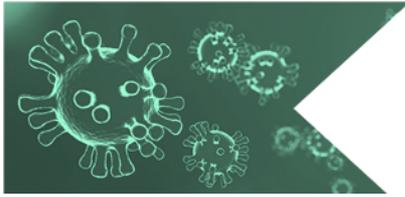


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SAMED COVID-19 NEWS

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](#).

SAMED is working with key stakeholders on MedTech supply

One of the key concerns around the pandemic in South Africa is that of supply. SAMED has been working with the Department of Trade, Industry and Competition to identify the current and future supply of COVID-19 essential medical technologies. A call went out to members to inform us of current and expected stock levels - we encourage you to please complete the spreadsheet and send it back to us for supply planning.

Additionally SAMED will be forwarding a request from the dti to collect information on issues impacting the MedTech Industry for escalating to the Minister. We will be forwarding this request daily over the next week. Please add concerns/issues as they arise

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

Export permits required for international trade

normally export or export as part of equipment and/or consignments of products.

You now require a special permit for this.

Please complete both forms to export stock intended and labelled for use in other countries:

[IE361 Application or export permit: General Goods](#)

[IE230 Application to register as an exporter or change of current information](#)

If you have URGENT shipments due out, in particular where life-saving devices/medicines are concerned, please email to Marius Collins (mcollins@itac.org.za). Please only use this in urgent matters. Otherwise, email the completed forms to Dumisani Mbambo (dmbambo@itac.org.za) or Meluleki Nzimande (mnzimande@itac.org.za). The application will take around 10 days to process. SAMED, under advisement, recommends that you explain why a particular product has to be exported, and why that would be important for patients.

Download the Notice under Trade Admin Act of 2002 [here](#)

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Duties rebate application

Duties have been waived in favour of reducing the cost associated with importing medical technology critical to the prevention, testing and management of COVID-19 in South Africa. The Department of Trade, Industry and Competition has made a provision of rebate item 412.11 for goods imported for the relief of distress. Should your import item be listed as [a remedy for critical medical supplies for COVID-19](#), you can download a [rebate application form](#) from the [ITAC website](#) for a duties rebate.

This Standard Operating Procedure (SOP) acts as a guideline for Business in importing critical supplies into South Africa under Rebate Item 412.11. Importantly, rebate item 412.11' means the full rebate of custom duties and VAT exemption on the critical supplies during the COVID-19 pandemic.

Download the SOP for Business Importing Critical Supplies [here](#).

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SAHPRA Warning: COVID-19 - Caution for the use of Health Products

At a time of unprecedented demand for health products that can be used to prevent, diagnose or manage the novel coronavirus disease COVID-19, there is a very real risk of the public and healthcare professionals being offered sub-standard or falsified medicines, personal protective equipment or diagnostic tests. There is also a risk of these products (medicines and medical devices) being misused or used inappropriately.

Members of the public and health care professionals are urged not to buy medicines or medical devices (including IVDs) from unauthorised vendors and websites, including those on social media platforms. Such health products may be sub-standard or falsified or contain the wrong or no active ingredients or the right active ingredients in the wrong amount. They may also contain harmful substances that are undisclosed. Health products, including diagnostic tests, may not be fit for purpose. Relying on such products may result in severe health problems.

Read the full notice [here](#).

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SOP for Business to request an update of critical supplies under COVID-19

This Standard Operating Procedure (SOP) acts as a guideline for Business in adding products to the established rebate item 412.11 list, as published by ITAC on their [website](#). The requests need to be duly motivated to BUSA who will forward the request to the HS Team. The motivation is directed to BUSA, PMO office, Jonathan.q.james@pwc.com and Nadeem.mohamed@kpmg.co.za.

Download the SOP [here](#).

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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-

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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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Extension of driver and vehicle licence validity

If you or your employees find that either their motor vehicle licence disk or their driving licence card are expiring during the lockdown period, the Minister of Transport, Fikile Mbalula, has gazetted an extension on the validity on learner's licences, driving licence cards, licence discs, professional driving permits and the registration of a motor vehicle for the during of the lockdown and a subsequent 30 day period thereafter.

See the full notice [here](#).

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BSA Update: 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 full Business for South Africa update, [here](#).

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COVID-19 EVENTS

The Effects of COVID-19 on South African SME's

In this webinar, Daily Maverick journalist, Ray Mahlaka will be in conversation with the CEO of Small Business Institute, John Dlodlu and Absa's Deputy CEO for Retail and Business Bank, Bongwiwe Gangeni to discuss the various effects that the spread of COVID-19 has had on South African SME's. This is a FREE webinar sponsored by ABSA.

When: Wednesday, 1 Apr 2020, 12:00 PM

To register, [click here](#).

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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

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When: 5 April 2020 at 9:30 to 11:00

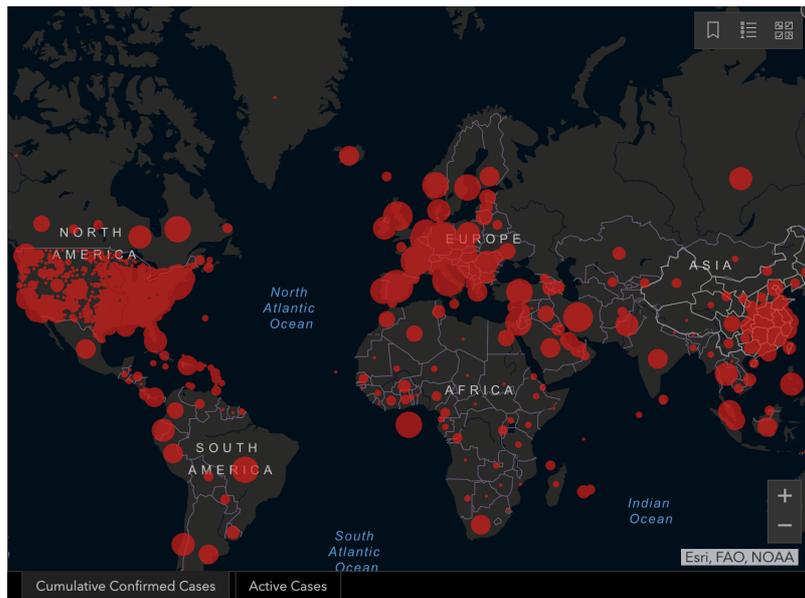
To book your seat, [click here](#).[Back to top](#)

SOME COVID-19 DEVELOPMENTS

TRACKING THE PANDEMIC

President Cyril Ramaphosa announced yesterday that SA has recorded its [third COVID-19 death](#) – an 86-year old man in Bloemfontein, as the national tally of confirmed cases rose to 1 326.

Acknowledging the hardship caused by the 21-day national lockdown the government put in place at midnight last Thursday, Ramaphosa said the measures were “absolutely necessary to save the lives of thousands, even tens of thousands of lives”.



HEALTHCARE RESPONSES AND DEVELOPMENTS

- Government is planning to roll out a **massive screening programme** in the days ahead. Ten thousand health-care workers would be deployed around the country to screen people for symptoms and refer them for testing. People with Covid-19 who had few symptoms would be required to self-isolate at home or go into state quarantine facilities, and those with more severe illness would be admitted to hospital. An extensive tracing system would be rapidly deployed to track down contacts of confirmed cases and to monitor the location of new cases in real time.
- However, as this [article](#) reports, community health workers are gearing up for community-based, door-to-door outreach with little protection and resources.
- [Johnson & Johnson](#) announced the selection of a lead COVID-19 vaccine candidate from constructs it has been working on since January 2020. The company expects to initiate human clinical studies of this lead vaccine candidate at the latest by September 2020 and anticipates the first batches of a COVID-19 vaccine could be available for emergency use authorisation in early 2021, a substantially accelerated timeframe in comparison to the typical vaccine development process.
- Condom shortage looms after coronavirus lockdown shuts Malaysia's factory [Karex Bhd which makes one in every five condoms globally](#). It has not produced a single condom from its three Malaysian factories for more than a week due to a lockdown imposed by the government.
- Private hospital group [Netcare](#) says the three-week lockdown initiated by President Cyril Ramaphosa might not be long enough to achieve the government's aim of slowing the spread of Covid-19 to prevent the health system from being overwhelmed.
- [WATCH](#) | Will Covid-19 make people with HIV sicker than others?
- As the numbers of those infected with COVID-19 continue to rise in South Africa, we look at what this could mean for those with HIV.

- Vietnam, South Korea, Taiwan have each managed to contain their Covid-19 infections, preventing the new coronavirus from reaching epidemic proportions within their borders. [What lessons can the world learn?](#)
- German Researchers at the Helmholtz Centre for Infection Research in Braunschweig soon [plan to send out hundreds of thousands of antibody tests over the coming weeks which could allow many thousands of people to break free of the lockdowns](#). The tests are designed to detect whether an individual has developed antibodies to COVID-19, indicating that they have at one time been a carrier and built up immunity. A positive test could allow individual Germans to leave the lockdown, or allow the national government to ease restrictions in areas where so-called "herd immunity" has been developed.

BUSINESS AND ECONOMY

Naspers has committed R1.5 billion in emergency funding to aid the government's response to the coronavirus outbreak, the group said in a statement on Monday.

TESTED POSITIVE FOR COVID-19 OR SOMEONE IN YOUR HOME HAS? READ ON.

QUARANTINE

- Remain in quarantine for 14 days. Even if the patient feels better during this time, they should continue to stay in quarantine for the full 14 days.
- The patient should be isolated in a well-ventilated single room. If a fan is available, point it out of one window and keep another window open to facilitate increased air exchange in the room.
- If possible, the patient should use a separate bathroom or bathroom/washing facilities should be cleaned after every use.

ISOLATION

- Maintain a distance of more than 3 steps from all household members.
- Assign one person to be the caregiver. The caregiver should ideally maintain a distance of more than 1 meter.
- Minimize use of shared spaces and use separate eating utensils where possible.
- No visitors should come to the home during the 14 days.
- Social support, including food support, is critical.

Logos for the Republic of South Africa and the NDP (2030) are visible at the bottom of the infographic.

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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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