SAHPRA
South African
Health Products
Regulatory Authority

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Communication to Stakeholders **July 2022**

MD037: Withdrawal of Section 21 Authorisation for use of unregistered rapidly developed non-invasive ventilators.

BACKGROUND

1. In response to the anticipated shortage of medical supplies and equipment in the health care system as a result of the outbreak of the Covid-19 pandemic, the South African Health Products Regulatory Authority (the Authority) published minimum requirements for the manufacture, importation, and distribution of rapidly developed invasive and non-invasive ventilators in 2020.
2. These products are regulated by the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the Medicines Act) and the Hazardous Substances Act, 1973 (Act 15 of 1973) (the Hazardous Substances Act).
    i. Invasive ventilation refers to the administration of ventilatory and respiratory support using an invasive artificial airway (endotracheal tube or tracheostomy tube).
    ii. Non-invasive ventilation refers to the administration of ventilatory support without using an invasive artificial airway.
    iii. A non-invasive ventilator can be used as an alternative to invasive mechanical ventilation to treat at least some patients with Covid-19 related acute respiratory distress syndrome (ARDS).
3. Section 21 Authorisation for unregistered rapidly developed non-invasive ventilators was put in place for the Authority to ensure quality, safety and performance when used during the current Covid-19 pandemic.
4. The National State of Disaster was uplifted on the 04th of April 2022, thus questioning the review and approval process for COVID 19 rapidly developed invasive and non-invasive ventilators.

CURRENT REQUIREMENT

2. In terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965 as amended), the Authority may authorise the sale of unregistered medicines, medical devices or IVDs for certain purposes—
    i. The Authority may in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or IVD which is not registered.

ii. Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.
iii. The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).

3. Authorisation for the sale of an unregistered medical device, in terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), for rapidly developed ventilators was issued by SAHPRA provided that they meet the above referenced WHO specification and the MHRA specifications, with adaptations in line with relevant South African legislation and standards.

REVISED REQUIREMENT

4. As per the National State of Disaster upliftment, The section 21 process for unregistered rapidly developed ventilators as detailed in MD010: Regulatory Requirements,Technical Specifications, Licence Conditions and Authorisation for Use of Unregistered Rapidly Developed Invasive and Non-Invasive Ventilators for Covid-19 is hereby withdrawn
5. Section 21 authorisations which have been issued and are due for renewal will no longer be renewed as per point 4 .
6. An application for a new licence for a medical device establishment, and an application for an amendment to an existing licence of a medical device establishment to manufacture, import and/or distribute an unregistered rapidly developed ventilator will be followed as per **MD019:** Processing of medical device establishment licence applications made to SAHPRA

NOTE:

7. The Authority reserves the right to request any additional information such as technical file (dossier) when necessary to establish the safety, quality and performance of an IVD in keeping with the knowledge current at the time of evaluation.

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CHIEF EXECUTIVE OFFICER OF SAHPRA

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