Sahpra allows controlled use of Ivermectin for Covid-19

The South African Health Products Regulatory Authority (Sahpra) has given the green light for the controlled use of Ivermectin, a veterinary parasitic drug, for Covid-19 infection management in humans.

Image: Taj Pharma

Earlier this month, the authority warned the public against the use of the drug for treating Covid-19, because there was no available confirmatory data.

However, Sahpra chief executive (CEO), Dr Boitumelo Semete-Makokotlela, said the authority would allow a controlled and compassionate programme for the use of the drug after embarking on extensive engagements with medical professionals. A guideline will be published shortly.

“We are in the second wave. We are seeing lives being lost and we have many medical practitioners that have reached out to us. We have considered all of that. The approach is that we will facilitate a controlled, compassionate access programme for Ivermectin,” she said.

Semete-Makokotlela said, however, this does not mean that the authority’s position on the matter has changed. “Our position [does not] change around the availability or lack of availability of data, but we had to have in-depth discussions around the context in which we find ourselves.

“We are in a pandemic with limited options available. It is on that basis that we are saying we will facilitate a controlled access programme that will enable us to monitor the use and [allow people] to get healthcare,” she said.

Sahpra has taken this posture, with several studies indicating there is not enough data on the risks and benefits of using the drug.

“We understand the position from which the health practitioners are coming. We also acknowledge that there are very limited but good evidence-based options that exist.

“We also understand the pressure healthcare practitioners are facing because of these limited options,” Semete-Makokotlela said.

Not registered for human use

One of the challenges faced by Sahpra, said Semete-Makokotlela, is that the drug is currently not registered for human use in South Africa.

“In many countries, it’s being utilised off-label because a rigorous review was conducted when it was registered for human use.”

Since 6 January 2021, Sahpra has reviewed an extensive piece of data that has emerged.

“Firstly, we engaged with the World Health Organisation (WHO) and there’s a statement they’ve issued around this, saying there’s limited information around [the drug]. WHO is working to review current clinical trials for them to get sufficient data to give to us.

“We’ve also engaged other regulators that we work closely with as Sahpra, such as the FDA (US Food and Drug Administration), the European Medicines Agency, MHRA in the UK, etc., and they have indicated a similar position to us,” said Semete-Makokotlela.

Sahpra chairperson, Professor Helen Rees, said the authority has taken into account the national context when considering the use of the drug.

“Since the pandemic began, the staff at Sahpra have worked extraordinarily hard because it’s not just on medicines… It’s not just a simple thing to say that a new medicine has come along, can we register it?” she said.

During the pandemic, Rees said Sahpra has been inundated by work needing its attention.

> *“During a wartime, there will be things that are not in the routine course of business, where the regulator has to think very hard and think of the context in which they are working, while still absolutely thinking of safety, quality and efficacy.”*
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> Rees said the authority is aware that, at the moment, there are limited options for the prevention and treatment of sickness.

“Although we now have good evidence for hospitalised patients, we’d like more. We are very supportive of our healthcare providers, who are in the frontline, who are really desperate and looking for solutions.