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COVID-19 news from SAMED, Government and Abroad.

FROM THE DESK OF THE PRESIDENT 29 JUNE 2020

In the latest letter from the President, Ramaphosa announced that COVID-19 deaths have surpassed the 2000 mark. Among those who have lost their lives are health care workers, consummate professionals who cared for the ill, and were a support and comfort to those in hospital isolated from their families.

He stated that it was a devastating blow that healthcare workers, on the frontline of fighting this pandemic, were among those who were lost to the virus. He calls them the true heroes and heroines of the battle against coronavirus. Ramaphosa called for support and PPE to allow these heroes to continue their Herculean work.

With the support of the Solidarity Fund and donations from many individual South Africans, businesses, foundations and other governments, personal protective equipment has been procured for frontline workers. Where there have been shortages of PPE, hospitals have urgently sought supply to ensure availability. Access to PPE is not the only challenge health care workers face. Across the country clinics and hospitals are facing staff shortages. Ramaphosa reassured that the problem is being attended to.

The stigmatisation of people who have proven positive with coronavirus has become prevalent and the President called on society to put this to an end.

"As a society, we have a collective responsibility to stamp out the stigmatisation of people infected with the coronavirus....Just as we came together to promote acceptance of people living with HIV and stood firm against victimisation, we must show understanding, tolerance, kindness, empathy and compassion for those who are infected with this virus and for their families."

Read the full message [here](#).

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CALLING ALL LOCAL MANUFACTURERS OF MEDICAL GRADE 3-PLY MASKS

Medident are calling on all local manufacturers of medical-grade 3-ply masks to please connect with Munsief Khan on [tel] or infor@medident.co.za. If your medical-grade 3-ply make are locally produced, please contact Munsief directly.



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NICD: HEALTH CARE FACILITIES OUTBREAK GUIDELINES

This practical guide (Part A), manual (Part B) and appendices are offered to support all health care workers from leadership to hands-on clinicians to prevent, detect, respond to and limit the impact of

the aged and infirm.

Most importantly, the manual includes often overlooked, but critically important sections on leadership, communication and an extensive section on the provision of psychological support for HCW during outbreaks. The manual reminds those in leadership the importance of clear, timely and transparent communication. It places emphasis on the need to involve all stakeholders in outbreak response, particularly organised labour.

Download the COVID-19 Outbreak Response & Investigation in Health Care Facilities Guidelines 25 June 2020 [here](#).

Download the COVID-19 Outbreak Response and Investigation in Health Care Facilities Training Slides 25 June 2020 [here](#)

Please note

The interim guidelines are based on what is currently known about the Coronavirus Disease 2019 (COVID-19). The National Institute for Communicable Diseases will update these interim guidelines as needed and as additional information becomes available.


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How US companies are planning for a safe return to the workplace

In a new survey of 100 executives, respondents expect most employees to be working on-site by December. To do so, they are implementing a range of interventions that could transform how people work.

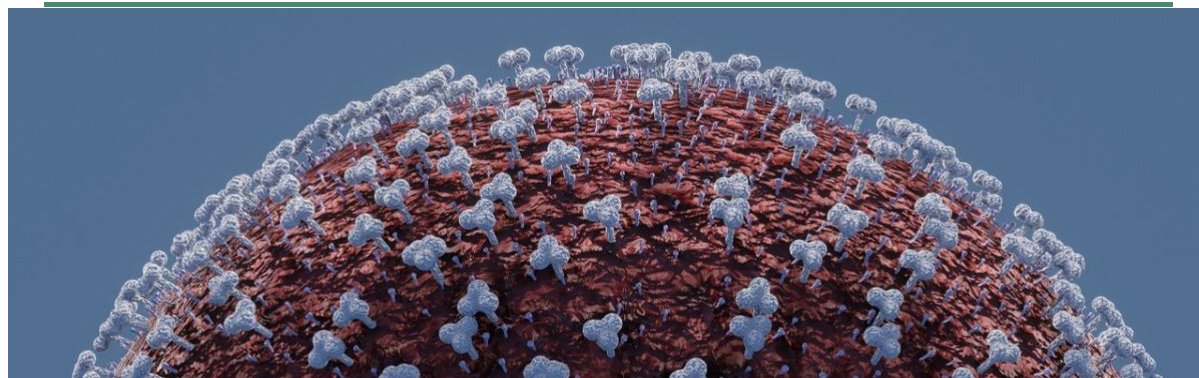
The survey tested four types of interventions in support of a safe return.

Interventions and their most common measures reported by respondents

 <p>Limiting person-to-person contact</p> <ul style="list-style-type: none"> ● Limiting large gatherings or switching to video-conference meetings ● Reducing number of employees on-site ● Physical separation of workstations 	 <p>Identifying and isolating potentially infectious people</p> <ul style="list-style-type: none"> ● Temperature checks for employees ● Contact tracing for infected employees ● At-home health surveys 	 <p>Increasing hygiene protocols</p> <ul style="list-style-type: none"> ● Reducing operating hours to facilitate cleaning ● Requiring sanitization breaks for employees ● Antiviral/disinfectant fogging 	 <p>Using protective personal equipment (PPE)</p> <ul style="list-style-type: none"> ● Employees' use of face masks ● Customers' use of face masks ● Employees' use of other PPE
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To read more and see the survey results, [click here](#).

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REPORT UNLICENCED COMPANIES TO SAHPRA

Several members have contact SAMED about companies trading medical technologies without a SAHPRA Medical Device Establishment License. These companies are trading illegally and it is essential

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[page](#) which you can use to check if the company has a Medical Device Establishment License before sending a report. You can download this list as at 26 May 2020, [here](#). Please ensure that you visit the SAHPRA website to obtain updates as this is an evolving list.

Report unlicensed companies by emailing: mokgadi.fafudi@sahpra.org.za

IMPORTANT SAHPRA MEDICAL DEVICE NOTICES

- [MD010_Guidance_Rapidly developed ventilators_26May2020_v1](#)
- [PCR Tests Authorised for Listing by SAHPRA – 19.05.2020 Specification criteria for COVID-19 serological test kits](#)
- [Joint Communication-Regulatory Status of Equipment Used to Help Prevent COVID-19](#)
- [NRCS media Release – Standards for Masks and Disinfectants](#)
- [Regulatory Requirements for the manufacture, distribution or wholesale of Serological COVID-19 Rapid Test Kits](#)
- [SAHPRA clarifies the issue of COVID-19 Rapid Test Kits](#)
- [MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS \(IVDS\) REQUIREMENTS FOR SUPPLY OF MEDICAL DEVICES IN LIGHT OF THE COVID-19 PANDEMIC](#)

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SAHPRA MEDICAL DEVICE CONTACTS

SAHPRA has launched a COVID-19 Medical Device Hotline to deal with COVID-19 related queries.

- 084 220 8037
- 072 993 2273
- 078 281 6334

For queries on COVID-19 please email mdcovid.@sahpra.org.za and all other regular medical device queries can be sent to MDnotifications@sahpra.org.za

For general licensing queries: June Searela june.searela@sahpra.org.za / 072 828 2416

For COVID-19 related applications: Matlapeng Shabalala Matlapeng.Shabalala@sahpra.org.za / 071 302 0409 or

Khanyisile Nkuku Khanyisile.Nkuku@sahpra.org.za / 081 854 7109

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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.

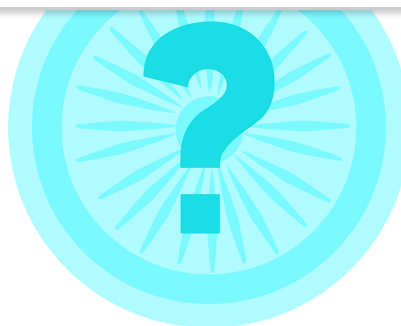
[CLICK HERE](#)

DO YOU HAVE A
COVID-19
QUESTION OR
QUERY?

Please visit the [FAQ](#)

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answers to many of the frequently asked questions we receive.



PARTICIPATE ON B4SA COVID-19 PROCUREMENT PORTAL

The information collected on the B4SA covid19manager.co.za platform will be used to ensure supplier verification, regulatory compliance, product availability, reasonable pricing and providing the accurate and most up-to-date logistical information to the procurement department division at BSA to place orders from you and/or assist with ramping up local production. It is an automated process to help facilitate the overwhelming demand currently being experienced in South Africa during the weeks to come.

NOTE: THIS IS A LIVE SYSTEM SO PLEASE UPDATE YOUR STOCK QUANTITIES AND LEAD TIME AS AND WHEN THEY CHANGE.

Please see the following [link to the video](#) for an explanation of how to use the portal and click on <https://covid19manager.co.za/> to add your company and product information.

You will most likely be contacted by a member of the BSA procurement team should your information provided need to be verified or an order need to be placed.

If you have any questions about the status of your registration, on the types of PPE and medical equipment that B4SA are procuring, if you are struggling to complete your application, or if you have any other queries, please get in touch with the B4SA support team via covid19portal@businessresponsecovid19.co.za. If you are not receiving feedback from the administrators, please check your spam/junk folders.

SAMED is appreciative of the support and commitment of our members in fighting this pandemic.

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THE SOLIDARITY FUND

The Solidarity Fund provided more details on its purpose and mandate of mobilising and coordinating efforts and resources from all South Africans and the international community to assist most vulnerable South Africans to deal with the impact of Covid19 and the consequences of measures intended to slow its rate of infection. One of its key focus areas is a Health Response with direct support for the healthcare system, augmenting both the private and government healthcare sectors to ensure they have what they need, as well as enabling emergency supplies.

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

For more information email info@solidarityfund.co.za

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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COVID-19 EVENTS

WEBINAR ON MANAGING SUPPLIERS & ESD BENEFICIARIES TO MINIMISE THE IMPACT OF COVID-19



Join us for a webinar on

Managing Suppliers and ESD beneficiaries to minimise the impact of COVID-19

10:00 A.M. | 30 June 2020
TUESDAY

COVID-19 has devastated South Africa's economy and business at large, with SMEs especially severely impacted. For organisations that support SMEs through Enterprise & Supplier Development (ESD) programmes or procurement, the risk of value destruction, carefully built over time prior the pandemic, is real. To save ESD beneficiaries and suppliers connected to your business, a proactive approach is needed.

Join us for a webinar hosted by Shenelle Nair & Tafadzwa Mudyiwa where we will be discussing how companies can support SME suppliers and ESD beneficiaries to minimise the impact of the COVID-19 pandemic.



Shenelle M Nair is an Engagement Manager in the Strategy & Economic Development practice at Letsema. She is passionate about leveraging her knowledge and expertise in business optimisation to unpack challenges and propose practical solutions that will catalyse growth in the SME market.



Tafadzwa Mudyiwa is an Associate Partner the Strategy & Economic Development practice at Letsema. He specialises in SME support, ESD and advising organisations that enable the development of SMEs. He is an experienced consultant with a proven track record in strategy, operations and execution across different platforms, industries and geographies.



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INVITATION TO B4SA ZOOMCAST: THE EFFECTS OF COVID-19 ON MENTAL HEALTH IN BUSINESS

How should Business respond to the mental health challenges related to COVID-19?

As we return to work, business owners, CEO's, managers, and employees are facing the prospect that a business-as-usual approach is no longer viable. It is not just about putting in place the practical requirements of social distancing and hygiene, it requires addressing the psychological impact of the virus in the workplace.

Employees are fearful of returning to work, not only because they may become infected on their way to work, in boardrooms or in their normal work scenarios, but also because of stigma, confusion in respect of new workplace policies and intra-workplace relations.

Please join B4SA for a webinar to discuss these challenges, and how to address them. This session will also touch on international learnings, re-imagining the workplace setting and why, in these unprecedented times, mental health should be a priority for companies large and small.

Date: Tuesday, 30 June 2020
Time: 12h00 - 13h00
Dial in: Zoom: <https://us02web.zoom.us/j/4459725244>
R.S.V.P.: Dani Cohen, dani@prologconsulting.co.za / 082 897 0443
 Sandra Sowray, sandra@prologconsulting.co.za / 079 167 6863
 Yankela Njingolo mazulu@madamnji.com / 071 252 3400

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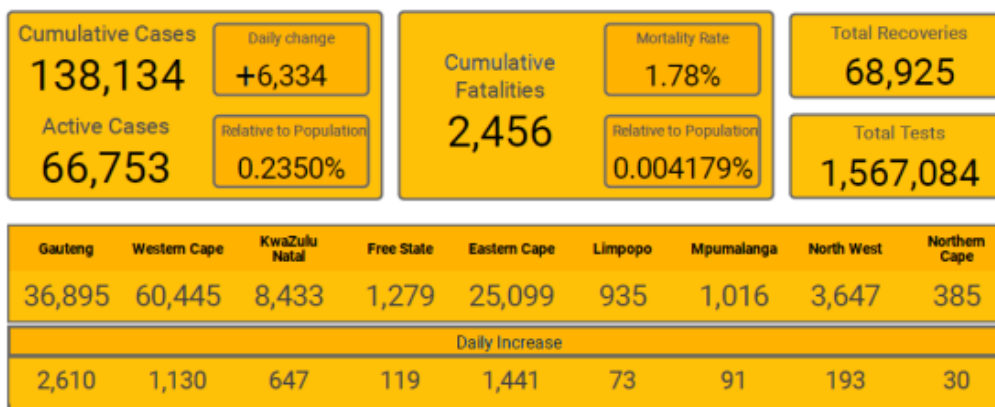
COVID-19 DEVELOPMENTS

TRACKING THE PANDEMIC

The sharp increase in new COVID-19 cases in **Gauteng** is the most noteworthy feature of the recent coronavirus updates.

Health Minister Zweli Mkhize has commented on it: "We believe that within the coming days, Gauteng will emerge with the highest COVID-19 numbers. Factors contributing to this trend are inward migration, the large population (especially in metros like Johannesburg, Ekurhuleni and Tshwane), increased congregating which spurs cluster outbreaks, and the level to which people are able to adapt to new behaviours such as social distancing and the wearing of masks." (News 24)

The apparent drop in the **mortality rate is misleading** – it is "diluted" by the sudden surge in new cases. Death typically occurs after weeks of illness, not in the first few days.



HEALTH DEVELOPMENTS

Rapport reports that **Eastern Cape hospitals are buckling** under the stress of the epidemic. It quotes a couple of doctors. "We are sitting with a situation where patients are lying in the corridors of hospitals like Livingstone in Port Elizabeth and are dying. Many of them need oxygen, but there is not enough for everyone. So, those without oxygen are fighting those who do have it to try to 'steal' it. Sick people are fighting each other," said one source. A doctor at Dora Nginza Hospital said the maternity unit was overloaded and unable to cope.

Provinces are experiencing **budget pressures in providing facilities** for coronavirus patients. Western Cape Transport and Infrastructure MEC Bonginkosi Madikizela told City Press that the funding issue is alarming because they need to secure more quarantine facilities to ensure that citizens are not left in the lurch. "We had to redirect some of our budget to fight COVID-19 because of our responsibility to ensure that there are enough quarantine sites. The problem is that we do not have the funds to secure the number of beds that [projections say will be required]," he said. Western Cape, with 4 766 beds, has enough capacity for its current demand. Gauteng, with 8 740 beds currently, is rapidly scaling up at seven hospitals to prepare for peak demand in July and August.

SOCIAL & DEVELOPMENT ISSUES

The South African National Taxi Council (Santaco) and the National Taxi Alliance (NTA) say the government is not taking the industry seriously and that they have decided to take the "the bull by its horns" and go back to **loading passengers at 100% capacity** from Monday. Long-distance taxis will also be back in operation, **crossing provincial boundaries** in disregard of regulations. Santaco has threatened to pull all its taxis off the road the minute a law enforcement officer stops one vehicle for breaking lockdown regulations. (News24 and SAfm)

Some journalists continue to be fixated on the **contradictions** in lockdown regulations. For example, News24, observes that the new Level 3 lockdown regulations gazetted allow people to visit friends and family at restaurants, cinemas and casinos, but you are not legally allowed to visit them at home.

A badly argued, but possibly true, feature article says that people are **returning to quality traditional news media** for the facts during these troubling times and are prepared to pay for subscriptions to trusted newspapers. [Read more](#)

RESEARCH & SCIENTIFIC DEVELOPMENTS

The head of the **World Health Organisation continues to caution** that the development of an effective COVID-19 **vaccine is not a foregone conclusion**. Speaking by video-conference to deputies from the

was at an advanced stage of development. (Reuters)

BCC reported at the weekend on a vaccine candidate developed by **Imperial College, London**, entering human trials. This vaccine uses synthetic strands of genetic code, called RNA, which mimic the virus. Once injected into muscle, the **RNA self-amplifies** and instructs the body's own cells to make copies of a spike protein found on the outside of the virus, which should train the immune system to recognise and fight coronavirus. Because miniscule amounts of genetic code are used in the Imperial vaccine, the Imperial College team says **one litre** of its synthetic material will produce **two million doses**.

Reuters reports that **China National Biotec Group (CNBG)** has announced that early human trial results for a coronavirus vaccine candidate suggested it could be safe and effective. The experimental shot has induced **high-level antibodies** in all immunised participants in a Phase 1/2 clinical trial involving 1 120 healthy people, according to preliminary data, CNBG said in a posting on the social media platform WeChat. It did not disclose specific results.

Mark Heywood conducted in-depth interviews with Helen Rees, chairperson of the South African Health Products Regulatory Authority (SAHPRA) and executive director of the Wits Reproductive Health and HIV Institute, and Professor Shabir Madhi, incoming dean of the Faculty of Health Sciences at the University of the Witwatersrand. (Daily Maverick) The focus is **whether politics and wealth will be a barrier to universal and equal access** to this critical vaccine. Here are some quotes:

- Rees: "Vaccines under these circumstances must be described as what's called a '**global public good**'. That means that they should be equitably made available to everyone in the world, irrespective of whether you're a big or a small country or a rich or a poor country."
- Madhi (commenting on the fact that the Ox1Cov-19 Vaccine VIDA-trial, a collaborative effort between Wits University and the University of Oxford, is Africa's only clinical vaccine trial for COVID-19): "There's a number of reasons that can influence why **vaccines work differentially** between different settings. So, if we don't generate evidence right now, we will never know just how well this vaccine will or will not work in our local context."
- Rees: "This cannot be **all for some and none for others**. This has to be an equitable distribution of vaccines."
- Rees: "The reason why there are so many types of vaccines is we are looking at not only having a variety of types to make sure that something works, but also that some types of formulations of vaccines are **much easier to manufacture** than others and can be done really quickly and to scale."
- Rees: "Many pharmaceutical companies are investing a lot and they're doing it at-risk. So, they are investing in the development of the technology in the clinical trials, but they're also looking at investing in manufacturing."
- Madhi, who is confident that a vaccine will be developed: "The **coronavirus is much less complex** than TB, HIV and malaria. It's much more genetically stable. Just over a short period of time, we're getting good insight in terms of what might be required for a vaccine to be effective."

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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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