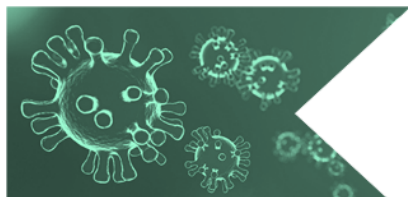


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SAMED COVID-19 NEWS south african medical technology industry association

COVID-19 news from SAMED, Government and Abroad.

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SAMED ON COVID-19

SAMED compliance guidance document on emergency support during COVID-19

This guidance document aims at supporting SAMED Member companies' legal and/or compliance teams when considering emergency processes to fast-track requests related to the COVID-19 crisis to the benefit to society while attempting to limit the inherent compliance risks.

Note: This Guidance document is not intended to supplant or supersede any national laws or regulations or professional codes, including company codes and companies' internal policies. The current situation is very fluid, and applicable laws change in a matter of hours through ordinances, decrees and other emergency legislative mechanisms.

Download the guidance document [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](#).

PLEASE PARTICIPATE: BSA COVID-19 products and company information 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.

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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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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.

Frequently Asked Questions (FAQs) relating to Essential Goods, clearance and movement of goods and service rendered by customs under the COVID-19 lockdown

- What is the difference between critical supplies and essential goods?
- What do we need to know about the importation of critical supplies or essential goods to the national state of disaster (COVID-19 pandemic)?
- Do I need to apply for the VAT exemption under rebate item 412.11?
- Where can I find the certificate issued in terms of Schedule 1(8) of the Value Added Tax Act, 1991, item 412.11/00.00/01.00 (RE: SARS Essential Goods List)?

Find the answer to these and other questions [here](#).

Disaster Management Tax Relief FAQ's for Employees' Tax, ETI and Provisional Tax

- Who are qualifying taxpayers?
- What are the requirements to claim the tax relief?
- What is the Employment Tax Incentive (ETI) tax relief?
- What is the Employees' Tax Deferral?

Find the answer to these and other questions [here](#).

COVID-19 UPDATES, NOTICES, LEGISLATION AND REGULATIONS

NRCS CMM - Chemical Disinfectants

The following documents are required for an application for the new product registration or modification or extension of registration of a chemical disinfectant formulation:

- Proof of payment of the non-refundable application fee for the modification or extension of registration of the chemical disinfectant formulation as published in the Government Gazette in terms of section 14(3)(b) of the National Regulator for Compulsory Specifications Act, 2008 (Act

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- Information of manufacturing plants and warehouses (see item No. 2 on NRCS form No. CMM FM 8054-2);
- List of raw materials and active substance(s) and their concentration(s) for the chemical disinfectant formulation (see item No. 3 on NRCS form No. CMM FM 8054-2);
- SDS satisfying requirements of SANS 11014 (see item No. 4 on NRCS form No. CMM FM 8054-2);
- Bill of materials of packaging material (see item No. 5 on NRCS form No. CMM FM 8054-2);
- New product label (see item No. 6 on NRCS form No. CMM FM 8054-2);
- Test reports (see item No. 7 on NRCS form No. CMM FM 8054-2);
- Evidence of QMS certification and product certification (see item No. 8.1 on NRCS form No. CMM FM 8054-2). QMS certificates are only applicable to the chemicals disinfectants used in food and medical areas.
- NRCS form No. CMM FM 8054:6 chemical disinfectants for use in industrial, domestics and institutional areas.

All applications to be emailed to CMMAPPROVALS@nracs.org.za

1. [CMM FM 8054-1-2019 - Items required for the registration of chemical disinfectants](#)
2. [CMM FM 8054-2-2019 - Technical file for chemical disinfectants](#)
3. [CMM FM 8054-3-2019 - Application for the registration of a chemical disinfectant formulation](#)
4. [CMM FM 8054-4-2019 - Application for the modification or extension of registration of a chemical disinfectant formulation](#)
5. [CMM FM 8054-5-2019 - Test reports for chemical disinfectants](#)
6. [Levies & Fees 2019-2020](#)
7. [NRCS Levy Registration Form](#)
8. [SALES PERMIT application form](#)
9. [VC8054](#)

For more information visit the [NRCS website](#).

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NRCS CMM - Sales Permit for Masks

For Sales Permit:

Please complete the application for sales permit fully. The table is compulsory, the non-compliance is that the KN/N95 masks are not approved as required. Your motivation as to why we need to issue a sales permit for your product. If you have test reports (**in English**) to the standards mentioned, please submit and **information for the user**. All photographic evidence of mask and packaging, we need to see clearly all the markings on both mask and packaging.

For full homologation:

Please find application forms for homologation of masks. If you have test reports to the standards mentioned, please submit and information for the user. All photographic evidence of mask and packaging.

In the wake of the Covid-19 and the resultant shortage, we are considering a Sale permit route for temporary approval. We will still need test reports to prove compliance. We have agreed with the test laboratories in the country to, as a minimum, FFP2 perform the following tests:

- Total inward leakage
- Particle penetration;
- Breathing resistance;
- Flammability;
- Practical performance (check face fit and comfortability)

For N95/KN95 masks, NRCS will test according to above, SANS 50149 and EN 14683. And will need to be licenced by SAHPRA for medical/health sector use. NRCS selected the most critical tests for the different products. This is only a temporary agreement with manufacturers and distributors, therefore after this critical period, they must ensure the full testing of their products for approval (homologation).

For local testing only:

Protechnik Laboratories a Division of Armscor SOC Ltd
103 Combretum Crescent, Highveld Techno Park, Centurion, Gauteng PO Box 8854, Pretoria, 0001
Tel: +27 12 665 9431 | Fax: +27 12 665 0240 |
E-mail: martinm@protechnik.co.za web www.armscordi.com

All application to be emailed to CMMAPPROVALS@nracs.org.za

NB: Kindly note that the type of mask, the intention of the masks, the environment in which mask is used

classified as Class A medical devices with sterility and require the establishment (manufacturer, distributor) to be licensed with SAHPRA under Act 101. In addition, compliance to SANS1866 is mandatory. If the mask is not making claims to protection of viruses or being used by medical personnel and is specifically for civilian use, which should be specifically labelled as such, then these fall outside the mandate of SAHPRA and the NRCS regulations.

If a medical mask is indicated on the label, the SANS1866 standard must be complied with can be tested by Protechnik for compliance.

- For Medical (Surgical) Mask/Respirators SANS 1866:2018 or EN14683 or equivalent.
 - For Surgical Mask tested to EN14683 or equivalent. Must be sent to SAHPRA, not NRCS
1. [Joint Communication to Stakeholders Regulatory Status of Equipment Being Used to Help Prevent Coronavirus \(COVID-19\)](#)
 2. [CMM FM 8072-1-2012.1 - Items required for the approval of RPDs](#)
 3. [CMM FM 8072-2-2012.1 - Technical file for RPDs](#)
 4. [CMM FM 8072-3-2012.1 - Application for the approval of a type of RPD](#)
 5. [CMM FM 8072-4-2012 - Test Reports](#)
 6. [CMM FM 8072-5-2012.1 - COP & routine tests - Filtering devices](#)
 7. [CMM FM 8072-6-2012.1 - COP & routine tests - BA](#)
 8. [CMM FM 8072-7-2012 - Application for the extension of approval of a type of RPD](#)
 9. [Levies & fees 2019](#)
 10. [NRCS Levy Registration Form](#)
 11. [SALES PERMIT application form](#)
 12. [VC8072](#)

For more information visit the [NRCS website](#).

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CEE Letter to designated employers on the impact of COVID-19

The Commission for Employment Equity (CEE) recognises the catastrophic impact of the COVID-19 on the various sectors of the economy and acknowledges the fact that it will be business will be exploring various COVID-19 Response and Recovery Plans with regard to Business Continuity.

In response to the inevitable consequences of the COVID-19 on organisations and in particular, on the implementation of employment equity in the various workplaces, the CEE request all designated employers to take into account the following guidelines:

1. All employers are reminded that they are still legally obligated to comply with all the provisions of all employment laws during their organisational restructuring/ configuration processes to ensure that there is no unfair treatment and unfair discrimination policies and practices against all employees.
2. All designated employers are requested to strive not to reverse the previously attained transformation gains, including to where reasonably practical, achieve their initially planned annual EE targets for 2020. In instances that it is practically not possible to maintain and achieve the initially planned EE targets, the employers may consider reviewing and amending their EE Plans in consultation with the EE Consultative Forums (Sections 16)
3. All designated employers are still required to submit their annual EE Reports as prescribed by Section 21 of the EEA and the EE Regulations, 2014 from 1 September 2020 until 15 January 2021. This EE data is critical in assessing the impact of the COVID-19 on the transformation agenda of the labour market and society as a whole. There is no legal provision for exemptions, condonations or appeals in the EEA for submission of EE Reports.
4. However, in instances where the designated employer is unable to submit an EE Report as per Section 21 of the EEA, such an employer must notify the Director-General of Department of Employment and Labour in writing with reasons before the last working day of August of 2020 as prescribed by Section 21(4A) of the EE Amendment Act, 2013 and the EEA14 form in the EE Regulations, 2014. The reasons that can be advanced as per the EEA14 form, include Section 197 of the LRA; Mergers/ Acquisitions; Labour Court Order; Liquidations/ Judicial Winding; Insolvency; and Other reasons (e.g. employer no longer designated because of size and/ turnover, or company closed down because of retrenchments, or company under business rescue, etc.).

All completed EEA14 forms must be accompanied by supporting documents as proof and must be emailed to ntsoaki.mamashela@labour.gov.za; lucia.rayner@labour.gov.za; tshililo.siobo@labour.gov.za; before the last working day of August 2020. Guidelines on how to process DG Notifications and the EEA14 form are available on www.labour.gov.za

Download the letter [here](#).

SAHPRA Medical Device Hotline

SAHPRA has launched a COVID-19 Medical Device Hotline to deal with COVID-19 related queries.



The graphic is a white rounded rectangle with a blue border. At the top center is the SAHPRA logo, which consists of the word 'SAHPRA' in large blue letters, with 'South African Health Products Regulatory Authority' in smaller blue text below it. Below the logo is the title 'SAHPRA COVID-19 Medical Device Hotline' in blue. Underneath is a paragraph: 'Commencing on Tuesday 14 April 2020, The SAHPRA Medical Device Hotline will be active. Direct all COVID-Related queries relating to Medical Devices to the following Hotline numbers.' This is followed by three phone numbers: '084 220 8037', '072 993 2273', and '078 281 6334'. Below the numbers is the text 'Hours of Operation: (Excluding weekends and public holidays)' and the time '08:00 – 16:00'. At the bottom center is a blue circular icon containing a white headset.

Download this notice, [here](#).

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Make sure you have read these SAHPRA Medical Device notices

Just a reminder to download and read all the below 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](#)

Just another reminder that 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

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B4SA Update**COVID-19 loan guarantee scheme opens**

The COVID-19 loan guarantee scheme announced by President Ramaphosa in April will operate from today, 12 May 2020. The loan guarantee scheme is an initiative to provide loans, guaranteed by the government, to businesses with an annual turnover of less than R300 million to meet some of their operational expenses. Funds borrowed through this scheme can be used for operational expenses such

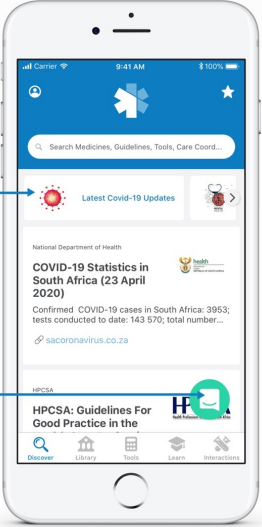
More details on the scheme can be found in a Frequently Asked Questions guide posted at [Loan Guarantee Scheme Q&A](#) or <https://www.banking.org.za/>. Further queries can also be directed to the individual banks, which are administering the scheme.

B4SA partner with EMGuidance to drive digital COVID-19 resource platform for HCPs

Business for South Africa's Health Workgroup has partnered with Essential Medical Guidance (EMGuidance), the country's largest free digital health care platform and community, which has launched a dedicated COVID-19 Support Channel for South African health care professionals (HCPs) in both the public and private sectors.



COVID-19 SUPPORT AND RESOURCE CHANNEL FOR SA HEALTHCARE PROFESSIONALS



Scroll here to find the latest support channels

For any queries, contact us here or use the COVID-19 chatbot

Support channels

- Latest Covid-19 Updates
- Mental Health Support for HCPs
- Private Practice Support
- Automated COVID-19 chatbot with instant response

The COVID-19 platform will provide four key support and resource channels:

1. **Clinical Updates Channel:** providing the latest South African COVID-19 clinical information, including National Department of Health (NDoH) alerts, digital guidelines, COVID-19 medicines information, local care coordination such as the location of COVID-19 testing sites, information on accessing and using personal protective equipment (PPE), and links to other critical clinical applications;
2. **Mental Health Support Channel:** Support and access to mental health support, through the South Africa Society of Psychiatrists (SASOP), the South African Medical Association (SAMA), the South African Society of Anaesthesiologists (SAMA), the Psychological Society of South Africa (PsySSA) and the South African Depression and Anxiety Group (SADAG). EMGuidance will serve as a dedicated channel to survey and monitor the mental health status of South Africa's health care community. It will also be used to disseminate mental health care content, and provide access to professional mental health support.
3. **Practice Business Support Channel:** Providing business resources, including advice on taxation, accounting and labour relations. This is provided in partnership with practice management companies and financial institutions; and
4. **COVID-19 Chatbot:** A dedicated machine learning chatbot which provides information based on NDoH guidelines and local care coordination information. In addition, a specialist pharmacologist is available online to provide guidance on COVID-related medicines queries.

Accessing EMGuidance:

We encourage all healthcare professionals to access the COVID-19 Support Channels within the EMGuidance platform. To download and register on the mobile application click here <http://onelink.to/sy896k> or visit the website and register here: www.emguidance.com. HCPs will need to input their South African professional registration details to gain access. For support, please contact support@emguidance.com or call 010 592 1818.

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The Solidarity Fund uniting South Africa against COVID-19

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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 PRODUCT REQUESTS

Manufacturers of hand sanitisers

As different industry sectors resume operations in accordance with the different stages of the national lockdown, and employers begin to prepare the workplace to meet health and safety standards, hand sanitisers will once again be in high demand.

In order to provide corporate South Africa with a centralised source of approved and locally manufactured sanitisers, Proudly South African is compiling a page on its website where the sale of these products can be advertised.

At the same time as soliciting information from companies who wish to list on our portal, we will drive a consumer campaign directing individuals and companies to source their sanitiser from the portal, which will be non-transactional.

The page will provide the capacity and contact details of each listed manufacturer, and buyers will make direct contact with those companies that can assist with their specific requirements.

It is imperative that we leverage this opportunity for our own local manufacturers and that we provide South Africa with locally manufactured sanitiser.

Qualifying companies wishing to register on the portal must:

- (1) ensure that their products comply with the relevant legislation that regulates such products
- (2) register with Proudly SA, by sending an email to info@proudlysa.co.za,
- (3) register on the portal by clicking on the link below.



For more information and to register as a vendor

[CLICK HERE TO REGISTER](#)

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Offer to supply plastic bottles

Members looking for plastic bottles for hand sanitisers, we have an offer from Brand Line to supply these to the market. **If you need bottles, please contact Johan Meiring directly on 082 903 8374 or** johanm@brandline.com.

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COVID-19 EVENTS

BSA Risk Assessment Presentation

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interconnectedness and velocity. This enables consideration of the contagion effect of risks and will assist to identify and highlight those risks which, when addressed, will have the greatest effect on mitigating the other risks. **To view the full document, [click here](#).**

Given the technical nature of the assessment set out in this report BSA would encourage the participation of the presentation session as per the slot below:

Thurs, 14 May; 07:30 to 08:30am.

To enrol for any of the above sessions please contact: Daniella de Gouveia: +27 66 307 0846 or Daniella.de.Gouveia@businessresponsecovid19.co.za

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AHF-WHO COVID-19 Dialogue



WHO AFRICA & AFRICA HEALTHCARE FEDERATION



A PUBLIC-PRIVATE DIALOGUE: HOW CAN WE WORK TOGETHER TO COMBAT COVID-19 IN AFRICA

SATURDAY, MAY 16, 2020
4.00PM - 5.30PM (EAT)

REGISTRATION LINK: [HTTPS://BIT.LY/35ALPR9](https://bit.ly/35ALPR9)

SPEAKERS:

Dr. Matshidiso Moeti, WHO Regional Director for Africa

Mr. David Clarke, WHO Leader UHC and Health Systems Law

Dr. Amit N. Thakker, President Africa Healthcare Federation

www.africahtf.com

@AfricaHealthFed

Africa Healthcare Federation

Registration Link: <https://bit.ly/35Alpr9>

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How to conduct a medical device risk assessment as per ISO14971:2019

Join SGS at 15:00 on 19 May 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.

Objectives:

- Understand the key elements required for the management of risk as specified in ISO 14971:2019 and changes from ISO 14971:2007
- Understand the relationship between risk management and regulatory requirements
- Understand the relationship between risk management and quality management system requirements
- What can SGS do to help?

This webinar is for current Medical Device companies and those that manufacture medical devices.

To register, [click here](#).

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An overview of clinical trials in South Africa during COVID-19, with keynote speaker Professor Salim Abdool Karim

The keynote speaker, Professor Salim Abdool Karim, South Africa's Chief COVID-19 Scientist and leader of the Government's Ministerial Advisory Committee, will provide an overview of the current COVID-19 situation in South Africa, including updates and suggestions for tackling the pandemic. In addition, Professor Karim will discuss how we can ensure the continuation of non-COVID-19 clinical trials and advancing drug development.

Date & Time: 20 May 2020, 11:30 - 14:00

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

To register, [click here](#).

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COVID-19 DEVELOPMENTS



- Of note is that the Eastern Cape has now overtaken KwaZulu-Natal with the third-highest cases in the country - with 1 504.

ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL

- There have been calls on the President to address the nation regularly – at least once a week – and that these briefings should include the opportunity to answer questions from the media (Daily Maverick)
- Schools' state of readiness to reopen during the Level 4 lockdown hangs in the balance yet again as teacher unions continue to raise what they call "gaps" in an updated report received from the Department of Basic Education.
- Government interventions, including the travel ban and lockdown, have potentially averted at least 20 000 deaths, says Professor Tulio de Oliveira, a bioinformatician and director of the KwaZulu-Natal Research and Innovation Sequencing Platform (Krisp) at the University of KwaZulu-Natal. The basic reproductive number of the infection has also slowed from three to two in most of the country.
- De Oliveira and his team at Krisp have provided real-time data analysis of the COVID-19 infection to the government. He said South Africa had followed the UK trajectory in the early days of the epidemic, but early intervention by the government had seen the two countries charting different paths (Fin24)

Interesting retail trends

- South Africa's lockdown has led to some interesting retail trends - like a spike in the sale of non-alcoholic beverages, and pineapples. Shoprite/Checkers and Pick n Pay supermarkets saw a "major spike" in the sale of bleach and other household cleaning products - which the group attributes to an increased interest in hygiene, and additionally more time to do some home spring cleaning.
- According to Pick n Pay's annual results presentation, released on Tuesday, bleach was one of the most commonly stockpiled items - the sales of which grew by 138%. The group also reported a 92% increase in hair colouring kits during lockdown (Business Insider)

Competition commission

- The Competition Commission has referred two face mask suppliers to the Competition Tribunal for allegedly charging "astronomically" high prices on face masks. The suppliers, Sicuro Safety and Hennox Supplies, allegedly charged more than 969.07% and 956% respectively, for face masks, an investigation by the Commission found.
- The Commission has referred the matter to the Tribunal to impose penalties and to prohibit these suppliers from charging excessive prices. It previously investigated Babelegi Workwear and Industrial Suppliers as well as Dis-Chem Pharmacies for excessive pricing of face masks. The Tribunal is yet to announce a decision on the Dis-Chem matter (Fin24)

Tourism industry

- There will be "nothing left" of South Africa's tourism industry if it is only able to start operating in general again in December - as seems likely in light of current coronavirus projections - Tshifhiwa

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for more than 700 000 people by 2019. The industry has been decimated by travel and movement restrictions imposed by in an attempt to curb the spread of the pandemic.

- South Africa's domestic tourism season will likely only start in December and international tourism only next year, [Minister of Tourism Mmamoloko Kubayi-Ngubane recently indicated](#) during an online briefing hosted by SA Tourism (News24)

CLINICAL & SCIENCE NEWS

- Cape Bio Pharms is using biotechnology to manufacture COVID-19 proteins in plants. These proteins, called antigens, are used in rapid diagnostic test kits that detect antibodies against the virus in a person's blood, indicating whether they have been exposed to the virus. But these test kits won't be rolled out on mass scale in South Africa just yet. The test kit manufacturers are struggling to secure a supply of positive serum, blood from COVID19 positive people, to test whether the kits work and are still waiting on approval from the South African Health Products Regulatory Authority.
- Tanzania says it has received its first shipment of Madagascar's self-proclaimed, plant-based "cure" for coronavirus, despite warnings from the World Health Organization that its efficacy is unproven. The Africa Centres for Disease Control and Prevention also said the drink should be "tested rigorously". Health specialists are worried that people who drink the product might feel they are immune to COVID-19 and engage in risky behaviour, the WHO's Africa head Matshidiso Moeti said. "We are concerned that touting this product as a preventive measure might then make people feel safe," she 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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