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COVID-19 news from SAMED, Government and Abroad.

DTIC: MEASURES TO ENSURE COMPLIANCE AND VERIFICATION

In a session with the Portfolio Committee on Trade and Industry, the dtic discussed localisation with the understanding that local content was a legislative requirement, in line with the 2017 preferential procurement regulations. In addition, organs of state could self-designate certain products and in the context of COVID-19, this meant that face shields, for example, could now be designated. Members of the committee asked if the South African Bureau of Standards (SABS) had the necessary capacity to handle the local verification of PPE electronically rather than manually; *'How far was the Department in the development of new rules regarding border tariffs and unfair trade rules'*; whether there was any strategy for the local beneficiation of raw materials; and *'How could the government protect black industrialists'*?

It was explained to Members that the Department was learning that supporting local manufacturing involved other instruments, beyond preferential procurement regulations; export control measures had been introduced as part of the lockdown to ensure that local demand for PPE was met; SABS was involved with monitoring local content and adherence to standards and was now also doing product testing before tender awards; the Department was learning through PPE procurement that for localisation to happen different instruments were required; and that there was an instruction note to provide a space for young people to participate in and for black industrialists to produce and supply PPE. Members were keen to find out what impact the African Continental Free Trade Area (AfCFTA) would have on local content requirements when it came into full force. Members heard that the negotiations on public procurement as part of the AfCFTA had been postponed but this would not prevent trade in PPE because as head of the African Union, President Cyril Ramaphosa was coordinating the supply of PPE in Africa.

Download the presentation [here](#).

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BUSINESS FOR SA | COVID-19

SOUTH AFRICA DONATES OVER 1.4 MILLION PIECES OF PPE TO FRONTLINE HEALTH CARE WORKERS

Business for South Africa (B4SA) issues a further call for PPE donations

Individual South African companies and the public have donated over 1.4 million pieces of Personal Protective Equipment (PPE), valued at R13.2 million through the B4SA PPE portal. The PPE has been donated to public sector doctors, nurses and community health care workers at the frontlines of the country's fight against the pandemic.

Donated products include 945 000 pairs of examination gloves, 233 000 surgical masks, 130 000 N95 respirators, 135 000 face shields, 9100 litres of sanitiser, 1100 coveralls and 1100 surgical aprons.

In March, B4SA launched a national PPE donations drive called 'Business Mzansi, we need you', which called on companies, especially those in lockdown, to donate medical-grade PPE in the national interest.

These donations are in addition to the almost 70 million pieces of PPE procured and donated to the public sector, underpinned by support from the Solidarity Fund, as well as the Motsepe Foundation, FirstRand's SPIRE Fund and Naspers.

The pandemic will be with South Africa for a long time to come, and so too will the need for PPE.

severe shortage of PPE and, like the rest of the world, had to urgently fill a gap while it procured emergency products from a highly constrained global market.

A boost for the local manufacturing sector

B4SA has since pivoted its procurement sourcing strategy from the global market, which remains volatile, to capacitating and supporting local manufacturers, black-owned companies and domestic SMEs. In the current round of B4SA's PPE procurement drive, it is sourcing 97% of products from local manufacturers, including black-owned companies.

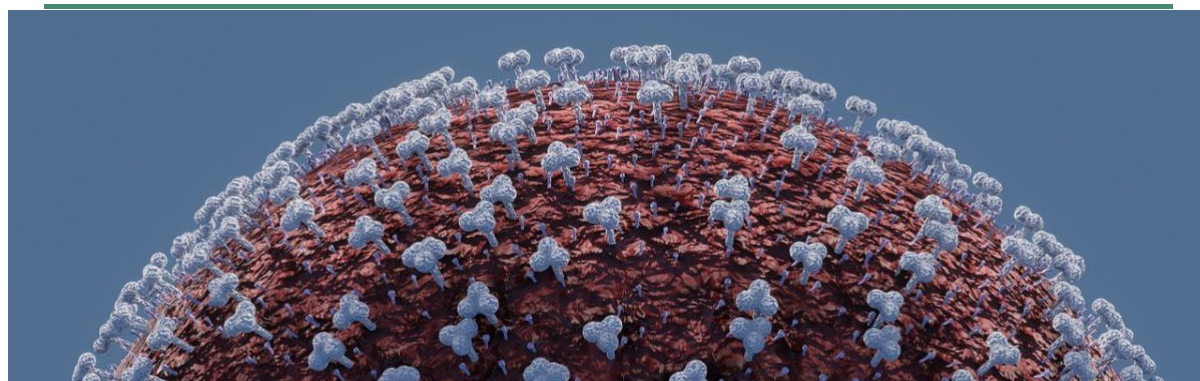
Many companies have reinvented themselves to meet the country's need for PPE, from beauty product and alcohol manufacturers supplying hand sanitizer, to car manufacturers pivoting to produce face shields, to diaper manufacturers producing medical-grade masks, to clothing manufacturers turning into cloth mask makers.

This crisis has provided the opportunity to create value in the local manufacturing industry. This will not only provide opportunities for domestic manufacturing but will also contribute to the country's economic recovery plan and the preservation of jobs.

On behalf of every doctor, nurse, paramedic, pharmacist and community health care worker, B4SA would like to thank all the companies and individuals that heeded our national call for PPE donations thus far, and those who will continue to do so.

B4SA's priority is to source quality medical grade PPE, at the best price. Its PPE portal is underpinned by robust quality assurance and standards, designed by the National Department of Health's Quality Assessment and Health Technical Assurance Unit, to ensure that the products donated and procured comply with the highest standards defined by regulators. B4SA is one of the entities procuring PPE on behalf of the country.

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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 that they be reported to SAHPRA for investigation.

SAHPRA has published a list of licenced companies under documents on their [medical devices 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](#)

[Subscribe](#)[Past Issues](#)[Translate ▼](#)**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](#)

[Back to top](#)**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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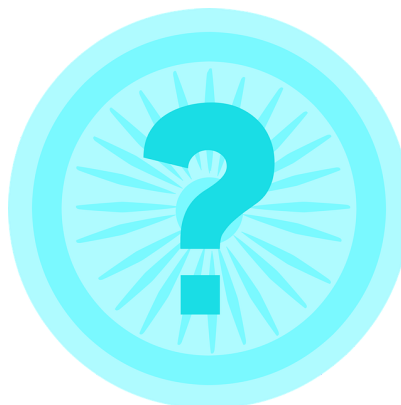
The SAMED Library is a dedicated resource for all COVID-19 related updates, regulations, notices and news.

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 Section](#) of our library as it provides 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

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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

OMMIA HEALTH COVID-19 VIRTUAL EXPO

Omnia Health Live are bringing together the global healthcare industry, for the largest virtual gathering ever seen before, a whole new concept planned from the ground up to be more diverse and accessible, **taking place 22-26 June 2020.**

[Join the experience here](#)

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VIRTUAL CONFERENCE: AFRICA'S LEADERSHIP ROLE IN COVID-19 VACCINE DEVELOPMENT AND ACCESS

Recognizing the urgent need for collaboration, cooperation, and coordination to ensure that Africa plays a leadership role in the development and access to potential vaccines, this two-day virtual conference, under the leadership of H.E. Moussa Faki Mahamat, Chairperson of the African Union Commission (AUC), will bring together healthcare professionals, researchers, public health experts, policymakers, media, civil society, community and religious leaders, and industries to explore this topic and help develop a framework for COVID-19 vaccine development and access in Africa.

When: 24 & 25 June 2020

Download the invitation [here](#).

To register, [click here](#).

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COVID-19 DEVELOPMENTS

TRACKING THE PANDEMIC

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100,108	+4,518	Fatalities	1.98%	33,043				
Active Cases	Relative to Population	2,102	Relative to Population	Total Tests				
48,961	0.1805%		0.003576%	1,382,772				
Gauteng	Western Cape	KwaZulu Natal	Free State	Eastern Cape	Limpopo	Mpumalanga	North West	Northern Cape
24,041	53,512	5,625	814	18,108	622	662	2,454	270
Daily Increase								
1,700	958	347	42	1,213	40	66	139	16

Describing the coming months as a [“decimating and devastating storm”](#) Health Minister Zweli Mkhize said on Tuesday that the indications are that Western Cape and Eastern Cape, due to well-established outbreak clusters in communities, will reach peak numbers of infections first. Warning South Africans to brace themselves as the country heads for the peak of coronavirus infections, Health Minister said that the outcomes are still better than the initial predictions that 20% of those who are infected would need hospitalisation.

ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL

- Cooperative Governance and Traditional Affairs Minister Nkosazana Dlamini-Zuma [does not have the reasons why the COVID-19 pandemic was declared a national disaster](#). The "scientific rationale" relied on to ban the sale of tobacco products is also not available, nor the reasons why alcohol sales are allowed under Level 3 lockdown. This according to Dlamini-Zuma's recent written replies to questions posed by opposition MPs which were published in the past week.
- South Africa's government is considering selling a [green infrastructure bond](#) worth tens of billions of rand as part of its biggest drive ever to kickstart private investment in projects ranging from energy to water reticulation. The proposed instrument is one of several mechanisms the country could use to raise finance for projects worth as much as R1.5 trillion over the next decade, said Kgosientsho Ramokgopa, head of the South African presidency's investment and infrastructure office.
- [Saudi Arabia barred international visitors from completing the Hajj](#) pilgrimage in July amid the coronavirus pandemic. The Hajj is worth around \$6 billion (R103 billion) to the Saudi government each year, and as over 70% of visitors come from abroad, the government is set to miss out on about \$4 billion (R69 billion). Muslims of any nationality currently residing in Saudi Arabia are still permitted to embark on Hajj. However, those going this year must be under 65 years old and will be tested upon arrival in Mecca. This is the first time since 1932 - the year of Saudi Arabia's founding - that limitations have been placed on the annual pilgrimage.

CLINICAL, MEDICAL, SCIENTIFIC

- [Wits University has announced South Africa's first COVID-19 vaccine trial](#) and its first participants will be enrolled this week. The trial aims to find a vaccine that will prevent SARS-CoV-2 infection. "This is a landmark moment for South Africa and Africa at this stage of the COVID-19 pandemic. As we enter winter in South Africa and pressure increases on public hospitals, now more than ever we need a vaccine to prevent infection by COVID-19," Professor of Vaccinology at Wits University and Director of the South Africa Medical Research Council Vaccines and Infectious Diseases Analytics Research Unit, **Shabir Madhi**, said in a virtual briefing on Tuesday. "We began screening participants for the South African Oxford 1 COVID-19 vaccine trial last week and the first participants will be vaccinated this week," he added.
- [Volkswagen may soon manufacture an innovative new ventilator](#) to help save COVID-19 lives. And the building skills by South Africa and VW have shown to be every bit as good as the famously fast hospital-builders in China. These were among the announcements on Tuesday from national Health Minister Zweli Mkhize in the Eastern Cape, upon **opening the new 3 300-bed field hospital** in Nelson Mandela Bay. **No more information was offered on the new ventilator** - but the technology could be part of oxygen supply to the thousands of patients in the new field hospital. "We are also very pleased to have had a conversation with VW on **manufacturing non-invasive devices to deliver oxygen** to patients who need assistance. We look forward to these developments because the guidelines for critical care are indicating that less invasive ventilation confers better outcomes," said Mkhize.
- New research led by National Institute for Health Research professor Waljit Dhillo, who is affiliated to the Imperial College Healthcare NHS Trust, shows that [high levels of cortisol](#) can be linked to the **level of severity of the illness**. The new research was published in the journal The Lancet Diabetes & Endocrinology.

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most European countries, Sweden did not impose a strict lockdown and kept open schools, restaurants, and bars, relying instead on citizens to enact voluntary social distancing measures.

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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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