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COVID-19 news from SAMED, Government and Abroad.

MEMBER FEEDBACK: DISCUSSION WITH NETCARE ON TESTING OF MEDICAL REPRESENTATIVES

A SAMED delegation met with Netcare senior management representatives today to discuss the rationale and requirements outlined in the recent communication regarding restricted representative access and COVID-19 screening and testing of medical representatives protocol.

SAMED proposed enforcing stringent screening protocols for representatives as well as formalised training on the correct use of PPE aligned with the CRICE Course. In addition, representatives and technical assistants to only be allowed in theatre at the express request of the surgeon.

In terms of the required 7-day testing protocol, the scientific evidence for this was challenged. SAMED raised concerns with regard to practical implementation, testing capacity, test resource constraints both current and future, cost, timelines and the need for consistency of the approach across all stakeholders.

Netcare indicated that their risk mitigation warranted the use of these tests. The 7-day testing protocol will remain in place at this stage, however, Netcare is prepared to consider a risk categorisation for medical representatives and technicians depending on which hospital department they visit. SAMED will draft this categorisation in the interim for consideration.

The meeting was constructive and all relevant points raised and discussed. Netcare has assured us they will communicate our concerns with their Executive team and revert once they have discussed the matter further internally.

SAMED will continue to engage as a matter of urgency with Netcare, clinical experts, surgical associations and our international counterpart associations on this matter to ensure that our members' interests are taken into account and that a pragmatic, fact-based mutually agreed solution is arrived at.



EXCLUSION OF MEDICINES, MEDICAL DEVICES AND IN VITRO DIAGNOSTICS (IVDs) DONATED TO THE STATE FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT

Dr Zwelini Mkhize, the Minister of Health, has published an exclusion on medicines, medical devices and in-vitro diagnostics donated to the State, or provided to the State as a sample as part of the submission of a bid for a tender published by the State, from provisions of section 18B of the Act: Provided that such donations are made or samples provided in accordance with the guidelines as determined by the Authority and relevant procedures required by the State.

This exemption shall be effective immediately for a period not exceeding three years from the date of signature of this Notice.

Download the notice [here](#).

SAHPRA and B4SA under the Pharmaceutical and Vaccines working stream are collaborating on providing the industry with regulatory guidance to ensuring essential COVID-19 related medicines supply in both the public and private sector are well managed in a clear and transparent manner.

To this end, the regulatory guidance is now available and we request that industry follow this process in order for SAHPRA to have coordinated efforts to address the South Africa public health medicines needs for COVID-19.

Download the guidance document [here](#).



B4SA UPDATE: IMPORTANT UPDATE FOR EMPLOYERS ON TERS

There has been a change in the process for applying for the UIF TERS benefit for on behalf of employees from May, in terms of which employers have a new option.

First, however, it appears that the UIF site is not yet ready to accommodate applications for May. We are trying to establish when this will become possible.

As to changes, employers applying will be able to indicate whether the benefits should be paid to the company or whether payment must be made directly into employees' bank accounts.

Employers will be entitled to receive a payment if they require a refund from the UIF, which would be the case where the employer has paid the benefit to the employees, or where the employees have been required to take annual leave. In other circumstances, the UIF will make payment directly to the employees.

The addition of this second option, under instruction from the Minister of Employment and Labour, follows complaints that some employers did not make the April payments to employees within the required 48 hours. While we have not been told how many employers failed to do this, or how many employees were affected, the non-compliance of a few drew comments from the Minister and the changes to the system.

The additional option has essentially been introduced with the intention of ensuring that the payments of the Unemployment Income Covid19 TERS benefits are smoother for May and June. Representatives of the UIF have informed us that they are confident that the Unemployment Income system has the capacity to pay individual employees directly. They further confirmed that processes are in place to inform employees once the payment has been made into their bank account. Employers will also be informed when an employee has been paid and how much.

Employers who have not submitted employee bank account details and mobile numbers to the UI when they initially applied should add the relevant details to their May applications. Employers who did so for April will not need to do so again.

It will still be necessary for the employer (or, where applicable, the bargaining council) to apply for the benefit on behalf of employees to whom the benefit is due. Where employers refuse or fail to do so, employees may apply directly.

Employers can also still make an advance payment to employees to ensure that they receive the amount on their regular pay date. In this case, the employer will need to indicate that they are applying for a refund when they make the application, and the amount will then be paid to the employer.

Please note that the UIF has indicated that many employers who received benefits for April have not yet provided the UIF with proof that the employees have been paid their April entitlements. Employers signed MOAs committing to send proof that they have paid their employees. B4SA thanks those who have complied. Those who have not yet submitted proof to the UIF are urged to do so.

Employers who have not received funds for April are asked to escalate this to the UIF call centre, but the UIF has also undertaken to contact employers directly to resolve any outstanding issues so that workers can get paid.

The Department says it has engaged the private sector, insurance sector, banking sector and other stakeholders to assist in making the application process more effective and efficient. The Department aims to launch a new web platform, which will automate the applications value chain and speed up the

Anyone with queries should be directed to the UIF call centre at 0800 843 843.

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ADVAMED UPDATE ON US COVID-19 LEGAL, REGULATORY & TRADE DEVELOPMENTS

AdvaMed held a meeting with members and key stakeholders to outline the US MedTech landscape with COVID-19 in mind. They overviewed their task teams approach to responding to certain areas of concern or priority within the market.

They noted the following FDA Regulatory changes:

FDA Emergency Use Authorization (EUA) process:

- Diagnostic tests (100 tests authorized)
- Ventilators
- Personal protective equipment

Changes in FDA review process:

- Enforcement discretion policies for certain device types
- Deploying review resources to divisions having greatest number of EUAs
- All meetings with FDA staff done virtually through June

Download the slide [here](#).

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WEBINAR INVITATION: EXECUTIVE REMUNERATION

Bowman's invites you to join members of their Employment and Benefits and Tax Practices for a **FREE** virtual discussion on executive remuneration.

The discussion will focus on:

- The latest remuneration responses to COVID-19, including approaches to base pay (increases/cuts/donations), benefits and short- and long-term incentives.
- Share plans and remuneration trends, including ESOPs, executive share plans and incentives, performance conditions and minimum shareholding requirements.
- Shareholder activism broadly, and in particular, Malus and Clawback and other methods of consequence management.
- The legal issues regarding malus and clawback.
- Legal risks associated with the application of discretion.
- The pay gap, living wage and optimising the financial wellness of workers using innovative benefits, including existing tax benefits for workers (housing, education).

Date: 26 May 2020, 10:00 - 11:00

Please click [here](#) to register

For further information, please contact Simon Dodd at simon.dodd@bowmanslaw.com or on +27 72 376 5777.

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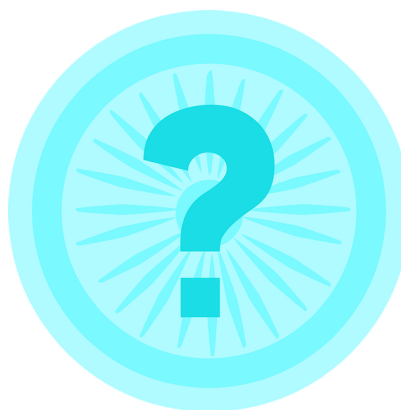
resource for all COVID-19 related updates, regulations, notices and news.

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.



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](#).



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.

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 SAMED office, IDC, the dti, Minister of Health and the BSA procurement team will have access to the data. No data will be shared with other suppliers.

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

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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

COVID-19 WORKPLACE RESPONSE TRAINING:

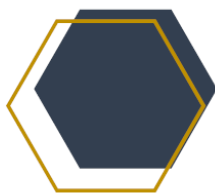
Occupational Safety & Health COVID-19 Training

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 1: 18 May
10h30 -12h30
(GMT+2)

Setting up coordination
team and workstreams



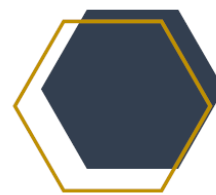
Training 2: 20 May
10h30 -12h30
(GMT+2)

Epidemiology and
management of COVID-
19 in the workplace



Training 3: 22 May
13h30 -15h00
(GMT+2)

Return to work post
COVID-19 illness &
lock-down



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

Implications of COVID-19
in the workplace: OSH
Context

Download the Training Flyer with registration links [here](#).

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EKA SNAP SESSIONS: COVID-19 & PRIVACY

Elsabe Klinck and Associates has scheduled another evening snap session

- COVID-19 & privacy: 28 May, 18:00

Download the form [here](#).

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**.

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

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COVID-19 EVENTS



OVERVIEW – SOUTH AFRICA AND GLOBAL FIGURES

- Projections by a consortium of experts advising the government have been clarified to show that 12 million to 13 million Covid-19 infections could have cumulatively occurred in the country by November, of which only roughly 3.7 million will be detected.
- Peak infection is expected to occur between early-July (pessimistic, 1.2 million cases) and mid-August (optimistic, 1 million cases), according to the consortium's model.
- The total number of detected cases would be around 3.7 million to 3.9 million cases by November, a report by the consortium published on the [National Institute for Communicable Diseases \(NICD's\) website](#)
- Projected need for ICU beds is between 20 000 and 35 000 between June and November, and 500 by the end of May.
- General hospital beds required are expected to be between 75 000 and 90 000 between June and November, with just more than 2 000 beds required by the end of May.

Cape Town hot spots

- Five areas within the Cape Town metro have been identified as "hot spots" by the Western Cape government. The province has recorded over 11 000 cases of the virus as at 13:00 on Thursday. Deaths in the province stood at 235, though 5 677 people had recovered from the virus. Most of the cases in the province are among essential service workers, such as in the retail sector, and the projections by the province's experts are that 90% of people will have no or mild symptoms. It is hoping to manage those cases through self-isolation and quarantine where possible, assisting those who do not need to go to hospital with self-management, unless otherwise necessary. The hot spots identified so far are:
 - **Tygerberg**
 - **Khayelitsha**
 - **Klipfontein**
 - **Western – Du Noon**
 - **Southern – Hout Bay**

ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL

Professor Gray debate continues

- Health minister Dr Zweli Mkhize has hit out at Professor Glenda Gray, a South African physician and scientist over her comments around the country's nationwide lockdown, saying that she made "factually incorrect and unfounded statements".
- He said, "we will keep emphasising this: as government we do not claim to have it all figured out when it comes to Covid-19. No country does. The president has constantly and correctly stated that we are in uncharted waters. But we are committed to doing everything in our powers to protect the lives of our citizens."

Schools re-opening

- The Gauteng Department of Education says it expects 300 000 Grade 7 and 12 pupils back when schools reopen on 1 June. Education MEC Panyaza Lesufi speaking at the province's weekly Coronavirus Command Council briefing on Thursday said that before the reopening can take place, health protocols will have to be met by all schools.
- The MEC said, in order for schools to be ready, it will need to have all the necessary personal protective equipment (PPEs) for pupils, while classrooms need to meet the necessary standards for physical distancing.
- Schools will be allocated more than R15 000 each to start deep cleaning in preparation for 1 June, after which officials from the district will inspect the premises to observe whether it is ready or not.

The battle against Covid-19 in SA's mines

- Mines are facing a devastating scenario. Barely a month after a limited return to production, infections have started rolling in, sparking anxiety among executives and unions alike.
- On Tuesday, the Department of Mineral Resources and Energy published guidelines for a mandatory Code of Practice for the mitigation and management of Covid-19 in the mining industry.

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[them at high risk of getting infected with the coronavirus away from work as the industry returns to production.](#)

- "Covid-19 is potentially a manageable challenge, but it is more challenging in an environment such as mining," said David Rees, Emeritus Professor Occupational Medicine and Epidemiology at the University of the Witwatersrand. But the mining environment makes it particularly difficult to adhere to practical safety protocols, such as physical distancing and regular washing of hands, while working deep underground and chasing production targets.

[Global lockdown restrictions have cut carbon emissions by 17%](#)

- Daily global **carbon emissions** fell by about one-sixth during the coronavirus pandemic, researchers say. But it's not likely to last.
- "Population confinement has led to drastic changes in energy use and CO2 emissions. These extreme decreases are likely to be temporary though, as they do not reflect structural changes in the economic, transport or energy systems," said study leader Corinne Le Quéré, of the University of East Anglia in Norwich, England.
- Worldwide, daily emissions fell by 17% – or 17 million metric tons of carbon dioxide – during the peak of the pandemic confinement measures in early April, compared to average daily levels in 2019, the researchers found.
- Economic stimulus packages after the pandemic must not make future carbon emissions higher by delaying new green initiatives or weakening emissions standards, Le Quéré and her colleagues warned.

[Wuhan bans eating of wild animals](#)

- Wuhan has banned the eating of wild animals, with officials declaring the city a "wildlife sanctuary." Neighbouring Hunan and Jiangxi have announced plans to stop farmers from breeding exotic animals, with cash offered for current stock.
- China's fur trade will continue, though, and wild animals can still be reared for medicine, entertainment, and scientific research, according to Reuters.
- The new measures are part of China's efforts to stem the transmission of zoonotic diseases from animals to humans

CLINICAL AND SCIENTIFIC

[SA facing 'significant constraints' with Covid-19 test kits](#)

- South Africa faces significant constraints with testing kits for Covid-19, Parliament's health committees heard on Wednesday evening.
- The Department of Health's deputy director-general for communicable and non-communicable diseases, prevention, treatment and rehabilitation, Yogan Pillay, said because of a "global scramble for test kits", suppliers' inability to provide enough kits and locked down airports, there were "significant constraints" with tests kits. "We need to be a bit more selective with who we test," he said.

[Mask industry](#)

- In the first quarter of this year, South Africa's normally staid and insignificant mask industry exploded.
- Customs data released by the Department of Trade, Industry and Competition shows a spectacular surge, starting in January and continuing into the state of disaster declared in March. As a baseline, back in the first quarter of 2019, South Africa exported medical and industrial face masks worth roughly R58 million. Fast forward to the first three months of 2020 and exports were worth nearly 10 times that, R524 million to be exact.

[Hand sanitizer](#)

- Some South Africans are reporting rashes from exposure to hand sanitiser dispensed at store entrances.
- There are concerns that some of these products may not include the right kind of alcohol and the wrong mix of emollients. To avoid these problems, arm yourself with your own sanitiser. The surge in demand for sanitiser means companies are turning to new manufacturers to provide the products. The industry isn't regulated, and questions are being asked about the ingredients of some of the hand sanitiser aimed for mass use.

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SAMED is the voice of the South African medical technology industry. The not-for-profit was formed in 1993 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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