



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



INTERNAL MEMO

Date:	16 February 2021		
To:	Minister ZL Mkhize, Honorable Minister of Health	From:	Ministerial Advisory Committee (MAC) on COVID-19

SECOND FOLLOW-UP ADVISORY ON IVERMECTIN

Problem Statement

On 7 January 2021, the MAC on COVID-19 submitted an advisory on ivermectin recommending:

- Until more robust evidence is available, the routine use of ivermectin for either the prevention or treatment of COVID-19 is not justified.
- Nonetheless, emerging evidence must be actively sought and carefully reviewed. Reports of clinical trials of ivermectin for the prevention or treatment of COVID-19 must be closely watched, as they become available. As always, reports in peer-reviewed publications will be preferred.

On 20 January 2021, a pre-print of a systematic review and meta-analysis of randomized control trials of ivermectin to treat SARS-CoV-2 infection (Hill, *et al.*) concluded that while there were some promising trends in smaller studies, there is still insufficient evidence to justify the use or regulatory approval of ivermectin.

Consequently, on 21 January 2021, the MAC on COVID 19 submitted an updated advisory with the following recommendations:

- The new evidence confirms that more robust evidence is needed. Hence, the routine use of ivermectin for either the prevention or treatment of COVID-19 is not recommended at this time.
- Clinical investigators in South Africa are encouraged to conduct rigorous randomised controlled trials in order to provide the evidence needed on ivermectin.

Evidence review

On 25 January 2021, the National Essential Medicines Committee COVID-19 subcommittee released the results of a rapid review of ivermectin^{1,2} (including those in pre-print format) regarding the use of ivermectin with or without other medicines for patients with COVID-19 and concluded the following:

1. The available randomised controlled trials have considerable heterogeneity with respect to ivermectin and comparator groups and suffer from significant methodological limitations that limit the confidence in any conclusions that can be drawn.
2. There is currently insufficient evidence to recommend ivermectin for the treatment of patients with COVID-19.
3. Further evidence is anticipated in the forthcoming weeks and will be incorporated accordingly.

The South African Health Products Regulatory Authority (SAHPRA) also conducted a review of new emerging data and came to the same conclusion as the independent NEMLC review group. SAHPRA has a team of expert reviewers to review any new data on the use of ivermectin for the prevention and treatment of SARS-CoV-2 infections, which are expected to become available in the forthcoming weeks and months.

On 28 January 2021, SAHPRA introduced a compassionate use access programme *via* the legal framework of Section 21 of the Medicine and Related Substances Control Act (No. 101 of 1965 as amended). Clear guidance on how this access programme works has been published by SAHPRA.³

On 4th February 2021, Merck, known as MSD outside the United States and Canada, affirmed their position regarding the use of ivermectin for SARS-CoV-2 infections.⁴ Their analysis concluded:

1. There is no scientific basis for potential therapeutic effect against COVID-19 from pre-clinical studies;
2. There is no meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease;
3. There is a concerning lack of safety data in the majority of studies reviewed and available.

Recommendations

- Based on the limited evidence available, the use of ivermectin for the prophylaxis of SARS-CoV-2 infections is not recommended at this stage.
- Support for ivermectin as a treatment option of SARS-CoV-2 infections is not justified until further and robust evidence is available.

¹ http://www.health.gov.za/wp-content/uploads/2021/01/Rapid-review-of-Ivermectin-for-prophylaxis-of-COVID-19_25January2021.pdf

² http://www.health.gov.za/wp-content/uploads/2021/01/Rapid-review-of-Ivermectin-for-COVID-19_25January2021.pdf

³ https://www.sahpra.org.za/wp-content/uploads/2021/01/Section_21_Ivermectin_Controlled_Compassionate-Use-Programme_Jan21_FINAL.docx.pdf

⁴ <https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/>

Thank you for consideration.

Kind regards,



PROFESSOR SALIM S. ABDOOL KARIM



PROF MARIAN JACOBS

CO-CHAIRPERSONS: MINISTERIAL ADVISORY COMMITTEE ON COVID-19

DATE: 16 February 2021

CC:

- » **Dr S Buthelezi (Director-General)**
- » **Dr T Pillay (Deputy Director-General)**
- » **Incident Management Team**