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COVID-19 news from SAMED, Government and Abroad.


SAMED MEMBER FORM WITH SAHPRA ON RAPIDLY DEVELOPED VENTILATORS

Join SAMED on a call with SAHPRA on the publication of Regulatory Requirements, Technical Specifications, Licence Conditions and Authorisation for Use of Unregistered Rapidly Developed Invasive and Non-Invasive Ventilators for COVID-19.

Download this important communication from the [SAHPRA website](#).

**Regulatory Member Forum:
SAHPRA on Rapidly Developed Ventilators**

12 June 2020


SAMED
south african medical technology industry association
advancing innovation responsibly

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 (SAHPRA) has drafted minimum requirements for the manufacture, importation and distribution of rapidly developed invasive and non-invasive ventilators. SAHPRA has added this new guidance on the rapidly developed ventilators to their [website](#).

It covers the regulatory requirements, technical specifications, licence conditions and authorisation for use of unregistered rapidly developed invasive and non-invasive ventilators for COVID-19.

The Regulator will present this position paper and address questions and concerns from the membership.

Programme: *subject to change*

09:00	Opening Madeleine Pearce – SAMED Regulatory Committee Chairperson
09:10	SAHPRA on Regulatory Requirements, Technical Specifications, Licence Conditions and Authorisation for Use of Unregistered Rapidly Developed Invasive and Non-Invasive Ventilators for Covid-19 Momeena Omarjee – Inspectorate and Regulatory Compliance, SAHPRA
10:30	Close

This will be a virtual meeting held via Microsoft Teams

Please use the link provided to attend at the specified date/time

[Join Microsoft Teams Meeting](#)

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NICD releases detailed data on demographics of those infected by COVID-19

Hospital data released by the National Institute of Communicable Diseases (NICD) has provided more insight into the race, gender, sex and underlying health issues of those infected by the coronavirus in South Africa. Data were submitted by public and private hospitals that have agreed to report COVID-19 admissions through DATCOV19 surveillance in all nine provinces of South Africa.

The Data is received from all private hospitals nationally, and a subset of public hospitals in all nine provinces (data are received from all public hospitals in the Western Cape (WC) Province). As of 31 May 2020, a total of 218 facilities, 57 from the public sector and 161 from the private sector submitted data on hospitalised COVID-19 cases.

Race

According to the NCID, of the 2,288 (48.5%) patients out of the 4,718 COVID-19 admissions, whose race was known

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- 128 (5.6%) were Indian.

Age

- The average age of patients admitted with COVID-19 was 49.
- The average age of patients who died from COVID-19 complications was 61
- For those who tested positive and were still alive, the average age was 47 years.

Sex

- Among admitted individuals with COVID-19, 2,563 (54.3%) were female.

Underlying health issues

Among the 2,422 patients with a reported comorbidity, the most commonly reported conditions were

- 1,353 (55.9%) Hypertension
- 1,167 (48.2%) Diabetes
- 467 (19.3%) HIV-infected
- 97 (4.0%) Active tuberculosis
- 276 (11.4%) Previous history of TB.

Obesity, while not consistently recorded for all reported COVID-19 admissions, was recorded as a risk factor in 87 patients.

Private vs public hospitals

In the first few weeks of the outbreaks, most deaths were reported in the private sector, but in recent weeks an increasing proportion of reported deaths was in the public sector. Of the 4,718 admitted individuals, there were 2,267 (48%) and 2,451 (52%) admissions reported in the private and public sector, respectively.

Download the detailed NICD report [here](#).

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EVENT : AFRICA AND COVID-19 WEBINAR SERIES: COVID-19 AND THE WORKFORCE IN AFRICA

COVID-19 simultaneously presents a global pandemic and an economic recession; healthcare-related decisions will impact the economy, and lack of economic security will have healthcare-related outcomes. How are companies and their employees impacted by lockdown, quarantine, and social distancing? Despite a growing digital economy, the sector remains small, and only a limited percentage of work can be done virtually. What is the impact on employers and employees? What will be the impact on households and individuals in a continent where more than half of economic activity is within the informal sector? Join the Harvard webinar as they discuss these points.

When: Wednesday, June 17, 2020, 10:00am to 11:00am

Register for the webinar [here](#).

Find out more about the topic and speakers [here](#).

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The SAMED Library is a dedicated resource for all COVID-19 related updates, regulations, notices and news.

All SAMED COVID-19 updates and related information can be found [here](#).

CLICK HERE



REPORT UNLICENCED COMPANIES TO SAHPRA

Several members have contact SAMED about companies trading medical technologies without a SAHPRA Medical Device Establishment License. These companies are trading illegally and it is essential that they be reported to SAHPRA for investigation.

SAHPRA has published a list of licenced companies under documents on their [medical devices page](#) which you can use to check if the company has a Medical Device Establishment License before sending a report. You can download this list as at 26 May 2020, [here](#). Please ensure that you visit the SAHPRA website to obtain updates as this is an evolving list.

Report unlicensed companies by emailing: mokgadi.fafudi@sahpra.org.za

IMPORTANT SAHPRA MEDICAL DEVICE NOTICES

- [MD010_Guidance_Rapidly_developed_ventilators_26May2020_v1](#)
- [PCR Tests Authorised for Listing by SAHPRA – 19.05.2020](#) Specification criteria for COVID-19 serological test kits
- [Joint Communication-Regulatory Status of Equipment Used to Help Prevent COVID-19](#)
- [NRCS media Release – Standards for Masks and Disinfectants](#)
- [Regulatory Requirements for the manufacture, distribution or wholesale of Serological COVID-19 Rapid Test Kits](#)
- [SAHPRA clarifies the issue of COVID-19 Rapid Test Kits](#)
- [MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS \(IVDS\) REQUIREMENTS FOR SUPPLY OF MEDICAL DEVICES IN LIGHT OF THE COVID-19 PANDEMIC](#)

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SAHPRA MEDICAL DEVICE CONTACTS

SAHPRA has launched a COVID-19 Medical Device Hotline to deal with COVID-19 related queries.

- 084 220 8037
- 072 993 2273
- 078 281 6334

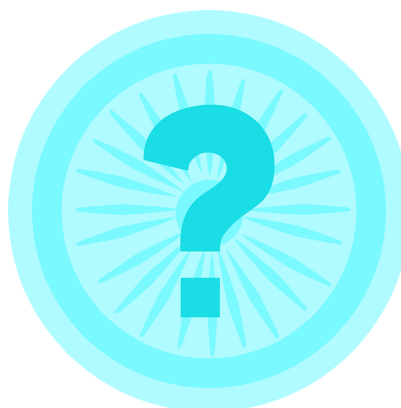
For queries on COVID-19 please email mdcovid@sahpra.org.za and all other regular medical device queries can be sent to MDnotifications@sahpra.org.za

For general licensing queries: June Searela june.searela@sahpra.org.za / 072 828 2416
For COVID-19 related applications: Matlapeng Shabalala Matlapeng.Shabalala@sahpra.org.za / 071 302 0409 or
Khanyisile Nkuku Khanyisile.Nkuku@sahpra.org.za / 081 854 7109

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DO YOU HAVE A
COVID-19
QUESTION OR
QUERY?

Please visit the [FAQ Section](#) of our library as it provides answers to many of the frequently asked questions we receive.



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facilities and practices, must adhere to. This applies to those who have been supplying essential goods this far, as well as those that may partially re-open from level 4 and down.

Download the directive [here](#)

You can also find useful tools on the [Return2Work website](#).

PARTICIPATE ON B4SA COVID-19 PROCUREMENT PORTAL

The information collected on the B4SA covid19manager.co.za platform will be used to ensure supplier verification, regulatory compliance, product availability, reasonable pricing and providing the accurate and most up-to-date logistical information to the procurement department division at BSA to place orders from you and/or assist with ramping up local production. It is an automated process to help facilitate the overwhelming demand currently being experienced in South Africa during the weeks to come.

NOTE: THIS IS A LIVE SYSTEM SO PLEASE UPDATE YOUR STOCK QUANTITIES AND LEAD TIME AS AND WHEN THEY CHANGE.

Please see the following [link to the video](#) for an explanation of how to use the portal and click on <https://covid19manager.co.za/> to add your company and product information.

You will most likely be contacted by a member of the BSA procurement team should your information provided need to be verified or an order need to be placed.

If you have any questions about the status of your registration, on the types of PPE and medical equipment that B4SA are procuring, if you are struggling to complete your application, or if you have any other queries, please get in touch with the B4SA support team via covid19portal@businessresponsecovid19.co.za. If you are not receiving feedback from the administrators, please check your spam/junk folders.

SAMED is appreciative of the support and commitment of our members in fighting this pandemic.

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THE SOLIDARITY FUND

The Solidarity Fund provided more details on its purpose and mandate of mobilising and coordinating efforts and resources from all South Africans and the international community to assist most vulnerable South Africans to deal with the impact of Covid19 and the consequences of measures intended to slow its rate of infection. One of its key focus areas is a Health Response with direct support for the healthcare system, augmenting both the private and government healthcare sectors to ensure they have what they need, as well as enabling emergency supplies.

Details on how to donate are available on the Fund's website www.solidarityfund.co.za

For more information email info@solidarityfund.co.za

For offers of supply of Medicines and Medical Devices send

to covid19supplies@businessresponsecovid19.co.za

If you are seeking PPE for your hospital, clinic, or NGO please email your request

to covid19requests@businessresponsecovid19.co.za

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COVID-19 EVENTS

OMMIA HEALTH COVID-19 VIRTUAL EXPO

Ommia Health Live are bringing together the global healthcare industry, for the largest virtual gathering ever seen before, a whole new concept planned from the ground up to be more diverse and accessible, taking place 22-26 June 2020.

[Join the experience here](#)

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SAMED is the voice of the South African medical technology industry. The not-for-profit was formed in 1993 and aims to provide members with a collective, objective and credible platform to engage with stakeholders. SAMED's members include individual medical technology companies, associate members and associations.

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