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Relief for cystic fibrosis patients? The Competition Commission Closes Investigation into Vertex Pharmaceuticals

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"*... poverty alleviation, the provision of high-quality education, the best health enhancing facilities or necessities, and the enablement of the best business environment and job opportunities, would all be a pipe dream in the absence of an inclusive, ethical, truly human rights-oriented and vibrant or prosperous economy. This is what the notion or philosophy of business with a conscience or a social justice-sensitive economy is about.*"[1]

In March 2022, the Competition Commission of South Africa ("**Competition Commission**") initiated a complaint against Vertex Pharmaceutical Incorporated ("**Vertex**"). In the complaint, the Commission alleged that Vertex engaged in excessive pricing, refused to give a competitor access to an essential facility, refused to supply scarce goods and engaged in exclusionary conduct in the provision of Trikafta and other drugs used in the treatment of cystic fibrosis ("**cystic fibrosis treatment drugs**"). The cystic fibrosis treatment drugs are approved drugs designed to treat the underlying cause of the disease. Cystic fibrosis is a rare and life-threatening genetic disease that primarily affects the lungs and the pancreas. It causes a thick sticky mucus to build up in the lungs, pancreas and other organs, which can result in breathing and digestion problems, infections, and organ damage. Trikafta, in particular, has been recognised as a miracle drug for treating cystic fibrosis as it eliminates many of its debilitating symptoms.[2]

In December 2024, the Commission announced that it had closed its investigation after Vertex provided certain undertakings to address the Commission's concerns.

The Commission's investigation found that while Vertex had begun efforts to make Trikafta available in South Africa through Section 21 of the Medicines and Related Substances Act, which Act enables the sale of unregistered drugs within South Africa, the drug was not registered with the South African Health Products Regulatory Authority (the "**SAHPRA**") ("**the Section 21 authorisation**"). This limited patients' access to Trikafta, who had to import the medication from the United States or other countries. The investigation also showed that Trikafta had largely replaced older medications like Kalydeco, Orkambi, and Symdeko among cystic fibrosis patients.

To address the Commission's concerns, Vertex agreed to supply Trikafta locally through a distributor, ensuring better availability and more affordable pricing. Vertex also agreed to continue to make Trikafta available in South Africa under the Section 21 authorisation. Vertex, however, refused to register Trikafta with the SAHPRA, citing that the Section 21 authorisation provides the fastest and most efficient route to sustainable access and does not require a regulatory filing.[3] Lastly, Vertex committed to supporting patient access through existing financial assistance programs.

The Commission regarded these undertakings sufficient to address its concerns. As a result, it decided not to prosecute Vertex before the Competition Tribunal. However, the Commission did reserve the right to re-open the investigation if new evidence of abuse emerged.

The Commission's decision not to prosecute drew mixed reactions from the public, with some criticising the decision and others applauding it.

A number of health organisations and non-governmental organisations criticised the decision as inadequate and inequitable, with the South African Cystic Fibrosis Association and Section 27 arguing that most cystic fibrosis patients are still left without access to life-saving treatment, as only those with high-end medical insurance will benefit.

Conversely, the media reports that many South Africans welcomed the decision as it ensures access to essential medication.[4] They believe the undertakings will provide relief to patients and their families who have struggled for a long time with the high costs and the limited availability of Trikafta.[5] Currently only four healthcare providers fund Trikafta for eligible patients but Vertex anticipates that this number is set to increase.[6]

Although the undertakings extracted by the Commission from Vertex should improve access to Trikafta at least for some, it remains to be seen if they will translate into tangible results for a meaningful number of people living with cystic fibrosis.

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[1] Competition Commission of South Africa v Mediclinic Southern Africa (Pty) Ltd and Another (CCT 31/20) [2021] ZACC 35 at para 2.

[2] https://www.spotlightnsp.co.za/2024/08/06/case-against-vertex-dropped-after-cystic-fibrosis-medicine-price-reduced/ (Last accessed 06 February 2025).

[3] https://www.dailymaverick.co.za/article/2024-08-21-case-against-pharmaceutical-company-dropped-after-legal-pressure-sees-price-of-generic-miracle-medicine-reduced/ (Accessed 6 February 2025)

[4] https://www.iol.co.za/business-report/economy/access-to-life-saving-cystic-fibrosis-medication-secured-in-south-africa-fec7b7e6-2260-4c90-8c5a-093b0038691b (Accessed 6 February 2025)

[5] See footnote 4 above.

[6] See footnote 3 above.

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