Practising in a post-truth world: Truth revision

To the Editor: A recent commentary[1] published in the journal's 'In Practice' section contains errors of fact and emphasis that warrant correction. The authors noted that a major challenge facing clinicians during the pandemic has been the need to interpret the rapidly evolving evidence for both treatment and prevention of COVID-19.

The authors state that the pandemic exposed 'a lack of neutrality of regulators and lawmakers as self-determining institutions'. They provide as evidence for this statement, 'the case of the South African (SA) Health Products Regulatory Authority (SAHPRA) registering ivermectin in the wake of extensive public pressure'. This statement is incorrect. SAHPRA received no application from a supplier for the registration of any ivermectin product for the prevention or treatment of COVID-19 during the pandemic and it has not registered any such products for this indication. There is only one registered ivermectin-containing product on the SAmarket, a cream registered for the treatment of rosacea.[2]

This ivermectin product was registered on 16 March 2021, which meant that in terms of section 14(4) of the Medicines and Related Substances Act No. 101 of 1965, ivermectin as a molecule could be prepared by compounding pharmacies. Before then the only legal way to obtain imported, unregistered ivermectin products was in accordance with section 21 of the Act. In January 2021, SAHPRA established the Ivermectin Controlled Compassionate Use Programme to enable healthcare practitioners to make ivermectin available to patients within a controlled and monitored environment.[3]

SAHPRA consulted widely with medical experts, who confirmed that there was limited, if any, scientific evidence on the efficacy of ivermectin for the management of COVID-19 at that time, but that clinical equipoise existed, which is why there were clinical trials being conducted around the world evaluating ivermectin for the prevention and treatment of COVID-19. As more clinical data were generated and demand for access to imported ivermectin products declined, SAHPRA stopped the ivermectin Controlled Access Programme on 30 May 2022.[4] SAHPRA's *bona fides* in this matter were confirmed by the Supreme Court of Appeal in November 2022.[5]

As much as we endorse Brannigan *et al*.'s[1] call for enhanced shared decision-making, an article of this nature must be accurate in order to draw evidence-based conclusions and make useful recommendations. The incorrect reporting of the registration status of ivermectin resulted in the authors making false assertions about the national regulator's competency and independence.

Brannigan *et al*. also argue that, post-pandemic, 'there is now more time to develop consensus documents and treatment guidelines'. They do not mention the work of the National Essential Medicines List Ministerial Advisory Committee on COVID-19 Therapeutics, which conducted numerous rapid reviews of the available evidence, in order to inform the development of national guidelines.[6,7] The development process was highlighted in this journal and elsewhere.[8,9]

The authors' failure to comment on the extensive evidence reviews undertaken by the COVID-19 Ministerial Committee on Essential Medicines undermines their own argument about a system failure. Public trust in national processes to evaluate evidence and produce timely and accurate clinical recommendations is of critical importance for high-quality patient interaction. The very nature of the reviews and their evidence to decision pathways allow for nuanced individual interpretation against a background of curated information, which seems to be exactly the process that the authors are seeking.

Boitumelo Semete-Makoketlela, *chief executive officer, SAHPRA, Pretoria, South Africa*
boitumelo.semete@sahpra.org.za

Andy Parrish, *National Essential Medicines List Ministerial Advisory Committee on COVID-19 Therapeutics; Department of Internal Medicine, Faculty of Health Sciences, Walter Sisulu University, Mthatha, South Africa; and Frere and Cecilia Makiwane hospitals, East London, South Africa*

Andy Gray, *National Essential Medicines List Ministerial Advisory Committee on COVID-19 Therapeutics, Division of Pharmacology, Discipline of Pharmaceutical Sciences, University of KwaZulu-Natal, Durban, South Africa*

Marc Blockman, *National Essential Medicines List Ministerial Advisory Committee on COVID-19 Therapeutics, Division of Clinical Pharmacology, Department of Medicine, Faculty of Health Sciences, University of Cape Town, South Africa*

Helen Rees, *Chair of the Board, South African Health Products Regulatory Authority; National Essential Medicines List Ministerial Advisory Committee on COVID-19 Therapeutics; Wits Reproductive Health and HIV Institute, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa*

1. Brannigan L, Etheredge HR, Lundgren C, Fabian J. Practising in a post-truth world: Pandemic ethics can inform patient autonomy and clinical communication. S Afr Med J 2023;113(1):5-8. https://doi.org/10.7196/SAMJ.2023.v113i1.16746
2. Soolantra cream (Galderma Laboratories SA (Pty) Ltd). Registration no. 49/13.12/0906.
3. South African Health Products Regulatory Authority. Ivermectin Controlled Compassionate Use Access Programme. https://www.sahpra.org.za/wp-content/uploads/2021/01/Section_21_Ivermectin_Controlled_Compassionate-Use-Programme_Jan21_FINAL.docx.pdf (accessed 24 January 2023).
4. South African Health Products Regulatory Authority. SAHPRA statement on the termination of the 'Ivermectin Controlled Compassionate Use Access Programme'. https://www.sahpra.org.za/press-releases/sahpra-statement-on-the-termination-of-the-ivermectin-controlled-compassionate-use-access-programme/ (accessed 24 January 2023).
5. South African Health Products Regulatory Authority. SAHPRA statement – latest development on ivermectin court case. https://www.sahpra.org.za/news-and-updates/sahpra-statement-latest-development-on-ivermectin-court-case/ (accessed 24 January 2023).
6. National Department of Health, South Africa. COVID-19 Rapid Reviews. https://www.health.gov.za/covid-19-rapid-reviews/ (accessed 24 January 2023).
7. National Institute for Communicable Diseases. Clinical management of suspected or confirmed COVID-19 disease (July 2021). https://www.nicd.ac.za/wp-content/uploads/2021/08/MANAGING-COVID19-2-FINAL_v3.35-DR-NDJEKA.pdf (accessed 24 January 2023).
8. Leong TD, McGee S, Gray AL, et al. Essential medicine selection during the COVID-19 pandemic – enabling access in uncharted territory. S Afr Med J 2020;110(11):1077-1080. http://doi.org/10.7196%2FSAMJ.2020.v110i11.15271
9. Leong TD, Gray AL, Kredo T, de Waal R, Cohen K, Parrish AG, Dawood H. Managing therapeutic uncertainty in the COVID-19 pandemic: Rapid evidence syntheses and transparent decision-making. In: Govender K, George G, Padarath A, Moeti T (editos). South African Health Review. Durban: Health Systems Trust, 2021:41-49.

Practising in a post-truth world: Response from the authors

To the Editor: Thank you for the opportunity to respond to 'Practising in a post-truth world: Truth revision'. We would like to clarify that we chose the case of ivermectin for our commentary because it was so controversial, and we welcome the dialogue. We admit it may have been better to include a more detailed timeline of the events regarding ivermectin, included below.

We acknowledge that SAHPRA (hereinafter referred to as the regulator) has not registered any ivermectin product for the management of COVID-19 in SA and apologise for this misrepresentation. As pointed out by the respondents, in January 2021 the regulator created access to unregistered ivermectin for managing COVID-19 through section 21 of the Medicines and Related Substances Act No. 101 of 1965 with the 'Ivermectin

Controlled Compassionate Use Programme'.[1] In April 2021, four cases were brought by medical practitioners and civil society groups (such as AfriForum) to the Pretoria High Court against the regulator and the Minister of Health.[2] The presiding judge ruled that a registered pharmacist or medical practitioner might compound and sell compounded medicine that contained ivermectin as an active ingredient in terms of section 14(4) of the Medicines and Related Substances Act, and ordered the regulator and the Minister of Health to contribute over ZAR1 000 000 to cover costs incurred by the applicants, and report to the court every 3 months on issues pertaining to the use of ivermectin for COVID-19. The regulator terminated the 'Ivermectin Controlled Compassionate Use Programme' in May 2021 and, with the Minister of Health, appealed the court order on 14 November 2022. The ruling was set aside by the Supreme Court of Appeal on 21 November 2022.[3]

Regarding the timeline, our commentary was submitted to the *SAMJ* in July 2022, prior to the outcome of the appeal, with implications for our argument.

We agree with the respondents that there was little evidence to support using ivermectin at the time of initiating the 'Ivermectin Controlled Compassionate Use Programme' and that terminating the programme was appropriate.[4] We also agree that the National Essential Medicines List Ministerial Advisory Committee on COVID-19 Therapeutics, the National Institute for Communicable Diseases (NICD) and the National Department of Health (NDoH) worked extremely hard during the COVID-19 pandemic to create guidelines for managing COVID-19.[5-7]

In our commentary we aimed to highlight the perspective and experience of clinicians at the coalface. Despite consistent messaging from the regulator, the NICD and the NDoH confirming little evidence supporting the use of ivermectin for COVID-19, creating access to ivermectin by the regulator and the subsequent court order against the regulator (and Minister of Health) galvanised those who supported its use. The point we wanted to make was that despite the regulator's decision to allow controlled access to ivermectin through section 21, a court ruling instructed the regulator otherwise. Thus, through no fault of its own, the turn of events with ivermectin challenged the neutrality of the regulator as a self-determining institution. As such, we respectfully disagree with the respondents that 'incorrect reporting of the registration status of ivermectin resulted in false assertions regarding the regulator's competency and independence' – at no point did we allege incompetency from the regulator.

We also disagree with the respondents' statement that our 'failure to comment on the extensive evidence reviews undertaken by the COVID-19 Ministerial Committee on Essential Medicines undermines their own argument about a system failure'. Rather, the point we were hoping to make was that in the face of an overwhelming amount of information, there was room for improvement in communication strategies at all levels to assist clinicians who, ultimately, bear the responsibility for managing patients and dealing with their loved ones, and have to face the consequences of unwanted side-effects that might cause more harm than good.

L Brannigan, *Wits Donald Gordon Medical Centre and School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa*

H R Etheredge, *Wits Donald Gordon Medical Centre and School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, and Department of Internal Medicine, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa*

C Lundgren, *Wits Donald Gordon Medical Centre and School of Clinical Medicine, and Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa*

J Fabian, *Wits Donald Gordon Medical Centre and School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, and Department of Internal Medicine, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa*
june.fabian@wits.ac.za

1. South African Health Products Regulatory Authority. Ivermectin Controlled Compassionate Use Access Programme. https://www.sahpra.org.za/wp-content/uploads/2021/Section (accessed 28 February 2023).
2. News24. Court order allows use of ivermectin for Covid-19. https://www.news24.com/news24/southafrica/news/court-order-allows-use-of-ivermectin-for-covid-19-20210406 (accessed 28 February 2023).
3. South African Health Products Regulatory Authority. SAHPRA statement – latest development on ivermectin court case. https://www.sahpra.org.za/news-and-updates/sahpra-statement-latest-development-on-ivermectin-court-case (accessed 28 February 2023).
4. South African Health Products Regulatory Authority. SAHPRA statement on the termination of the 'Ivermectin Controlled Compassionate Use Access Programme'. https://www.sahpra.org.za/press-releases/sahpra-statement-on-the-termination-of-the-ivermectin-controlled-compassionate-use-access-programme (accessed 28 February 2023).
5. Leong TD, McGee S, Gray AL, et al. Essential medicine selection during the COVID-19 pandemic – enabling access in uncharted territory. S Afr Med J 2020;110(11):1077-1080. http://doi.org/10.7196%2FSAMJ.2020.v110i11.15271
6. National Department of Health. COVID-19 Rapid Reviews. https://www.health.gov.za/covid-19-rapid-reviews (accessed 28 February 2023).
7. National Institute for Communicable Diseases. Clinical management of suspected or confirmed COVID-19 disease (July 2021). https://www.nicd.ac.za/wp-content/uploads/2021/08/MANAGING-COVID19-2-FINAL_v3.35-DR-NDJEKA.pdf (accessed 28 February 2023).

S Afr Med J 2023;113(4):e809. https://doi.org/10.7196/SAMJ.2023.v113i4.809