

Ivermectin Proponents Celebrate South African Court Victory



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The civil rights organization AfriForum and Dr George Coetzee today achieved a further success in the South African struggle for access to the antiparasitic drug ivermectin off-label for the indication of SARS-CoV-2, the virus behind COVID-19. TrialSite has covered this unfolding legal saga with far reaching societal implications, when the settlement for the compounding of and access to ivermectin with the South African Health Products Regulatory Authority (SAHPRA) was made an order of court.

What does the Court Order Mean?

This court order determines that a medicine containing ivermectin as an active ingredient has been registered by SAHPRA on 16 March 2021. The effect of the registration is that ivermectin may be compounded and made accessible in accordance with the provisions of Section 14(4) of the Act. The order also determines that access to imported ivermectin may be provided in accordance with the provisions of Section 21 of the Act. The order further determines that SAHPRA and the Minister of Health, jointly and severally, will pay a total contribution to the costs of the four applicant groups in the amount of R1,8 million (plus VAT) or U.S. \$124,000.

From Criminalized to Available Off-Label for COVID-19

Because a medicine that contains ivermectin as an active ingredient is now registered and ivermectin is listed as a schedule 3 substance, ivermectin can now be used for other purposes than stated on the label of the registered medicine (off-label use) – which includes the treatment of COVID-19.

“Access in accordance with Section 14(4) of the Act practically means that doctors can prescribe ivermectin on their own judgement and that no Section 21 application or reporting is required for compounded ivermectin. Patients can then use this prescription to buy ivermectin from any pharmacy where compounded ivermectin is available,” says Barend Uys, Head of Research at AfriForum.

“We are very glad that the settlement was made an order of court as this provides certainty for doctors and patients,” says Dr George Coetzee.

Engaged Regulator?

The order further determines that SAHPRA must report back to the court every three months about the state of affairs relating to ivermectin and that any party to the application may approach the court by way of a notice of motion and supplementary affidavits, for relief pertaining to any further aspects relating to the administration and allowance of the use of ivermectin as a treatment against COVID-19. This part of the order did not form part of the original settlements that was agreed to between the parties.

The Plaintiffs Collective

The plaintiff sought to acknowledge the contribution of their legal team, Dr George Coetzee and other stakeholders like the Pharma Valu pharmacy group, as they can make a difference for doctors group, and the ACDP that worked with dedication to ensure accessibility to ivermectin for citizens.

A TrialSite POV

[TrialSite reported](#) that there were limitations in this victory in that the rules didn't necessarily facilitate large production efforts. However, after speaking with a few individuals with information there, apparently groups are already using the ingredients that make up the particular approved product to produce at least some batches to treat people.

COVID-19 in South Africa

While the cases truly spiked in January, reaching nearly 20,000 cases per day, the situation has markedly improved, as the number of weekly reported cases has waned to 920 per week. Just under 264,000 people have been vaccinated in the country of nearly 60 million.

And the country just [inked a deal with Pfizer](#) to access the BNT162b2 mRNA-based vaccine. Involving 20 million doses, the deal is a boost for the worst hit country in Africa and adds to the 31 million doses of the Johnson & Johnson vaccine product already secured by the government here.

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Canada is working to getting the same result. Canadians: please consider signing the petition:
<https://petitions.ourcommons.ca/en/Petition/Details?Petition=e-3265>

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