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**COVID-19 news from SAMED, Government and Abroad.**

## COVID-19: ISSUES WITH PERMITS & CIPC

### PERMITS

Elsabe Klinck & Associates has indicated that there have been some cases on the following matters:

- Police stopping company/practice staff saying that the permit has expired, as it refers to regulation 16 and Level 4.
- Documentation required when travelling across provincial borders
- Documentation required when flying for business reasons

**Form 2, Annexure A was not amended** with the insertion of the Level 3 Regulations when the Regulations were published on 28 May. It therefore still refers only to regulation 16 (i.e. the level 4 permissions) and not regulation 33 (level 3 permitted travel).

EKA has now, on their own accord, amended the Form to refer, as it should, to also regulation 33 (but kept the reference to regulation 16, in case any area or the entire country goes back to level 4).

There are two versions:

- [HCPs/practices/facilities](#)
- [Companies \(pharma/devices\)](#)

The Regulations say this on level 3 travel:

*33(4) Movement of persons between provinces, metropolitan areas and districts and hotspots is prohibited, except for—*  
*(a) persons doing so in the course of carrying out work responsibilities or performing any service permitted under Alert Level 3, provided that such person is in possession of a permit issued by the employer which corresponds with Form 2 of Annexure A;*

The above permit should be adequate to get an employee across borders or districts, and the EKA letter should assist. However, make sure that addresses that the employee will visit for work purposes are indicated on the permit. If the person does repairs or has some clinical role to fulfil, some card or certificate of their professional status would also help, if available.

The amended air travel directive reads as follows:

*5 (1) Only employees who work at the airport with a permit, foreign consular and diplomatic agents rendering consular services to foreign nationals, crew and, **passengers** are allowed in the terminal building*

*(5) Passengers are required to provide **written authorisation** or proof of travel, confirming the reasons consistent with direction 5(1)(b)(i) and failure to produce such written authorisation or proof of travel, the passenger shall be automatically denied travel.*

To fly, one requires, not only the permit, but details of the specific work that will be undertaken, and it is recommended to also have a separate letter of the authorisation indicating why travel is needed, and the accommodation arrangements provided.

### NO MORE CIPC

No CIPC certificates are required - the High Court declared those to have not been authorised by the law.

### ANNEXURE E PLAN TO BE UPDATED



## URGENT: COURT ON THE LOCKDOWN - REGULATIONS ARE STILL IN PLACE UNTIL 23 JUNE 2020

### **FINDING & ORDERS**

***Parts of the Lockdown regulations were found to be irrational and not justifiable limitations to constitutional rights. Due to the regulatory void, given that COVID-19 is still with us, the judge ruled that the regulations remain in place until the minister and cabinet review the regulations and their approach to it.***

***The Regulations were declared unconstitutional and invalid, but the order is suspended for 14 business days (until 23 June or longer, if they approach the court).***

### **Here are the main issues addressed in the case:**

- The Court did not accept the argument that the COVID-19 pandemic has been over-exaggerated and accepted that the declaration of the State of Disaster was not irrational (paragraph 4.12).
- It is clear that the Disaster Management Act (DMA) contemplated disaster other than the pandemic, more aligned to natural disasters (paragraph 4.14).
- Despite laudable objectives of the lockdown regulations, the regulations were argued to be unlawful for not getting the approval of the NCOP - the National Council of Provinces in Parliament as many of the issued fall within the competence of the provinces, but this only applied to section 59(4), not section 27(2) (paragraph 5.3 & 5.4).
- In paragraph 6.1 the Court explained that the DMA powers must be exercised for the purposes as set out in the Act, not go beyond what is expressly provided for and be rationally related to those purposes, and where rights are limited, it passes the human rights limitation test it in s36 of the Constitution. In terms of rationality, the measures chosen must be connective to the purpose, i.e. it must achieve such purposes (paragraph 6.4 to 6.6).
- The reply of the Minister to simply state that the “means justify the ends”, without providing any factual information, was not taken too kindly to (paragraph 6.7 and 6.8).
- Judge Davis makes the point in paragraph 7.1. that when one is terminally ill, one’s family cannot visit one, but when one passes away, a funeral with up to 50 people can travel and attend the funeral.
- The contradictions between minibus-taxis (filled to 70% capacity) versus hairdressers were mentioned, as well as whether lesser intrusive means versus total prohibitions (e.g. on vigils) as examples of irrationality (par 7.3 and 7.5). Also on exercise, the Court found that the regulations should rather have said one should not exercise in close proximity of others and not limit areas (e.g. street and not the beach, or times (paragraph 7.7 & 7.9), etc.
- Regulations that were found to pass muster are those on education, evictions, initiation practices, night clubs and fitness centres (paragraph 7.14).
- Little or no regard was had for the impact on individual rights and no evidence was presented to that effect (paragraph 7.17), and the Court described the attitude by the DG was “paternalistic” instead of “constitutionally justifiable” (paragraph 7.18).
- The judge found that in an overwhelming number of instances the Minister has not shown how the limitation of rights was justifiable (paragraph 7.21).
- He did not deal with the tobacco ban - as being before another judge at this time (paragraph 8.2).

Download the findings [here](#).

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Government has taken note of the judgment delivered by the Gauteng Division of the High Court today, 2 June 2020, declaring the Alert Level 4 and Alert Level 3 Lockdown regulations unconstitutional and invalid. The court suspended the declaration of invalidity for a period of 14 days. This means that the Alert Level 3 regulations remain in operation for now.

The court has further directed the Minister of Cooperative Governance and Traditional Affairs, in consultation with the relevant Ministers to review, amend and republish the regulations with "due consideration to the limitation each regulation has on the rights guaranteed in the Bill of Rights". Cabinet will make a further statement once it has fully studied the judgment.

Download the Government notification [here](#).

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## BUSINESS UNITY SA (BUSA) STATEMENT ON ANC ECONOMIC RECOVERY STRATEGY

BUSA, a founding sponsor and affiliate of Business for South Africa today commented on the release of a document by the African National Congress (ANC) about an economic recovery strategy post-COVID-19.

BUSA is of the view that the COVID-19 pandemic has caused a significant upheaval in the global economy and in the SA economy. The SA economy is particularly impacted because we were in a recession and a severe fiscal crisis before the impact of the pandemic. Real GDP grew at an estimated 0.7% in 2019. The fiscal deficit was an estimated 4.3% for that year.

The economy was further battered by Moody's, the only major rating agency that rated us at investment grade, downgrading the sovereign to sub-investment grade during the COVID-19 crisis.

Work done by Business for South Africa estimates a drop in the SA GDP of between 8.8% to 16.1% in 2020. Unemployment could range between 33.1% (narrow definition) to more than 43.9% (broad definition) and the South African Reserve Bank estimates our fiscal deficit could be over 10% of GDP. The economic impact of COVID-19 is thus severe and this is exacerbated by the severe social impact because of the pandemic and the economic lockdown. The pandemic has also made starker the inequalities in our country.

This set of circumstances need a significant rethinking of our economy and measures to resuscitate it post COVID-19. We will need to build an economy that attains sustained growth of beyond 5% and is structured to be inclusive and equitable. This will require the critical stakeholders, particularly government, business, and labour to put aside ideology and dogma to put national interest above all else. However, some fundamental truths remain in any discussion on rebuilding our economy. These are:

- The absolute imperative of getting local and global businesses to invest in SA. This will be extremely difficult in the COVID-19 and post COVID-19 period. The absolute imperative to grow the economy at levels that address the inequalities and is inclusive so that the majority of our people are economically active.
- This means business need to agree on the structural reforms which are critical to enabling investment, growth, and inclusion. It means business must recognise the resource constraints faced, and available resources must be utilised in productive economic and social growth. It means business can only invest in projects that will deliver meaningful social or economic returns.

The ANC document considers some but not all these issues. This document re-surfaces old ideology and dogma of a significantly increased role in the economy for the state, interfering in the mandate and independence of the South African Reserve Bank, supporting ailing and un-strategic state-owned enterprises (SOEs) and creating new ones. In all instances, BUSA calls to persuade society that there is a fundamental and rational basis for any such moves, consistent with an inclusive, mixed, and sustainable economic growth trajectory. BUSA remain convinced the private sector is best placed to stimulate such economic growth, provided the state creates an enabling environment and business and labour reach a constructive compact taking all criteria including inclusivity, affordability, and competitiveness into account.

BUSA is a co-sponsor of Business for South Africa, which is doing a significant amount of work on developing fact-based options for rebuilding our economy, within the context of a fundamental socio-economic recalibration. BUSA will engage government, labour, and other stakeholders on the outcome of

[Statement courtesy of Business Unity South Africa](#)

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### W.H.O. SOLIDARITY CALL TO ACTION

**To realize equitable global access to COVID-19 health technologies through a pooling of knowledge, intellectual property and data**

The single most important priority of the global community is to stop the COVID-19 pandemic in its tracks; to halt its rapid transmission and reverse the trend of consequential global distress. WHO proposed that this goal is only achievable when everyone, everywhere can access the health technologies they need for COVID-19 detection, prevention, treatment and response. Now more than ever, international cooperation and solidarity are vital to restoring global health security, now and for the future.

Toward this aim, WHO calls to action key stakeholders and the global community to voluntarily pool knowledge, intellectual property and data necessary for COVID-19. Shared knowledge, intellectual property and data will leverage the collective efforts to advance scientific discovery, technology development and broad sharing of the benefits of scientific advancement and its applications based on the right to health.

The COVID-19 pandemic has revealed the fallibility of traditional ways of working when it comes to equitable access to essential health technologies. This initiative sets out an alternative, in line with WHO's efforts to promote global public health goods, based on equity, strong science, open collaboration and global solidarity.

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

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### SARS NOTICES ON EXPANDING ACCESS TO LIVING ANNUITY FUNDS - 2 June 2020

- [Notice 618 in GG 43379](#) – Notice in respect of method or formula for purposes of determination of amount for purposes of paragraph (b) of the definition of "living annuity" in section 1(1) of the Income Tax Act, 1962
- [Notice 619 in GG 43380](#) – Notice in respect of the amount of value of assets that may be paid in a lump sum for purposes of paragraph (c) of the definition of "living annuity" in section 1(1) of the Income Tax Act, 1962

The **Notices on Expanding Access to Living Annuity Funds were gazetted on Monday 1 June 2020**. These Notices give effect to the legislative framework required to implement the tax measures in this regard to combat the COVID-19 pandemic, following the President's address to the nation on 21 April 2020 and the announcement by the Minister of Finance on further tax measures to combat the COVID-19 pandemic. Included in the further tax measures was the expansion of access to living annuity funds as outlined in the Treasury's Media Statement published on 23 April 2020.

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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](mailto:mokgadi.fafudi@sahpra.org.za)

## IMPORTANT SAHPRA MEDICAL DEVICE NOTICES

- [MD010\\_Guidance\\_Rapidly\\_developed\\_ventilators\\_26May2020\\_v1](#)
- [PCR Tests Authorised for Listing by SAHPRA – 19.05.2020](#)[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 IN-VITRO DIAGNOSTICS \(IVDS\) REQUIREMENTS FOR SUPPLY OF MEDICAL DEVICES IN LIGHT OF THE COVID-19 PANDEMIC](#)

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## SAHPRA MEDICAL DEVICE CONTACTS

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

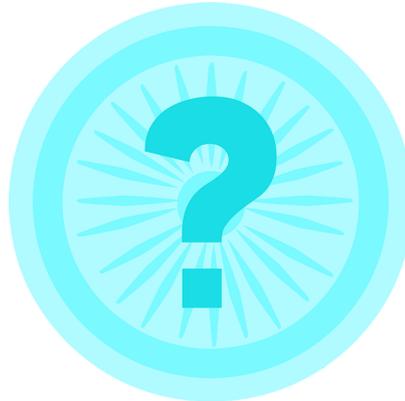
- 084 220 8037
- 072 993 2273
- 078 281 6334

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

For general licensing queries: June Searela [june.searela@sahpra.org.za](mailto:june.searela@sahpra.org.za) / 072 828 2416

## 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](https://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](mailto:covid19portal@businessresponsecovid19.co.za). If you are not receiving feedback from the administrators, please check your spam/junk folders.

SAMED is appreciative of the support and commitment of our members in fighting this pandemic.

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## 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.

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For offers of supply of Medicines and Medical Devices send to [covid19supplies@businessresponsecovid19.co.za](mailto:covid19supplies@businessresponsecovid19.co.za)  
If you are seeking PPE for your hospital, clinic, or NGO please email your request to [covid19requests@businessresponsecovid19.co.za](mailto: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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## COVID-19 DEVELOPMENTS

### TRACKING THE PANDEMIC

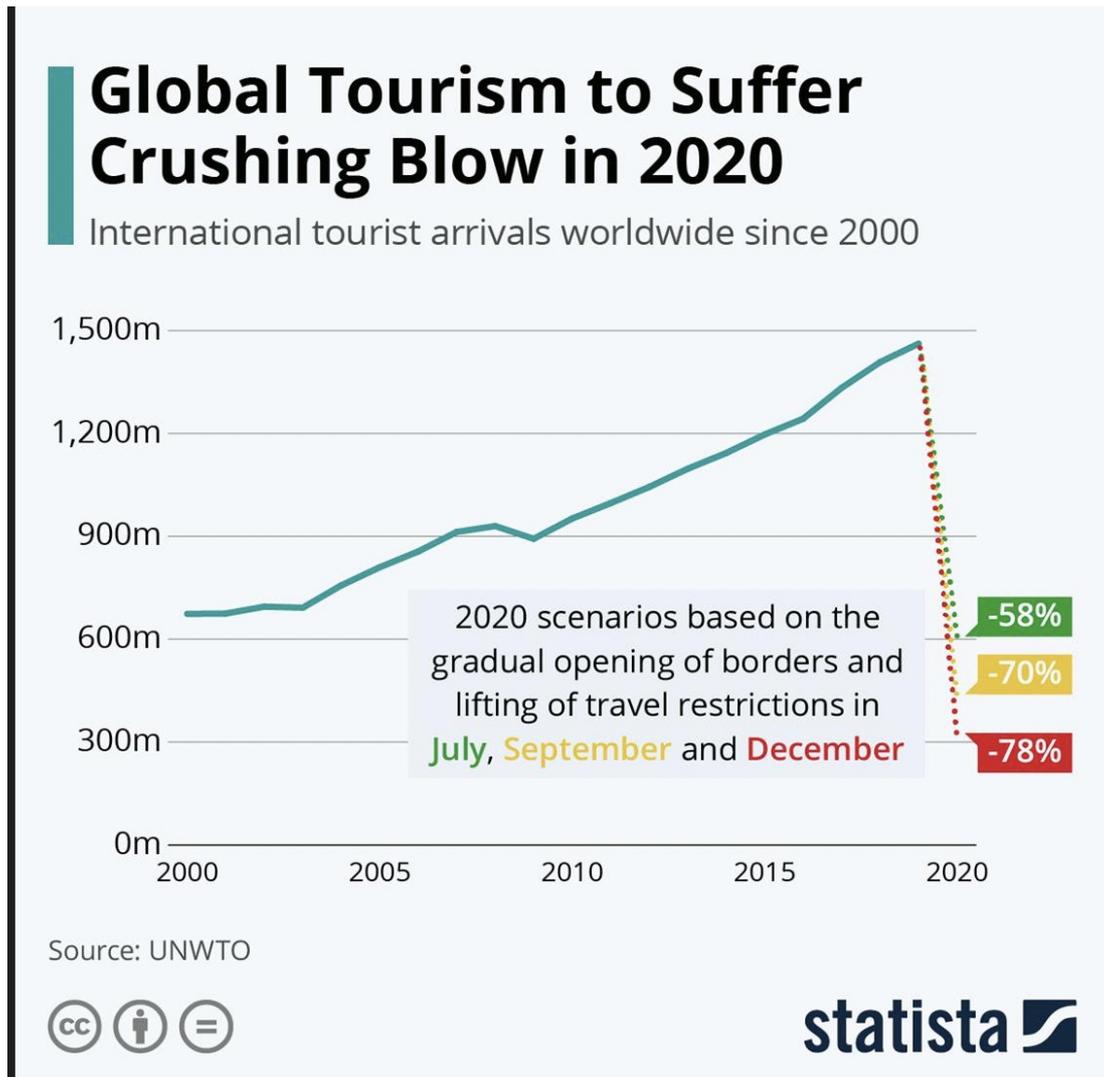


### ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL

- In a [hard-hitting judgment \(download it here\)](#) that found the government had failed to fully consider Covid-19 lockdown regulations, the Pretoria High Court found that while declaring the State of Disaster because of the COVID-19 pandemic was rational, the overwhelming number of regulations are 'unconstitutional and invalid'.
- President Cyril Ramaphosa said the government's response to the COVID-19 pandemic is a building block towards [South Africa's healthcare future under the National Health Insurance programme](#). The government's reliance on a private-public partnership to deal with the coronavirus outbreak adequately prepared the ground for the NHI. "Because of Covid-19, we have had to quickly improve our health system to be ready to serve everyone, regardless of their ability to pay - which is a fundamental principle of the NHI," he said.
- South Africans who cannot afford private healthcare will still benefit from a deal the [government is negotiating with the private sector for COVID-19 beds](#). Speaking at the Sonstraal state facility in Paarl where extra beds had been installed to prepare for a "surge" in COVID-19 cases, Minister Zweli Mkhize said negotiations between the government and private hospital associations would be completed by Tuesday (i.e. yesterday). "What we want to insist on is: We will use the beds in the private hospitals - we have agreed on that. There will also be one protocol, for the patients. So there's no such thing as 'this one will be treated differently because they come from a public hospital [or] they're from a poor community'. Everyone's going to get the same treatment. The negotiations involved one point of agreement only: the price. "Between the national department and the hospital association, our discussion is going to be about the price - how much

positive for the virus don't need hospitalisation, [COVID-19 patients made up less than 5% of Mediclinic's total beds occupancy](#) as at the beginning of June. As a result, Mediclinic has been able to carry on performing other emergency operations and even elective surgeries on limited basis when these were allowed again in May. However, should more people require hospitalisation because of the pandemic, the group would reduce the number of elective surgeries it carries out. Like its peers, Netcare, Life Healthcare and others, Mediclinic is currently in negotiations with the department of health about accepting people without medical aid who would have relied on state hospitals if diagnosed with COVID-19 and needed hospitalisation. Van der Merwe said they would do this only on a cost-recovery basis, meaning private hospitals would not be earning a profit for the beds they avail to the state.

- Mcebisi Jonas, current MTN board chairperson and a former deputy Finance Minister of South Africa, has [published an op-ed in the Daily Maverick](#) (also available for a 22-minute listen). He looks at humanity's challenge of **how to emerge from the pandemic**, and the accompanying economic near-apocalypse, as a much wiser society dedicated to all of its people. As it is not an easy task, we need to be clear-eyed about what we want, and how to achieve it. He speaks of a rethink and zooms in on rethinking: the globe, government, technology, poverty and politics.
- The COVID-19 pandemic is keeping policymakers awake at night. But the challenges raised by the **climate crisis** are not going away even as global CO2 emissions – linked by most scientists to changing weather patterns – have temporarily declined in 2020 because of the economic havoc wreaked by the pandemic and lockdown measures to contain it. "The focus of policymakers globally has shifted to Covid-19, but climate change is still one of the biggest threats facing the world today. It is causing long-term variations in temperatures and weather patterns, threatening everything from food security to national infrastructure," the [South African Reserve Bank's Financial Stability Review \(FSR\) noted](#). The SARB said it was "concerned about two distinct classes of climate risk" – physical risks and those linked to the transition to cleaner, greener forms of energy.



- Nearly half of the employees of [Avis Budget Rent-a-Car](#), part of Barloworld Group [JSE: BAW], will be affected by a **retrenchment consultation process**, according to an internal memo seen by

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- Privately-run regional airline [Airlink will begin operating flights on Monday 8 June](#), with tickets for flights between Johannesburg and Cape Town, as well as between Johannesburg and Durban now for sale. Air travel for business purposes is now permitted under Alert Level 3, after being banned in previous stages of the lockdown. Airlink tickets are available from Monday, 8 June – with one-way flights from Johannesburg to Durban starting at around R1,600, while a ticket between Johannesburg and Cape Town is on sale from R2 200. Airlink starts flying between Joburg, Durban, Cape Town on Monday – with tickets from R1 600.

## CLINICAL, SCIENTIFIC

- [Capetonians younger than 55](#) – who also have no serious underlying medical conditions which may make them vulnerable – **may no longer be tested for COVID-19**. This appears to represent a dramatic change to testing policy and is a recommendation by the Western Cape government's Department of Health, aimed at prioritising testing for those most at risk. Department head Dr Keith Cloete confirmed this to News24 on Tuesday afternoon. He said that the provincial health department had already begun implementing its new policy, along with the City of Cape Town. He stressed that the policy was a "recommendation", and was not binding on all healthcare services, such as private or NGO facilities.
- A private-sector research group called Panda (Pandemic Data Analysis) has strongly [questioned predictions as to South Africa's COVID-19 fatalities](#) that were made by modelling advisors to government. Panda released an open letter to Professor Juliet Pulliam of the South African Centre for Epidemiological Modelling and Analysis (Sacema) calling for the **models used to arrive at COVID-19 death projections to be made public**. These estimates were presented at a [modelling symposium](#) held on 21 May 2020, coordinated by Health Minister Zweli Mkhize. At the meeting, Pulliam gave the projections on behalf of the South African COVID-19 Modelling Consortium (SACMC), which is made up of infectious disease modelling experts from Pulliam's unit Sacema, the National Institute for Communicable Diseases (NICD) and various academic institutions. Panda believes that the current modelling underplays the extent to which age has played a role in the majority of COVID-19 fatalities worldwide.
- As experts around the world are trying to find an effective treatment for COVID-19, many clinicians are [using existing drugs that have already been approved to treat other diseases](#), in the hope that these would make a difference. When an existing drug is repurposed for another disease, it is referred to as being used "off-label". During the past months, media have reported extensively on various drugs being investigated for the treatment of COVID-19, including the Solidarity Trial launched by the World Health Organization in March 2020. Now, [researchers](#) from the Perelman School of Medicine at the University of Pennsylvania have catalogued every known off-label effort by various clinicians since the start of the outbreak. In this process, the **researchers have recorded more than 100 different off-label treatments**, according to the [news release](#).

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