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COVID-19 news from SAMED, Government and Abroad.

SAMED ENGAGES WITH HOSPITAL GROUPS ON TESTING REQUIREMENTS

It has been brought to SAMED's attention that all the hospital groups have introduced more stringent COVID-19 protocols for representative access to their hospitals. In addition to this, Netcare has introduced a new COVID-19 protocol update which requires all representatives in theatres to present a negative test result on a weekly basis.

This update has created enormous concern among members about the cost and time implications of this requirement, which could be unfeasible for companies, individuals, or even medical aid funders to carry. While SAMED can understand that these hospital groups are trying to mitigate transmission risk, this requirement would prove very onerous and the scientific evidence available is unclear whether more frequent testing prevents virus transmission.

Furthermore, even if all who encounter patients were tested weekly, the potential outbreak of COVID-19 would still be influenced by the social distancing practices outside of the theatre/normal day. In order to comply with the proposed new protocol, some representatives would likely require daily testing.

Apart from cost and logistical considerations, the hospital groups would need to consider further points associated with such a requirement:

- Increased exposure risk for representatives when frequenting the testing labs;
- Depletion of test to be utilized for genuine screened patients referred for testing –a leading industry expert currently recommends that SARS-CoV-2 testing only be done for persons with symptoms as any other testing would waste these scarce resources.

While SAMED fully supports any screening, controlled/reduced access to hospitals and correct utilization of PPE/hand sanitization, SAMED is of the opinion that the above requirement would prove too burdensome and that patient care could be compromised as company representatives reduce/cease activities at these hospitals.

SAMED has deliberated on the matter and has engaged with some of the hospital groups as well as subject matter experts on the above concerns, asking for greater clarity and offering further engagement on the matter.

We will continue to keep you informed of our engagement on this matter and we encourage you to contact us with any relevant information.



REMINDER TO PARTICIPATE IN THE SAMED 'INDUSTRY SUSTAINABILITY IN THE FACE OF ECONOMIC CHALLENGES SURVEY'

COVID-19 has impacted business in a significant way. SAMED is undertaking to better understand the impact it has had on the sustainability of the medtech sector considering the economic challenge companies have and will continue to face.

We hereby request that you participate in this important survey so that SAMED has the necessary data to understand the impact on jobs should members not be able to implement price increases due to increased cost impacts within the market.

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Please complete the survey [\[click here\]](#) by Wednesday 20th May 2020.

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](#)


BUSINESS FOR SA | COVID-19

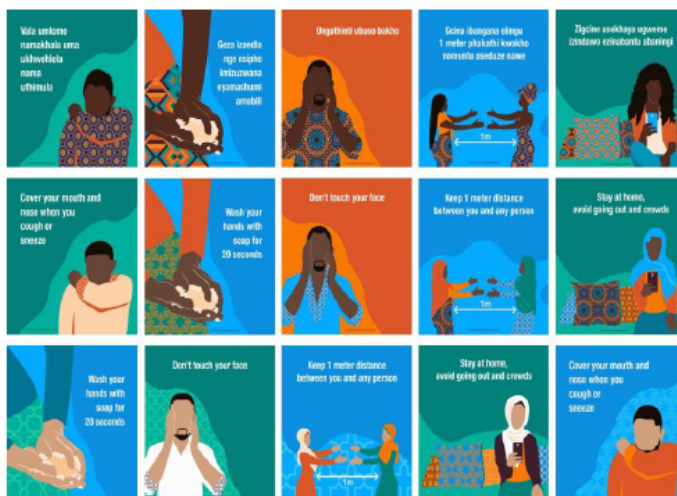
B4SA UPDATE: GUIDELINE FOR RETURN TO WORK

Business for South Africa (B4SA) has developed an overview of the Regulatory Framework pertaining to the COVID19 in South Africa in so far as workplaces are concerned. The purpose is to enable employers to ensure that when they resume operations, at the appropriate time and in line with Government Regulations and/or Directives, they do so in a manner that is safe with minimal risk to the health of employees and the health of members of the public.

Since it is impossible to address every and all aspect of the various industries, this document provides a general overview for organisations. Whilst these guidelines will provide a basis for organisations to adopt, it is recommended that each sector supplements this guide with workplace procedures specific to its conditions pertaining to its industry.

This document was prepared with information available as of 14 May 2020. B4SA will endeavour to regularly update the information contained herein as and when new information and regulations are issued.

To view the overview, please go to [Return to Work during COVID-19](#)



This week at a glance

PPE order book over **ZAR 1bn:**

- 12.0 million N95 masks
- 39.0 million surgical masks
- 900 000 sterile gloves
- 120 000 goggles
- 100 000 gowns
- 500 000 sanitizers (500ml bottles)
- 200 ventilators

B4SA continues to be in contact with air freight operators and can share with interested parties details for >10 operators offering inbound air freight, primarily from Europe, China, and India. If you would like access to these details, please reach out to Nicola Brink: nicola@selfcareassociation.co.za.

Download the B4SA Newsletter [here](#).

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DHL AVAILABLE FREIGHT FLIGHTS

DHL has an aircraft that it needs to fill to continue supporting the medical fraternity in South Africa. They have a responsibility to the market and wish to ensure the charter continuity.

Download the Ubuntu Connect Schedule Planning [here](#).

Download the AIMS Global Logistics Form [here](#).

For more information contact Mike Wood on 082 939 1768 or m.wood@dhl.com

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DEADLINE 29 MAY 2020: APPLICATIONS FOR DEVELOPMENT OF LOCAL DIAGNOSTICS & REAGENTS FOR COVID-19

The South African Medical Research Council (SAMRC) has announced a funding opportunity aimed at supporting the development of a local capacity to supply reagents for existing gold standard COVID-19 testing as well as to offer rapid alternatives for the direct detection of the virus.

The SAMRC invites researchers from recognised South African public universities, science councils and public research organisations, including the SAMRC's intra and extramural units and collaborating centres, to apply.

The RFA is also open to not-for-profit and for-profit companies in South Africa who are involved in developing and manufacturing diagnostics and/or components. For more information and to download the relevant documents, [click here](#).

Please direct queries or requests for information on this RFA to:

Dr Michelle Mulder, Senior Program Manager: michelle.mulder@mrc.ac.za

Application Closing Date: **29 May 2020**

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OMMIA HEALTH COVID-19 VIRTUAL EXPO

With COVID-19 impacting almost every aspect of day-to-day life, it may not be 'business as usual'. But at this critical time if you would like to feel connected with the healthcare community across the world (despite social distancing) and stay up-to-speed on the latest developments within the global healthcare industry...join us for this **free-to-attend virtual expo** – [Omnia Health Live](#)

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**.

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Omnia Health Live

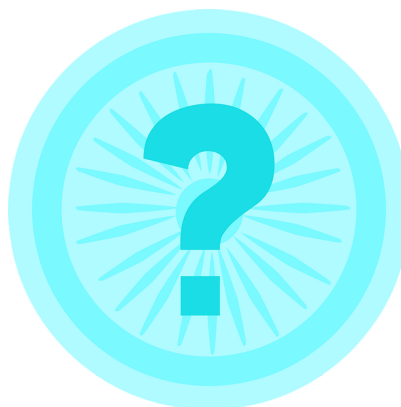
Don't miss out on this exciting opportunity to network with a plethora of solution providers, continue your learning initiatives, and connect with the world-wide healthcare community at large – all from just a keystroke. Yes, it's that simple.

Ready to be part of this exhilarating new journey? [Join the experience here](#)

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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.



What must I do to prepare my workplace and have staff return to work?

There are now Occupational Health & Safety Measures that all businesses, apart from health facilities and practices, must adhere to. This applies to those who have been supplying essential goods this far, as well as those that may partially re-open from level 4 and down.

Download the directive [here](#)

You can also find useful tools on the [Return2Work website](#).

Where can I get a list of goods that are banned from export by the government?

The restrictions on Personal Protective Equipment are set out in the published [Export Regulations](#).

The regulation provides that items listed in schedules 1,2,3 and 4 shall not be exported from the Republic of South Africa except by virtue of an export permit issued in terms of Section 6 of the said International Trade Administration Act,2002.

IMPORTANT SAHPRA MEDICAL DEVICE NOTICES

It is imperative to first read the notices as the regulatory is currently being inundated with calls and queries which are covered in these notices.

- [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 IVDS requirement for supply in light of 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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PARTICIPATE ON BSA COVID-19 PORTAL

This effort is part of the broader SAMED collaboration with the Minister of Health via Business Unity South Africa's "Business for South Africa" initiative (BSA). During the current pandemic, up-to-date information is critical to ensure all key stakeholders in the value chain make the best-informed decisions at the right time.

The information collected on the 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. The

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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. In this regard, we have put in place a security measure. The BSA procurement team will always supply you with your security code that only you have access to on the portal. See the video for reference as to where to find this code. Please never share or read this code to anyone but only have them read it back to you for validation. If at any point you feel your security code is compromised please let Tanya Vogt (tanya@samed.org.za) know and it will be reset.

We are extremely 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

CONDUCT A MEDICAL DEVICE RISK ASSESSMENT: ISO14971:2019

Join SGS for a FREE webinar that will provide an overview of the changes to ISO 14971:2019 and will help you to understand the relationship between risk management, regulatory requirements, and the quality management system.

Date and time: 19 May, 15:00
To register, [click here](#).

SA CLINICAL TRIALS OVERVIEW DURING COVID-19

The keynote speaker, Professor Salim Abdool Karim will provide an overview of the current COVID-19 situation in South Africa, including updates and suggestions for tackling the pandemic.

Date & Time: 20 May 2020, 11:30 - 14:00
For more information, [click here](#).
To register, [click here](#).

COVID-19 WORKPLACE RESPONSE TRAINING:

Occupational Safety & Health COVID-19 Training

AUDA-NEPAD in partnership with the African Union, Department of Health South Africa, The International Labour Organisation (ILO) and partners will be hosting a series of COVID-19 Workplace Response Training on Occupational Safety and Health for all sectors.



**Training 4: 25 May
10h30 -12h30
(GMT+2)**

Implications of COVID-19 in the workplace: OSH Context

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THE GREAT LOCKDOWN DEBATE

The **media agenda** is firmly focused on **opinions arguing for a rapid easing of the lockdown**, at least to Level 3 and even to Level 2. There is particular interest in a possible division of opinion in the **Ministerial Advisory Committee (MAC)** comprising 51 health scientists.

On Saturday, SA Medical Research Council Chair and MAC member **Prof Glenda Gray** grabbed the headlines by contending, in an interview with News 24, that the levels defined in the lockdown and the regulations applicable to them had **no basis in science, were nonsensical** and that the lockdown should be scrapped. She referred to some shopping restrictions to illustrate her point. Her comments seem to have been motivated by a concern with early indications of a rise in malnutrition among children in Soweto.

- The Sunday Times reported that some of **Prof Gray's MRC colleagues** supported her and quoted one or two unidentified scientists on the Ministerial Advisory Committee (MAC) who stated the **MAC had never been consulted on easing the lockdown** or on the restrictions on tobacco and alcohol sales. It was noted, however, that the MAC met regularly with the Health Minister and MAC Chair Prof Salim Abdool Karim expressed his satisfaction with relationships between the MAC and government.
- The **Department of Health** came out guns firing if not blazing. It **convened a meeting** of the MAC committee chairs on the day that Gray's interview appeared (Saturday) and issued a statement indicating that the **MAC's advice had always been followed** but the MAC was there to offer health expertise, **not to stray into the economic territory**.
- News24 published a follow-up interview on Monday contending that **MAC members were also frustrated** by the DoH's **failure to share important data** with them – on the geospatial distribution of Covid-19 cases, screening and testing and contact tracing.
- On SAfm this morning, political commentator Steven Friedman, reflecting on the matter, noted that **“lockdown” vs “no lockdown” dichotomies were not useful** in the present circumstances where a fine balance between health and economic risks needed to be maintained. He also cautioned against the **“cult of the scientist”**. Also on SAfm this morning **Prof Gray sought to explain** her earlier statements, moderating her position.

Sunday Times reported on an **online survey** by University of Cape Town economists which found that **90% of the 12 000 smokers** who completed the questionnaire said they had **bought cigarettes** despite the ban. Many smokers had switched from multinational to local brands and the price of cigarettes had skyrocketed.

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HEALTH DEVELOPMENTS

- A feature article in Daily Maverick notes that the demand for ICU care is likely to outstrip the combined resources of public and private hospitals in South Africa when the epidemic reaches its peak. It also highlights the Bill of Rights provision that **no person may be refused emergency medical treatment**. Urgent planning is needed, the authors argue, to ensure that facilities are equitably shared and that **non-medical aid patients** also have **access to private hospitals** which have a greater share of ICU facilities. The article explores some of the payment models that could be considered. [Read more](#)
- The **NGO MSF** warns that **community screening** for the coronavirus is a resource-intensive activity and says that South Africa may well be reaching the **limits of its capacity**.

ECONOMIC DEVELOPMENTS

- Hilary Joffe of Business Times speculates that **the Reserve Bank will opt for another large interest rate cut** when it meets this week. Factors driving this probability are the falling oil price, lack of demand and a worsening economic outlook.
- **Barloworld** is reported to have issued a notice of intention to institute **voluntary retrenchments** in its automotive and logistics divisions. The report is based on sources among workers. The company would not comment at this point as it would be incorrect procedurally. (Fin24)
- The **Agricultural Disaster Fund** has approved **R500m in assistance to more than 15 000 farmers** to mitigate the impact of the epidemic and support food security. According to Minister of Agriculture Thoko Didiza, more than 55 000 applications for assistance were submitted. (Fin24)

EDUCATION DEVELOPMENTS

- Basic Education Minister Angie Motshekga is due to brief the media today (Monday) about the readiness of schools to resume teaching and learning. Sunday Times reports that she is expected to table a plan in which some **5 000 big city schools – both private and public – will remain shut** during June. (Note the time of the briefing is being constantly shifted and it may ultimately be postponed.)

RESEARCH & SCIENCE DEVELOPMENTS

- Two more studies have shown that hydroxychloroquine, the drug touted by US President Donald Trump as a potential solution to the coronavirus, has no positive impact on patients with the virus. The British Medical Journal published a study in France on patients hospitalised with pneumonia complications which showed hydroxychloroquine did not speed up recovery. A study in China (Shanghai Jiao Tong University) on patients with mild to moderate infection not only showed that those receiving hydroxychloroquine recovered no faster than those receiving standard treatment, but established that the former experienced more adverse events.

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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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