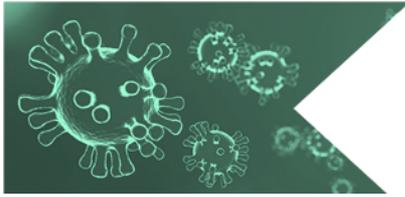


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SAMED COVID-19 NEWS

south african medical technology industry association

COVID-19 news from SAMED, industry and abroad.

SAMED ON COVID-19

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. Deputy Director of Medical Devices, Andrea Julsing Keyter will take members through the processes for applying for new or updating existing Medical Device Establishment Licences and discuss other SAHPRA COVID-19 related matters.

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](#)

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

REGULATION: COVID -19 Export Control Regulation

The Minister of Trade, Industry and Competition published regulations regarding the export of medical goods in light of the national state of disaster. In the regulation, it states that goods described in Schedules 1, 2, 3 and 4 shall not be exported from South Africa except under an export permit issued in terms of Section 6 of the said International Trade Administration Act, 2002, and in which export permit such goods are specifically described. The regulation also inserts a schedule 4 and lists description of the good together with relevant tariffs.

Download the regulation [here](#).

[Back to top](#)

SAHPRA on rapid testing for COVID-19

In line with the recommendation of the South African National Institute for Communicable Disease (NICD) and the recommendation of the World Health Organization (WHO), [serological tests that are being offered for the](#)

contact tracing at the point of the pandemic in the country.

SAHPRA further outlines the test to be used for COVID-19 [here](#).

COVID-19 – The Appropriate place for Rapid Test Kits

In a media statement, SAHPRA pointed out that the so-called Rapid test kits (serological test kits) that are being offered for the diagnosis of COVID-19 are not suitable for this purpose. They are not helpful to guide decision-making regarding patient management, decisions around the need for quarantine, isolation or contact tracing. Serological tests are used for epidemiological surveys, but not for the diagnosis of acute infections. These tests are designed to be used under the direct supervision of a health care professional in epidemiological surveys.

Read the media statement [here](#).

[Back to top](#)

Clinical management of suspected or confirmed COVID-19 disease

The National Department of Health released version two of the guidelines for managing suspected or confirmed COVID-19 cases. The updated version now includes:

- New de-isolation criteria for confirmed cases (section 4.5)
- Statement on therapeutics for hospitalized cases (section 4.3)
- Statement on the use of ACE-inhibitors, angiotensin receptor blockers, and nonsteroidal anti-inflammatory drugs (section 4.3).

The guideline summary as follows:

Testing

- Apply the latest case definition from the NICD to determine testing eligibility. <http://www.nicd.ac.za/diseases-a-z-index/covid-19/>
- Combined nasopharyngeal and oropharyngeal swabs should be sent in all suspected cases. Lower respiratory tract samples (e.g. sputum) can also be sent if present (do not perform sputum induction, however).
- Ensure that the specimen is labelled and packaged correctly, and stays between 2-8°C during specimen storage and transport.

Suspected COVID-19 cases

- Any suspected case should be identified as soon as possible (ideally before entering the facility). Such cases should immediately be given a surgical mask, and be isolated. Good hand hygiene and cough etiquette should be taught, and appropriate samples obtained.
- A broad differential diagnosis should be entertained for suspected cases, and appropriate testing for alternative diagnoses should be undertaken.
- Suspected COVID-19 cases who are medically well, or who are assessed as having only mild disease, may be managed at home while awaiting test results.

Confirmed COVID-19 cases

- Patients with mild disease may be considered for management at home, provided they can safely self-isolate and are not at risk of developing severe disease (see criteria in table 2).
- Supportive oxygen therapy is the cornerstone of management for patients with severe disease – target oxygen saturations of $\geq 90\%$ for most patients, using nasal prong oxygen, a simple face mask, or a face mask with a reservoir bag.
- For intubated patients with ARDS, use lung-protective ventilation strategies.
- There is currently no good evidence for any specific therapy for COVID-19. Any investigational drugs or therapeutics should be reserved for hospitalized patients. It should ideally be administered as part of a trial, but at a minimum, it should be administered under the Monitored Emergency Use of Unregistered Interventions (MEURI) framework.
- Patients may be de-isolated without the need for repeat PCR tests. Those with mild disease may be de-isolated 14 days after symptom onset, while those with severe disease may be de-isolated 14 days after achieving clinical stability (e.g. once supplemental oxygen is discontinued).
- There is currently no good evidence to suggest that patients on ACE-inhibitors, angiotensin-receptor blockers need to discontinue these agents.

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For the majority of direct COVID-19 patient interactions, appropriate healthcare worker personal protective equipment consists of gloves, a gown or apron, and a surgical mask.

- When performing aerosol-generating procedures (e.g. taking nasopharyngeal swabs, performing CPR, or intubating a patient), an N95 respirator should be used in place of a surgical mask, and eye protection (shield or goggles) should be added to the above.

Download the complete guideline [here](#).

[Back to top](#)

Gauteng Health Department embarks on a massive recruitment drive to fight against COVID-19

The Gauteng Department of Health (GDoH) has embarked on a massive recruitment drive to ensure that there is enough capacity in the province to deal with the anticipated rise in the number of people testing positive for COVID-19. People in the following fields; medical officers, nursing, operational managers, pharmacy, physiotherapy, radiography, speech and audiology therapy are called upon to offer their skills to help contain and mitigate against the Coronavirus. All available health professionals are called upon to take up this opportunity to make a meaningful contribution. Applications can be made online on www.healthjobs.co.za where all positions are advertised.

Read the full notice [here](#).

[Back to top](#)

SMMEs business growth/resilience facility

Businesses geared to take advantage of supply opportunities resulting from the Coronavirus pandemic or shortage of goods in the local market have been identified as the benefiting SMMEs. 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 about the qualifying criteria [here](#).

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

[Back to top](#)

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 about the qualifying criteria [here](#).

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

[Back to top](#)

Transnet: Application of the COVID-19 Lockdown with proactive measures to ensure throughput of essential services

Transnet reaffirmed its commitment to rendering essential services for the effective functioning of the South African economy. Transnet has, however, scaled-down all its transportation services and operations for non-essential cargo during the lockdown period. Measures will be implemented by the respective operating divisions to ensure that critical business continuity services are supported. They request that customers who provide essential goods and service inform their respective Transnet account executive to ensure the necessary requirements are met and to plan accordingly.

Read the full notice [here](#).

Further clarification

Transnet Port Terminals (TPT) has established that all shipping lines are carrying essential goods. Based on this information TPT will provide a practical application of planning on a first planned, first-served basis, based on the firm five day ETA (to avoid confusion this is not on a first-come-first-served basis). **Further applications are detailed [here](#).**

[Back to top](#)

South African business collaborates with government to reduce COVID-19 risks and economic impacts

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Significant resources within Business for South Africa are being provided on a pro bono basis by various institutions, including Business Unity South Africa (BUSA) and its member organisations; the Black Business Council; and a range of consulting firms, companies and business associations.

PLEASE UPDATE YOUR BUSINESS WEBSITES

As of Thursday, every website with a domain name that ends in .za – including every company website that uses the .co.za suffix, every organisation in .org.za, and every academic institution in .ac.za – must link to the South African government's Covid-19 portal at sacoronavirus.co.za.

Download the BSA update [here](#).

[Back to top](#)

Business for SA statement of lockdown regulations

Business for South Africa (BSA) has released a statement to its membership on the lockdown regulations. The effect of the Regulations, as amended, is a general closure of all businesses and a mandatory order that “[a]ll businesses and other entities shall cease operations”, other than those providing essential goods or services, subject to the right to continue operating remotely through electronic means. This should be read with the closure of retail shops and shopping malls (again, subject to the provision of essential goods and services), and the general restriction confining “every person to his or her place of residence”. While we all face challenging times, we must take as our starting point that businesses should do everything in their power to abide by these general rules to assist with flattening the curve of COVID-19.

Read the full statement [here](#).

[Back to top](#)

Business for South Africa (BSA): COVID-19 Testing

The NICD is responsible for development and maintenance of guidelines around laboratory testing for COVID-19. Please note that these will be revised in response to the progress of the pandemic in South Africa. BSA has provided an update based on official NICD and NDOH updates.

Official resources:

[NICD website](#)

[COVID-19 information website](#)

Coronavirus 24-hour Hotline: 0800 029 999

Coronavirus WhatsApp: 060 012 3456

Official guidelines for testing: At this time, ONLY those displaying symptoms will be tested.

Download the BSA update [here](#).

[Back to top](#)

COVID-19 economic impact on East and Southern Africa

The rate and global spread of infections by the coronavirus (COVID-19) - and the related sense of panic across a globalized financial, political and social architecture - sets this particular pandemic apart from any other in modern times. Bowman's highlights the extent of the economic impact on Sub-Saharan Africa.

Read the full report [here](#).

[Back to top](#)

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 adjustment. If you are a BEE champion who is managing and navigating your company's Y.E.S programme and need to report to your exco on the way forward, please join Transcend in their 90minute Y.E.S online webinar workshop.

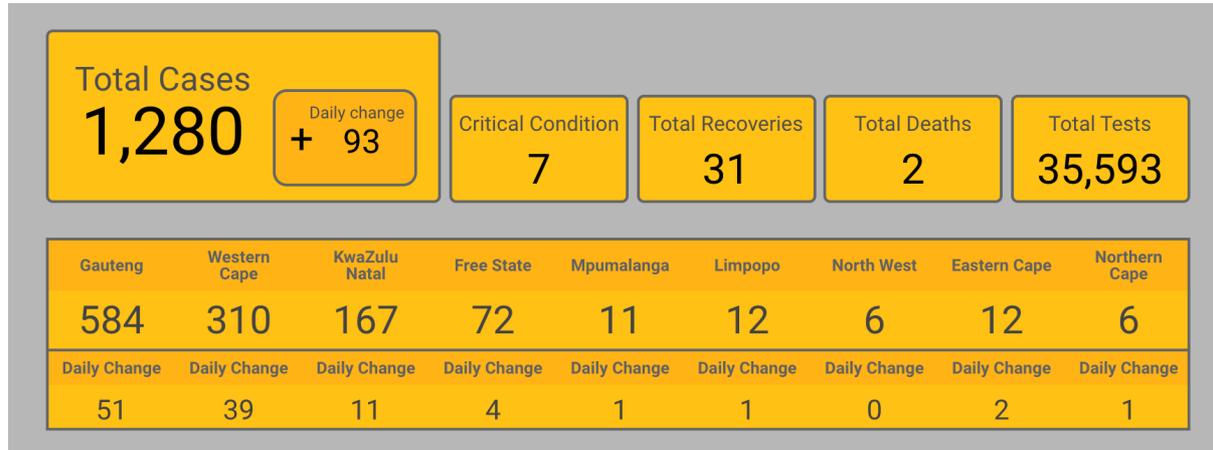
When: 3 April 2020 at 9:30 to 11:00

To book your seat, [click here](#).

[Back to top](#)

[Subscribe](#)[Past Issues](#)[Translate ▼](#)**TRACKING THE PANDEMIC**

During the lockdown weekend, South Africa's confirmed cases reached 1280, with the second death – a 74-year-old male had been in ICU and ventilation in a private hospital in Ladysmith after returning from the Kruger National Park. Western Cape with 310 cases, reported its first case in Khayelitsha.



<https://datastudio.google.com/reporting/15817068-62f2-4101-8e0f-385e2ddd9326/page/wl9JB>

- Worldwide, the number of cases has reached more than 718,000. Some 149,000 people have recovered, and more than 33,000 have died.
- Donald Trump has extended federal guidelines on social distancing until April 30 after a top health official, Dr Anthony Fauci (US director of the US National Institute of Allergy and Infectious Diseases), warned 100 000 – 200 000 Americans could die from the coronavirus. The US has 139 000 confirmed infections from the coronavirus, more than any other country in the world, while more than 2 400 people have died from COVID-19. A rare case of a [baby dying](#) due to the infection was announced in Illinois.
- Germany's death rate from the coronavirus is substantially lower than that seen in Italy, Spain, and the UK. 49,603 Germans had tested positive for the coronavirus as of March 27, with 308 deaths. That gives a death rate of 0.62%. Spain's rate is 7.6% and Italy's is 10.2%. Germany is testing as many as 120,000 people a week, meaning the number of cases keeps rising while the number of deaths trickle in slowly. Germany is also in an early stage of its outbreak, has excellent intensive care facilities, a young average age of infection, and a severe lockdown in place.

SCIENCE NEWS

- Professor Cheryl Cohen from the National Institute for Communicable Diseases says the ability of the Covid-19 coronavirus to mutate is, for now, not a big problem. "The virus has not mutated substantially and there is no problem with the polymerase chain reaction tests which we use to test mutations," she told City Press.
- In a podcast interview with [Prof Adrian Hill](#), a professor leading Oxford University's team working around the clock to developing a vaccine, says one is now in sight and will probably be ready for release before the end of the year. But the Ebola and malaria specialist frets that without changed behaviour, Covid-19 could wreak fearful damage in Africa.

ESSENTIAL TECHNOLOGIES

- Car giant [Ford](#) is entering into partnerships with medical firms to use its 3D printing capacities to produce critical medical equipment.
- Dyson, known for vacuum cleaners and hand dryers, has designed a ventilator in just 10 days and will be making 15,000 of them.
- South African hospitals and healthcare workers may soon be faced with a disastrous shortage of life-saving ventilators due to global undersupply. Africa, and by extension South Africa, is not currently on the top of supply lists. Marius Fourie, the managing director of Draeger South Africa, one of several companies supplying ventilators currently contracted to South African government under a transversal contract, says that the current epicentre of the global pandemic is Europe and supply chains are focusing on getting machines to the countries that need them most. "There is definitely a shortage of ventilators

ECONOMICS OF THE PANDEMIC

- Due to the Moody's downgrade announced on Friday 27 March, economists expect SA's borrowing costs and government bond yields to rise. Increased capital outflows, meanwhile, are expected to further weaken the rand/dollar exchange rate. Moody's estimates that SA's debt burden will reach 91% of GDP in the 2023 fiscal year, above Treasury estimates included in the February budget.
- The rand will likely breach R18\$ on Monday following the decision by Moody's to cut South Africa's credit rating to junk, an analyst, Bianca Botes, Treasury Partner at Peregrine Treasury Solutions warns.
- According to the United Nations Economic Commission for Africa, the continent is two to three weeks away from the worst of the coronavirus storm and needs an emergency economic stimulus of \$100 billion to bolster preventative measures and support its fragile healthcare systems. One measure that can provide some immediate relief is the creation of the special purpose vehicle requested by African finance ministers through which interest payments on sovereign bonds could be sequestered and provide all countries on the continent, regardless of income level.
- Finance Minister Tito Mboweni now has political space from the president to pursue the structural reforms which most economists have said for years are needed to kickstart investment, economic growth and job creation. Mboweni said that a unit would be established in the Finance Ministry – but not the National Treasury – called "Vulindlela", Zulu for "Lead the way," also the title of a popular song by the late Brenda Fassie. Austerity measures such as slashing the public sector wage bill, or structural reforms such as making it easier to fire employees, are going to be a tough sell. The mounting costs of the lost Zuma years and the dithering since have now risen past a possible tipping point. Mboweni also addressed the issue of potentially going to the International Monetary Fund (IMF) or World Bank. He stressed it would be to support the health sector, so the typical balance of payments crisis which generally sparks an IMF bailout does not seem to be on the cards at the moment.
- EFF is running a campaign to pay '[nice special visits](#)' to businesses that don't comply with the lockdown. SAB is one of the targeted companies. Similarly, KwaZulu-Natal police have rescued 14 workers from a [mask factory in Glen Anil, Durban](#), where they were allegedly locked up since Monday last week. Business Insider South Africa reported that the [ban on the sale of cigarettes could be lifted](#) following high-level talks. This, according to a well-placed source, is to prevent underground sales of cigarette.
- The Motsepe family has pledged R1 billion towards the fight against coronavirus, in partnership the Motsepe Foundation, African Rainbow Capital, African Rainbow Minerals and Sanlam. The family had been in contact with government, health workers and other stakeholders to identify specific projects and needs with the "primary objective of saving lives" and slowing the spread of the virus. This would include the purchase of sanitisers and the purchase of personal protective equipment (PPEs).
- [Waste pickers](#), also known as reclaimers, are people who sort through waste to find and sell recyclable material. But during the lockdown period in South Africa, which started on Friday, reclaimers are not allowed to work. "We are trying to get the City [of Johannesburg] to classify reclaimers as essential services during this lockdown because of the amount of waste that we move from landfills and the streets," says Luyanda Hlatshwayo, a waste picker from the African Reclaimers Organisation (ARO). Hlatshwayo also said the government should provide reclaimers with protective gear, such as masks and gloves, if they are allowed to continue working during the lockdown because they may be at risk of contracting the virus.
- South Africans are turning their [offline businesses into online](#) ones in the face of Covid-19 closures.
- Covid-19 may [tear apart the European Union](#). The new crisis arrives after years of populist pressure on the EU from around Europe, with many asking whether the idea of a union was wrong from the start. The virus will ratchet up the tension.
- The state [finance minister of Germany's Hesse region, which includes Frankfurt](#), has been found dead. Authorities said he appears to have killed himself and the state's governor suggested Sunday that he was in despair over the fallout from the coronavirus crisis.

[Back to top](#)

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