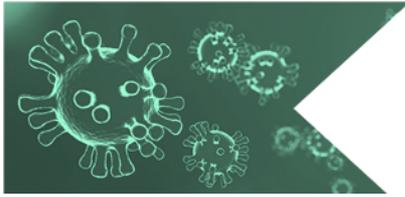


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## **SAMED COVID-19 NEWS** south african medical technology industry association

**Covid-19 news from SAMED, industry and abroad**

### **SAMED ON COVID-19**

#### **SAMED shows support during Covid-19 epidemic**

SAMED is engaging with various entities i.e. The National Department of Health, The National Health and Laboratory Services, the Department of Economic Development, the South African Health Products Regulatory Authority (SAHPRA), Business Unity South Africa (BUSA) and other stakeholders to ensure that there is sufficient supply and access to COVID-19 medtech products.

In return, we ask that you heed all efforts and regulations to curb price-hikes and profiteering at this exceptional moment for South Africa and the whole world. In this regard, the Trade and Industry Minister Ebrahim Patel has implemented regulations to prevent excessive pricing by dominant firms in terms of the Competition Act, and unfair or unreasonable pricing by all SA suppliers to whom the CPA applies.

These regulations ban excessive price increases on basic food and consumer items, medical and hygiene supplies, emergency items and emergency clean-up products – and medical services for the testing, prevention and treatment of Covid-19. There are significant penalties, and firms which do hike prices over this period are at risk.

#### **REGULATION: Consumer and customer protections in relation to the supply of goods and services**

These Regulations aim to protect consumers from unlawful pricing behaviour in respect of products and services that are critical to effectively responding to the COVID-19 pandemic. These products and services are listed in the annexures. These Regulations put in place two measures to avoid unlawful price increases in respect of goods listed. First, the Regulations introduce the following new considerations that will count towards an assessment of whether a dominant firm has engaged in excessive pricing. Second, the Regulations go on to state that price increases that have either of the abovementioned characteristics will be deemed to be unconscionable, unfair, unreasonable and unjust in terms of the Consumer Protection Act (the “CPA”).

Notably, these Regulations provide that the Minister may, in consultation with the Minister of Health, issue directions to set maximum prices on medical goods and services relating to the testing, prevention and treatment of COVID-19 and its associated diseases during the National State of Disaster. Dominant firms which contravene these Regulations must be investigated by the Competition Commission and, if found to be in contravention, will be liable in accordance with the penalties provided for in the Competition Act. The Regulations go on to set in place the general penalties for a contravention of these Regulations, subject to the Competition Act and the CPA.

[View the Consumer and customer protection & national disaster management regulations and directions](#)

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**MEDTECH SUPPLIERS TO HEED THE FOLLOWING COVID-19 NOTICES, LEGISLATION AND REGULATIONS**

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manufacturing and business in general across the globe. SAHPRA has put in place a series of initiatives aimed at minimising the potential negative impact of the pandemic on the availability of medicines and medical devices in South Africa. Read more about them [here](#).

**Given the critical nature of the current situation, SAHPRA calls on the support of business and/or applicants to inform them of any medicine and medical device shortages directly to Dr Shyamli Munbodh via [shortages@sahpra.org.za](mailto:shortages@sahpra.org.za)**

### Medical Technology Requirements for the supply of medical devices in light of COVID-19

SAHPRA has sent out a communique to stakeholders with regards to Medical Device Establishment Licences and the requirements for the supply of medical devices during the COVID-19 pandemic.

Read the full notice [here](#).

### REGULATION: COVID-19 Block Exemption for the Healthcare Sector, 2020

These Regulations exempt certain agreements or practices solely aimed at responding to the COVID-19 pandemic. In other words, conduct that would ordinarily be caught by the cartel and vertical restrictive practices prohibitions of the Competition Act will now be exempt for the duration of the National State of Disaster. Notably, these Regulations come with the important caveat that any communication or agreement on prices between healthcare companies must be specifically authorised by the Minister.

The Regulations note that the management of the COVID-19 pandemic is not static and the Minister may expand the scope of these Regulations. The Regulations require that parties that take advantage of the Block Exemption keep minutes of meetings held and written records of any agreements struck or practices followed. Notably, even though the Regulations are effective immediately, any person may still make representations regarding the regulations within 14 days from their date of publication.

#### [View the COVID-19 block exemption for the healthcare sector](#)

It is very important to note that where the application of an exemption, e.g. on procurement of supplies by hospitals, take place, no price-setting would be permitted, and that price negotiation to lower costs must take place under auspices of the Minister of Health.

We, therefore, urge members to be extremely cautious when implementing these exceptions and to seek assistance before commencing, with “communication”, “coordination”, “transfer” or “procurement” in a collective fashion. The exemptions can be summarised as follows :

	Coordination on patient allocation	Disease data	Communication on availability	Communication on capacity & utilisation	Coordination of procurement	Professional and employee coordination & transfer	Transfer of stock / supplies
Hospitals & facilities	✓		-	✓	✓	✓	✓
Suppliers	-		✓	-	✓	-	-
Medical specialists; radiologists	✓	✓	-	✓	✓ (testing)	-	✓
Pathologists, laboratories	-			✓	✓ (testing)		✓
Pharmacies	-	-	✓ (medicines etc)	-	✓	-	✓
Healthcare funders	Funders can amongst themselves agree on reducing the costs of tests, treatment, etc. Funders can also agree with practices and/or facilities on cost reductions.						

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### Workplace Preparedness: COVID-19

outbreaks involving many staff members, planning for COVID-19 may involve updating plans to address the specific exposure risks, sources of exposure, routes of transmission, and other unique characteristics of SARS-CoV-2.

Employers who have not prepared for pandemic events should prepare themselves and their workers as far in advance as possible of potentially worsening outbreak conditions. Lack of continuity planning can result in a cascade of failures as employers attempt to address challenges of COVID-19 with insufficient resources and workers who might not be adequately trained for jobs they may have to perform under pandemic conditions.

Download The Department of Employment and Labour guidelines, [here](#).

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### Medical representative access to Life Healthcare facilities

In line with the NICD and WHO COVID-19 guidelines, Life Healthcare has implemented infection prevention and control measures to reduce the risk of spreading the coronavirus. As such, medical representatives will not be allowed into Life Healthcare facilities without an invitation for critical visits at the discretion of hospital management. **View the full notice [here](#).**

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### Mediclinic coronavirus containment measures

In light of the increase of positive Coronavirus cases in South Africa, Mediclinic has implemented additional measures to reduce the potential exposure within the Mediclinic facilities. To this end, they have limited visits to the facilities by medical representatives. If it is critical that a theatre is to be visited in order to assist a doctor, there are protocols and additional policies which must be followed. **View the full notice [here](#).**

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The Company Representatives In a Clinical Environment programme requires Company Representatives to have had the necessary vaccinations and Company Representatives sign a declaration of responsibility to be free of infectious diseases requiring disclosure.

[Find out more](#)

### REGULATION: Regulations issued in relation to Disaster Management: COVID-19

Regulations have been set out in a Government Gazette with regards to the steps necessary to prevent an escalation of the disaster or to alleviate, contain and minimise the effects of the disaster.

Access the Government Gazette [here](#).

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### Impact of Coronavirus on SARS Services

SARS has communicated to the Customs and Excise stakeholders on the impact of COVID-19 on the services and activities of the different ports of entries. Stakeholder Management will communicate how customs functionalities are affected should there be additional changes.

[Download the notice](#) to External Stakeholders

[Download the notice](#) to Business and Trade Associations

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Partner wanted for COVID-19 products

Lebo Sephoti has access to imported products with relevance to COVID-19 and is looking for a licenced medical device distributor to partner with regarding:

- Test kits
- Contamination protective clothing
- Hand sanitizers “70% alcohol”
- Non-touch Thermometer
- Medical Gloves and Goggles

If you are interested, please contact Lebo on 082 564 1175 or [lsephoti@gmail.com](mailto:lsephoti@gmail.com)

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COVID-19 EVENTS

Coronavirus impact on Transformation with Dr Robin Woolley

Transcend is hosting a free webinar on 26 March 2020. With coronavirus impact on companies budgets and focus, there will likely be impacts on transformation efforts. It is essential for companies to have a short-term response, and start to think about maintaining the investment and capacity that you have built up. Join Transcends special webinar to create a Transformation action plan.

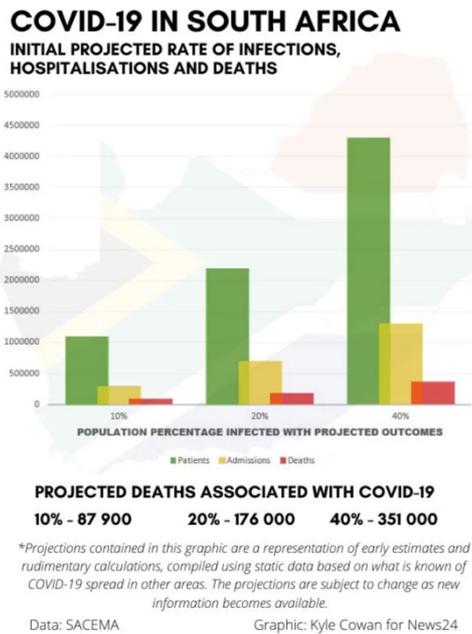
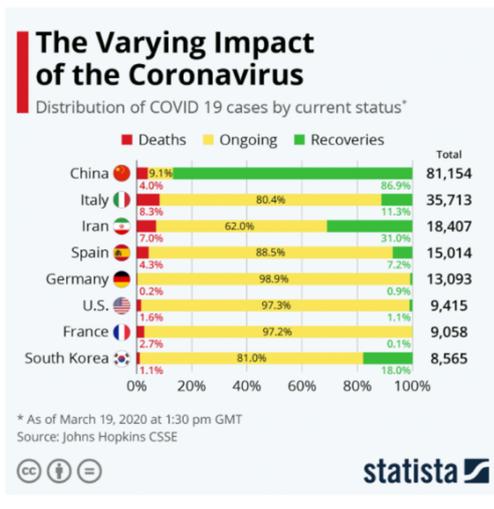
Find out more or register, [here](#).

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SOME COVID-19 DEVELOPMENTS

Globally more than 10 000 people have died because of COVID-19, with Italy overtaking China on the number of deaths. The Health Department has confirmed that South Africa’s currently has 202 confirmed cases (the breakdown of 200 infections recorded on 19 March 2020 is available [here](#)).

South Africa’s government-led policies are taking note of projections by [SACEMA](#) which provide alarming potential infections, hospitalisations and deaths due to COVID-19 (see graph below).



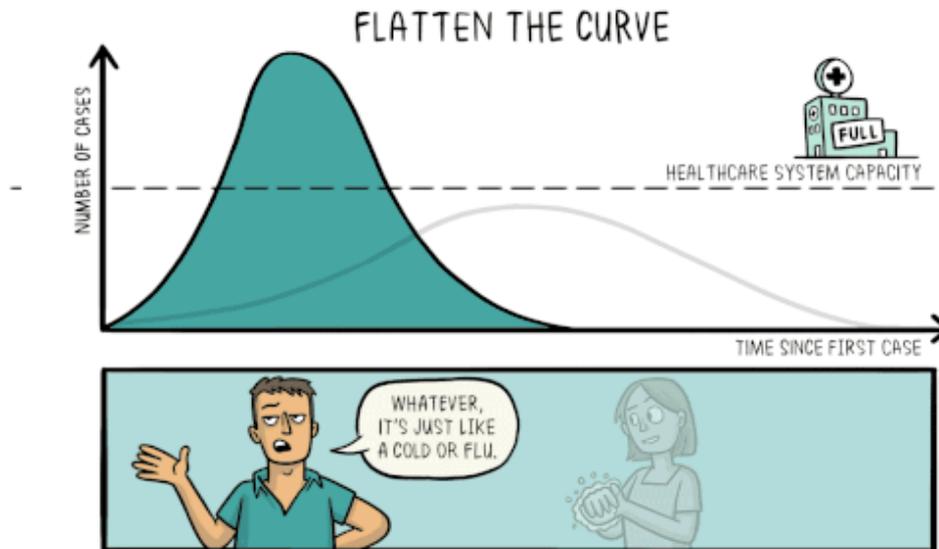
The NICD has issued [advice](#) for GPs how to prepare their practices for patients who may be infected with COVID-19. These may be relevant to other health practices or smaller clinics. The updated [State of Disaster regulations](#) provide for the compulsory medical examination, testing, treatment and quarantine of anyone suspected or confirmed positive for Covid-19.

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oxygen) and four drugs (Remdesivir, Lopinavir/ritonavir, a combination of Lopinavir/ritonavir and interferon beta, and chloroquine or hydroxychloroquine).

As President Cyril Ramaphosa said in his statement on measures to combat COVID-19 epidemic: “This national emergency requires cooperation, collaboration and common action. More than that, it requires solidarity, understanding and compassion.”

SAMED commends government on its robust, committed and proactive stance and confident roll-out of policies and measures to limit the spread of Covid-19. SAMED and our members will continue to support national and regional health initiatives wherever possible.



Source: The Daily Maverick

We also thank you, our members, for playing an invaluable role in our common mission to **#FlattenTheCurve** of **#Covid19InSA**.

SAMED will continue to bring you covid19 news as it develops.

Wishing you good health and positive spirit.

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