SAHPRA
South African Health Products Regulatory Authority

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## Communication to Stakeholders 22 July 2020

# MD005: Expedited regulatory pathways for medical devices during the COVID-19 pandemic

***BACKGROUND***

1. On 30 January 2020, the World Health Organization (WHO) declared the COVID-19 (SARS-CoV-2) outbreak as a Public Health Emergency of International Concern (PHEIC).

***EXPEDITED REGULATORY PATHWAY***

2. The South African Health products Regulatory Authority (SAHPRA) is providing active support for monitoring a number of issues relating to medical devices including in-vitro diagnostics (IVDs) in response to the novel coronavirus (COVID-19).

3. Through the use of expedited regulatory pathways SAHPRA is able to help strengthen the nation's public health protections by facilitating the availability and use of medical devices needed during public health emergencies.

4 Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) may allow unapproved medical devices or unapproved uses of approved medical devices to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused when there are no adequate, approved and available alternatives.

***TIMELINES***

5. Only SAHPRA licence holders may manufacture, distribute (including import and export) and/or wholesale medical devices. SAHPRA is committed to reducing the time taken to review and process licence applications for medical device establishments from 6 – 8 weeks to 10 – 15 working days.

6. The licence application process will be expedited with the aim of concluding the licence process within 10 – 15 working days. This timeline is dependent on the submission of complete applications that meet the requirements. This timeline is also dependent on timeous responses from applicants. To meet this timeline, only two response cycles will be permitted to address deficiencies identified within licence applications.

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