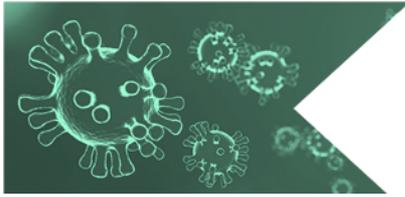


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SAMED COVID-19 NEWS south african medical technology industry association

COVID-19 news from SAMED, industry and abroad

SAMED ON COVID-19

SAMED implements proactive response to COVID-19

In response to the outbreak, SAMED has established a COVID-19 task group. The group is mandated to work on MedTech concerns and needs that arise through ongoing COVID-19 engagement. They will work through and with stakeholders to identify challenges and put in place proactive measures to mitigate the impact of these challenges

The task group has established sub-groups to actively drive SAMED COVID-19 initiatives. These sub-groups will deal with regulatory matters, trade and sustainability, current supply and supply chain and communications associated with the coronavirus in South Africa. SAMED will continue to work with stakeholders and members to create direct links to critical medical consumables and devices for COVID-19 response.

SAMED is aware of the concerns being raised around [President Ramaphosa's lockdown announcement](#) and the uncertainty relating to requirements for exemption/continued services. We expect some information to become available toward the close of 24 March 2020. We assure you that we continue to monitor and will forward all relevant information to you as it becomes available.

For now, we request from members to compile your company-specific data on the categories of employees that would need an exemption for travel and work, so that all relevant categories of your staff are included in our liaison with government. Please forward this information to info@samed.org.za, if possible please by noon on Wednesday 25 March.

You can find COVID-19 updates and documentation under the [SAMED library](#).

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

The regulatory requirement for COVID-19 rapid test kits

COVID-19 Rapid Test Kits are classified as Class D Medical Devices according to Classification Rule 1 for IVDS - Detection of transmissible agents posing a high public health risk. As there are a number of unauthorised suppliers entering the South African market, SAHPRA has published the regulatory requirements for COVID-19 Rapid test kits.

Download the SAHPRA notice [here](#).

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National Department of Health ramps up preparedness efforts

The National Department of Health (DoH) has developed an Epidemic Preparedness and Response plan for COVID-19 in collaboration with the World Health Organisation. The plan outlines key functional areas which require strengthening. The department is in the process of scaling up preparedness and is, therefore, increasing the number of equipment and supplies. The DoH has published a list of items

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Funding for COVID-19 MedTech intervention

The Department of Trade and Industry has established a fund to support COVID-19 interventions. There are a number of qualifying criteria and only for the identified priority products.

Qualifying Criteria:

- Available for working capital and plant & equipment requirements;
- Available to companies that have been operational for at least a year;
- Companies must have a valid contract/purchase order or letter of intent;
- Only applicable to manufacturers of the targeted priority products as listed below;
- Companies with BBBEE Level 4 will be encouraged.
- Funding provided can be stand-alone MCEP funding or blended with IDC.

Download the qualifying criteria, instruments and pricing as well as the identified priority products [here](#). For more information, contact Swasthi Soomaroo on SSoomaroo@thedti.gov.za

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COVID-19 SMME emergency funding package

The Department of Small Business Development has detailed the packages which will be administered by sefa in order to support SMMEs in response to the COVID-19 pandemic. The following interventions are included:

- Business Growth Facility
- SMME Relief Finance and2.
- Restructuring of sefa funded SMMEs3.

For qualifying businesses, the Emergency Funding package will under no conditions be used for what it was not intended for. SMMEs can submit funding applications with www.smmesa.gov.za registration number and supporting documentation to dedicated sefa email address info@sefa.org.za

View the details [here](#).

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Key messages from the Department of Health and NICD (and others)

Below is some important information, mostly from the Department of Health and the National Institute for Communicable Diseases.

From the Department of Health

- [10 Steps to self-quarantine](#)
- [What 'lockdown' means](#)
- [Department of Health Radio Announcements in all language](#)

From the National Institute for Communicable Diseases

- [COVID-19 Frequently Asked Questions](#)
- [Maps and dashboard for mobile](#)
- [Maps and dashboard for web](#)

External to the Department of Health and the NICD, the Desmond Tutu HIV Foundation conducted a webcast yesterday with comprehensive and important information about the coronavirus. The presentation and an audio file are available [here](#).

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Can we join hands on this, and flatten the curve? A proposal...

The pathology labs are under tremendous pressure. So too, many hospitals. Understandably, many

staff are increasingly in distress, and hospital protocols are being disregarded. Can we start by getting this message out, that there is a protocol as to who should, and who should not be treated? That protocol is here, under the heading "[Criteria for Person Under Investigation \(PUI\)](#)". Also, Please note the following freely available information and resources:

1. The [NICD website](#) and the [Department of Health information portal](#) are indispensable.
2. All the private hospitals have a range of information and communication tools (see <http://www.netcare.co.za>; <http://www.lifehealthcare.co.za>; <http://nhn.co.za>; <http://www.mediclinic.co.za>; <http://www.lenmed.co.za>), among others.
3. Mediclinic has an online [personal risk assessment tool](#). An assessment preceding testing will reduce the pressure on path labs and hospitals. Let people know.
4. Discovery Health also has a highly informative and useful Covid-19 information hub at <http://www.discovery.co.za> as does GEMS at <https://www.gems.gov.za/corporate/news-and-events/COVID---12-Coronavirus>
5. As you know, our future success in managing Covid-19 depends on the success we have in enforcing and observing social distancing. Here are some [excellent infographics](#) available to download and share. Included is a wonderful flow chart that deals with the management of fellow South Africans from identification, to diagnosis and through to discharge – this is indispensable for the physicians among you.

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SAHPRA COVID-19 website

Please note that all information relating to COVID-19 processes and SAHPRA can be found on [their website](#). This includes the below and more.

- Valuable insights
- SA & SAHPRA readiness
- Presidential priorities
- Communications to stakeholders

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WHO COVID-19 medtech technical specifications

The World Health Organisation has published a list of technical specifications on medical technology used with COVID-19 in the areas of surveillance, prevention and control and case management.

Surveillance

Laboratory confirmation of a COVID-19 case will trigger a thorough investigation. Because no PCR test is currently available, testing may take several days or longer, WHO's recommended strategy is to begin an investigation immediately, thus requiring immediate operational support and supplies.

Prevention and Control

Based on current information it is assumed that COVID-19 is a zoonotic disease with human-to-human transmission occurring through droplets or contact. This human-to-human transmission may occur due to breaches in infection prevention and control (IPC) practices. Thus, a central focus of any prevention/control strategy is protecting health care workers with appropriate IPC supplies and ensuring basic health logistics at responding facilities.

Case Management

There is no specific treatment or vaccine for COVID-19; however, R&D efforts for MERS-CoV are ongoing.

Access the WHO technical specifications document [here](#).

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COVID-19 Labour Guidelines

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- [Coronavirus easy aid UIF](#)
- [Compensation Fund - Occupational Acquired Coronavirus \(claim procedures\)](#)
- [Health and Safety Guidelines - Workplace Preparedness: COVID-19 \(SARS-CoV-19 virus\) by the Department of Employment and Labour](#)
- [Coronavirus – A Practical Guide For Employers by Cowan-Harper-Madikizela Attorneys](#)
- [Urgent Directive From The Director Of The CCMA In Respect Of The Response To Covid 19](#)

You may also find this downloads at www.labour.gov.za and www.ccma.org.za.

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WHO: Getting your workplace ready for COVID-19

As an employer, you have a responsibility to provide a safe working environment in which employees operate. The World Health Organisation offers guidance on:

- Simply ways to prevent the spread of COVID-19 in your workplace
- How to manage COVID-19 risk when organising meetings and events
- Things to consider when you and your employees travel
- Getting your workplace ready in the case of COVID-19 arrives in your community

Access the WHO guidance document [here](#) and [here](#).

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COVID-19: Impact on businesses and investments in South Africa

While it is still early days, the impact of COVID-19 on South Africa, its people and its economy will be significant.

Bowman's highlighted certain issues to be considered by businesses, investors and transaction teams during this challenging time.

Click [here](#) to read the note, which addresses the potential impacts below.

Bowman's has also created an information hub to house this as well as all the other information they compile.

Click [here](#) to access the page.

Some of the topics covered here include:

- The effects of the crisis on existing [employment relationships](#) and our guidance for employers during the affected period.
- [Remuneration](#) model alternatives in light of the impact of the crisis.
- The handling of [personal data and sensitive personal data](#) by businesses as data controllers and processors, and our guidance on compliance with legal requirements in relation to data protection.
- The [consumer laws](#) pertaining to the right to cancel certain services and the restrictions on business in charging cancellation fees.
- Recommendations to business associated with the [pricing of goods](#) owing to consumer panic and restrictions from a [competition](#) perspective.
- The effect of the Regulations on the ability of a municipality or municipal entity to engage in emergency [procurement](#).
- The most recent travel bans and regulations on the [shipping, aviation and logistics](#) industries.

Bowman's continues to track these and other developments. Please [contact them](#) if you need any further information or assistance.

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Theft of medical devices in light of the epidemic

SAMED would like to alert all suppliers to the potential theft of medical supplies; particularly supplies

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We are inundated with offers of product from unknown source. Please emphasize vigilance – also where product arrives at customs

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COVID-19 EVENTS

Coronavirus impact on Transformation with Dr Robin Woolley

Transcend is hosting a free webinar on 26 March 2020. With coronavirus impact on companies budgets and focus, there will likely be impacts on transformation efforts. It is essential for companies to have a short-term response and start to think about maintaining the investment and capacity that you have built up. Join Transcends special webinar to create a Transformation action plan.

Find out more or register, [here](#).

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SOME COVID-19 DEVELOPMENTS

SA IN LOCKDOWN

- On 23 March – when there were 402 confirmed infections from COVID-19, President Cyril Ramaphosa [announced](#) a 21-day national lock-down to slow down the progress of COVID-19. It entails various far-reaching security, economic and healthcare measures including a directive that people will need special permissions to leave home. Media reports comment on the President's address as "majestic", "decisive", "moment of historic clarity", "time when the President became a war-time president". The common reflection is about needing to come together – read columnist and lawyer Judith February's take on it [here](#).
- The UK has also announced its three-week shut-down, although it seems to be less drastic than SA's, since it allowed for going out to exercise and to travel to/from work, in addition to shopping for necessities.

CLINICAL RESPONSES AND DEVELOPMENTS

WHO's latest reports warn that the **coronavirus pandemic is "accelerating"**, with more than 300 000 cases now confirmed. It took 67 days from the first report of Covid-19 to reach 100 000 cases, 11 days for the second 100 000, and just four days for the third 100 000. WHO Director General Tedros Adhanom Ghebreyesus said it was still possible to "change the trajectory", and has urged countries to adopt rigorous testing and contact-tracing strategies.

WHO's top emergency expert Mike Ryan also warns that countries **can't simply lock down their societies to defeat coronavirus** and that public health measures are needed to avoid a resurgence of the virus later on.

This is timeous advice as reports suggest that in **Wuhan, where the virus first appeared, asymptomatic people are still testing positive** for it— four days after the country said there have been no new cases at the epicentre of its outbreak. That raises concerns that the virus could still be spreading in the city. Asymptomatic carriers appear to be able to transmit the virus to others, complicating efforts to stop its spread. Unlike other countries like South Korea, which counts everyone who's tested positive as a confirmed case, China does not include asymptomatic infections in its official count. Across the world, scientists are calling for urgent studies on this.

Health experts have provided insight into why **Italy's high mortality rate** because of COVID-19. They are calling on other countries to learn from the experience. Key take-outs:

- Most of the deaths were among people over 70 who had three pre-existing conditions (or more).
- Italy has the world's second oldest population and a specific "social mix" with continued close interaction between older and younger people.
- Italy is now in an advanced epidemic phase and other countries which are slow to impose stringent measures are likely to experience similar effects.

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- In the US, states of New York, Washington and California are the worst hit by COVID-19. State politicians are raising alarm of shortage of tests and other essential medical supplies.
- A UK private clinic has been criticised for charging \$434 for one coronavirus test.
- Australian firm Rapidward is supplying COVID-19 blood tests from China to Switzerland, Italy and Iran at a cost of \$12 each. The test, which detects antibodies, claims to have 93.4% accuracy, although it has not yet been approved by the official bodies in the US or UK.
- Academics at Leicester University are developing a mask-based test that could cost just £2 per unit. The mask collects a sample of what the wearer is breathing out - which then requires laboratory analysis.

ECONOMIC IMPACT

President's announcement of a three-week lockdown includes a directive that **all businesses must close except those considered "vital"**. This list is expected to be updated but for now, these are the types of businesses and service providers who will be exempt from the shut-down:

- Supermarkets, companies involved in making or distributing food, basic goods, and medical supplies; pharmacies, laboratories, banks, petrol stations, healthcare providers, and essential finance systems (eg JSE).
- Health workers in public and private sectors; emergency workers, security services including police, soldiers, traffic officers, those in the production, supply and distribution of food and other basic goods, those in essential banking systems, and people who maintain water, electricity, and similar systems.

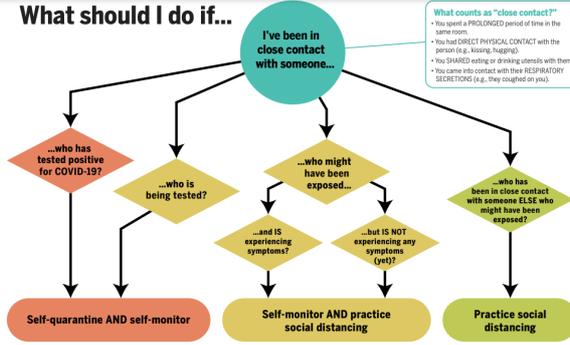
Access a comprehensive [list](#) of key announcements in what the president called the "first phase" of the state's economic interventions. Among them are:

- A [solidarity fund](#) has been established to help support vulnerable South Africans.
- Rupert and Oppenheimer families have each pledged R1bn to support small businesses.
- More details on a planned safety net to help people in the informal sector will be provided.
- The state was working on a special dispensation for companies in distress eg employees could receive wages via a temporary employee relief scheme to let companies pay employees directly.
- Ramaphosa called on large businesses to take care of their workers.
- The UIF reserves may be used to extend support to SMME workers while the Departments of Small Business Development and Tourism have made R500m and R200m allocated to assist relevant SMMEs.
- The state will provide a tax subsidy of up to R500 pm for four months for private sector workers earning less than R6 500 a month.
- Tax-compliant businesses with a turnover of less than R50m would be allowed to delay 20% of their PAYE liabilities over the next 4 months, and a portion of their provisional corporate income tax payments over 6 months.
- The state is exploring the temporary reduction of contributions to the UIF and the Skills Development Fund.
- Commercial banks have been exempted from provisions of the Competition Act to enable them to develop common approaches to debt relief.

SA analysts are reflecting on the growing and in their views prolonged negative economic impact of COVID-19. It is suggested that 2020 Q1 performance may look more positive because of agricultural output but that **Q2 will show the full COVID-19 impact**.

All eyes are turned this week towards a **ratings announcement by Moody's which is expected on Friday**. A sub-investment grade rating would be a massive blow for the ailing economy, whose sovereign rating has already been junked by Fitch and Standard & Poor's.

What should I do if...



How do I...

| | | |
|--|---|--|
| <p>...self-quarantine?</p> <p>STAY HOME for 14 days. AVOID CONTACT with other people. DON'T SHARE household items.</p> <p>Learn more at medical.mit.edu/HowTo/self-quarantine</p> | <p>...self-monitor?</p> <p>BE ALERT for symptoms of COVID-19, especially a dry cough or shortness of breath.</p> <p>TAKE YOUR TEMPERATURE every morning and night, and write it down.</p> <p>CALL your doctor if you have trouble breathing or a fever (temperature of 100.4°F or 38°C).</p> <p>DON'T seek medical treatment without calling first!</p> <p>Learn more at medical.mit.edu/HowTo/self-monitor</p> | <p>...practice social distancing?</p> <p>STAY HOME as much as possible.</p> <p>DON'T physically get close to people; try to stay at least 6 feet away.</p> <p>DON'T hug or shake hands.</p> <p>AVOID groups of people and frequently touched surfaces.</p> <p>Learn more at medical.mit.edu/HowTo/distance</p> |
| <p>And practice great hygiene!</p> <p>WASH your hands frequently • AVOID TOUCHING your face • WIPE DOWN frequently touched surfaces regularly</p> <p>Learn more at medical.mit.edu/HowTo/hand-hygiene</p> | | |

What if I have symptoms?

If you experience symptoms, such as fever, dry cough, or difficulty breathing, call MIT Medical's COVID-19 hotline: 617-253-4865.



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