

Communication to Stakeholders

20 August 2020

COVI-Vig reporting system:

In the interest of public health, SAHPRA has launched the COVI-Vig reporting system for vigilance and monitoring of health products being used for prevention or treatment of COVID-19 outside of a clinical trial and outside of the MEURI framework.

Under these circumstances, we are aware that a number of therapeutic modalities are being tried by clinicians in the absence of robust clinical data and appreciate 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 COVID-19 infection and cannot endorse the off-label use of licensed medicines for this condition in the absence of robust confirmatory data. However, we have 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.

To this end SAHPRA has launched a COVI-Vig programme which 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 COVID-19 infection.

SAHPRA is eliciting information on both positive and negative 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 COVID-19 infection.

SAHPRA requests all health care workers involved in the care of COVID-19 patients to support this programme. Identities of both the health care providers and the patients will be kept confidential as is the case for all SAHPRA's vigilance-related activities.

A valid reported case requires the following essential information:

- a) identifiable patient,
- b) identifiable reporter,
- c) a known 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

Clinical staff including doctors, pharmacists and nurses caring for COVID-19 patients should submit reports through the online COVI-Vig portal.

Which patients should be included in the COVI-Vig Programme?

- All patients who are being treated for COVID-19-related conditions with unregistered medicines obtained via the Section 21 access process.
- Patients who are being treated for COVID-19 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 condition stabilised or 1 month after initiation of the 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 2-3weeks after the initial report.

How do I report?

Please complete the online COVI-Vig form. This form can be accessed by clicking on ONLINE SERVICES on the SAHPRA website homepage, www.sahpra.org.za, then navigate to COVI-Vig reporting.

All-related enquiries and correspondence must be sent to covidvig@sahpra.org.za.

DocuSigned by:
Boitumelo Semete-Makokotlela
E2F5B27720A46A
DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
25 August 2020