



SASA COVID-19 **UPDATE**

Statement:

Vaccinations and Ivermectin use in critically ill patients with COVID-19 infection.

The Critical Care Society of Southern Africa (CCSSA) and The South African Society of Anaesthesiologists (SASA), two professional organisations representing many practitioners involved in the management of critically ill patients with severe COVID-19 infection, raise their concern with the large numbers of patients requiring critical care especially in provinces such as Gauteng. Their concerns are further escalated by several Society members highlighting that many patients under their clinical care in the 3rd wave have not received the COVID-19 vaccination, whilst a large majority of these patients have been treated with Ivermectin.

The current COVID-19 pandemic has had a massive impact on the medical and scientific community. The collaborative work by many role players has seen the rapid and safe development of vaccines against the SARS-COV-2 virus, an amazing achievement in a limited time. Vaccinations, together with stringent public health measures, remain the most crucial steps of our response to the COVID-19 pandemic.

Whilst there has been much debate around vaccination options and effectiveness, current evidence clearly points to the need for as much of the population to be vaccinated against the SARS-COV-2 virus as possible. Despite initial challenges in the roll-out of the COVID-19 vaccination programme in South Africa, the programme is expanding, and members of the public are encouraged to get vaccinated urgently. There is no substitution for vaccination.

CCSSA and SASA are also deeply concerned that many patients and their families view treatment with Ivermectin as an alternative to getting vaccinated.

Ivermectin has been plagued with controversy since the initial consideration of its possible role in the management of COVID-19, with advocates both for and against its use. Many anecdotal reports are circulating in the press and social media as to the drug's effectiveness with it being erroneously seen as a "miracle cure." Such assertions have been based on poor quality evidence, including studies such as the recently retracted Egyptian study that purported to show very positive outcomes, only to be subsequently found to be fraught with allegations of scientific fraud and plagiarism.

As with all interventions that are applied in clinical care, careful consideration needs to be given to the body of evidence available to evaluate effectiveness and harm in relation to therapies.

The recent updated South African National Department of Health Rapid Review Report on Ivermectin for treatment of COVID-19 describes a well-conducted, detailed evidence review of clinical benefits and harms of ivermectin with or without other medicines for patients with

COVID-19. The report highlights that the available randomised controlled trials have considerable differences with respect to interventions and comparator groups, and many suffer from significant methodological limitations that limit the confidence in any conclusions that can be drawn. The current evidence for the use of ivermectin in COVID-19 does not suggest any clear benefits with respect to mortality, clinical improvement, or viral clearance.

This was followed in this week's clarification by SAHPRA CEO Biotumelo Semete-Makokotlela that "Ivermectin should not be used routinely in the management of any stage of Covid-19, except in the context of sufficiently powered Randomised Clinical Trials (RCTs), with well-defined study endpoints intended for regulatory marketing authorisation."

CCSSA and SASA are supportive of this recommended approach currently while further trials are awaited. We do not recommend the use of Ivermectin for either prophylaxis or therapy in patients with COVID-19 outside of an ethically approved formal study.

Additionally, a major mutual protection organisation for healthcare professionals recently cautioned practitioners who are considering prescribing Ivermectin to be aware of the potential pitfalls in doing so, as this could have implications for practitioners' indemnity if specific stipulations are not followed. Healthcare practitioners are urged to heed this caution.

This statement is based on the current best evidence available regarding Ivermectin, vaccinations and COVID-19 infections, and will be reviewed as and when new evidence emerges.

EVDS Vaccine Registration Portal: <https://vaccine.enroll.health.gov.za/#/>

END

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CCSSA

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