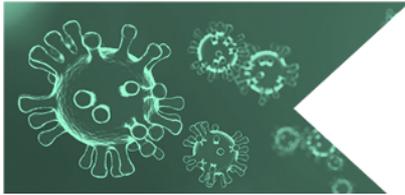


✉ Share this with those who need to know



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

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](#).

SAMED-SALDA Regulatory Forum: SAHPRA Licencing and amendments - A beginners guide

Programme: *subject to change*

09h45	Log-on via Microsoft Teams link (please mute and turn off video when joining)
10h00	Welcome <i>Madeleine Pearce, SAMED Regulatory Committee Chairperson</i>
10h05	Understanding the SAHPRA licencing Process <i>Andrea Julsing-Keyter, Deputy Director Medical Devices, SAHPRA</i>
	<ul style="list-style-type: none"> • SAHPRA licencing process – a step by step guide <ul style="list-style-type: none"> • Forms to complete; Required documents; Cover letter; Important considerations; Who to contact/where to submit; Time frames • SAHPRA licencing amendments <ul style="list-style-type: none"> • When to submit a notice and when to apply for an amendment; Required documents; Important considerations; Who to contact/where to submit; Time frames • SAHPRA licencing/amendment in light of COVID-19 – an expedited process <ul style="list-style-type: none"> • Who should make use of this process; Who to contact/where to submit; Time frames • COVID-19 Matters <ul style="list-style-type: none"> • NRCS mask & disinfectant requirements & processes; • Serological test kits requirements and processes • SAHPRA appeals process
11h05	Q & A Session with the Regulator <i>Sarah Cohen, Executive Officer, SALDA will facilitate questions with the regulator.</i> Please make use of the comment/chat stream to post questions
12h00	End

Click the link to Join

This will be a virtual meeting held via Microsoft Teams

Please only click the link at the above, specified date/time.

[Join Microsoft Teams Meeting](#)

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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.

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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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

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- 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

Mediclinic Coronavirus containment measures

In light of the current increase of positive Coronavirus cases in South Africa, we have to implement additional measures in order to try and reduce the potential exposure to the virus to all patients, staff and doctors working within the Mediclinic facilities. One of these measures is that all representatives must be CRICE trained on the safe and responsible use of PPE. They should provide proof of having completed this CRICE training before they will be allowed to enter the theatre complex. The protocols to follow are those recommended by the WHO and the NICD.

Download the notice [here](#).

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Competition Law and Pricing in light of COVID-19

SAMED hosted a members forum this morning presented by Heather Irvine. Heather is a partner in Bowmans Johannesburg office Corporate Department and a member of the Competition Practice. Heather specializes in complex mergers, competition law complaints and pricing disputes. Today, she covered the recent exemptions for collaboration, what competitors can and cannot do and potentiates about abuses by dominant purchasers.

Essentially pricing adjustments can be made as long as they are well documented with evidence that the price increase was in lieu of a number of factors and so long as the profit margins remain in line with pricing prior to the pandemic. This will be on all essential goods and affects both large and small enterprise.

Download the slide presentation [here](#).

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Call to comment on the list of essential goods

The South African Development Community (SADC) has proposed an updated list of essential products during COVID-19. They have put out a call for inputs, comments and validation of the list. Those members who export into the SADC region are encouraged to review and comment. Submissions can be made to Alberto Alexandre on aalexandre@sadc.int.

Download the call to comment [here](#).

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SAHPRA Medical Device Hotline

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



SAHPRA COVID-19 Medical Device Hotline

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.

084 220 8037

072 993 2273

078 281 6334

Hours of Operation: (Excluding weekends and public holidays)

08:00 – 16:00



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: Business for SA partners with EMGuidance to drive digital COVID-19 resource platform for HCPs

Business for South Africa's (B4SA) 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.

The COVID-19 platform will ensure South African HCPs, including doctors, nurses, pharmacists, dentists, and paramedics have ongoing access to resources, advice and support to help them navigate the many challenges they face at the frontlines of fighting the pandemic.

and the confidence to face each day. We believe this digital platform will prove invaluable.

B4SA will share information and guidance relevant to HCPs via the EMGuidance platform, which is only accessible by South African health care professionals. It will also act as a two-way channel of communication with the HCPs, which allow the team to understand and address their concerns or questions.

B4SA and EMGuidance urge health care stakeholders with supportive information and services for HCPs to participate in this collaborative effort, by emailing: info@emguidance.com.

EMGuidance's platform has a mobile and digital community of over 25 000 local health care professionals (HCPs). Over 50% of practising doctors already use EMGuidance as well as several thousand pharmacists, nurses and paramedics. In addition, several medical societies, the National Department of Health and medical companies educate and communicate with the medical community through EMGuidance.

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The Solidarity Fund uniting South Africa against COVID-19

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 PRODUCT REQUESTS

URGENT: Request for manufacturers of body bags

Please note that there is a shortage of body bags for the COVID-19 response. Members who are able to manufacture body bags to kindly **contact Thandiwe Magagula (MDMSA secretariat) as soon as possible on 060 885 5305 or mdmsasecretariat@mdmsa.co.za.**

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COVID-19 EVENTS

EKA Work Sessions

A special session is arranged relating to UIF / **TERS benefit** that can be claimed, as well as the **labour law implications of Covid-19**. Yvonne, from Elsabe Klinck and Associates, will take attendees through the requirements of labour law (e.g. can you send employees on unpaid leave?), how to regularise your UIF status and how to claim from the TERS if you are unable to pay staff or had been unable to do so in the past- and/or coming months.

WHEN: 7 May 2020, 18:00 - 20:00

COST: R500, excl. VAT

BOOKINGS: eugenia@elsabeklinckassociates.co.za

Download the **EKA Worksession form** [here](#).

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BSA Risk Assessment Presentation

Business for SA has performed a comprehensive risk assessment of the significant strategic risks arising from the COVID-19 crisis. The risk assessment has gone beyond the conventional two-dimensional approach to depicting risk and has taken a four-dimensional view by including considerations of risk 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](#).**

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Tues, 05 May; 07:30 to 08:30am

Tues, 12 May; 07:30 to 08:30am

Wed, 06 May; 07:30 to 08:30am

Wed, 13 May; 07:30 to 08:30am

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

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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COVID-19 DEVELOPMENTS

TRACKING THE PANDEMIC

Statistics for South Africa on 6 May

- 279 379 tests conducted
- 7 808 positive cases identified (236 in the last 24 hours)
- 3 153 recoveries
- 153 deaths (5 in last 24 hours)

Province	Deaths	Recoveries
Eastern Cape	18	388
Free State	6	102
Gauteng	15	1036
KwaZulu Natal	38	420
Limpopo	3	27
Mpumalanga	0	22
North West	0	20
Northern Cape	0	16
Western Cape	73	1122
Total	153	3153

Global figures

Confirmed	Recovered	Deaths
3,76M	1,25M	264K
+81 451		+3 797

Selected countries with major epidemics

- UK has a total of 201 000 cases (6 111 in last 24 hours) and 30 076 deaths – the highest death toll in Europe.
- US has 1.26 million cases (24 572 new) and 74 577 deaths.

HEALTH DEVELOPMENTS

Health workers affected

A total of 511 South African health workers have tested positive for COVID-19, 26 have been hospitalised and a doctor and nurse have succumbed to the virus, according to Health Minister Zweli Mkhize. He was speaking in Rustenburg, North West, where he received a donation of personal protective equipment (PPE) from Sibanye Stillwater and Old Mutual. (News 24)

Model shows devastating TB impact

The global lockdown caused by COVID-19 risks a "devastating" surge in tuberculosis cases, with nearly 1.4 million additional deaths from the world's biggest infectious killer by 2025, according to new research released by the Stop TB Partnership on Wednesday. The model that produced these figures was developed in partnership with epidemiologists at Imperial College, London, using TB response data from three high-incidence countries: India, Kenya and Ukraine. The predicted surge in infections is because social distancing will make it impossible for health care workers to test vulnerable populations and for patients to access ongoing treatments. (News 24)

Reliance on proprietary test materials

South Africa is struggling to access adequate testing materials to scale up COVID-19 testing and a key challenge faced by laboratories in South Africa is that most diagnostic infrastructure requires the use of proprietary test materials – including reagents, consumables and cartridges. This largely prevents laboratories from making their own test materials or procuring test materials from sources other than the diagnostic machine's manufacturer. (News24)

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used to treat the coronavirus, and additional supplies to treat lupus sufferers had to be procured from India, said Prof Salim Abdool Karim, chairman of the ministerial advisory group on the COVID-19 outbreak. There is no clear evidence that chloroquine mitigates effects of the coronavirus (despite President Trump's support of the drug) and major concerns about its side-effects. (Fin 24)

SOCIAL DEVELOPMENTS

Continued concerns over back to school plan

The NGO, Equal Education, has raised concerns about the impact the national COVID-19 lockdown has had on teachers and learner, who have expressed fears around the phased re-opening of schools. The movement said it believed plans by the Department of Basic Education had caused more confusion.

ECONOMIC & BUSINESS DEVELOPMENTS

R11m settlement for inflation of face mask prices

The Competition Tribunal has confirmed, as an order, an R11-million consent agreement between the Competition Commission and Matus, a distributor of face masks and personal protection gear. The Competition Commission referred the agreement to the tribunal after it found the company had inflated the prices of face masks, which are considered essential hygienic items, and negotiated a settlement with the company. R5.9m of the settlement is an administrative penalty and R5m is a contribution to the Solidarity Fund. Matus will revert to prices applicable in late February.

SAHPRA registration issues

Local medical technology firms are frustrated with SAHPRA delays in modifying their registration to allow them to distribute COVID-19 testing products. SAHPRA says applications by companies are often incomplete. (eNCA midday news on 6 May)

The lighter side

Scientist Fauci cast as romantic lead

For viewers of international news channels, US scientist Anthony Fauci has been the ever-present voice of reason in the face of the pandemic in that country. Here's a fun fact about him.

Extract from the Washingtonian:

"In 1991, **Sally Quinn**—doyenne of the Washington intelligentsia, who was then on a streak of popular novels—published "Happy Endings," which climbed the bestseller list. Across 500-plus pages, Quinn unspools the juicy romance of a widowed First Lady who falls head over heels for a dashing and cutting NIH scientist (who, by the way, has recently discovered a therapy for AIDS) while a white-hot and secretive love affair takes wind. Bellinis are spilled, love is made, hearts are broken and mended—all for the singular and mysterious scientist, who goes by the name of Michael Lanzer. Or better known by his real name: **Anthony Fauci.**"

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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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