

✉ Share this with those who need to know



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

**COVID-19 news from SAMED, industry and abroad.**

### SAMED ON COVID-19

#### **Important Notice: CIPC certificates**

SAMED is aware that companies have registered but not yet received their certificates. As long as a company complies with the definitions and descriptions in the Regulations, and have issued the [necessary permits](#) together with an accompanying company letter to their staff/contractors, that should be fine. Once they get their certificate they can then also keep that on hand. SAMED is aware of courier companies refusing delivery, shipping etc. without the certificate. We have escalated this to the dti and await their feedback.

**Please note that the certificate is NOT a legal requirement.** The DTI tweeted the following messages:

1. "The service will continue to run tomorrow and beyond and it is not a requirement that companies complete registration before the lockdown begins."
2. "The system is currently running with full functionality and we ask that companies be patient through the registration process, as there are large volumes presently being experienced. No companies will be prejudiced by any delay in the system."

With regard to the accompanying company letter, herewith some additional recommendations:

- The letter must be an original company letterhead (in colour if possible).
- The full name/s, Surname, ID number and address of the employee and short Job Description.
- The letter must describe the services provided by the company in order to indicate that they provide essential services.
- The employer's name and address and official business stamp.
- Mention that the staff member might need to be allowed to travel after business hours/irregular hours.
- Name and contact number of CEO.
- Original signature of CEO.

#### **AMED applauds industry response**

SAMED would like to commend the MedTech and broader healthcare industry's response to this pandemic. We are all in this together and are working on the single goal of protecting the health system and saving lives.

We continue to provide information to you as rapidly as we receive it. We additionally ask that you remain vigilant for requests for information from us.

[Back to top](#)

---

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

#### **Guideline for the completion of the permit to perform essential services in terms of the Disaster Management Act.**

The published guidelines have been issued in order to assist enterprises to comply with the above

provide critical maintenance services to one or more of the listed goods and services in Annexure B of the Regulations may operate within the borders of the Republic of South Africa during the lockdown period.

Contact details in the event of enterprises wishing to clarify their status as an essential good or service:

- Enterprises may contact the Department of Trade, Industry and Competition (DTIC) on lockdownexemptions@thedtic.gov.za
- Enterprises may call the DTIC on 0861 843 348 or +27 12 394 9500

Download the guidelines [here](#).

[Back to top](#)

---

### NDoH: Rational medicine use during COVID-19 Pandemic

Due to this pandemic, there is now an increased global demand for pharmaceuticals and decreased active pharmaceutical ingredient production. It is anticipated that supply constraints may result. The National Department of Health (NDoH) is, therefore, making an urgent plea to all healthcare workers to take measures to promote rational medicine use.

The NDoH outlines those measures [here](#).

[Back to top](#)

---

### NDoH request to use chloroquine rationally

The National Department of Health issues a statement that due to the fact that chloroquine has shown potential clinical benefits, there has been a substantial increase in the purchase of chloroquine tablets for storage 'in-case' it is needed. This restricts access to the drug to those who have a genuine medical need for the drug. To this end there are now new guidelines to adhere to when prescribing, selling or using chloroquine as a treatment in relation to COVID-19.

Download the notice [here](#).

[Back to top](#)

---

### Important NICD notices

The NICD has requested that you be aware of the following two notices:

- [National Infection Prevention and Control Strategic Framework](#): this strategic framework gives guidance to public and private health facilities and health workers on compliance with standards relating to IPC practices
- [Practical Manual for implementation](#): this practical implementation manual has been developed in parallel the framework

[Back to top](#)

---

### Q & A for business operations during lockdown

There has been a lot of questions during these uncertain times. Is there an official list of which businesses that should remain open? Which businesses may continue to operate during the lockdown? Do I have to register my business on the <http://www.bizportal.gov.za/> CIPC portal in order to carry on business as an essential business?

These and other questions, together with unofficial answers can be found on [the Business Q&A](#).

[Back to top](#)

---

South Africa is receiving many kind offers of donations of personal protective equipment (PPEs) such as gloves, masks, gowns etc; equipment such as test kits and medicines, and also offers of supply. We need to validate all of these. This validation needs to be done by a qualified person i.e. in this case a pharmacist or someone skilled in medical devices. If you have access to the internet and have a phone and a bit of spare time during the lockdown, your help will be HUGELY appreciated. If you are able to help, please email your details to [Nicola Brink](mailto:Nicola.Brink@samed.org.za) or WhatsApp 082 410 5859.

[Subscribe](#)[Past Issues](#)[Translate ▼](#)

The deadline for using your acknowledgement letter in lieu of the establishment licence remains 31 March 2020. SAHPRA is issuing licences and clearing the backlog. SAMED put out a call that those members who have not yet received their licences provide us with their details for follow up.

### Collection of Medical Device Establishment Licences

Due to the epidemic, the SAHPRA office is closed. If you have received a notice to collect your medical device establishment licence, please send your proof of payment (and a copy of your old certificate if applicable) to June Searela ([june.searela@sahpra.org.za](mailto:june.searela@sahpra.org.za) or 072 828 2416) and she will issue you with an electronic copy of your licence.

### SAHPRA Communications

SAHPRA has issued several communications around COVID-19 which can be found on their website: [www.sahpra.org.za/be-prepared-for-covid-19](http://www.sahpra.org.za/be-prepared-for-covid-19).

#### 1. [Backlog Clearance Program:](#)

Be advised that while the SAHPRA offices are closed, backlog applications will only be submitted electronically and following procedures have been implemented for both new registrations and Variations. For Backlog-related submissions e-mail: [backlog@sahpra.org.za](mailto:backlog@sahpra.org.za)

#### 2. [Updated: Interactions with SAHPRA](#)

SAHPRA has also updated their interactions notice to include a comprehensive list of key contacts during the lockdown (see attached). This update includes:

- Priority Process Guidance for Ne Application related to COVID-19
- Priority Process Guidance for Variation related to COVID-19

These two processes are to assist company's wishing to manufacture or distribute COVID-19 related products in expediting the Medical Device Establishment Licence application process.

- For new application: [newmedicines@sahpra.org.za](mailto:newmedicines@sahpra.org.za)
- For variations on existing applications: [Variations@sahpra.org.za](mailto:Variations@sahpra.org.za)

Furthermore, email [MDcovid@sahpra.org.za](mailto:MDcovid@sahpra.org.za) for all medical device queries related to COVID-19.

#### 3. [SAHPRA Medical Device Requirements-COVID-19](#)

SAHPRA has put together a guidance document on the requirements for applying for or amending an establishment licence (see attached). This details the processes to follow as well as the documentation which will be required.

Please take the time to read these documents should you wish to apply for or amend your Medical Device Establishment Licence during the next few weeks.

[Back to top](#)

---

### The solidarity fund uniting South Africa against COVID-19

On Monday night President Cyril Ramaphosa announced the creation of the Solidarity Fund. The Solidarity Fund is designed to unite the nation and to accelerate the country's response to COVID-19. The focus of the fund is to alleviate the suffering and distress caused by the virus on our country and will mobilise the support of business and civil society in support of government's efforts in response to COVID-19.

Details on how to donate will be available on the Fund's website [www.solidarityfund.co.za](http://www.solidarityfund.co.za)

For more information, [click here](#) or email [info@solidarityfund.co.za](mailto:info@solidarityfund.co.za)

[Back to top](#)

---

### IDC COVID-19 essential supplies intervention

The IDC COVID-19 Essential Supplies Intervention is established to provide funding to companies for the acquisition and/or the manufacturing of essential supplies on an urgent basis to combat the COVID-19

---

other products that are critical to the treatment and curtailment of the spread of the disease.

For more on the qualifying criteria, terms and priority sectors [click here](#).

[Back to top](#)

---

### Directive on COVID-19: implications on BCEA leave provision

South Africa is under lockdown and this will force many employees to stay away from work. All employees in South Africa as a condition of their employment are entitled to leave provisions as set out in the Basic Conditions of Employment Act (BCEA). During the lockdown period, an employee may be requested by the employer to take annual leave from his/her annual leave credits. The BCEA allows employers to determine the time that employees can take their annual leave.

Read the full notice [here](#).

[Back to top](#)

---

### COVID-19 Temporary employee/employer relief scheme

In view of the declaration of the National Disaster, the Minister of Employment and Labour issued a Directive called COVID-19 Temporary Employee / Employer Relief Scheme. During this period of lockdown, companies will have to shut down and employees laid off temporarily. This means that employees are compelled to take leave, which is not out of choice. They, therefore, anticipate that employees may lose income. Employers are, however, encouraged to continue to pay employees, but where this is not economically possible; they have created a special benefit under the Unemployment Insurance Fund as per the Directive COVID-19 Temporary Employee / Employer Relief Scheme.

Download the directive [here](#).

[Back to top](#)

---

### Q & A: Workforce issues during the lockdown

Employers are unsure of how to handle labour and labour queries during the lockdown. Are employers obliged to pay employees during the lockdown? Can an employer require its employees to take leave during the lockdown? Should employers issue employees with masks for work and travel, if employed in an essential service?

The (unofficial) answers to these and other questions can found on [the Workforce Q&A](#).

[Back to top](#)

---

### Contact information for incentives

There are several incentives during the COVID-19 period. It is essential that you direct your queries to the correct person in order to expedite a response. Download the consolidated list of contact [here](#).

[Back to top](#)

---

### European Commission proposes one-year delay for Medical Devices Regulation

The European Commission has issued a statement that they are working on a proposal to delay the date of application of the Medical Devices Regulation (MDR) by one year. This will go to the European Parliament at the beginning of April, so it may be adopted by the end of that month.

[Read more](#)

---

## **COVID-19 PRODUCT REQUEST**

### Request for protective clothing

Please [download](#) the order and request for quotation for protective clothing from Humana People to People. If you are able to assist, please respond to Chiwoniso Maonya (011 661 7261) as a matter of urgency.

[Back to top](#)

---

## **SOME COVID-19 DEVELOPMENTS**

[Subscribe](#)[Past Issues](#)[Translate](#) ▼

yesterday, described by analysts as being on target with the 60% daily growth curve from other parts of the world.



<https://datastudio.google.com/reporting/15817068-62f2-4101-8e0f-385e2ddd9326/page/1M>

### CLINICAL NEWS

South Africa's largest black-owned pharmaceutical company, Austell Pharmaceuticals, has offered to supply the Department of Health with [500 000 chloroquine tablets](#) which has been shown to reduce the infection and recovery time of patients with the Covid-19 virus – at no cost to the public purse. The medicine is included in the regimen of the WHO-led Solidarity clinical trial which SA is participating in.

### OTHER MAIN NEWS IN SA

As of Thursday 26 March, [every website](#) with a domain name that ends in .za – including every company website that uses the .co.za suffix, every organisation in .org.za, and every academic institution in .ac.za – must have a visible link on its front page to [the South African government's Covid-19 portal at sacoronavirus.co.za](#). The instruction was gazetted by the Department of Communications. The regulations do not say what will happen to websites that do not comply, and do not specify a deadline by when websites must be updated, though the rules are immediately in force.

The Basic Education Department says its [school nutrition programme](#) will continue during the lockdown. The issue of nutrition was a complex one because pupils were not at school, saying the department would therefore be working with the social development department to ensure underprivileged families would be provided with nutrition support. The plan is that one member of the family will be allowed to collect one food parcel once a week during the three weeks for the use of the entire family. Several food companies – such as Tiger Brands, Nestle, Pioneer, Old Mutual, First Rand and Add Hope Foundation – have expressed their willingness to support the initiative.

Makro will remain open during the lockdown. As per government regulations, its stores will only sell food, personal hygiene items, cleaning equipment, gas and a limited range of essential basic items. Among large companies being severely impacted by COVID-19 are Edcon, whose survival is being questioned and Mr Price which won't sell a single item during the lockdown. Over the same three-week period last year sales reached R1.2 billion. Also SAA acting CEO Zuks Ramasia will take early retirement from 14 April – becoming the struggling airline's third chief executive to leave in five years. The airline, currently under business rescue, announced that acting CEO Ramasia would leave on 14 April, becoming the third chief executive to do so in five years. The SAA board accepted her request for early retirement.

### INTERNATIONALLY

Leaders from the [Group of 20 nations](#) on Thursday said they were injecting over \$5 trillion into the global economy and committed to do "whatever it takes" to overcome the coronavirus pandemic and its fallout.

[Subscribe](#)[Past Issues](#)[Translate ▼](#)

---

member countries and included representatives of international organizations such as the United Nations. [Moody's and S&P Global have stripped Ford of its investment-grade credit rating](#), consigning \$36-billion of its debt to junk. There have been a string of other high-profile corporate downgrades this year including Kraft Heinz, Macy's and Occidental Petroleum.

[Back to top](#)

---

*Copyright © 2020 SAMED, All rights reserved.*

Telephone: 011 704 2440 - Email: [info@samed.org.za](mailto:info@samed.org.za) - [www.samed.org.za](http://www.samed.org.za)

Want to change how you receive these emails?

You can [update your preferences](#) or [unsubscribe from this list](#).

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.

Disclaimer: The information contained in the mailer is for general information purposes only. The information is provided by SAMED and while SAMED endeavours to ensure the information is current and correct, it makes no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability or availability with respect to the information, services, or related graphics contained in this mailer for any purpose. Any reliance the user places on such information is therefore strictly at the user's own risk. In no event will SAMED be liable for any loss or damage including without limitation, indirect or consequential loss or damage, or any loss or damage whatsoever arising from loss of data or profit arising out of or in connection with the contents or use of this mailer.