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COVID-19 news from SAMED, Government and Abroad.

EXCLUSION OF CERTAIN ALCOHOL-BASED HAND-RUBS FROM THE OPERATION OF SPECIFIC PROVISIONS OF THE MEDICINES & RELATED SUBSTANCES ACT

The Minister of Health, as supported by SAHPRA, has published provisions from which Category A medicines in class 13 or 20, consisting of alcohol-based hand rubs use or purporting to be suitable for the use to prevent or treat infection within a health establishment as defines in the National Health Act or other high-risk environments are excluded.

Download the notice [here](#).

[Back to top](#)

PRODUCT REQUEST: RFQ 2 CRANK HOSPITAL BED

Please contact Vuyisani Bill (vuyisani@mashigebill.co.za or 072 511 5686) directly should you have stock of the below specifications product:

Description

2 Crank Manual Hospital Bed

- Hospital Bed – Manual universal bed with folding side

Function

Head and leg power adjustment

- Head 0.75
- Legs 0.40

Additional specifications

- Locking swivelling castors
- Patient weight capacity – 182 KG
- Net weight 108 KG

[Back to top](#)



BUSINESS FOR SA | COVID-19

BUSINESS FOR SA GUIDANCE NOTE: ALERT LEVEL 3 REGULATIONS

This note serves to outline the present regulatory framework pertaining to AL3 and to highlight the likely areas of interest or concern for B4SA members.

Since adopting a risk-adjusted strategy to COVID-19, the South African government has gradually lifted restrictions on economic activity by promulgating new [regulations](#) in terms of the Disaster Management Act, 2002 (the regulations), amending the regulations on 28 May and 25 June 2020, and issuing several sector-specific directions to manage the safe reopening of the economy.

As amended, the Regulations are structured in three broad parts:

1. general measures governing the national response to the state of disaster in overarching terms;
2. a chapter setting out the law applicable under Alert Level (AL) 4; and

The Minister is empowered to determine which of ALs 1 – 5 applies at national, provincial, metropolitan or district level or in a “hotspot”, and the Regulations provide for different ALs to apply to different areas. Conceivably, therefore, areas with higher levels of infection and less capacity in their health facilities may revert to AL4 or AL5. Thus far, however, there is no indication that this will occur. Any shift to a different AL in any area is enforceable only after the Minister has published a notice to that effect in the Government Gazette. If that happens, different regulations will be applicable in different geographical areas. Business for SA encourages the business community to continue to be aware of that possibility, and of the possibility that the Regulations will continue to be amended and supplemented from time to time as the situation unfolds.

To read the full guidance note, [click here](#).

[Back to top](#)

B4SA COVID-19 RESPONSE (12-26 JUNE)

The Latest Gap Analysis - Private Sector Supply

The latest private sector gap analysis suggests there are 10 drugs with supply gaps. You can view the 10 drugs in the update below. If you are able to address these reported gaps please contact Sandri Yssel on Sandri.Yssel@iqvia.com

The Latest Gap Analysis - Public Sector Supply

The latest public sector gap analysis suggests there are 20 drugs with supply caps. This analysis is based on the NDoH updated demand forecasts against the committed supply from its contracted suppliers. You can view the 20 drugs in the update below. For those able to address these reported gaps, please contact Khadija Jamaloodien on Khadija.Jamaloodien@health.gov.za and cc Sandri Yssel on the details above.

Amendments of Regulations: Export to Neighbouring Countries

B4SA are delighted to note that the requirement for an export permit for medicines to neighbouring countries Botswana, Swaziland, Namibia and Lesotho have been lifted. This will significantly reduce the administrative burden on exporters.

Download the B4SA update [here](#).

[Back to top](#)



COVID-19 WEBINAR: LET THE CHILDREN HEAR THEIR SAY

COVID-19 and the general response to it (lockdown and school disruption) has impacted on the social wellbeing and mental and physical health of everyone, especially children.

The socio-economic fall out will be felt by children as caregivers may lose income, contract the disease, possibly be quarantined or succumb to the virus. Despite this, the voices of children are hardly ever heard.

Their fears, hopes and bewilderment remain unheard and in the margins. Parents may be unwittingly failing to engage in important conversations with their children.

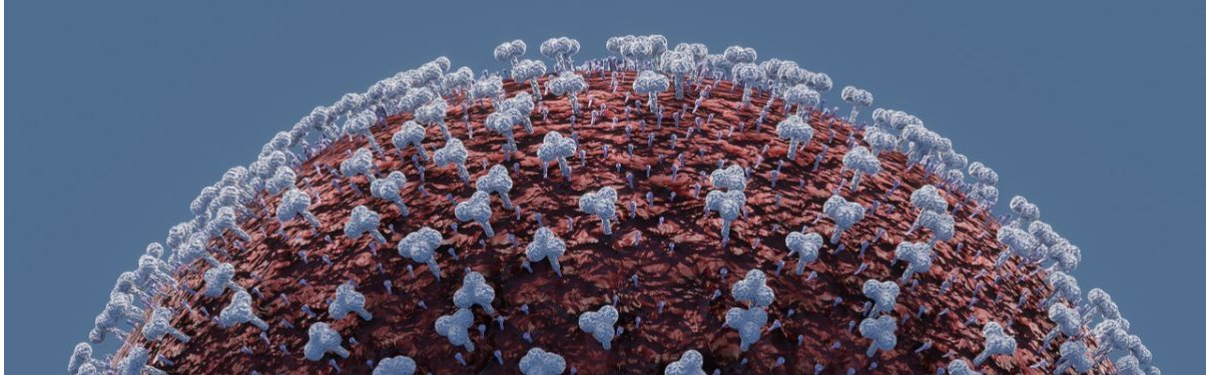
In this COVID-19 Connect Conversation, there will be a panel of experts in children affairs - the children themselves. Pharma Connect Africa will host an open forum and invite parents to sit with their children and listen as children talk to other children about their current experiences. Pharma Connect Africa will also have psychologists on hand to guide the conversation.

When: Thursday 2 July 2020, 14.00 – 15.30 CAT

Who: This meeting is open to any company, organization or individual

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Password: 524534

Download the invitation [here](#).[Back to top](#)

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 – 19.05.2020 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](#)

[Back to top](#)

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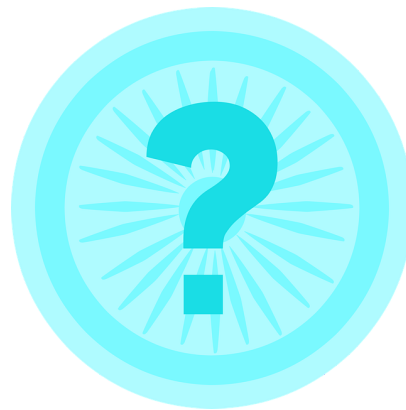
The SAMED Library is a dedicated resource for all COVID-19 related updates, regulations, notices and news.

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 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.

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

[Back to top](#)

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

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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

[Back to top](#)

COVID-19 EVENTS

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[Join Zoom Meeting](#)

Meeting ID: 847 2062 8857

Password: 524534

Download the invitation [here](#).

[Back to top](#)

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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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