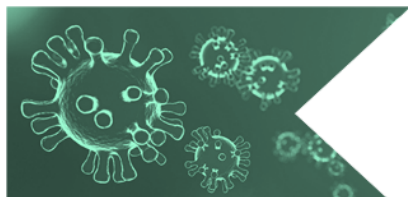


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SAMED
south african medical technology industry association

COVID-19 NEWS

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](#).

Reminder to attend the Member Forum - Competition law & pricing in light of COVID-19

Please see the invitation below. Please [complete the anonymous survey on this link](#) prior to the meeting to aid us in understanding the COVID-19 impact on members.

Competition Law and Pricing

07 May 2020



Speaker: Heather Irvine
Competition Lawyer
Bowmans

Join us for a short webinar on competition law issues raised by COVID-19, which will cover the following topics:

- The recent exemptions for collaboration in the healthcare industry passed by Minister Patel;
- What competitors can do: pro-competitive joint ventures (e.g. joint sourcing of products/inputs and logistics)
- What competitors can't do: discussion of selling prices, collectively bargaining against customers, collective boycotts
- Potential complaints to the competition authorities about abuses by dominant purchasers?

Please Note: This would be a general info session and there will be no discussion of specific sellers, prices or buyers on the call.

Date: 07 May 2020, Thursday
Venue: Virtual Meeting
Time: 11:00 – 12:00

**Click this link
to Join**

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

[Join Microsoft Teams Meeting](#)

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

SAMED / SALDA Regulatory Forum

12 MAY 2020



Programme: *subject to change*

- 09h45** Log-on via Microsoft Teams link (please mute and turn off video when joining)
- 10h00** **Welcome**
Madeleine Pearce, SAMED Regulatory Committee Chairperson
- 10h05** **Understanding the SAHPRA licencing Process**
Andrea Julsing-Keyter, Deputy Director Medical Devices, SAHPRA
- SAHPRA licencing process – a step by step guide
 - Forms to complete; Required documents; Cover letter; Important considerations; Who to contact/where to submit; Time frames
 - SAHPRA licencing amendments
 - 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
 - Who should make use of this process; Who to contact/where to submit; Time frames
 - COVID-19 Matters
 - NRCS mask & disinfectant requirements & processes;
 - Serological test kits requirements and processes
 - SAHPRA appeals process
- 11h05** **Q & A Session with the Regulator**
Sarah Cohen, Executive Officer, SALDA will facilitate questions with the regulator.
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.

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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.

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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

CIPC certificates & other important COVID-19 updates

There are three relevant new regulations/directives on COVID-19:

CIPC level 4 certificates have to be re-obtained via the BizPortal (not Gazetted)

Previously, updates were sent automatically, now they will need to be downloaded manually by visiting the CIPC site. Certificates issued late last week differ in their wording from the one's issued from today (e.g. whether the reference is made only to "essential" services, or also to "permitted" services), as well as how

[S2 to S4 medicine prescriptions can now be valid for 12 \(and not only 6\) months GG No 43260 of 30 April 2020, Notice No R481](#)

The Minister of Health issued an exemption via s36 from s22A(6) of the Medicines Act applicable to all prescriptions issued from 30 Oct 2019 to 30 Oct 2020. The prescriber can now issue the prescription for 12 months, or, if it was only issued for 6 months, the pharmacist may dispense post those 6 months on the proviso that the dispenser is satisfied that the authorised prescriber initiated the therapy, with the intention of that the therapy be continued.

[Public transport travel hours - only 05:00 to 19:00 \(GG No 43284 of 6 May 2020, Notice No 504\)](#)

Directive 8 was amended today to allow public transport to only operate till 19:00, i.e. the very last person must be dropped off by 19:00. This affects many businesses who operate in providing permitted services, meaning that one has to allow employees sufficient travel time at the end of a day to keep within this limit. These time limits do not coincide with the curfew, which is from 20:00 to 05:00.

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Updated COVID-19 Export Control Regulations - 27 March 2020

The Minister of Trade, Industry and Competition has amended the regulations with regards to export.

The code "DTIC" in column 2 of Schedule 4 indicates that the Department of Trade, Industry and Competition as well as any other department (the Line Department) as determined by the Minister of Trade, Industry and Competition must be consulted by the International Trade Administration Commission (ITAC) upon receipt of an application and the DTIC and /or the Line Department must provide a recommendation to ITAC before a determination on an application for an export permit can be considered by ITAC. If no recommendation is received from the DTIC and /or the Line Department within a period of ten (10) working days, or such an extended time period as requested, from the date of the request, it will be deemed that a recommendation will have been made that there is no objection to the issuing of an export permit.

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

Download form to register as an exporter [here](#).

Download the form to apply for an export permit [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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MDMSA: COVID-19 opportunity for local manufacture

MDMSA has been in discussion with B4SA (Business for South Africa), the DTIC, the African Union and the WHO. All of these agencies have expressed an interest in the local manufacture of COVID-19 related Health products. These products fit largely into three major categories:

1. Capex type products like Ventilators
2. PPE
3. Disinfectants

To take advantage of this opportunity MDMSA will align their support for this initiative with these groupings.

The MDMSA Chairman, Marlon Burges, wish to ask members to share information on their capacity to manufacture COVID-19 related products. In order for them to compile a collated response kindly provide the information below:

- Company Name
- Key contact person
- Contact number
- Email address
- Products
- Volumes per day/week
- PPE, ventilators or Disinfectants?

Please complete and send back to mdmsasecretariat@mdmsa.co.za

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SARS: COVID-19 VAT 412.11 Mapping of Essential Goods

As published on 3 April 2020, the SARS VAT Rebate 412.11 provides a mapping of essential goods with reference to Annexure B of the Regulations under the Disaster Management Act, 2002. The revised list includes plastic face shields.

Download the mapping of essential good [here](#).

[Subscribe](#)[Past Issues](#)[Translate ▼](#)**SARS. How to apply for the waiving of penalties for tax debt**

Larger businesses (with gross income of **more than R100 million**) that are incapable of making payment due to the COVID-19 disaster, may apply to defer tax payments without incurring penalties by emailing SARS on COVID19IPAaboveR100m@sars.gov.za.

Similarly, businesses with gross income of **less than R100 million** can apply for an additional deferral of payments without incurring penalties by emailing SARS on COVID19IPAbelowR100m@sars.gov.za.

For more information on the requirements and documents to include in the application, see the [How do I query my debt webpage](#).

[Back to top](#)**BSA Update: The obligations on businesses operating during COVID-19 alert level 4**

Regulation 16(6)(b) of the Regulations in terms of the Disaster Management Act issued on 29 April 2020 places four obligations on each business, industry and entity in both the public and private sector which are permitted to operate during Alert Level 4:

1. **Covid-19 compliance officer:** They must designate a Covid-19 compliance officer. This person should oversee the implementation of the Workplace Plan (see below), as well as adherence to the standards of hygiene and health protocols relating to Covid-19 at the workplace.
2. **Phased-in return from other provinces/metropolitan areas/districts:** They must phase in the return of their employees to work in order to manage the return of employees from other provinces, metropolitan areas and districts. In terms of regulation 16(4), workers who perform an essential or permitted service who have to commute to and from work on a daily basis between provinces, metropolitan areas or districts, must have a permit (Form 2 of Annexure A) to travel and perform such work.
3. **Measures:** They must develop measures to ensure that the workplace meets the standards of health protocols, adequate space for employees (i.e. one person per 1.5 metres of floor space), and social distancing measures for the public and service providers, as required.
4. **Workplace Plan:** They must develop a Workplace Plan for the phased-in return of their employees to the workplace, prior to reopening the workplace for business. This Plan must correspond with Annexure E, and must contain the following information:
 - which employees are permitted to work;
 - what the plans are for the phased-in return of their employees to the workplace;
 - the health protocols that are in place to protect employees from Covid-19; and
 - the details of the Covid-19 compliance officer.

The measures that must be taken, and the Workplace Plan can be viewed on the [Business for South Africa website](#).

[Back to top](#)**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

[Back to top](#)**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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Africa Healthcare Federation Live Webcast



LIVE WEBCAST

FINANCIAL SUSTAINABILITY FOR PRIVATE HOSPITALS INVOLVED IN COVID19

Wednesday 6th May 2020, 5:00pm to 6:30pm (East African time)

Private Healthcare Associations, Federations, Organisations and Professional in Africa are encouraged to participate.



Moderator
Dr. Amit N. Thakker,
President,
Africa Healthcare Federation
Kenya



Dr. Mark Hellowell,
PhD. Professor at Edinburgh and
WHO Consultant
United Kingdom



Dr. Albert Tuyishime,
Rwanda Biomedical
Center Manager of the
COVID19 Response Team
Rwanda



Dr. Tryphine Zulu,
Senior Manager for
Disease Risk and
Medicines Management
South Africa


<https://bit.ly/2VQ5QYW>

www.africahf.com


@AfricaHealthFed



Africa Healthcare Federation

SAVE THE DATE & REGISTER!

Date: Wednesday 6th May 2020

Time: 5:00pm to 6:30pm East African Time

TOPIC: Financial sustainability for private hospitals involved in COVID19

Registration link: <https://bit.ly/2VQ5QYW>[Back to top](#)

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.zaDownload the EKA Worksession form [here](#).[Back to top](#)

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](#).**

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

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

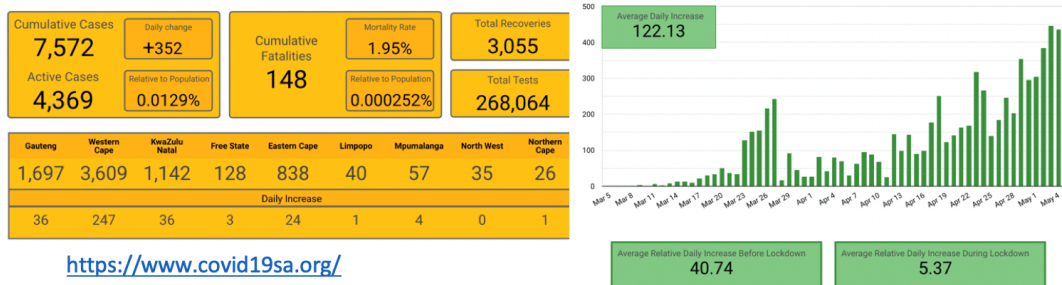
Daniella.de.Gouveia@businessresponsecovid19.co.za[Back to top](#)

COVID-19 DEVELOPMENTS

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Speaking during a visit to [KwaZulu-Natal yesterday](#), [President Cyril Ramaphosa](#) says South Africa needs to plan for the worst, as the country is yet to experience the worst of the COVID-19 pandemic – and that as the country and economy come out from the crisis, South Africa needs to “clean up”. “We are informed that the worst is still coming. We are going to get more people infected. The important thing is that we need to show that we lessen the pace at which these infections take place. As we move down other levels of the lockdown, the time has arrived to clean up our country. We now need to embark on a massive campaign countrywide to clean up South Africa.” Ramaphosa said government had to deal with issues like waste dumps and hygiene and had to “clean up the streets of our country, including rural areas, as well including high-density areas like townships”.

[Not all experts agree on just what the increase will be](#), but two of the country’s foremost experts on COVID-19 believe the easing of the lockdown will see the infection rate increase until about September. Professor Tulio de Oliveira, director of the KwaZulu-Natal Research and Innovation Sequencing Platform at the University of KwaZulu-Natal, an organisation that has assisted the government with data analysis for its COVID-19 response, says the infection rates will increase to about 10% per day after the lockdown is downgraded. Professor Salim Abdool Karim, who chairs the ministerial advisory committee on COVID-19, which advises the Minister of Health on how the government should respond to the pandemic, said the infection rate would increase, although he said he did not know what the percentage increase would be.

Globally, there are over 3.6m infections, with 257 288 deaths recorded – the UK now has the highest number of fatalities in Europe (nearly 30 000).

ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL

- SARS Commissioner Edward [Kieswetter sees a revenue shortfall this financial year](#) of about R285bn — 15%-20% shy of what the revenue service had expected to collect.
- Comair, the operator of low-cost carrier kulula.com and British Airways under licence in Southern Africa, has become the latest victim of COVID-19, with the company voluntarily submitting itself for [business rescue](#).
- Early childhood development centres also face closures. Parents are struggling to cover the fees and it is feared that the centres will have to close without urgent government intervention. As [Vincent Cruywagen](#) reports, up to a million children could be stranded by the time the centres are due to open in September.
- Businesses listed on the National Treasury’s publicly inaccessible Central Supplier Database have been the target of a scam. The businesses were contacted by people claiming to be health department officials and offering tenders for a non-existent sanitiser machine. Gemma Ritchie, who spoke to a [business owner](#) almost caught in this trap, explains what to do when faced with a [suspicious-sounding official](#) and how and why scams are rising.
- A “concerned group of professionals” headed by actuaries has sent a report to President Cyril Ramaphosa which shows that a continued, restrictive lockdown will damage the economy and create a “humanitarian disaster to dwarf COVID-19”. As [Terry Bell](#) writes, the report says that if the restrictions are not lifted immediately, they might cause 29 times more deaths than the measures aim to prevent.
- [The UK must avoid lurching from the coronavirus crisis into a deeper climate crisis](#), the government’s advisers have warned. They recommend that ministers ensure funds earmarked for a post-COVID-19 economic recovery go to firms that will reduce carbon emissions. They say the public should work from home if possible; and to walk or cycle. And investment should prioritise broadband over road-building, the Committee on Climate Change (CCC) says. The government will reply later, although the Energy Secretary Alok Sharma has already spoken in favour of a green recovery to the recession.

CLINICAL & SCIENCE NEWS

The antiviral drug [remdesivir has been approved by the FDA](#) for hospitalised patients with ‘severe disease’, such as those who need supplemental oxygen or ventilators to breathe.

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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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