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**COVID-19 news from SAMED, Government and Abroad.**

### TIPS/BUSA SURVEY ON PROSPECTS FOR BUSINESS UNDER LEVEL 3

BUSA is partnering with TIPS on a survey, which aims to provide insight into the challenges businesses face as the country moves to Level 3, what the likely employment implications are over the next few months, and how government support can be refined especially as the UIF's special COVID-19 TERS programme draws to an end. It builds on the insights from the survey conducted in April, as the lockdown began. We greatly appreciate your support in helping to improve government understanding of the challenges faced by business.

Please answer as fully as you can; feel free to add comment on any of the questions. If the questions are unclear, please contact Neva Makgetla at 079 516 0450 or [neva@tips.org.za](mailto:neva@tips.org.za). Information will only be published or included in documentation in an anonymous form, where the company cannot be identified unless you indicate otherwise.

**Download the survey [here](#).**

Please can you submit your response by **Friday 12 June 2020**.

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BUSINESS FOR SA | COVID-19

### LEVEL 3 HEALTH AND SAFETY DIRECTIVE INTRODUCES CHANGES

On 04 June 2020, the Minister of Employment and Labour published amendments, by way of a consolidated [Direction on Health and Safety in the Workplace](#) which sets out additional obligations in respect of the safe opening and continuing operation of a workplace.

This note should be read with the [initial summary](#) we supplied last month.

Changes include the following:

1. Employer obligations in respect of employees over the age of 60 or those with specified co-morbidities. Additional special arrangements need to be made in this regard for those unable to work from home. More detail on this can be found in this Department of Health [guideline](#).
2. It is now a requirement in terms of clause 17.3 to consult with any representative trade unions and health & safety committees as part of a risk assessment and risk mitigation plan.
3. When an employee is sick or presents with COVID-19 related symptoms he or she must be placed on paid sick leave in terms of section 22 of the Basic Conditions of Employment Act. If the employee's sick leave entitlement under the section is exhausted, the employer should apply on the employee's behalf for an illness benefit in terms of clause 4 of the COVID-19 Temporary Employer Relief Scheme Directive.
4. The Direction sets out procedures an employer must follow when an employee at work tests positive for COVID-19. Such employee must immediately be isolated. A risk assessment must then be carried out to assess the risk of transmission to others, disinfect the employee's workstation, carry out contact tracing determine what precautions should be put in place for those employees who have been in contact with an employee who has tested positive. If it is determined that there was a high risk of exposure for an employee who came into contact with the COVID-19-positive employee, the contact employee must be placed on sick leave in terms of section 22 of the BCEA or if the employee's sick leave is exhausted, make application for an illness benefit in terms of clause 4 of the Temporary Employer Relief Scheme Directive. If there is evidence of occupational exposure to the virus, a COIDA claim may be made.

return to work on the following conditions:

- The worker has completed the mandatory 14 days of self-isolation;
  - the worker has undergone a medical evaluation confirming fitness to work if the worker had a moderate or severe illness;
  - the employer ensures that personal hygiene, wearing of masks, social distancing, and cough etiquette is strictly adhered to by the worker;
  - the employer closely monitors the worker for symptoms on return to work; and
  - the worker wears a surgical mask for 21 days from the date of diagnosis.
6. Sectoral or industry associations must, in the event of high health risks, develop sector-specific health protocols in consultation with the Department of Health to limit the spread of COVID-19 in the sector including providing for those circumstances where a firm within the sector cannot stagger working hours or provide transport for its employees.
7. Finally, employees may refuse to perform any work if circumstances arise which with reasonable justification to pose an imminent and serious risk of their exposure to COVID-19.

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## MEDTECH EUROPE: GUIDANCE FOR THE RE-ENTRY OF MEDICAL TECHNOLOGY REPRESENTATIVE IN HEALTHCARE FACILITIES

The COVID-19 pandemic has brought uncertainty and disruption in the delivery of needed medical care and treatments to non-COVID-19 patient communities that rely on access to hospitals, clinics, and other healthcare facilities, as well as on medical technologies and solutions.

Medical technologies manufacturers remain committed to doing the utmost possible to ease the difficulties that patients might face in these challenging times by ensuring that medical technologies and services are available without disruption and by contributing to a safe and swift return to regular healthcare services, including medical procedures.

A critical element to meet this mission is the continuation of medical technology experts being able to be present in healthcare facilities in order to support healthcare professionals in delivering patient care and ensuring the safe and effective use, installation, servicing, and maintenance of medical technologies. This is particularly crucial for medical procedures that include complex medical technologies.

MedTech Europe supports that these representatives should return to healthcare facilities as soon as healthcare services resume in order to be able to contribute to the safe and effective use of the technologies. The presence and activities of these representatives must at any time be in line with all applicable regulatory requirements as well as with local hospital policies and rules.

Furthermore, in the context of managing the ongoing COVID-19 pandemic, the industry supports that representatives of medical technology manufacturers follow all additional protocols and requirements in place in light of COVID-19 that aim to protect the safety of patients and healthcare workers.

Those measures can include:

- Rules and policies related to social distancing and safety policies, including specific considerations on Personal Protective Equipment (PPE) or hand hygiene;
- Hospital's testing policies for medical technology representatives entering both restricted and nonrestricted areas;
- Any training and qualification requirements that may have been established, including a clear understanding of infection prevention recommendations for COVID-19, and facility policy related to COVID-19 safety principles.

MedTech Europe and its network of National Associations are dedicated to engaging in discussions with European and national policymakers to find timely and practical solutions and relevant guidance to support the above-mentioned possible measures. The purpose is to make the industry's technical expertise available and accessible for doctors and hospitals, as soon as possible and where and when needed.

The medical technology industry reaffirms its longstanding commitment to serve and protect patients whose lives depend on safe services, technologies and treatments being available and accessible to all.

Download the MedTech Europe guidance [here](#).

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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](#)



## 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](mailto: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](mailto:mdcovid@sahpra.org.za) and all other regular medical device queries can be sent to [MDnotifications@sahpra.org.za](mailto:MDnotifications@sahpra.org.za)

For general licensing queries: June Searela [june.searela@sahpra.org.za](mailto:june.searela@sahpra.org.za) / 072 828 2416  
For COVID-19 related applications: Matlapeng Shabalala [Matlapeng.Shabalala@sahpra.org.za](mailto:Matlapeng.Shabalala@sahpra.org.za) / 071 302 0409 or  
Khanyisile Nkuku [Khanyisile.Nkuku@sahpra.org.za](mailto: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](#).

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## PARTICIPATE ON B4SA COVID-19 PROCUREMENT PORTAL

The information collected on the B4SA [covid19manager.co.za](https://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](mailto: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](http://www.solidarityfund.co.za)**

**For more information email [info@solidarityfund.co.za](mailto:info@solidarityfund.co.za)**

**For offers of supply of Medicines and Medical Devices send to [covid19supplies@businessresponsecovid19.co.za](mailto:covid19supplies@businessresponsecovid19.co.za)**

## COVID-19 EVENTS

### **WEBINAR: FINDING NEW REALISTIC EXPORT OPPORTUNITIES - COVID-19 EDITION**

The NWU's TRADE research focus area and TRADE Research Advisory extend an invitation to the **TRADE-DSM® webinar**.

This will provide non-subscribers with a peek behind the scenes of the TRADE-DSM® and its newly expanded functionality. To assist their users, they worked with some to address requirements for COVID-19 specific dimensions in the TRADE-DSM® to further inform analysis of realistic export opportunities within the context of the pandemic. Additional indicators include:

- WCO/WHO COVID PPE products (HS6);
- COVID-19 market (country) indicators such as number of cases, markets impacted from a logistics and lock-down strategy perspective and stringency of lock-down regimes and
- IMF COVID-19 revised GDP forecasts.

Join them for a **webinar** focused providing some direction on where potential opportunities for product-based trade may be emerging, according to the TRADE-DSM®.

**When: 10:00 - 11:00, 9 June 2020**

**Time: 10:00 – 11:00**

The Zoom link will be emailed to registered attendees, on Monday (8 June 2020).

**RSVP: Email Francois Fouche to confirm your seat: [francois.fouche@tradeadvisory.co.za](mailto:francois.fouche@tradeadvisory.co.za)**

Please note seats ARE LIMITED.

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### **OMMIA HEALTH COVID-19 VIRTUAL EXPO**

Ommia 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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## COVID-19 DEVELOPMENTS

### **TRACKING THE PANDEMIC**



#### SA sees record jump in coronavirus cases

South Africa recorded 3,267 novel coronavirus cases in 24 hours, the biggest jump since the pandemic hit the country. According to the health ministry, the country now has a total of 40,792 infections, the health ministry said. It saw a rise of 56 deaths for a total of 848 fatalities. More than half of the cases are in the **Western Cape region** where health services are under pressure. The **Eastern Cape** has also seen a rise in cases and now surpasses Gauteng as the province with the second-highest infections. Health Minister Zweli Mkhize said the Eastern Cape was showing the "same pattern that drove up the outbreak"

**ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL**The National State of Disaster extended until mid-July.

- South Africa will remain in a National State of Disaster until 15 July 2020, according to Minister in the Presidency, Jackson Mthembu. Mthembu briefed the media on the outcomes of the Cabinet meeting held on Thursday.

Cabinet to appeal judgment declaring lockdown regulations for levels 3 and 4 invalid

- On Tuesday, Judge Norman Davis found that little or no regard was given to the extent of the impact of the regulations on the constitutional rights of people, and whether the extent of limitation of their rights was justifiable or not.
- Cabinet on Thursday announced it would appeal the High Court judgment. President Cyril Ramaphosa held a special Cabinet meeting on Thursday to discuss the judgement. Minister in the Presidency Jackson Mthembu said the decision was taken after advice from legal experts. Mthembu said Cabinet would appeal through the Gauteng High Court in Pretoria before going to the Supreme Court of Appeal.

Lockdown regulations ruling: 'Flawed' judgment creates more confusion than clarity, say experts"

- Legal counsellor at Lawyers for Human Rights Thandeka Chauke said judges should ensure their judgments were clear and well-reasoned, particularly in cases that concerned public interest. "It is a flawed judgment and if it goes on appeal it will most likely be overturned. The main problem with the judgment is that while there was an attack on the regulations as a whole, the judge only looked at specific regulations, the regulations dealing with curfews on exercise, and the regulations dealing with visitations of families and regulations dealing with funerals."
- Dr Justice Alfred Mavedzenge, an academic and legal advisor at the International Commission of Jurists, said the judgment served as a reminder that even during a crisis such as COVID-19, government measures should still be rational in order for them to be constitutionally valid. He, however, added the judgment should have provided more detail on why each regulation was irrational. "The judgment falls short [by] failing to engage with each regulation and demonstrate the irrationality. The judgment could have provided more detail on why each regulation is irrational."
- Another legal expert, Professor Pierre de Vos, stated that constitutionally speaking, the judgment was flawed, adding it also raised important questions about the duty of the government to act rationally and in a transparent manner. De Vos said despite its many flaws, the judgment "raises important questions of constitutional principle regarding the government's management of the lockdown and its belief that as long as it pursues the laudable goals of saving lives for the public good, the regulations will be constitutionally compliant".

Working from home

- 152 HR executives in U.S.-based organisations were surveyed. Less than one in 10 businesses polled said more than 20% of their full-time employees worked from home before the epidemic. The Conference Board report said 77% of respondents in the survey expect more employees to work from home more than three days a week, with information technology and financial services, already areas with the highest remote working rates, set to lead the way.
- Tech giants such as Alphabet Inc's Google, Facebook Inc and Twitter Inc have said they would allow most employees to work remotely until the end of the year.
- Businesses with at least 10% of their staff working from home before the epidemic were more likely to self-report productivity gains over the past several weeks, the survey also showed.
- More than three out of four U.S. human resource executives think more employees will continue to work from home even after the threat of the novel coronavirus subsides.

How the coronavirus could change SA's food market

- Sifiso Ntombela from Fin24 says: the COVID-19 crisis has not only affected food demand levels, it has also created a new pattern in food purchasing, influenced by social distancing and the emergence of multifunctional homes. As people modify their houses to allow working and exercising at home, they are changing their behaviour, which subsequently alters the type of food demanded and the packaging and manner in which food is distributed.
- Consumers are increasingly demanding fresh, healthy and locally produced food directly from a farm or processor. The direct connection between a farmer and consumer is facilitated by technology innovations which enables online food trading.
- The expanding e-commerce has the potential to create a new cohort of domestic food processors and distributors thus presenting new opportunities to reshape the food system in the country. It is promising to break entry-barriers in the food market for new players, especially the youth and women, who were previously unable to secure market contracts to supply large and centrally organised supermarkets.

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meals on Uber Eats. Uber Eats reports that usage of the keyword "healthy" grew by 82% from customer searches and they have seen a 71% increase in the number of healthy meal orders in April.

#### Woolworths is using more than 1 million plastic bottles to make its puffer jackets

- Woolworths says it is diverting over one million 500ml PET bottles and turning them into clothes as part of its winter 2020 fashion range.
- The bottles have been converted into a recycled polyester which is being used mainly for the inner "wadding" of the chain's puffer jackets. The material gives consumers an alternative to wearing goose down, which is also a popular inner wadding material.

#### No student will enter a campus without being screened

- Universities and Technical and Vocational Education and Training (TVET) campuses will be expected to have isolation and quarantine facilities set up before students return, according to Deputy Minister of Higher Education, Science and Technology, Buti Manamela. Universities and Technical and Vocational Education and Training colleges are expected to start phasing in the student population from mid-June but no campus or residence will be allowed to welcome students without being COVID-19 compliant.

### **CLINICAL & SCIENTIFIC DEVELOPMENTS**

#### Western Cape govt to pay private hospitals R16 000 per bed if it runs out of space

- The province's transport department says 13 government facilities are already in use with a 2 452-person capacity, and 19 private facilities are in use for 1 396 people.
- The provincial government has 13 facilities for 749 people ready to be activated and has arranged, in the private sector, for another 160 facilities with an 8 933-person capacity.
- The province is looking at using police training facilities and SA National Defence Force sites as other possible sites.

#### Western Cape to use high-flow nasal oxygen as early signs show improved treatment

- Western Cape doctors are feeling hopeful about the early results of using nasal oxygen instead of ventilators to treat serious COVID-19 cases at public hospitals. As a result, the provincial Department of Health will now be rolling out high-flow nasal infrastructure, it was revealed during a digital press conference on Thursday.
- Head of department Keith Cloete said at Tygerberg Hospital, the team had decided to test the measure on seven people who were in critical care for COVID-19, which can cause serious respiratory problems.
- This after a low recovery rate was recorded on the previous six patients who were placed on ventilators. According to Cloete, of the seven on high-nasal oxygenation, six recovered and the seventh was not placed on a ventilator.
- This had changed the way Tygerberg was treating patients critically ill with COVID-19, he said. Since then, 114 patients in critical care were assessed, with 70% going on to high-flow nasal oxygen. None of them required it. Of the 70% who used it, 70% recovered, which was considered an "excellent result", Cloete said

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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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