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COVID-19 news from SAMED, Government and Abroad.

NOTICE OF EXPIRATION OF VAT CERTIFICATES ISSUED IN TERMS OF ITEM 412.11

SARS has issued a notice which serves to advise interested parties that the global Value-Added Tax (VAT) Certificate issued by the International Trade Administration Commission of South Africa (ITAC) on 8 April 2020 under Schedule 1(8) of the Value-Added Tax Act, 89 of 1991, Item No. 412.11/00.00/01.00 (Rebate Item 412.11) **will expire at midnight on Friday, 5 June 2020.**

Download the notice [here](#).

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BUSINESS FOR SA | COVID-19

COVID-19 LOAN GUARANTEE SCHEME: WHAT YOU NEED TO KNOW

The COVID-19 Loan Guarantee Scheme is aimed at supporting small and medium businesses who have lost significant income as a result of the steps taken by the South African government to curb the spread of COVID-19. Announced by President Cyril Ramaphosa as part of the R500 billion stimulus package, the details of the scheme were agreed by the National Treasury, the SA Reserve Bank and the Banking Association of SA (Basa) in May.

The National Treasury has provided an initial guarantee of R100 billion to the scheme and it has indicated there is an option to increase the guarantee to R200 billion if necessary and if the scheme is deemed successful.

The scheme will provide government-guaranteed loans through participating banks to firms with an annual turnover of less than R300 million. The loans will improve business liquidity and help these businesses stay active for the duration of lockdown restrictions and return to being economically productive once all restrictions are lifted. In the longer-term, its objective is reviving the economy and preserving jobs.

How it works

The National Treasury, South African Reserve Bank and commercial banks represented by the Banking Association South Africa, have agreed on the relevant legal framework, and financial and operational requirements.

The National Treasury provides a guarantee to the Reserve Bank, which records the guarantee as a contingent liability on the government's account. The Reserve Bank will then lend the money to commercial banks at the repo rate (currently 3.75%) plus a 0.5% guarantee fee.

Banks will lend this money to qualifying small and medium-sized businesses at the repo rate plus a fixed spread of 3.5%. Each applying business may get only one loan under the scheme and they have five years to repay the loan.

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The Reserve Bank is the administrator of the scheme and it will publish an annual report setting out how much each bank has used from the scheme and the performance (default rate) of each bank's COVID-19 loan portfolio.

The government and commercial banks are sharing the risks of these loans and while the arrangements are designed to encourage banks to lend more than they would otherwise lend, the Treasury still expects banks to make sound lending decisions and avoid reckless lending.

Treasury said the intention is not for the banks to make a profit from the loans. It said any net profits would be pooled to offset losses in the scheme to minimise total losses to SA taxpayers.

Which banks are participating?

Absa, First National Bank, Investec, Mercantile Bank, Nedbank and Standard Bank are accepting loan applications from eligible businesses which bank with them.

Which businesses qualify?

To qualify for the COVID-19 Loan Guarantee Scheme a business must:

- have a group annual turnover of less than R300 million
- have been up to date with its loan payments to the relevant bank or be an account holder without any loans at the relevant bank as at end-February 2020
- have an existing relationship with the bank that grants it the COVID-19 loan
- be registered with SARS
- be financially distressed as a result of the COVID-19 outbreak and subsequent lockdowns

Links

National Treasury <http://www.treasury.gov.za/>

The South African Reserve Bank <https://www.resbank.co.za/Pages/default.aspx>

The Banking Association of South Africa <https://www.banking.org.za/>

Further queries regarding applications should be directed to the individual banks, which are administering the scheme.

However, Business for South Africa would be interested in hearing about any difficulties people may be experiencing in accessing the loan. Please write to them at info@businessforsa.org.

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POCKET GUIDE FOR BUSINESS DIRECTORS OF FINANCIALLY DISTRESSED COMPANIES IN A COVID-19 WORLD

The COVID-19 is a human tragedy of enormous proportions. There will be both short and long-term economic implications as countries continue to grapple with an effective way to limit the spread of the coronavirus and which will allow economies to be kick-started in the near term. Will a recessionary economic climate be the new norm? What restructuring tools are available to promote businesses and jobs? How do directors, business leaders and professionals deal with this ever-evolving situation and the implications it holds for companies.

This guide looks to unpack certain of these perspectives and where the survival of the entity might just feed into opportunities for the restructuring of the corporate and which might lead to a more sustainable outcome.

Werkmans Attorneys has put together this pocket guide.

Download the pocket guide [here](#).

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ENSAFRICA: COMMENTARY ON PTA HIGH COURT JUDGEMENT DECLARING LOCKDOWN REGULATIONS INVALID

On 2 June 2020, Judge Norman Davis handed down judgment in *Reyno Dawid De Beer and Another v the Minister of Cooperative Governance and Traditional Affairs*, declaring the regulations promulgated in terms of section 27(2) of the Disaster Management Act, 2002 unconstitutional and invalid. Judge Davis suspended the declaration of invalidity for a period of 14 days, during which time the Minister of Cooperative Governance and Traditional Affairs, after consultation with other relevant ministers, was ordered to amend the regulations “with due consideration to the limitation each regulation has on the rights guaranteed in the Bill of Rights contained in the Constitution”.

While many citizens are likely to be pleased with Judge Davis’ decision, it is likely, in ENSAfrica’s view, that the judgment will not survive should it be appealed by the government.

Mootness

The application was heard on 28 May 2020, the same day the alert level 3 regulations were promulgated. The alert level 3 regulations had therefore superseded those regulating alert level 4 and, as Judge Davis acknowledged, the alert level 3 regulations had not been placed before him.

In ENSAfrica’s view, the question of the validity of the alert level 4 regulations had, therefore, become moot, and the question of the validity of the alert level 3 regulations could not properly be decided if the attack relating to those regulations were not properly pleaded on the papers.

Rationality

The court correctly noted that the exercise of all public power is subject to a rationality requirement and that the role of a court, in assessing rationality, “is not to determine whether some means will achieve the purpose better than others but only whether the means employed are rationally related to the purpose for which the power was conferred”.

However, in assessing the rationality of the regulations, the court appeared to apply a different standard. At times, the court considered whether a specific regulation was “rational” relative to what was permitted by other regulations. For example, the court held that it was “irrational” for minicabs to be permitted to operate, while hairdressers could not, and for people to be prohibited from visiting their ailing loved ones, while attendance at a funeral was permitted.

Elsewhere, the court appears to have assessed the reasonableness rather than rationality of the regulations. For example, the court held that it would be more appropriate to regulate night vigils, by imposing restrictions on how such vigils can be conducted than to ban night vigils entirely.

In ENSAfrica’s view, this constituted a misapplication by the court of the test for rationality.

A further peculiarity with the courts’ rationality assessment is that the regulations relating to education, the prohibition against evictions, initiation practices, the closure of night clubs and fitness centres, and the closure of borders, were, without explanation, held to be rational.

Declaration of invalidity

The court declared the regulations invalid, with the few exceptions described above, without considering the constitutionality of each regulation. Because the court did not hold that the act of promulgating the regulations was itself unconstitutional, ENSAfrica’s view is that without an assessment of each of the various regulations, a court could not declare the regulations invalid in their entirety.

Conclusion

Various constitutional law experts have expressed views similar to ENSAfrica’s about the prospects of this judgment being overturned on appeal. It is hoped that the appeal will quickly be heard in order to avoid the uncertainty that this judgment has likely created.

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ENSAFRICA: AFRICA REGULATORY INSIGHT

ENSAfrica has put together some insights into the African regulatory environment specifically focusing

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individual countries:

- Angola
- Botswana
- Cabo Verde
- Cameroon
- Chad
- The Republic of Congo
- Eswatini
- Ghana
- Guinea-Bissau
- Lesotho
- Mauritius
- Namibia
- Nigeria
- Rwanda
- Sao Tome and Principe
- Seychelles
- Uganda
- Zambia
- Zimbabwe

Download the regulatory ENSight [here](#).

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AFRICA CDC GUIDANCE ON EASING LOCKDOWN

Widespread distancing measures may not always be feasible, particularly in settings like informal settlements or other crowded urban environments, and/or may cause more harm than benefits through indirect effects on access to healthcare and on livelihoods.

Where access to WASH infrastructure is limited, maintaining appropriate hygiene is likely to be a greater challenge. Where the household composition is large and multi-generational, isolating the sick or quarantining contacts risks requiring individuals to adhere to policies that are not locally feasible. Similarly, where livelihoods are dependent on the informal sector and therefore do not entail access to formal relief measures provided by employers or the state, adhering to public health and social measures (PHSM) is likely to be harder.

Public support for wide-ranging control measures may also be weaker under these conditions, increasing the risks of insecurity and violence in response to measures. These harms are likely to disproportionately affect the poorest and most vulnerable, and therefore to exacerbate existing inequities.

Strategies combining self-isolation, physical distancing and shielding will probably achieve substantial reductions in mortality in African Union Member States. Temporary lockdowns, where socioeconomically acceptable, can help gain crucial time for planning and expanding healthcare system capacity.

Given the likely duration of this epidemic, it is important to plan for easing measures in ways that allow the trajectory of the virus to be controlled.

This document outlines the implications of sustained PHSM, including lockdowns, and aims to provide a framework for easing such measures while ensuring COVID-19 case numbers remain under control. It is aimed at policymakers and public health agencies in African Union Member States.

Download the Africa CDC guidance [here](#).

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WEBINAR: FINDING NEW REALISTIC EXPORT OPPORTUNITIES - COVID-19 EDITION

The NWU's TRADE research focus area and TRADE Research Advisory extend an invitation to the **TRADE-DSM® webinar**.

This will provide non-subscribers with a peek behind the scenes of the TRADE-DSM® and its newly expanded functionality. To assist their users, they worked with some to address requirements for COVID-

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- WCO/WHO COVID PPE products (HS6);
- COVID-19 market (country) indicators such as number of cases, markets impacted from a logistics and lock-down strategy perspective and stringency of lock-down regimes and
- IMF COVID-19 revised GDP forecasts.

Join them for a **webinar** focused providing some direction on where potential opportunities for product-based trade may be emerging, according to the TRADE-DSM®.

When: 10:00 - 11:00, 9 June 2020

Time: 10:00 – 11:00

The Zoom link will be emailed to registered attendees, on Monday (8 June 2020).

RSVP: Email Francois Fouche to confirm your seat: francois.fouche@tradeadvisory.co.za

Please note seats ARE LIMITED.

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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.

[CLICK HERE](#)



REPORT UNLICENCED COMPANIES TO SAHPRA

Several members have contact SAMED about companies trading medical technologies without a SAHPRA Medical Device Establishment License. These companies are trading illegally and it is essential that they be reported to SAHPRA for investigation.

SAHPRA has published a list of licenced companies under documents on their [medical devices page](#) which you can use to check if the company has a Medical Device Establishment License before sending a report. You can download this list as at 26 May 2020, [here](#). Please ensure that you visit the SAHPRA website to obtain updates as this is an evolving list.

Report unlicensed companies by emailing: mokgadi.fafudi@sahpra.org.za

IMPORTANT SAHPRA MEDICAL DEVICE NOTICES

- [MD010_Guidance_Rapidly developed ventilators_26May2020_v1](#)
- [PCR Tests Authorised for Listing by SAHPRA – 19.05.2020Specification 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 IN-VITRO DIAGNOSTICS \(IVDS\) REQUIREMENTS FOR SUPPLY OF MEDICAL DEVICES IN LIGHT OF THE COVID-19 PANDEMIC](#)

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[Subscribe](#)[Past Issues](#)[Translate ▼](#)**SAHpra MEDICAL DEVICE CONTACTS**

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

- 084 220 8037
- 072 993 2273
- 078 281 6334

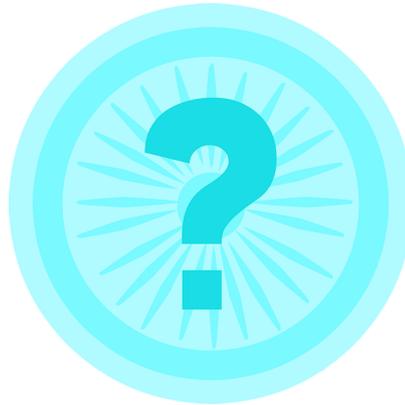
For queries on COVID-19 please email mdcovid.@sahpra.org.za and all other regular medical device queries can be sent to MDnotifications@sahpra.org.za

For general licensing queries: June Searela june.searela@sahpra.org.za / 072 828 2416
 For COVID-19 related applications: Matlapeng Shabalala Matlapeng.Shabalala@sahpra.org.za / 071 302 0409 or
 Khanyisile Nkuku Khanyisile.Nkuku@sahpra.org.za / 081 854 7109

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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.

**What must I do to prepare my workplace and have staff return to work?**

There are now Occupational Health & Safety Measures that all businesses, apart from health facilities and practices, must adhere to. This applies to those who have been supplying essential goods this far, as well as those that may partially re-open from level 4 and down.

Download the directive [here](#)

You can also find useful tools on the [Return2Work website](#).

PARTICIPATE ON B4SA COVID-19 PROCUREMENT PORTAL

The information collected on the B4SA 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.

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.

If you have any questions about the status of your registration, on the types of PPE and medical equipment that B4SA are procuring, if you are struggling to complete your application, or if you have any other queries, please get in touch with the B4SA support team via covid19portal@businessresponsecovid19.co.za. If you are not receiving feedback from the administrators, please check your spam/junk folders.

THE SOLIDARITY FUND

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 EVENTS

PTCMA WEBINAR: INSIGHTS DURING COVID-19

Measuring the impact of COVID-19 on our healthcare environment - what about our economy?

- Where is the Ministerial Advisory Committee (MAC) coming from?
- A vaccine needs to be developed sooner rather than later for COVID-19 but what happens in between?
- Where do we stand with the treatment development for COVID-19?

Date: 5 June 2020, 09:45 - 12:30

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

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OMMIA HEALTH COVID-19 VIRTUAL EXPO

Omnia Health Live are bringing together the global healthcare industry, for the largest virtual gathering ever seen before, a whole new concept planned from the ground up to be more diverse and accessible, **taking place 22-26 June 2020.**

[Join the experience here](#)

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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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