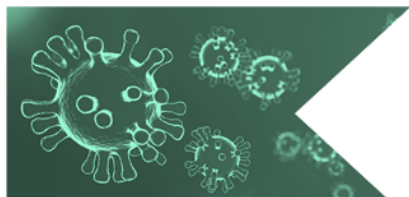


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SAMED
south african medical technology industry association

COVID-19 NEWS

COVID-19 news from SAMED, Government and Abroad.

SAMED ON COVID-19

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](#).

SAMED supports the Ministry in sourcing COVID-19 essential MD and IVDs industry

SAMED continues to work with Business for South Africa (BSA) on the supply of essential medical equipment during this pandemic. You will have seen the call from SAMED to participate in this critical exercise. Having a collated data map of who has products and who will have products in the upcoming weeks as well as who requires these items enables Business for South Africa (BSA) to direct these essential supplies where they are needed in a fair and equitable manner and expedite manufacture or procurement where necessary. Should you receive a call from PWC in this regard, please work with them and provide the information requested. SAMED is working with BSA to refine the excel sheet and make it a real-time portal for members to update. We will inform you of progress in due course. In the interim:

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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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 COVID-19 QUESTION OR QUERY?

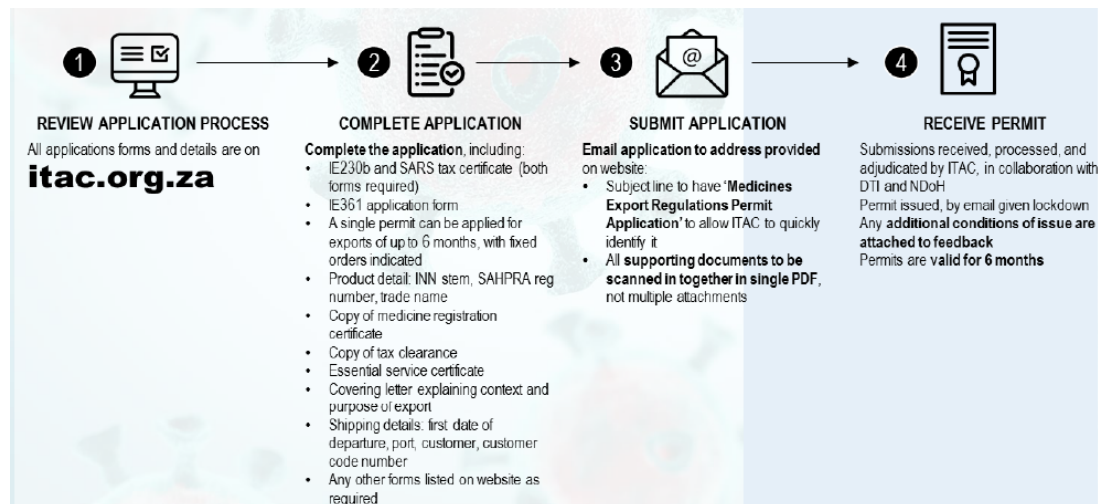
Please visit the [FAQ Section](#) of our library as it provides answers to many of the frequently asked questions we receive.

QUESTION: With who do I register and what documents do I need to export products during the lockdown?

You will need to complete the following documents:

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

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



UPDATED COVID-19 NOTICES, LEGISLATION AND REGULATIONS

REGULATIONS: Tribunal rules for COVID-19 excessive pricing complaint referrals

The purpose of these Regulations is to provide for Competition Tribunal rules regulating complaint referrals for alleged contraventions of excessive price increases during the period of the declaration of a National State of Disaster in respect of COVID -19. These Rules apply to complaints of an alleged contravention of section 8(1) (a) of the Act read with Regulation 4 of the Consumer Protection Regulations.

Download the regulation [here](#).

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SAHPRA - update for interaction with SAHPRA

SAHPRA has updated how stakeholders engage with them during the Pandemic. See [SAHPRA Interactions with Stakeholders during Lockdown](#) - updated 3 April. will continue working and its operations will continue. Please note that all permits, certificates, licences, recommendations, resolutions and letters will not be collected from SAHPRA offices during this lockdown period. These will be e-mailed to applicants.

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National Ventilator Project - Respond by 23:00 on 6 April 2020

The Department of Trade, Industry and Competition (dtic) has issued a call for proposal on their National Ventilator Project (NVP). The timelines on this are very quick. This is a call for proposals to identify role players to assist the dtic on NVP in an effort to meet the anticipated demand for critical medical equipment such as ventilators. The DTIC is inviting companies and experts to submit their proposals in respect of the design, development, production and procurement of ventilators in South Africa.

The CFP is for a non-invasive pre-intubation ventilator solution that a clinical team has determined to be applicable to the treatment of the majority of hospitalized cases that could be developed on a short timescale. It is important to note that the entire submission must be electronic. Partial proposals and multiple proposals will be accepted.

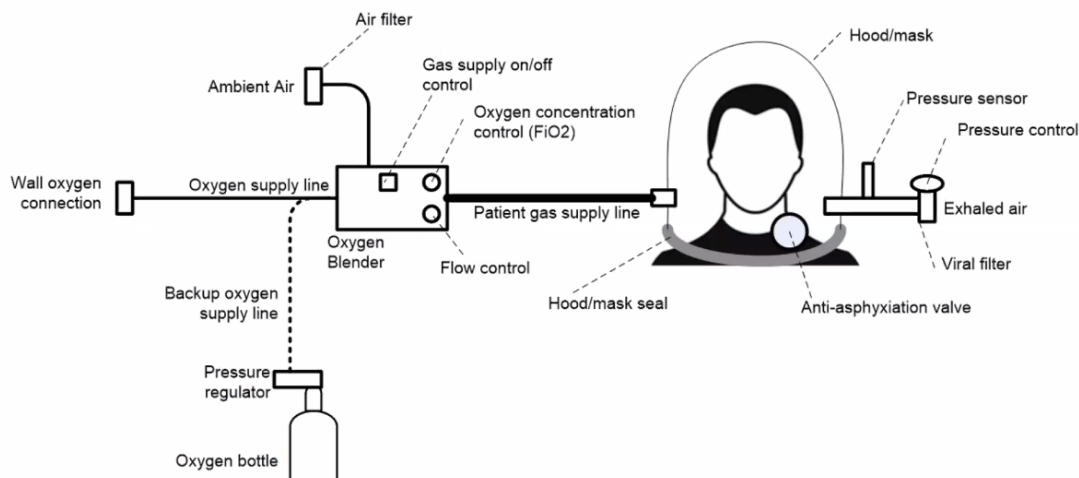
An evaluation of the submitted proposals will be done on Tuesday the 7th after which entities that have submitted the most promising solutions will be requested to present their solutions to the evaluation panel on Wednesday the 8th of April.

The current timeline looks as follows:

- Launch: Friday 3 April 2020 (22:00)
- Information session: Monday 6 April 2020 (10:00)

Reference Design

Talking: Willem Esterhuyse



For more information, download the call for proposals [here](#) or contact Willem Esterhuyse, westerhuyse@ska.ac.za, NVP Project Manager.

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German Development Cooperation seeks to upscale local COVID-19 production

The German Development Cooperation (GIZ) is supporting the SADC Secretariat in advancing regional integration in Southern Africa. Their project which is funded by the EU and the German government is currently adjusting to the COVID-19 outbreak and therefore redirecting their focus of operations. GIZ CESARE would like to support companies in the SADC region that produce relevant medical equipment such as sanitizers, gloves, gowns, masks, oxygen flasks, ventilators etc. to increase the local production. They hope this will help address the worldwide shortage of said medical supplies and facilitate access for the SADC region.

If you would like to apply for their support, please contact Kim Höpner directly on +26777933583 or via email kim.hopner@giz.de

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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 **monetary 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 are available on the Fund's website www.solidarityfund.co.za

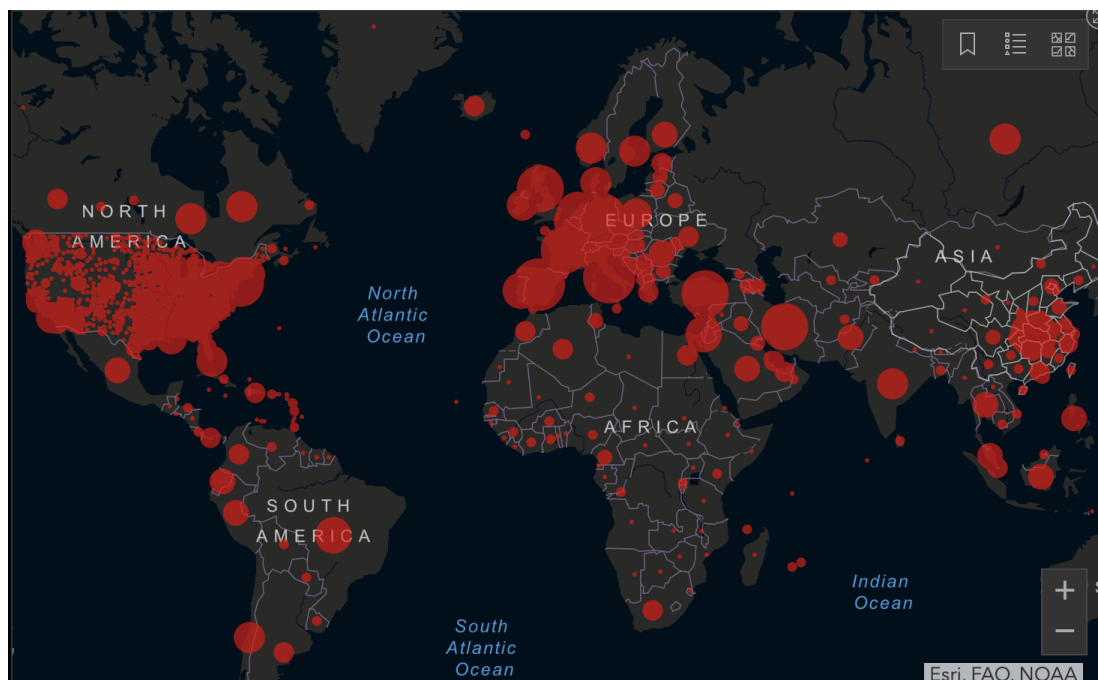
For more information, [click here](#) or email info@solidarityfund.co.za

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COVID-19 DEVELOPMENTS



- Latest numbers for South Africa are 1 655 cases and 11 deaths. The latest casualties are an 82-year-old woman who was admitted to ICU on 29 March. She had presented with fever, short breath, body pains, dry cough and sore throat. She also had comorbidities that included hypertension, diabetes and cholesterol. The second deceased patient is an 86-year-old male admitted to hospital on 26 March with a diagnosis of bronchopneumonia and respiratory distress. He had an underlying condition of chronic obstructive airway disease.
- Mainland China reported 30 new coronavirus cases on Saturday, up from 19 a day earlier as the number of cases involving travellers from abroad as well as local transmissions increased, highlighting the difficulty in stamping out the outbreak. Asymptomatic patients who are carriers and can infect others but don't display symptoms are a big concern.

RESPONSE TO THE PANDEMIC

- South Africa's planned mass testing for COVID-19 may be affected by an unofficial clampdown by the US government on the **exports of test kits**. South Africa does not manufacture machines or kits capable of testing for COVID-19 and relies on imports from companies in the US, China, South Korea and Switzerland. The Guardian reported on Wednesday that Cepheid was one of three US companies manufacturing similar types of test kits which "have been told not to export them, leaving Africa... with a single supplier, Roche in Switzerland".
- Minister of Justice and Correctional Services Ronald Lamola has appointed former Constitutional Court judge Kate O'Regan as the designate judge to **oversee the tracing** of those who have contracted COVID-19.
- [Lockdown rules](#) should isolate violators, not the general public and physical distancing should not mean home detention. Blanket COVID-19 lockdowns may feel like a collective act of caution and responsibility for now, but the longer they last, the more they are likely to feel like a collective punishment for violations committed by a minority. Such draconian measures threaten to diminish public morale and make compliance much more difficult.

SCIENTIFIC AND CLINICAL DEVELOPMENTS

- Scientists have discovered that there are **eight specific strains of COVID-19** affecting the globe. Because the virus is mutating slowly, a once-off vaccine is a possibility. The other good news is that the slow mutation of the virus indicates that it's not likely to mutate to a more lethal strain.
- [Ivermectin](#), an FDA-approved **anti-parasitic** previously shown to have broad-spectrum antiviral activity *in vitro*, is an inhibitor of the causative virus (SARS-CoV-2). A single treatment was able to effect ~5000-fold reduction in virus at 48h in cell culture. Ivermectin is FDA-approved for parasitic

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- **Younger people are far less likely to die**, but there is an unusual pattern that seems to be emerging. Scientists are investigating three possible causes: a gene variation in the ACE2 gene, an enzyme that attaches to the outer surface of cells in the lungs, as well as the heart; a critical ingredient produced by the body, known as surfactant, which better allows the lungs to expand and contract, becomes depleted in some patients infected with the coronavirus; body's immune system response to viruses and bacteria in the first place – in some young, healthy people, a very reactive immune system could lead to a massive inflammatory storm that could overwhelm the lungs and other organs.

ECONOMIC MATTERS

- On Saturday, President Cyril Ramaphosa chaired a meeting of the Coordinating Committee of the **African Union's Continental Response to COVID-19** including a briefing from Dr John Nkengasong, director of the Africa Centres for Disease Control and Prevention (ACDC). Ministers agreed to strengthen coordination efforts to limit the number of deaths and to curb the spread of COVID-19.
- All ministers agreed that the pandemic was an unprecedented health disaster and shared concern about the disastrous impact of the virus due to high levels of poverty and the "explosive spread in densely populated areas of human settlement". They also all agreed to embark on a strategy to raise funds to ensure self-sufficiency, promote manufacturing on the continent and pool procurement within countries.
- **The rand** fell late Friday, crossing above R19 to the US dollar after Fitch Ratings downgraded SA's by a further notch, pushing it deeper into sub-investment grade territory. That followed Moody's downgrade to junk just a week earlier. According to Fitch, the downgrade is a result of the lack of a clear path towards the government's debt stabilisation as well as the expected impact of the coronavirus shock on public finances and economic growth.
- Companies are resorting to **cutting employees' salaries** as an alternative to forced retrenchments as they start to feel the effect of COVID-19 and the 21-day lockdown.
- Malawi's president and all government ministers are taking a **10% wage cut for three months** to raise money to tackle the coronavirus outbreak. Malawi reported its first cases of the coronavirus on Thursday - one of the last countries to do so.
- The government is looking at **providing relief to waste pickers**, who have been left without a livelihood since the national lockdown began. Minister of Environmental Affairs, Forestry and Fisheries, Barbara Creecy, said waste pickers are experiencing "extreme hardship", and a proposal has been made to use some of the National Solidarity Fund to aid them. Government has approached the Consumer Goods Council and its members to look at an intervention that will see the provision of food parcels with immediate effect to waste pickers.
- It is expected that COVID-19 might [change forever is how we buy cars](#). Public and retail spaces will remain environments best avoided for some time after the lockdown regulations ease. After COVID-19, the truth will become self-evident. Customers are going to favour being home more where they feel safe and less at risk of unpredictable, viral exposure of any kind. Those palatial car dealerships are going to be places that even wealthy South Africans don't wish to visit anymore. Meanwhile, the **automotive industry** is playing various roles in the local and global COVID-19 response, with some activities being the following:
- **Jaguar Land Rover and Isuzu Motors** are providing vehicles for NPOs working at the coalface of the coronavirus response, including 11 Land Rovers for the SA Red Cross Society and a fleet of Isuzu test vehicles for Gift of the Givers' testing stations. Jaguar Land Rover has also assigned its rapid prototype 3D-printing facility in the UK to the production of 1,300 face shields per week with an aim to develop the operation for mass production.
- **Lamborghini, Ferrari, JLR, Ford and General Motors** are all participating in the production of masks, protective face shields, ventilators and other essential items.
- **Honda and Audi** have made large donations to programmes in north and central America, and Germany.
- The spread of the pandemic has brought to the fore the **need for business leaders to recognise the crucial interdependencies** between business and its environmental, social, and governance context. Five factors are highlighted:
- Paying attention to planetary boundaries: Many scientists – and also an increasing number of [business leaders](#) – see COVID-19 as a tragic example of the broader risks to business and societies from our seeming inability to address environmental risks associated with climate change, biodiversity loss, and other ["planetary boundaries."](#)
- The health of the society on which businesses depend thus depends on the existence of a decent social welfare system and the absence of extreme poverty and inequality. This has been referred to as

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- Building capable and accountable states
- Managing crises responsibly: In the coming decades, business leaders will need to distinguish themselves by showing strong crisis management capabilities in maintaining business continuity, and by contributing more clearly to societal resilience.
- **Collaborating in a new social contract:** The crisis is of such scope and depth that many business leaders and managers are engaging in a radical shift towards coordination and collaboration with the government and civil society organisations. In South Africa, for example, business leaders have [established](#) working groups interacting with the national government to coordinate the crisis response in terms of public health, as well as social and economic impacts.

ENSAFRICA'S LATEST INSIGHTS

- [South Africa: essential services during lockdown | employer FAQs](#) (Lauren Salt, Edward James and Jessie Moore)
- [Mozambique: Coronavirus \(COVID-19\) state of emergency comes into effect](#) (Alex Ferreira)
- [South Africa: travel directions during the national state of disaster and the national lockdown](#) (Zahida Ebrahim)

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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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