SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

Mpox Disclaimer

SAHPRA is aware that several therapeutic modalities may be tried by clinicians in the absence of robust clinical data and appreciates that this option often features in therapeutic decision-making in times of public health emergencies.

SAHPRA has not registered any medicinal products for the treatment or prevention of Mpox infection and cannot endorse the off-label use of licensed medicines for this condition in the absence of robust confirmatory data. However, there is a shared ethical responsibility to maximize the benefit of knowledge gained from sharing the experiences of patients in whom these therapies have been used while protecting the confidentiality of these individuals.
The Mpox Monitoring programme aims to systematically collect data on the benefits and risks encountered by individuals exposed to these various treatment modalities either for the prevention (pre- or post-exposure prophylaxis) or treatment of Mpox infection.

A valid reported case requires the following essential information:
a) identifiable patient,
b) identifiable reporter,
c) a known/unknown patient outcome at the time of the report and
d) an identifiable treatment and treatment regimen with known start and stop dates for the treatment

What is the purpose of this reporting?

SAHPRA has implemented the Mpox Monitoring system for vigilance and monitoring of health products that are used for the prevention or treatment of Mpox infections outside of a clinical trial and outside of the MEURI framework. This aims to systematically collect data on the benefits and risks encountered by individuals exposed to the various treatment modalities either for the prevention (pre- or post-exposure prophylaxis) or treatment of Mpox infection.

Who should report?
Clinical staff including doctors, pharmacists and nurses caring for Mpox patients.

What?
Clinicians are invited to report both positive and negative treatment outcomes. The programme will apply to both unregistered medicines sought under Section 21 of the Act as well as medicines already registered for other indications, but which are now being used "off label" for the prevention or treatment of Mpox infection.

Which patients should be included in the Mpox Monitoring Programme?
- All patients who are being treated for Mpox-related conditions with unregistered medicines obtained via the Section 21 access process.
- Patients who are being treated for Mpox with repurposed medicines which are already registered in South Africa.
- The form should be completed regardless of whether the patient’s outcome was favourable or

unfavourable.

When should the report be completed?
The report should be completed once the patient has completed the course of treatment and the outcome is known, i.e. the patient has died or the condition stabilised or 1 month after initiation of Section 21 or repurposed treatment, whichever comes first. Where the treatment outcome is not known by 1 month after initiation of treatment, SAHPRA staff will contact the reporter to follow up on the outcome of the event approximately 2-3 weeks after the initial report.

How do I report?
Please complete the online Mpox Monitoring form. This form can be accessed by clicking on ONLINE SERVICES on the SAHPRA website homepage, www.sahpra.org.za, and then navigating to Mpox Monitoring reporting.

Where can I send a related enquiry to?
All related enquiries and correspondence must be sent to section21@sahpra.org.za.