

Response from NDoH to Spotlight questions: 10 July 2026

1. It is my understanding that flucytosine is not currently being supplied via a tender but instead is being bought by NDoH on quotation, is this accurate?

Yes. Flucytosine is currently being procured by participating authorities through a Request for Quotation (RFQ) process rather than through a national tender contract.

The 500 mg presentation was previously awarded under Contract HP02-2023AI to Viatris. During the HP02-2025AI contracting process, no responsive bids were received.

In the supplementary tender (HP02-2025AI/01) no bids were received for either the 250mg or 500 mg presentation

A Request for Quotation (RFQ) was subsequently issued to Viatris on 1 October 2025; however, in March 2026 the supplier advised the Department that it was unable to supply due to manufacturing and global supply constraints. The RFQ was therefore cancelled.

2. If so, why is flucytosine not being supplied via a tender, despite being listed on the Essential Medicines List?

Although flucytosine is included on the Essential Medicines List (EML), no responsive bids were received during the HP02-2025AI and no bids were received HP02-2025AI/01 contracting processes.

3. Has the drug ever been supplied via a tender? If so, please provide more detail.

Yes. The 500 mg strength of flucytosine was previously supplied under Contract HP02-2023AI by Viatris.

4. Which pharmaceutical company or supplier is currently supplying flucytosine to the public sector?

Following the unsuccessful tender processes, Macleods flucytosine was registered with SAHPRA. The Department then engaged Macleods to negotiate and secure supply. A Request for Quotation (RFQ) process was initiated in May 2026. Based on information provided by the supplier, the estimated manufacturing lead time is approximately 112 days from the placement of confirmed purchase orders.

The participating authorities are currently procuring flucytosine from Macleods through an RFQ process. The product supplied is a 500 mg scored tablet, which may be divided where clinically appropriate to meet both the 500 mg and 250 mg dosing requirements.

5. At what price is NDoH currently procuring stock of flucytosine and how much stock is/has been procured for 2026?

For planning purposes, participating authorities have estimated a requirement of approximately 4,000 packs of 100 × 500 mg flucytosine tablets over a six-month period. The estimated procurement price is approximately R1,750 per pack.

6. Flucytosine was registered in South Africa in late 2021. At what point was it included in the public sector treatment guidelines and the Essential Medicines List?

Flucytosine was included on the national Essential Medicines List (EML) in 2023. Both the Adult Hospital Level and Paediatric Hospital Level editions of the Standard Treatment Guidelines (STGs) and EMLs currently recommend oral flucytosine as a critical part of the induction phase treatment regimen for cryptococcal meningitis (CCM) used in combination with intravenous amphotericin B and oral fluconazole. All published documents may be accessed at the following link: <https://www.health.gov.za/nhi-edp-stgs-eml/>

7. Leading on from this, when did NDoH start procuring stock of flucytosine for the public sector?

The Department commenced procurement of flucytosine in 2023 following its inclusion on the Essential Medicines List and the award of Contract HP02-2023AI.

8. Since then, how many instances of stockouts of flucytosine have occurred and what caused those stockouts? Have there been any stockouts of flucytosine in the public sector this year? If so, how long was the stockout, what caused it and has it since been resolved?

During 2026, the availability of flucytosine has been constrained, requiring available stock to be carefully managed and distributed to facilities based on clinical need.

The supply constraints arose because the only registered supplier in South Africa at the time experienced global manufacturing and supply challenges, affecting both contractual supply and the subsequent RFQ procurement. Supply has not been interrupted due to a lack of procurement by the Department but rather due to limited global product availability.

9. What steps are being taken to ensure that there is sufficient stock of flucytosine in the country and that another stockout does not occur?

The Department has secured supply of flucytosine through an RFQ with Macleods and continues to monitor national stock availability and coordinate distribution based on clinical need. In addition, the Department intends issuing a supplementary tender once market intelligence indicates that sufficient supplier participation can be expected, thereby supporting a sustainable long-term procurement solution.

10. Is there anything else you would like to add?

The Department remains committed to ensuring uninterrupted access to essential medicines. Where national tenders do not result in responsive bids or suppliers experience global manufacturing constraints, alternative procurement mechanisms are implemented to minimise the impact on patient care while sustainable long-term procurement solutions are pursued.

Additional response received

-When did NDoH start procuring stock of flucytosine for the public sector?

The National Department of Health has procured flucytosine through the national anti-infective medicine tender. Under HP02-2023AI, which commenced on 1 October 2023, flucytosine 500 mg tablets were awarded to Viatris Healthcare (Pty) Ltd, with an estimated quantity of 1,940 packs of 100 tablets.

In July 2024, stock of flucytosine was written off after expiring due to low uptake by provinces. In October 2024, the NDoH issued a notice confirming that the supplier had stock available and requested facilities to place orders through their pharmaceutical depots based on their requirements.

The 500 mg flucytosine item was subsequently included in HP02-2025AI. However, the item was not awarded under that tender because the bids received were non-compliant and the item was therefore referred for retendering.

The Department is currently addressing procurement of the item through the appropriate procurement mechanism to support continued access. The item will be advertised on another supplementary tender.