# IVERMECTIN AND THE RULE OF LAW

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## BACKGROUND

The rule of law is a founding value of South Africa's democratic dispensation,[1] and refers to the principle of governance in which all persons, including the state, obey the law, and requires measures to ensure, inter alia, legal certainty, transparency, and avoidance of arbitrariness.[2] It is the cornerstone of democratic and accountable governance. Litigation relating to ivermectin suggests cause for concern about respect for, and compliance with, the rule of law by the South African Health Products Regulatory Authority's (SAHPRA).

There is considerable professional controversy about whether ivermectin should be prescribed to prevent or treat Covid-19, with SAHPRA initially taking a firm stance against approving this, in part because it was the medication had not been approved for human use, stating that it is 'unproven in the management of Covid-19 infections', and warning that its use could potentially lead to harmful effects or death.[3] Dissatisfied medical practitioners and civil society organisations argued, however, that in early studies ivermectin shows promise as a medical 'tool' to combat Covid-19, and, in the absence of other effective treatments, they should be allowed to prescribe it, especially in the midst of a pandemic-induced crisis conditions during which the normal standards for approving a medicine should be relaxed.[4]

SAHPRA was soon facing mounting public pressure and two lawsuits.[5,6] While insisting that it did not buckle under pressure and was responding to consultations with the scientific and medical community,[7] it announced the Ivermectin Controlled Compassionate Use Programme Guideline on 28 January 2021.[8] Ivermectin would not be registered as a medicine, but medical practitioners could apply to SAHPRA for permission to prescribe it for individual, named patients.[8] This Programme provided a basis upon which litigants were able to craft a consent order that was made an order of court on 2 February 2021, which recorded that:[9]

1.1 Ivermectin will be made available in terms of section 21 of the Medicines and Related Substances Control Act 101 of 1965;

1.2 Any person … is eligible for access to Ivermectin in terms of the Programme;

1.3 … any registered Medical Practitioner … [is] entitled to apply for access to Ivermectin on the terms and conditions, including the reporting obligations, specified in the Programme; …

In terms of the Programme, applications by medical practitioners for permission to prescribe ivermectin had to be submitted via SAHPRA's online system, and an SMS had to be sent to SAHPRA confirming the

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application.[8] Several issues of concern soon arose among medical practitioners,, the most important of which was that applications that were lodged on SAHPRA's online system simply remained 'pending' for days on end, a period inconsistent with the urgency needed to treat patients with Covid-19 and who frequently needed intervention much more quickly.[4,10] This also violated the commitment in the Programme guideline document attached to the court order, in which SAHPRA undertook to respond to all applications within 24 hours.[8]

The situation described above raises the question: Did SAHPRA comply with a court order with which it had a legal duty to implement? The result was new litigation, [11,12] in response to which SAHPRA acknowledges that its online application system 'collapsed' from 28 January to 1 February 2021[13] or 2 February 2021.[14] It admitted that lost all the data that were submitted during this critical period.[15]

The affidavit explains that the system collapsed because it was originally created as an 'emergency' system in the early days of SAHPRA and was not able to handle the 'sudden abnormal increase in volume of applications'.[13] This, it says was 'unforeseen',[16] and that it has already commissioned a more stable system with enhanced functionality.[17]

According to SAHPRA, it knew of 127 ivermectin applications received by 16 February, though an unknown number had been lost as a result of system failure.[13,15] Of the 127 applications, 54 had been approved, 41 rejected, and 32 were pending.[13] SAHPRA admits that it did not meet the 24-hour response time, but states that it is confident that going forward an 'expeditious turnaround time will be met'.[19]

The various cases against SAHPRA, as main respondent, are set to be heard together in the Pretoria High Court at the end of March.

## ANALYSIS

SAPHRA should have foreseen an increase in the volume of applications after announcing its Programme. Its choice to use a dated, emergency system was a poor one, and it would have been possible to use a more stable platform or even email. A reasonable person (or reasonable organ of state) in the position of SAHPRA would have ensured beforehand that whatever system it planned to use would be sufficiently robust. As such, SAHPRA's system malfunction is a self-inflicted wound.

The bigger concern, however, relates to how SAHPRA handled the 'collapse' of the online application system. SAHPRA, in its affidavit, states that it has already commissioned a new, enhanced system.[17] Superficially, this action might seem sufficiently responsive. But is it? The Pretoria High Court granted medical practitioners the right to apply for access to ivermectin, which created a concomitant duty on SAHPRA to process such applications. As pointed out previously, an unknowable number of medical practitioners attempted to exercise this right between 28 January and 1 (or 2) February 2021, but whose

applications were lost. SAHPRA knew of the loss of these applications, and given its duty to process applications, should immediately have taken steps to remedy such loss.

SAHPRA could and should have used the contact details from confirmatory SMSs that applicants sent to confirm submission[20] to make contact with them and fails to explain why it did not do so. In the event that the SMS records were somehow also lost, SAHPRA could simply have issued a public statement of apology and requested resubmission of applications. It is unacceptable that SAHPRA kept the data loss secret until the new wave of litigation forced it to reveal this embarrassing fact.

While the five (or six) day-long system malfunction arguably constitutes negligence on the part of SAHPRA, SAHPRA's failure to take measures to contact the medical practitioners who applied during the malfunction period, constitutes intentional breach of the court order, which the Constitutional Court held in *Nyathi v MEC for Health, Gauteng* to be a minimal requirement of organs of state if the rule of law is to be maintained.[21]

SAHPRA, as an organ of state, should set an example of respecting the rule of law – which includes strict compliance with court orders. In its press statements, SAHPRA has threatened any person who imports ivermectin with a harsh legal response.[3] Now, given its failure to act, SAHPRA itself is in contempt of court. This not only erodes SAHPRA's own moral authority and legitimacy, it chips away at the rule of law.

Another problem is that SAHPRA fails to provide criteria for approving or rejecting applications for the use of ivermectin. As can be expected, this causes frustration.[22] Importantly, the rule of law requires that rules made by public bodies must be clear and accessible,[23,24] and that any exercise of public power must be rationally related to the purpose for which the power is exercised.[25] To conform to these standards, SAHPRA should immediately publish objective, measurable criteria for evaluating applications for the use of ivermectin.

Arguably, SAHPRA's statement that applications will be processed expeditiously is vague and does not meet the requirement of the court order that it will respond to all applications within 24 hours, which is itself too long in the context of a medical emergency.

## CONCLUSION

The Covid-19 crisis is exposing cracks in an already strained health system in South Africa. It is in crisis situations that adherence to the rule of law is essential as these are the circumstances in which rights are often trampled. SAHPRA's silence about its system malfunction, and its failure to contact the medical practitioners whose applications were lost due to the system malfunction caused unnecessary anguish for medical practitioners and their patients. Moreover, it constitutes non-compliance with an order of the High Court, and hence is a violation of the rule of law.

## SOURCES


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22. *'I can make a difference' doctors and medical practitioners group v SAHPRA* Case 6391/2021 ZAHCGP. Replying affidavit paras 5.1.3 and 83.
23. *Dawood v Minister of Home Affairs* 2000 (3) SA 936 (CC) para 47 ('it is an important principle of the rule of law that rules be stated in a clear and accessible manner').
24. *Affordable Medicines Trust v Minister of Health* 2006 (3) SA 247 (CC) para 108 ('The doctrine of vagueness is one of the principles of common law that was developed by courts to regulate the exercise of public power...the exercise of public power is now regulated by the Constitution…The doctrine of vagueness is founded on the rule of law, which…requires that laws must be written in a clear and accessible manner').
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