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COVID-19 news from SAMED, Government and Abroad.

CALL FOR COMMENT: ITAC AMENDED GUIDELINES FOR REBATE ITEM 412.11(a)

ITAC started issuing rebate permits from 30 March 2020 onwards, which certificates were valid for a period ending on 31 May 2020. Given significant levels of imports of critical goods under Rebate Item 412.11(a) and increases in domestic production, the rebate certificate programme was not renewed and came to an end on 31 May 2020.

The Covid-19 pandemic in South Africa is ongoing. To combat the pandemic, there still may be a need to import critical goods that may be in short supply domestically. It is for this reason that ITAC is considering again issuing rebate certificates under Rebate Item 412.11(a). It is for this reason that ITAC is also publishing draft Amended Guidelines for notice and comment.

ITAC has identified certain critical goods for which domestic production may be insufficient to meet anticipated demand and which would, therefore, be eligible for rebate certificates. These goods are identified in the notice. The Amended Guidelines contemplate a process whereby potential importers of goods must first consult with domestic manufacturers of the goods in questions to see if these manufacturers can supply them. Only where it has been demonstrated through engagement with domestic manufacturers that there is an insufficient domestic supply of a good, will ITAC consider issuing rebate certificates.

It is anticipated that the rebate certificate programme will be in effect from July 2020 to September 2020.

We encourage affected members to make comment by the deadline 29 June 2020.

- Comments must be submitted electronically.
- **"Amended Guidelines for Rebate Items 412.11(a)"** in the Subject line of the e-mail

Please submit comments to Alexander Amrein, Senior Manager: Policy and Research on aamrein@itac.org.za

Download the amendment [here](#).

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DISASTER MANAGEMENT TAX RELIEF BILLS

SARS has issued the amended Tax Relief Bill and Tax Relief Administration Bill under the Disaster Management Act. These are in relation to the Minister of Finance's Supplementary Budget Review.

Download the Supplementary Budget Speech by the Minister of Finance [here](#).

Access the Budget Review [here](#).

Disaster Management Tax Relief Bill [here](#).

Download the Disaster Management Tax Relief Administration Bill [here](#).

You can also view the [Memorandum of Objects of the Disaster Management Tax Relief Administration Bill, 2020](#)

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SANCD A REQUEST FOR HUMANITARIAN ASSISTANCE

For nearly three months, since late March 2020, the SANCD A has hosted a diabetes helpline during COVID-19 pandemic. The purpose of the helpline is to empower people living with diabetes to stay

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Since then, the scale of the pandemic has increased, and the enormous impact on people living with diabetes is what we expected. A vital aspect of a person's blood glucose control is self-monitoring using the correct equipment. These include glucometer, the right strips for the meter and lancets. There are problems with supplies in both the public as well as the private sector.

SANCDAs request a humanitarian donation of glucose meters and test strips for those in need who do not have control of their condition and urgently need to do so. If you are able to assist, please contact Dr Vicki Pinkney-Atkinson directly.

Download the call for aid [here](#).

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BUSINESS FOR SA | COVID-19

INVITATION TO B4SA ZOOMCAST: THE EFFECTS OF COVID-19 ON MENTAL HEALTH IN BUSINESS

How should Business respond to the mental health challenges related to COVID-19?

As we return to work, business owners, CEO's, managers, and employees are facing the prospect that a business-as-usual approach is no longer viable. It is not just about putting in place the practical requirements of social distancing and hygiene, it requires addressing the psychological impact of the virus in the workplace.

Employees are fearful of returning to work, not only because they may become infected on their way to work, in boardrooms or in their normal work scenarios, but also because of stigma, confusion in respect of new workplace policies and intra-workplace relations.

Please join B4SA for a webinar to discuss these challenges, and how to address them. This session will also touch on international learnings, re-imagining the workplace setting and why, in these unprecedented times, mental health should be a priority for companies large and small.

Date: Tuesday, 30 June 2020
Time: 12h00 - 13h00
Dial in: Zoom: <https://us02web.zoom.us/j/4459725244>
R.S.V.P.: Dani Cohen, dani@prologconsulting.co.za / 082 897 0443
 Sandra Sowray, sandra@prologconsulting.co.za / 079 167 6863
 Yamkela Njingolo mazulu@madamnji.com / 071 252 3400

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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.

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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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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

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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.

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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

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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