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COVID-19 news from SAMED, Government and Abroad.

DETERMINATION OF ALERT LEVELS AND HOTSPOTS

In the President's address, Ramaphosa indicated that South Africa would be moving to level 3 Nationally, but that certain hotspots have been identified. Areas which are hotspots could be adjusted to higher levels of lockdown, subject to specific criteria.

Hotspots include:

- Tshwane
- Johannesburg
- Ekurhuleni
- Ethekwini
- Nelson Mandela Bay
- Buffalo City
- Cape Town
- West Coast, Overberg and Cape Winelands
- Chris Hani district in the Eastern Cape, and
- iLembe District in KwaZulu-Natal

The regulations have been updated with Alert Level 3 in mind. Please note, there are still specific economic exclusions which can be found under table 2. There is also the addition of Form 6 which is for persons intending to travel to and from another province during alert level 3.

Download the updates to the regulations [here](#).



ORGANISATIONAL RESPONSIBILITIES TO VULNERABLE EMPLOYEES

Guidelines have been issued on **vulnerable employees**, i.e. those 60+, with co-morbidities, pregnant, etc. This gives the details on what is expected of employers, and healthcare professionals, in terms of regulation 5(5)(e) of the 29 April Regulations.

Important points are:

- Work from home for these groups is best as per the regs, but if not possible at all, then:
- A **doctor's report** is required (page 2, point 3) - this takes the form of a notice to the employee and the doctor does NOT disclose the specific health circumstances if it falls within the list. If outside of the list, details would need to be provided, with the patient's consent.
- **Special measures**, BEYOND the normal (i.e. PPE, hygiene, etc.) must be taken, namely reasonable accommodation to a setting where exposure is eliminated, isolation, task changes, etc.

- Return to work policies must be in place (include in Annexure E plans)

HCPs are fearful that their assessment could lead to employees or even students/learners facing **negative repercussions**. However, no person may be discriminated against on their COVID-19, suspected COVID-19 status, and sick leave must be paid, and/or the TERS fund utilised for illness benefits (even if the employee is not sick), etc. The Employment Equity Act (EEA) would apply to prevent employment discrimination and the Promotion of Equality and Prevention of Unfair Discrimination Act (PEPUDA) to all non-employee situations.

Disclosures have also now become a much bigger issue. If a co-worker tests positive or becomes a PUI, e.g. a family member tested positive, disclosures to others with whom the person was in direct contact must be made. The person who tests positive and all direct contacts must be reported by the HCP to the NICD. The employer must include the issues of disclosure of positive and PUI employees, and third parties (e.g. customers/clients/patients) in its **Annexure E plan**.

Download the guidance document [here](#).

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REQUIREMENTS FOR THE MANUFACTURE, IMPORTATION & DISTRIBUTION OF RAPIDLY DEVELOPED INVASIVE & NON-INVASIVE VENTILATORS

In response to the anticipated shortage of medical supplies and equipment in the health care system as a result of the outbreak of the COVID-19 pandemic, the South African Health Products Regulatory Authority (SAHPRA) has drafted minimum requirements for the manufacture, importation and distribution of rapidly developed invasive and non-invasive ventilators. SAHPRA has added this new guidance on the rapidly developed ventilators to their [website](#).

It covers the regulatory requirements, technical specifications, licence conditions and authorisation for use of unregistered rapidly developed invasive and non-invasive ventilators for COVID-19.

Download the communication [here](#).

UPDATED JOINT COMMUNICATION WITH SABS & NRCS

To assist manufacturers during the COVID-19 crisis, the South African Bureau of Standards (SABS) in collaboration with the South African Health Products Regulatory Authority (SAHPRA), the National Regulator for Compulsory Specifications (NRCS), and the Department of Trade and Industry will provide support to manufacturers and distributors in respect of applicable standards and conformity assessments to assist them to prepare for the licensing and approval process. The joint communication between SAHPRA, SABS and the NRCS has been amended to include an annexure A clarifying regulatory requirements for face masks in light of COVID-19.

Download the communication [here](#).

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ITAC COVID-19 DEDICATED COMMUNICATION PATHWAYS

ITAC has provided dedicated e-mail addresses for the respective COVID-19 goods that are subject to export control. Please ensure that you send your requests to the correct email address for the process to be expedited.

- meds@itac.org.za (for medicines)
- masks@itac.org.za (for masks)
- sanitizer@itac.org.za (for sanitizers)

These are for submission of complete applications and supporting documents ONLY and not for general correspondence or enquiries.

General enquiries will be attended to by administrators.

Please note that Aarifah Ahmed aahmed@itac.org.za is on study leave from today. Please do not send

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PPE SUPPLIERS SHORTLIST

The Board for Healthcare Funders has issued a call for PPE suppliers for their shortlisting process. They have asked for the following documents by Monday 1st of June 2020 by no later than 9:00 am.

- Tax Clearance Certificate
- BEE Certificate
- Company Registration Documents
- Company Profile
- VAT registration document/certificate

These can be sent to Sasha-Lee Lindoor at sasha-leel@bhfglobal.com and queries can be directed to Sasha on 011 537 0200 or 067 847 9969

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B4SA UPDATE: BUSINESS FOR SOUTH AFRICA PROVIDES UPDATE ON PPE PROCUREMENT

In March, Business for South Africa (B4SA) was set up as an independent and broad coalition of volunteer resources, made up of business organisations and large and small companies, to assist the country in its response to the pandemic. Its core executive sponsors are the Black Business Council and Business Unity South Africa.

As part of this coalition, B4SA established an independent, efficient and scalable procurement platform to urgently help secure the personal protective equipment (PPE) needed in South Africa. This is a critical function that is underpinned by a team of skilled and capable volunteers with a robust governance structure and enables buyers and donors of PPE to timeously access bulk orders of products which meet the necessary specifications, on a cost effective basis.

B4SA's PPE procurement platform is one of many initiatives that are assisting the country to procure critical PPE for frontline health care workers. All parties involved in B4SA operate on the premise that they do so on either a pro bono or not-for-profit basis.

MEDICAL GRADE MASKS TO BE USED FOR FRONTLINE HEALTH CARE WORKERS ONLY



Business for South Africa calls on all businesses and the public to heed Government's call to reserve ALL medical-grade masks, including N95 respirators and medical surgical masks, for the exclusive use by frontline health care workers. Government has also recommended that members of the public and businesses wear cloth masks, and has provided guidelines for their manufacture and use.



The pandemic has exposed the global risk of an over-reliance on single markets for the supply of PPE. South Africa, as a historic net importer of PPE, is no different. At the onset of the pandemic, PPE represented less than 2% of the overall medical equipment sales in the country, with surgical gloves making up the vast majority of this. To compound this, South Africa, like much of the world, had limited internal manufacturing and supply capacity and capability to deliver the vast quantities of PPE needed in the country.

B4SA's order book is currently at R1.1 billion. This includes the procurement of:

- N95 respirators: 12 million
- Surgical masks for patients and health care workers: 38,2 million
- Gowns: 100 000
- Goggles/face visors: 120 000
- Gloves (pairs): 900 000
- Sanitizers: 275 000 litres
- Ventilators: 200

The forward looking procurement pipeline stands at R200 million and B4SA's procurement focus is on securing gloves, gowns, scrubs, sanitiser, face visors, biohazard bags and FFP2 masks.

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PTCMA WEBINAR: INSIGHTS DURING COVID-19

Measuring the impact of COVID-19 on our healthcare environment - what about our economy?

- Where is the Ministerial Advisory Committee (MAC) coming from?
- A vaccine needs to be developed sooner rather than later for COVID-19 but what happens in between?
- Where do we stand with the treatment development for COVID-19?

Date: 5 June 2020, 09:45 - 12:30

For more information or to register, [click here](#).

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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



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.

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

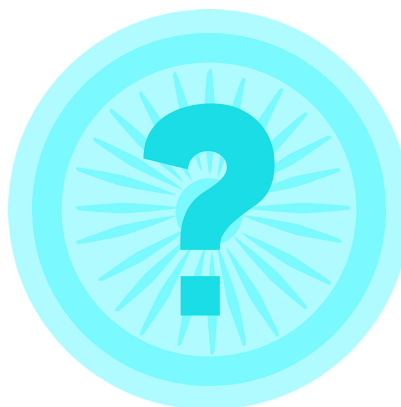
For COVID-19 related applications: Matlapeng Shabalala Matlapeng.Shabalala@sahpra.org.za / 071 302 0409 or

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

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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](#).

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

CONFIDENTIALITY & COVID-19: EKA SNAP SESSION

EKA is again hosting one of its **Snap Sessions** in response to pertinent COVID-related issues on **28 May 2020, 18:00 - 20:00** via Zoom.

The Disaster Management Regulations and the Notifiable Medical Conditions Regulations authorise the **collection, use and disclosure of personal information**, including health information and information on age and addresses.

Employers are expected to keep a list of employees 60 years and older, as well as all employees with co-morbidities. Screening criteria are applied by health facilities and businesses to visitors, (prospective) patients, company representatives, etc. Tests are expected and results are to be disclosed in some cases. Vast amounts of personal information are collected, stored, used, and in, some cases, passed on to others. This raises important compliance questions.

As limitations to the right to privacy are constitutionally determined, **pertinent questions** will be addressed:

- *Are these disclosures mandatory? Can someone refuse to provide this information?*
- *What can, or must, an employer or a business do with this information? To whom can it be disclosed, if at all?*
- *How can or should this information be used?*
- *Can the Department of Labour, the NDoH / NICD or third parties insist on accessing this information?*
- *How should businesses, practices and employers protect this information? Should it be destroyed and if so, at what stage?*
- *If an employee or visitor is being quarantined, should that fact be disclosed to protect others, or not?*

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WEBINAR: A SUSTAINABLE EXIT STRATEGY - OPTIONS FOR LIFTING COVID-19 CONTAINMENT MEASURES

A SUSTAINABLE EXIT STRATEGY: OPTIONS FOR LIFTING COVID-19 CONTAINMENT MEASURES

May 29th 04:00PM East African Time

			
Mr. Farid Fezoua President & CEO, GE Healthcare, Africa	Hon. Kwaku Agyemang-Manu Minister for Health, Ghana	Dr. Benjamin Djoudalbaye Head, Division of Policy, Health Diplomacy and Communication, Africa CDC	Dr. Mercy Mwangangi Chief Administrative Secretary, Ministry of Health, Kenya

Logos: GE, Ghana, Africa CDC, Kenya, Curated by: AHB

Please register [here](#) in advance to secure your place

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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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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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