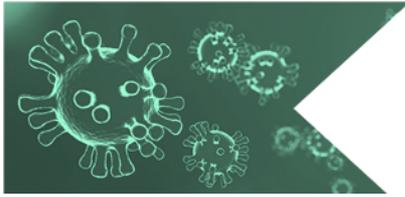


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SAMED COVID-19 NEWS south african medical technology industry association

COVID-19 news from SAMED, industry and abroad.

SAMED ON COVID-19

The [SAMED Library](#) is now a dedicated resources for all COVID-19 related regulations, notices and news. All SAMED COVID-19 updates and related information can be found [here](#).

SAHPRA licence deadline extended

Some members were concerned about trade being hampered due to the deadline for using the acknowledgement letter in lieu of SAHPRA Medical Device Establishment Licence given that the deadline falls within the national lockdown. SAHPRA has since issued a statement to extend the use of the acknowledgement letter until 17 April 2020 when the current lockdown is scheduled to end. It is still essential to use this time to communicate with SAHPRA in order to meet the newly set deadline and ensure compliance.

Download the notice [here](#).

Contact June Searela june.searela@sahpra.org.za (072 828 2416) for general licensing queries.

SAMED/SALDA Regulatory Forum

While we are unable to provide face to face sessions with members, we invite you to attend a virtual regulatory forum. SAMED has received queries regarding SAHPRA licencing processes given the current pandemic.

SAMED / SALDA Regulatory Forum

8 APRIL 2020



Virtual Session: *subject to change*

10h00-11h30

SAHPRA COVID-19 processes

Andrea Julsing Keyter, Deputy Director Medical Devices, SAHPRA

This will be a virtual meeting held via Microsoft Teams. Please mute your microphone and turn off video when joining the meeting. Should you have questions for SAHPRA, please send these to communication@samed.org.za in advance or to make use of the in-session chat function.

Use this link to participate: [Join Microsoft Teams Meeting](#)

DO YOU HAVE A QUESTION OR QUERY?

Please visit the [FAQ Section](#) of our library as it provides answers to many of the frequently asked questions we receive. You can also browse the many resources available in the dedicated COVID-19 library.

MEDTECH SUPPLIERS TO HEED THE FOLLOWING COVID-19 NOTICES, LEGISLATION AND REGULATIONS

REGULATION: Public transport limited trading hours approved

Public Transport will be permitted to ferry essential services workers will operate from 05h00 to 10h00 and from 16h00 to 20h00. During the lockdown period, private institutions or companies may make arrangements for the transportation of their workers who are rendering essentials services as listed

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schedules. The operating shifts or work schedules or time table should be stamped and signed by such person with authority as contemplated.

Download the amendment to regulation [here](#).

Please note that the regulations with regards to [measures to prevent and combat the spread of COVID-19 in public transport services](#) should still be considered.

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Companies requested to divert stocks of PPE

Business for SA's Public Health Workgroup is calling on all companies, especially those in lockdown, to urgently divert their stocks of personal protective equipment (PPE) for use in the national healthcare sector. The PPE is critically needed to protect frontline doctors and healthcare workers, and to keep them healthy in their fight against the pandemic.

PPE required:

- Masks (N95 Grade)
- Surgical masks
- Latex-free gloves (do not need to be sterile); preferably nitrile
- Plastic aprons
- Visors and goggles for eye protection
- Gowns and suits
- Overshoes.

Besides this urgent call to companies, the workgroup is driving efforts to boost local manufacturing and production where possible, and also expanding the sourcing from global suppliers. Securing stocks from companies that already have these available, especially those that are not currently using them, will provide much needed immediate assistance.

Throughout South Africa, there are storerooms of PPE that could be used as part of the emergency response. This includes stocks that are held by companies in the manufacturing, forestry and agriculture, construction, mills, spray painting, mining and signwriting industries, amongst others.

Please send the information to Covid19supplies@businessresponsecovid19.co.za

Download the press release [here](#).

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COVID-19 Lockdown: South African Ports Open for Cargo Operations

All South African ports remain open for port operations. Cargo and Stevedore operations will continue in all ports and all types of cargo will be allowed to be loaded and offloaded.

Read the full notice [here](#).

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Arrangement for customs services during the lockdown

Procedures that SARS Customs has put in place during the period 27 March 2020 until 16 April 2020, focusing primarily on facilitating trade in essential services for Services at Customs offices, Registration, Licensing and Accreditation, Applications for Embargoes, Special Attendance, Degroup Removal in Bonds, etc. and Physical Inspections.

The procedures that SARS Customs has put in place during the period 27 March 2020 until 16 April 2020, is focused primarily on facilitating trade in essential goods. Please contact your local [customs branch manager](#) for assistance. In urgent cases where your issue has not been resolved via the branches, you can mail the Customs Command Centre at osc@sars.gov.za or call 012-4228463. Please include as much detail as possible, including attachments of your prior correspondence with the relevant branch.

Find out more about the customs service arrangements [here](#).

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Cancellation of certificates not designated as essential services

Services have either fraudulently or negligently applied on the Bizportal website (www.bizportal.gov.za).

In a number of cases, companies have applied and received Essential Service certificates without compliance with the regulated conditions. Businesses in the CIPC database that are not eligible to continue operations during the lockdown have had their certificates cancelled and will be handed over to the South African Police Services for further investigation and potential prosecution. Any business which is not authorised to continue operating during the lockdown in terms of the applicable regulations and directions should cease operations with immediate effect.

Download the full notice [here](#).

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Process for traders to register as rebate users in the manufacturing of disinfectants

SARS has published a streamlined temporary registration process for traders to register as rebate users in the manufacturing of disinfectants for the duration of the national state of disaster.

- For more information, see the SARS letter [COVID-19 communication - clarity regarding the use of ethyl alcohol in the manufacturing of hand sanitisers](#) or contact Simphiwe Hlazo (012 647 9839) shlazo@sars.gov.za
- The process for registration as rebate user in the manufacturing of disinfectants was documented in the [Government Gazette No. 43156 No. R.411](#).

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SMMEs: Debt Relief Finance Scheme

Businesses which are negatively affected, directly or indirectly, due to the Coronavirus pandemic may qualify as a benefiting SMME. These companies will need to meet the qualifying criteria. Applicants need to register on <https://smmesa.gov.za/>, complete online Application Form (to be released on Thursday, 02 April 2020) and upload Required Supporting Documents.

Read more on the guidelines for application [here](#).

Direct queries to info@dsbd.gov.za or 0860 663 7867

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The solidarity fund uniting South Africa against COVID-19

The Solidarity Fund, established by President Ramaphosa will be a rapid response vehicle through which individuals and organisations will be able to support South Africa's mobilisation against COVID-19 through secure, tax-deductible donations. The Chairperson of the Fund is Ms Gloria Serobe and the Vice-Chairperson is Mr Adrian Enthoven and will operate with the highest principles of corporate governance. All activities will be reported in a transparent manner.

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

For more information, [click here](#) or email info@solidarityfund.co.za

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Tax measures to combat the COVID-19 Pandemic

The Minister of Finance has announced the following exceptional tax measures as part of the fiscal package outlined by President Cyril Ramaphosa on 23 March 2020 in his speech on the Escalation of Measures to Combat COVID-19. The tax adjustments are made in light of the National State of Disaster and due to the significant and potentially lasting negative impacts on the economy from the spreading of the COVID-19 virus. There is a critical need for government interventions to assist with job retention and assist businesses that may be experiencing significant distress.

Read the full media statement [here](#).

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COVID-19 EVENTS

The Youth Employment Service (Y.E.S) Programme during the lockdown and after. What are your questions?

COVID19 has fundamentally changed the way we are doing business during the 21-day lockdown and will for the foreseeable future. Our BEE strategies and implementation plans will require re-evaluation and

[Subscribe](#)[Past Issues](#)[Translate](#) ▼[T.E.S online webinar workshop.](#)**When: 3 April 2020 at 9:30 to 11:00**To book your seat, [click here](#).[Back to top](#)

SOME COVID-19 DEVELOPMENTS

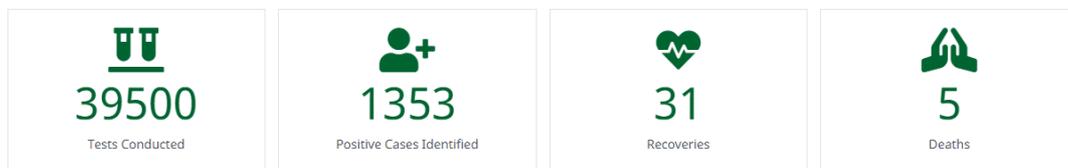
SOUTH AFRICA LATEST

Minister of Health Zweli Mkhize said yesterday (Tuesday) that he was cautiously optimistic about the country's progress in curbing the spread of the virus, as the rate of new coronavirus cases seems to have reduced for now. He announced details of **five deaths registered so far**:

1. 48-year-old woman in the Western Cape with an underlying condition.
2. 74-year-old man from Ladysmith in KwaZulu-Natal.
3. 85-year-old elderly pastor, who was at the Bloemfontein church gathering attended by five international guests who later tested positive for the coronavirus.
4. Louis Wilsenach, 79-year old marketing expert behind advertisements for products like NikNaks, Simba and Ouma biscuits, died in Gauteng.
5. 46-year-old woman from Umlazi, KwaZulu-Natal, who suffered from chronic asthma and hypertension.

A potential sixth case is a person who allegedly died of COVID-19 in KwaDukuza, north of Durban, and had been buried under Muslim burial rites is being investigated. The coronavirus has also **claimed the life of Professor Gita Ramjee**, an influential, decorated and award-winning South African scientist, who died in London. She was a world-renowned scientist who worked to research ways to prevent HIV infection, especially among women.

COVID-19 Statistics in South Africa



UPDATE ON THE MASS SCREENING PROJECT

Minister Zweli Mkhize said the government's mass screening project will target areas like Diepsloot, Alexandra and Khayelitsha. **Screening will begin on Friday**, with workers having conducted a dry run on Tuesday (yesterday). Workers will go out to people to screen them for COVID-19, then refer the person to a hospital depending on the severity of the case. Mobile testing units will be rolled out across the country from Thursday.

INTERNATIONALLY

The current coronavirus outbreak is the biggest challenge for the world since World War Two, **UN Secretary-General António Guterres** has warned. He said it could bring a recession "that probably has no parallel in the recent past". Mr Guterres was speaking at the launch of a UN report on the potential socio-economic impact of the outbreak. The number of confirmed cases around the world is now nearing 860,000, with more than 42,000 deaths.

New York is new virus epicentre, as US death toll climbs higher than 9/11. New York state reported a 9,300 increase in coronavirus cases on Tuesday to 76,000, surging past China's Hubei province, the former epicentre.

A **13-year-old boy from London and 12-year old girl in Belgium** have reportedly died due to the coronavirus. Genetic mutations that put some younger people at high risk for severe illness from the will be investigated in an international study, led by Howard Hughes Medical Institute in Chevy Chase, Maryland.

THE LOCKDOWN, FUTURE-PLANNING AND FUTURE-PROOFING

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case clause in its measures dealing with the COVID-19 disaster, and the national treasury is providing for an extra month of leeway in public finance management deadlines. The US, Italy and Denmark have already announced longer lockdowns, and various European countries are considering longer periods of restrictions or stricter rules to keep people apart.

[What happens after the lockdown](#): Although our current three-week lockdown will temporarily suppress transmission in the South African epidemic, it won't eradicate it, and if we just go back to business as usual, we will have endured the lockdown for nothing. Alex Welte from GroundUp reflects on some key questions:

- Post-lockdown, how do we monitor if the epidemic is getting out of control again, and how do we then respond?
- How do we scale up testing to the level at which it plays a real role in controlling the epidemic?
- What physical distancing measures can be maintained for the long term?
- What do we do about schools?
- What steps can be taken to prepare hospitals, both public and private?
- How do we support the economy? Leading local economists have written a [letter to President Ramaphosa](#), with key proposals to mitigate the economic fallout of both the epidemic itself and the ongoing and coming social countermeasures. Engaging seriously and transparently with these proposals is now a matter of great urgency.

Dr Kaymarlin Govender, research director at HEARD, UKZN, leads a project on social determinants of HIV in East and southern Africa. He has provided his view on how COVID-19 has shown that the [world is ill-prepared to handle a sustained and threatening public health emergency](#): "...Unfortunately, there remain far too many blind spots around the globe where public health systems lack trained staff, functional laboratories and quality surveillance data to make timely decisions to respond to infectious diseases. The **slow momentum in vaccine research for coronaviruses and, more generally, the lack of investment in research on infectious and emerging diseases** does raise some tough questions about the **relationship between science, the "need-for-profit industry"** and the suitability of the current medical research and development model in addressing the world's health priorities. Questions have been raised about the **global pharmaceutical sector** being largely geared towards developing products to maximise profits and with little therapeutic value; and when innovative treatments are produced they are unaffordable (for example, the hepatitis-C drug was first introduced at a price of \$84,000 in the US, which was totally out of reach for millions of people living with this disease worldwide).."

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SAMED is the voice of the South African medical technology industry. The not-for-gain was formed in 1985 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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