risk related to COVID-19.

3. Scope

This guidance relates to:

- a) Onsite inspection of sites subject to compliance with Good Manufacturing Practice and Good Wholesaling Practice that handle medicines for human and veterinary use as per the Medicines and Related Substances Act, Act 101 of 1965 (as amended) and its regulations
- b) Onsite inspection of sites subject to compliance with Good Clinical Practice guidelines
- c) Onsite inspections required for law enforcement activities

Sites that may be subject to onsite inspections include, but are not limited to:

- a) Pharmaceutical Holder of Certificate of Registration
- b) Pharmaceutical Manufacturers
- c) Pharmaceutical Wholesalers
- d) Pharmaceutical Bond Stores
- e) Pharmaceutical Quality Control Laboratories
- f) Clinical Trials Sites
- g) Medicinal Cannabis Cultivators
- h) Premises subject to investigation as part of law enforcement activities
- i) Premises holding product that is subject to investigation as part of law enforcement activities

4. GxP Inspections

4.1 Virtual vs Onsite Inspections

The decision regarding the method of inspection will be decided by the Inspector/s, based on risk.

Inspectors may choose either a virtual inspection, an onsite inspection or a hybrid approach to conduct an inspection.

Inspection Approach	Detail
Virtual Inspection	Inspection is conducted virtually as per SAHPRA's Guidance on Good Practice (GxP) Inspections During Emergencies/Disasters Including the COVID-19 Pandemic)
Onsite Inspection	Inspector is onsite for entire inspection
Hybrid Inspection	Aspects of the inspection are conducted virtually, and the inspector conducts an onsite visit for other predetermined aspects of the inspection.

4.2 Planning for onsite inspection

In preparation for onsite visits, sites will be asked to complete a questionnaire (Annexure 1) to confirm protective measures at the site.

Inspections requiring onsite visits will be pre-notified a minimum of 14 days (2 weeks) to enable completion of the questionnaire and conclusion of COVID-19 risk mitigation planning.

In the event of an unannounced inspection, where necessary for public health, COVID-19 risk mitigations and requirements will be discussed on arrival at the site. Inspectors are expected to accommodate reasonable requests from the site in terms of PPE, social distancing and the procedures/practices of the site related to management of COVID-19, provided these measures do not interfere with purpose of the inspection.

Visits will be conducted subject to arrangement with the site and with all necessary protective and hygiene measures in place.

4.3 Conduct during onsite inspection

During inspection the inspectors and the personnel of the site should ensure the implementation of South African guidance on Safety in the Workplace (<https://www.gov.za/covid-19/companies-and-employees/safety-workplace>). SAHPRA will ensure that inspectors are provided with sufficient masks and sanitizer, in keeping with government workplace requirements.

The site is required to ensure that necessary precautions for the inspection are in place, such as, but not limited to:

- Meeting Rooms with sufficient space to allow adequate social distancing and sufficient ventilation
- Restrictions on the number of participants in the inspection
- Adequate electronic resources to reduce the occasions of contact between inspectors and site personnel during the inspection
- Hand washing and hand sanitising facilities
- Logs for contact tracing purposes

The surface area of the inspection room that houses the inspector/s during the inspection must be enough to allow the inspectors to be sufficiently distanced. The number of participants in the room should not exceed 50% capacity, taking into account required distancing. Surfaces should be adequately and regularly sanitized.

Masks should always be worn by both inspectors and site personnel during interaction.

During site walkabouts, the inspectors and accompanying site personnel should be sufficiently socially distanced, and masks should be worn. The number of persons accompanying the inspectors should be limited. Where possible, subject matter experts may be contactable on via phone for specific questions.

Prior to the site walkabout, the inspector may request to see specific operations, which provides opportunity for site to decrease the number of personnel in the area to only those related to the activity which the inspector requires to witness.

Where possible, personnel required for the inspection may participate remotely. There is no expectation for personnel to be on site if their input can be received remotely, via telephone or other technology.

Opening and closing meetings and other personnel interviews should be kept to the minimum. Only essential personnel should be being physically present with an option to include more personnel virtually, where required. Interviews should be scheduled with enough notice to limit the number of people required in the inspection room. Interviews may be conducted virtually, even if the interviewee is in the same building. Likewise, documentation and electronic systems may be presented electronically.

The inspector may terminate the inspection if noncompliance with South African Guidance on Safety in the Workplace results in possible high risk of COVID-19 exposure to the inspector.

4.4 Contact tracing in the event of a COVID-19 infection

Should anyone directly involved with the inspection test positive for COVID-19 within 2 weeks of the initiation of the onsite phase of the inspection, both site and SAHPRA should inform each other.

5. Onsite inspections for law enforcement activities

Due to the ad hoc nature of onsite inspections for law enforcement activities, COVID-19 risk mitigations and requirements should be assessed and determined on arrival at the point of inspection.

During inspection the inspectors should ensure the implementation of South African guidance on Safety in the Workplace (<https://www.gov.za/covid-19/companies-and-employees/safety-workplace>). SAHPRA will ensure that inspectors are provided with sufficient masks, sanitizer, relevant gear and other required tools of trade, in keeping with government workplace safety requirements.

Inspectors should keep a log of persons physically encountered during investigations, ensure that masks are always worn and that there is sufficient social distance during physical interactions.

Should anyone directly involved with the inspection test positive for COVID-19 within 2 weeks of the initiation of the onsite phase of the inspection, both the contact person and SAHPRA should inform each other.

6. Definitions

The definitions provided below apply to words and phrases used in these guidelines. Facilities / sites should also consider the definitions as prescribed by the Medicines and Related Substances Act, 1965 as amended, and the Pharmacy Act, 1974 (Act 53 of 1974).

- Remote Virtual Inspection:** This is Inspection of a facility conducted using information sharing platforms which is agreed upon prior to inspection. At this point SAHPRA is using Microsoft Teams Software.
- Covid-19 pandemic:** The COVID-19 pandemic, also known as the coronavirus pandemic, is an ongoing pandemic of coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- Site:** Farm, manufacturing site, laboratory, warehouse or clinical trial site that is subject to GxP inspection
- GxP:** Good Manufacturing Practices, Good Wholesaling Practices, Good Clinical Practices, Good Distribution Practices, Good Laboratory Practices etc.
- Good Clinical Practice (GCP) :** A standard for clinical trials/studies which encompasses the design, conduct, performance, monitoring, termination, auditing, recording, analyses, and reporting and documentation of clinical trials/studies and which ensures that the trials/studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical product (diagnostic, therapeutic or prophylactic) under investigation are properly documented and the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

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ANNEXURE 1:

CONFIRMATION OF PROTECTIVE MEASURES FOR INSPECTIONS DURING COVID-19 PANDEMIC

SAHPRA has developed a questionnaire to determine site measures for COVID-19 risk mitigations during onsite inspections. We kindly request confirmation of measures that the site has implemented to comply with work safety during the COVID-19 pandemic for the protection of all persons involved. SAHPRA also requests the history of positive cases identified at the site. For any questions regarding this questionnaire, kindly contact SAHPRA offices.

1	Hygiene and cleaning	Yes	No
1.1	Regular hand disinfection facilities	<input type="checkbox"/>	<input type="checkbox"/>
1.2	Regular cleaning of work surfaces and inspection room	<input type="checkbox"/>	<input type="checkbox"/>
1.3	Adequate ventilation of workspaces and inspection room	<input type="checkbox"/>	<input type="checkbox"/>
2	Social distancing during inspection		
2.1	Separate, large enough meeting room for inspection to allow social distancing	<input type="checkbox"/>	<input type="checkbox"/>
2.2	Restriction of persons present in the room to 50% capacity	<input type="checkbox"/>	<input type="checkbox"/>
2.3	Ability to accommodate additional respondents virtually	<input type="checkbox"/>	<input type="checkbox"/>
2.4	Ability to access or present documents and/or electronic systems virtually	<input type="checkbox"/>	<input type="checkbox"/>
2.5	Ability to reduce participants to minimise contacts and to allow sufficient social distancing during site walkabout	<input type="checkbox"/>	<input type="checkbox"/>
2.6	Sufficient distancing during meals/lunch break	<input type="checkbox"/>	<input type="checkbox"/>
2.7	Ensure that persons with co-morbidities do not make contact physically in the inspection	<input type="checkbox"/>	<input type="checkbox"/>
2.8	Ensure that persons with symptoms of COVID-19 do not make contact physically in the inspection	<input type="checkbox"/>	<input type="checkbox"/>
3	COVID-19 Policy or Procedure		
3.1	Implemented Policy or Procedure for managing COVID-19 risk (If yes, please attach to completed questionnaire)	<input type="checkbox"/>	<input type="checkbox"/>
4	Contact tracing		
4.1	Ensure that contact logs are present during inspection	<input type="checkbox"/>	<input type="checkbox"/>
4.2	Site confirms to contact SAHPRA should anyone directly involved with the inspection test positive for COVID-19 within 2 weeks of the initiation of the onsite phase of the inspection	<input type="checkbox"/>	<input type="checkbox"/>
5	Further measures / comments		
6	Site COVID-19 history (provide detail below or on separate attachment)		

TITLE	
NAME	
SIGNATURE	
DATE	