SAHPRA
South African
Health Products
Regulatory Authority

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

Communication to Stakeholders/Industry Date: 05 June 2021

MD029: Renewal of Section 21 Authorisation for use of unregistered rapidly developed non-invasive ventilators.

1. Attention is drawn to the provisions of Section 21 of the Medicine and Related Substances Act, 1965 (Act 101 of 1965), to authorise the sale of unregistered medicines or medical devices for certain purposes.

2. 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 or medical device which is not registered.

3. Any medicine or medical device sold in pursuance of any authority granted under Section 21(1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

4. The Authority may at any time by notice in writing withdraw any authority granted in terms of Section 21(1) if effect is not given to any determination made in terms of Section 21(2).

5. SAHPRA's intent is to foster the continued availability of safe and effective medical devices while being flexible regarding modifications made to non-invasive ventilators, anaesthesia gas machines and other respiratory devices, and their accessories, in response to the COVID-19 public health emergency.

6. As per the conditions of said Section 21 authorization and the establishment License, the authorization and License is valid for up to twelve (12) months or until the cession of the circumstances justifying the authorization of the emergency use of the non-invasive and invasive ventilators during the Covid-19 pandemic, whichever may come first, and may be withdrawn or extended by the SAHPRA at any time.

7. As the 12 months validity of the License and authorization nears, the applicant is requested to submit an application for the extension of the section 21 authorization and License for the manufacture and sale of rapidly developed non-invasive and Invasive ventilators.

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8. The application should include:
   - Cover letter
   - Motivation for extension of the License and authorisation;
   - A report on the full details of all adverse incidents in relation to the device or the use of the device; and
   - A report on the performance of the medical device over the 12 months period.
   - A report listing the organization's customers including hospitals using the product.
   - Proof of payment for the retention fees of the License establishment using the relevant reference number MDRET

9. The fees applicable to the retention of medical device establishment licences are published in the Government Gazette dated 22 December 2020 [http://www.gpwonline.co.za/Gazettes/Gazettes/44026_22-12_Health.pdf].

10. To provide clarity for the submission of fee payments and categorization, SAHPRA has published a guideline [SAHPRA Payment Guideline_Nov 2020, https://www.sahpra.org.za/wp-content/uploads/2020/11/SAHPRA-Payment-Guideline-Nov-2020.pdf

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Dr B Semete-Makokotlela

Chief Executive Officer of SAHPRA

Date: 02 June 2021