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COVID-19 news from SAMED, Government and Abroad.

POPI, TACK AND TRACE, TRIPS & PMBs

POPI

The **Protection of Personal Information (POPI) Act** was [brought into full force and effect](#) from 1 July 2020. Health sector entities now have a year to make the necessary changes to:

- The necessary **wording** on attendance registers, emails, websites, distribution lists, etc.
- Data, privacy and access to information **policies**, including updating one's PAIA Manual.
- The appointment of an **Information Officer**, and his/her duties.
- **Standard clauses** in all contracts, including contracts of suppliers and employees.
- Amendments to practice forms and templates.
- Assessing types of information and how the Conditions of Processing would apply to it.

TRACK & TRACE

As most of the economy is opening up as part of **Lockdown Level 3 Regulations**, the obligation on employers to ensure that they comply with key aspects of the Regulations, the Occupational Health and Safety Act (OHSA) and the Notifiable Medical Conditions Regulations, is receiving more attention. Most significant, employers have to:

- Undertaken **contact tracking** in cases of COVID-infections, which may include other employees, patients, clients, etc., provide such contacts with direct **communication and advice**; and report the contacts to the NICD on a prescribed form.
- Investigate all COVID-19 related **incidents** in the workplace under the OHSA.
- Update one's **screening form** to also include questions on whether a person has been a close contact of a COVID-19 case, or person under investigation, which includes household cases.
- Clarify and formalise **cleaning protocols** that are (a) routine, (b) frequent and (c) cleaning of areas post a COVID-19 case.

TRIPS

The Department of Trade, Industry and Competition updated Parliament on its programme of **localisation** in June. The **designation of pharmaceutical tenders** for local content, as well as local criteria for PPE were addressed, as part of the legislative mandate to all procuring entities. For copies of the minutes and presentations, please contact Elsabe.

South Africa also participated in the **WTO TRIPS Council**, registering its concern over the lack of implementation of TRIPS flexibilities during the COVID-19 pandemic. Compulsory licensing and local manufacturing formed part of [South Africa's statement](#). This is of increasing importance as the world moves towards more treatments, possible vaccines and local development or importation of medical devices and IVDs.

PMBs

The [CMS's updated COVID-19 as a PMB](#) document (v3) now contains various further delineation of circumstances that would **(not) be funded as PMBs**, including:

- Follow-up treatment and care for any person (symptomatic) who tests negative for Covid-19 (RT-PCR test) as not being PMB care;
- **Routine RT-PCR testing** of asymptomatic, unscreened and un-referred patients which turns out negative is based on scheme rules;
- Routine pre-admission (including elective admissions) RT-PCR testing for asymptomatic patients which turns out negative is based on scheme rules;
- Personal protective equipment (**PPE**) is **not** currently recommended as PMB level of care;
- Off-label medication is not PMB level of care;
- **Serological and point of care testing** for COVID-19 is not currently PMB level of care;

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- Cough suppressants not PMB level of care for COVID-19.

The document also contains clarity on out of hospital **symptomatic medicine** and the applicable procedure- and ICD10 codes.

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ITAC OFFICE CLOSURE: NEW DEVELOPMENTS

Due to new developments relating to the suspected case of COVID-19 at the DTI Campus, the DTIC has arranged to fog and disinfect Block B and Block D. Part of ITAC is housed in Block D. It is expected that the building will be ready on Monday, 6 July 2020. ITAC's services in the Import and Export Control Unit have been affected and the staff will be working from home.

Download the notice [here](#).

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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](#)

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- [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 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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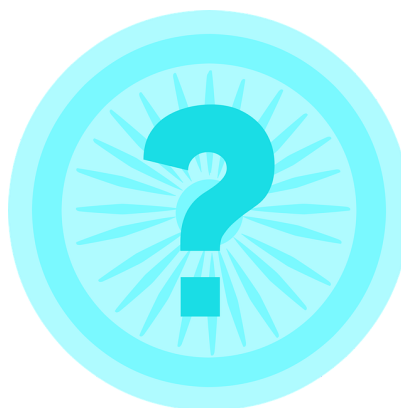
The SAMED Library is a dedicated resource for all COVID-19 related updates, regulations, notices and news.

All SAMED COVID-19 updates and related information can be found here.

[CLICK HERE](#)


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.



PARTICIPATE ON B4SA COVID-19 PROCUREMENT PORTAL

The information collected on the B4SA covid19manager.co.za platform will be used to ensure supplier

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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.

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.

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

WEBINAR: THE MAURITIUS - AFRICA STRATEGY POST COVID-19

On this webinar entitled "The Mauritius – Africa Strategy Post COVID-19", panellists will be called to share insights and views whilst addressing the following questions:

- What is your evaluation of the achievements?
- What are the opportunities remaining to be further seized by the country and by national and international business operators?

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MON TRESOR
MAURITIUS

WEBINAR:
THE MAURITIUS - AFRICA STRATEGY POST COVID

						
L. AMEDEE DARGA <i>Host</i> Managing Partner StraConsult Africa Business Development Services	LILOWTEE RAJMUN-JOOSEERY Director Mauritius Export Association	KEN POONOOSAMY Ag CEO Economic Development Board (Mauritius)	JACQUES D'UNIENVILLE Chief Executive Officer Omnicane Ltd	MONIQUE LABAT Director Monique Labat Consulting (Pty) Ltd	DR. McLEAN SIBANDA Managing Director Bigen Global Limited	SRIDHAR NAGARAJAN Regional Managing Director IQ-EQ

THURSDAY - 09 JULY 2020 | MUR 06:00 PM | CAT 04:00 PM | EAT 03:00 PM

To Register, [click here](#).[Back to top](#)**JOIN SAMED FOR THIS MEMBER FORUM ON BUSINESS SUSTAINABILITY**



PROGRAMME

- 14:00 Opening**
Marlon Burgess, SAMED COVID-19 Working Group Business Sustainability Lead
- 14:10 Maximising UIF/TIERS**
Jonathan Goldberg, CEO, Global Business Solutions
- 14:40 Export as a trade opportunity**
Francios Fouche, Trade Research Advisory
- 15:00 Funding mechanisms and manufacture expansions**
Hawie Viljoen, Chief Director: CIC, the dtic
- 15:20 Ensuring a safe workplace for business continuity**
Jahni de Villiers, Director, Labour Amplified
- 15:30 SEDA PPE & Medical Devices Cluster initiatives for sustainable business**
Andrew Bam, Senior Manager, PAD & Learning, SEDA
- 16:00 Close**

Sessions may be recorded. The link will open 15 minutes before the start of the session. Please turn off your camera and mute your microphone when joining.

Business Sustainability has become a central theme for 2020. COVID-19, the economic downgrade and interruptions in supply/trade has impacted all sectors.

Join us to unpack some of the opportunities to consider in ensuring business continuity and market sustainability.

DATE: 9 JULY 2020

TIME: 14:00 – 15:30

PLACE: Virtual Teams



JOIN VIA THE VIRTUAL LINK PROVIDED

[Click Here to join Microsoft Teams Meeting](#)

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IHRM: Webinar Update on the Impact of COVID-19

IHRM invites you to join them for a webinar on 31 July at 09h00 when Christoff Raath, Joint CEO of Insight Actuaries and Consultants, will provide an updated analysis on the Impact of COVID-19 on Medical Schemes and Private Hospitals, as South Africa reaches the peak of the pandemic.

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

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COVID-19 EVENTS

TRACKING THE PANDEMIC

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108,001	18,728	Fatalities	1.89%	81,999	
Active Cases	Relative to Population	2,844	Relative to Population	Total Tests	
83,218	0.2859%		0.004839%	1,706,127	
Gauteng	Western Cape	KwaZulu Natal	Free State	Eastern Cape	Limpopo
49,937	65,841	11,669	1,886	30,603	1,286
					1,478
					4,788
					573
Daily Increase					
3,993	1,464	1,037	214	1,263	111
					172
					395
					79

Over 160,000 coronavirus cases reported every day in past week, a record: WHO

- The global coronavirus pandemic is accelerating, the World Health Organisation said on Wednesday, with the number of daily cases surging beyond 160,000 every day in the past week, a record.
- Data provided by the UN health agency showed that the highest number of new daily COVID-19 cases ever recorded came on 28 June, when more than 189,500 new cases were registered worldwide.
- With over 511,000 deaths and more than 10.5 million known infections worldwide, the coronavirus pandemic is "not even close to being over", the WHO warned.
- "Find, isolate, test and care for every case, trace and quarantine every contact, equip and train health workers and educate and empower communities to protect themselves and others. Not testing alone. Not physical distancing alone. Not contact tracing alone. Not masks alone. Do it all."
- Countries that have implemented a wide range of measures, including contact tracing, isolation, physical distancing and mask-wearing "have suppressed transmission and saved lives".

CLINICAL, MEDICAL, SCIENTIFIC

How close are we?



Masuku: Gauteng hospitals not full and not turning COVID-19 patients away.

- Gauteng Health MEC Bandile Masuku said that while the department was feeling the pressure of new COVID-19 infections, it was not true that hospitals in the province were full. A WhatsApp message has been making the rounds that Gauteng hospitals have started turning COVID-19 patients away.
- Masuku said that the province had started equipping public hospitals like the Chris Hani Baragwanath Hospital with more beds using alternative building technology. He said that to deal with the shortfall, the province had activated field hospitals such as the one at Nasrec where more beds would be stationed.
- "So we have not yet got to the point where we are turning patients away, we're trying by all means to accommodate them."

'We are not guinea pigs,' say Covid-19 anti-vaccine protesters in Joburg

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over Africa's first human trials for a potential coronavirus vaccine. The involvement of South Africa in vaccine trials is intended to ensure the continent will have access to an affordable vaccine and not be left at the back of the queue.

- About 50 people held protests at the University of the Witwatersrand in Johannesburg, saying they did not want Africans to be used as guinea pigs, reflecting concerns among some on the continent over testing drugs on people who do not understand the risks.
- "I'm not happy at all! I mean this feels like the 1980s all over again when the AIDS pandemic just broke out in South Africa," said 29-year-old graphic designer Tebogo Legoale.

Cipla to bring Covid-19 treatment remdesivir to SA

- Indian drug manufacturer Cipla is set to bring its generic version of Gilead Science's coronavirus drug remdesivir to SA within the next few weeks, it emerged on Thursday. Remdesivir is the first drug to have been approved by US authorities to treat COVID-19 and has been shown to speed up the recovery of hospitalised patients.
- Cipla plans to sell the drug at \$55 a shot, or \$330 (R5,600) for a five-day course, according to Cipla SA CEO Paul Miller. This is considerably lower than the \$520 a vial price tag Gilead has set for US patients with private insurance. Patients start with a double dose on the first day and then go to a vial a day.

Med scheme support sought for distressed private practitioners

- COVID-19 has slashed patient numbers, leaving many private doctors in financial distress and worsening patient health outcomes writes **MedicalBrief**. While private health offers to help the state have "elicited little traction" a novel plan for medical scheme emergency funding for private practices could be the solution, says advocacy group **PHF**.
- **SA Medical Association** figures show that private practices in **Gauteng** had a 60% average decline in patient numbers during the hard lockdown whilst some specialists like ophthalmologists, ENTs and dentists effectively shut down. Since the introduction of Level 3, patient numbers have increased, but they are still 40-50% lower than normal.
- The **Progressive Health Forum (PHF)**, a national advocacy group, said in a statement that COVID-19 pandemic poses an "existential danger" that necessitates "the mobilisation of all the country's healthcare resources ... to comfort and care for an increasingly anxious populace facing an unprecedented and devastating plague".
- All the major representative organisations of the medical profession – the **Progressive Health Forum (PHF)**, the **SA Medical Association (Sama)**, **SA Private Practitioners Forum (SAPPF)**, **SA Medical and Dental Practitioners (SAMDP)**, the **Radiological Society of SA (RSSA)** and the **Independent Practitioner Associations Foundation (IPAF)** – "insist that only an integrated public and private sector approach can provide the best healthcare response to COVID-19".

Deaths in SA rise significantly higher than predicted - SAMRC report

- The national number of deaths for the period 1 January 2020 till 23 June 2020 has increased and is significantly higher than the predicted number, based on historical data. According to a report prepared by the South African Medical Research Council (SAMRC), the number of deaths from natural causes is also significantly higher than the predicted number.
- The number of deaths from unnatural causes, however, such as road traffic fatalities and homicides, was slightly below the predicted number.
- "While the number of deaths from natural causes of persons aged 1 to 59 years has increased in the week ending 23 June 2020, the number of deaths of persons 60 years and older has become significantly higher than predicted.
- "Between 6 May and 23 June 2020, there has been an excess of 4 039 deaths from natural causes of persons," said the SAMRC.
- So far, COVID-19 related illnesses have claimed 2 657 lives in the country. The majority of deaths are in the Western Cape.

New ICU ward at Charlotte Maxeke could change Gauteng's Covid-19 trajectory

- A new 29-bed ICU ward at Charlotte Maxeke Johannesburg Academic Hospital is expected to double capacity and change Gauteng's trajectory as it deals with COVID-19 patients, according to Professor Mervyn Mer, the clinical head of critical care and the adult multi-disciplinary intensive care unit. "What this particular project has done is change the number of beds available, virtually doubling them from a general intensive care perspective.
- "We turn over about 2 500 critically ill patients a year across a variety of spectra," he said. This will allow us to expand that and offer patients the opportunity of having critical care services when they are severely ill and reliant on life support devices. Many of those patients we are salvaging." He

[Subscribe](#)[Past Issues](#)[Translate ▼](#)[Western Cape's Covid-19 peak could be 'flatter, longer', but that's good news for bed capacity](#)

- The Western Cape's COVID-19 "peak" is likely to be flatter than first expected, but will also last for longer, which could mean the Western Cape may no longer run out of hospital beds. This was reported on Thursday in a briefing by Western Cape Premier Alan Winde, and top experts in the province's team.
- Winde explained the first estimates about hospital beds expected to be required had been based on information available in April. "These projections could not be based on real data in the province, as there simply wasn't enough cases in the Western Cape and South Africa at the time. It, therefore, looked at international trends, our population size, and factored in reasonable epidemiological assumptions.
- "Once the number of cases climbed in the province, and we had more data available to us, we again looked at our provisioning scenarios and checked whether it was still reasonable to follow these original projections."

[Netcare sets up free-standing mortuaries at some hospitals](#)

- The Netcare hospital group have set up "free-standing" mortuaries at some of its hospitals to ensure the safety of health and funeral parlour workers, this as COVID-19 numbers continue to exponentially rise in South Africa.
- Coastal director for Netcare's Hospital division Craig Murphy on Thursday said: "We have, as a precautionary measure, recently acquired free-standing mortuaries at a number of our hospitals in case funeral parlours find themselves in a position where they cannot promptly collect deceased patients from our hospitals. Our hospitals, therefore, have arrangements in place with a number of private funeral parlours to collect deceased patients from our hospitals, in consultation with their families and based on their preference of funeral parlour."
- He said they aimed to ensure hospital and funeral parlour workers were not compromised. "To ensure that the health of those who handle COVID-19 deceased patients at our hospitals and funeral parlours will not be compromised, we adhere to Netcare's comprehensive precautionary guidelines for the management of deceased COVID-19 patients, which are aligned to guidance by the Department of Health."

[Mkhize: Invasive ventilation of COVID-19 patients should be avoided if possible](#)

- Ventilating COVID-19 patients is not always in their best interest, according to Health Minister Dr Zweli Mkhize who said that despite the fast-growing number COVID-19 patients in South Africa, the current treatment protocol evidence supported the avoidance of invasive ventilation strategies as far as possible. The avoidance of ventilation was among the newer clinical management protocols. "We soon expect the **ministerial advisory committee on COVID-19 to issue advisories on the use of high-flow oxygen for patients who are very ill but can be managed without intubation and ventilation.**" The minister also explained another of the new treatment protocols that was showing success: the prescription of **dexamethasone**. This, he said, "has shown that deaths can be reduced by a third for patients on ventilators and can also help patients who only need supplemental oxygen". The **NICD looked at 10,700 COVID-19 admissions** from 269 facilities across South Africa, of which 71 were in the public sector and 198 in the private sector, between 5 March and 21 June.
- These were among the **key findings of the study**: the median age of COVID-19 admissions was 50, with 338 (3%) admissions in patients younger than 18 and 1,386 (13%) older than 70; 54% of people admitted were female; among 8,245 (77%) patients with data on comorbid conditions, 2,810 (34%) had one condition and 3,126 (37%) had two or more; of the 5,836 patients with comorbidities, the most commonly reported were hypertension (3,419 or 59%) and diabetes (2,813 or 48%); there were 1,116 (19%) patients admitted with HIV, 240 (4%) with active tuberculosis (TB) and 579 (10%) with a previous history of tuberculosis; and obesity was noted by clinicians as a risk factor in 297 (3%) patients. NICD's informative weekly report from 20 June 2020 can be accessed [here](#).

[CBC and other outlets report on new data on possible immunity](#)

- "A closer look at people who tested positive for COVID-19 but never developed symptoms has found that such asymptomatic carriers have few to no detectable antibodies just weeks after infection, suggesting they may not develop lasting immunity.... There's growing evidence that a significant proportion of people who test positive for COVID-19 never show symptoms, although it's **not clear what percentage** of people that is and **what role they play** in spreading the disease." The information comes from a study published in [Nature](#) which "followed 37 people in Wanzhou District in China who did not show any outward signs of the disease, despite testing positive when their respiratory tracts were swabbed and being kept in hospital for observation."

ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL[Lockdown: Public concern about the rise in violence following lifting of booze ban, survey finds](#)

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- The biggest concern facing the country remains the fear of contracting COVID-19 (22% of those surveyed).
- As the economy reopens, economic opportunities resurface and the prospect of unemployment and a loss of income decreases, thereby bringing some hope to a few respondents.
- Concerns about food shortages remain the second biggest concern among respondents.
- Data suggests this social issue has strong ties to alcohol consumption. At the same time, reckless behaviour is assumed to lead to an increased spread of the virus in our societies.

How to make working from home better for the Earth

- Working from home has reduced carbon emissions— that much is clear. And while this state of affairs won't go on forever, with offices around the globe starting to reopen, some companies won't return to normal. Instead, they will implement long-term work-from-anywhere policies.
- So that will make a bit of difference once the pandemic recedes, and is one of the few silver linings in this public health catastrophe. Telecommuting eliminates the air pollution from your actual commute, paper and plastic waste from your to-go cups, and many other climate-unfriendly derivatives of the workaday world.
- Transportation before the novel coronavirus contributed about one-quarter of global emissions. Daily US carbon emissions, it turns out, were down 15% from March to early June.
- Here are little things to do at home that make a difference. Washing clothes in cold water or putting dishes in the dishwasher is often more energy-efficient than hand washing. Buying toilet paper made from more recycled content can have a lighter impact on the planet than the fluffier stuff, which is often made of virgin wood pulp from trees.

ON THE LIGHTER SIDE

Labia Theatre offers independent films online

- One of Cape Town's most iconic independent cinemas, The Labia Theatre, has launched an at-home video-on-demand streaming platform to allow for simulcasting its curated new releases to both cinema screenings and home viewers. The streaming service launched today and will be available to all South Africans who have the infrastructure to support streaming video.
- This move is one of many innovative responses traditional businesses have had to make, due to the COVID-19 lockdown. Cinemas across the country temporarily suspended operations on 23 March, and today marks the 100th day most cinemas remain closed.
- This value proposition is for those who want to see independent films, which will likely not make their way to Netflix and Showmax as the larger theatrical releases eventually do.
- Opening films on the service are *Portrait of a Lady on Fire*, *Clouds of Sils Maria*, *Tracks*, *Elle*, and *Cold War*.

Proudly South African launches new commercial encouraging South Africans to buy local featuring John Kani and filmed in Johannesburg and Alex

- <https://youtu.be/sdyj05fjtuQ>
- [#BuyLocalToCreateJobs](#) [#ProudlySouthAfrican](#)

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SAMÉD 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. SAMÉD's members include individual medical technology companies, associate members and associations.

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