



SAHPRA responds to coronavirus (COVID-19): Medicines/medical devices supply challenges

The new coronavirus (COVID-19) will continue to have far-reaching consequences on public health as well as manufacturing and business in general across the globe. SAHPRA has put in place a series of initiatives aimed at minimising the potential negative impact of the pandemic on the availability of medicines and medical devices in South Africa.

- SAHPRA is in constant communication with manufacturers, wholesalers, pharmacists and other healthcare providers to identify and respond to medicine and/or medical device shortages that may arise as a result of the COVID-19 pandemic.
- Pharmaceutical and medical device manufacturers and suppliers for both public and private sectors are requested, in terms of section 19(2) of the Medicines and related Substances Act (Act 101 of 1965) as amended, to notify SAHPRA of any anticipated disruptions in supply, any shortages of products experienced, and any planned withdrawals of products from the market. The information requested is to be reported as soon as it comes to the attention of manufacturers or suppliers. This request for mandatory supply of information will remain in force until the notice is withdrawn by SAHPRA.
- SAHPRA is working with the National Department of Health (NDoH) and industry to actively monitor the potential impact of the COVID-19 pandemic and respond to any disruptions or shortages as the public health emergency develops.
- SAHPRA in collaboration with NDoH will make every effort to ensure the uninterrupted supply of medicines, medical devices, in vitro diagnostics and medical equipment, particularly those that will be used to manage COVID-19 as well as other priority diseases. Should any shortages come to light, SAHPRA and NDoH, in collaboration with Industry, will communicate these to the relevant health sector stakeholders soon as possible via the SAHPRA website, in terms of section 22B of the Act. SAHPRA will also ensure expedited review of variation applications, where needed.

- SAHPRA is also part of a collaborative network of regulators around the world who are communicating regularly to ensure availability of safe, efficacious and quality medicines and medical devices required to manage patients affected by COVID-19.

Currently, there are no antiviral medicines or vaccines which have been approved globally for the prevention or treatment of COVID-19. However, a number of vaccines are under development and some medicines are currently being assessed in clinical trials for efficacy against COVID-19 infection.

When a vaccine or medicine is developed to prevent or treat COVID-19, SAHPRA will take appropriate action to ensure availability.

Measures include fast-tracking through the:

- Scientific review of new medicines or vaccines through a priority review process
- Special Access Program for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed or are unavailable
- Expedited review of clinical trials for new vaccines, new or repurposed antivirals, or supportive therapies

The COVID-19 outbreak has resulted in travel restrictions that will affect our ability to perform Good Manufacturing Practice (GMP) inspections of overseas manufacturers. We are working to ensure that these restrictions have minimal impact on the licensing and supply of medicines and other health products without compromising the quality of these products.

Given the critical nature of the current situation, SAHPRA calls on the support of business and/or applicants to inform us of any medicine and medical device shortages directly through the contact details provided below.

- The information provided should include:
 - a. the name of the product and Registration number / reference number if applicable
 - b. The manufacturer of medicines / medical device, or holder of certificate of registration/Applicant
 - c. the name of the active ingredient/s
 - d. API source manufacturer and country
 - e. Current availability,
 - f. Possible stock out date/period

Contact:

Dr Shyamli Munbodh

shortages@sahpra.org.za