AUDITOR-GENERAL
SOUTH AFRICA

# Portfolio Committee on Defence and Military Veterans

## Procurement of the unregistered Heberon drug

1 December 2021

# Our mission and vision

OUR MISSION

We have a constitutional mandate and, as the supreme audit institution of South Africa, exist to strengthen our country's democracy by enabling oversight, accountability and governance in the public sector through auditing, thereby building public confidence.

OUR VISION

To be recognised by all our stakeholders as a relevant supreme audit institution that enhances public sector accountability

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# Findings on the importation of unregistered Heberon drug

# Progress on findings from the second special report (SR2)

## Key findings as reported in SR2

- Non-submission of information resulted in a number of audit limitations, as a result not all required audit procedures could be performed.
- Inadequate planning for the procurement of Heberon ® Alfa R (Heberon), which contains the active ingredient interferon alpha 2b, procured for approximately R260,59 million. It was not clear how the department determined the required quantities.
- The open-ended contract used during procurement was only signed after the first delivery had taken place.

## Follow up and status

- Not all requested information was provided, this includes the manufacturer's stability data, some documentation supporting the international import for all three shipments, transportation and manual recording for second shipment and an internal report on the procurement of the drug.
- We could not obtain sufficient evidence to substantiate how the department determined the number of vials procured.
- The department confirmed that no procurement process was followed as the drugs were procured under project Thusano. We have concluded that all expenditure incurred under this project is irregular.

# Progress on findings from the second special report (cont.)

## Key findings as reported in SR2

- No post-importation testing. Breach of cold-chain requirements resulted in approximately 40% of vials' integrity being possibly compromised.
- None of the 970 895 vials of Heberon were accounted for on the department's inventory system and the payment of R34,86 million was not accounted for in the financial records.
- No evidence of South African Health Products Regulatory Authority (Sahpra) approval prior to importation of Heberon. Subsequent Sahpra approval was for 10 vials as opposed to the 970 895 vials imported.

## Follow up and status

- The testing of the possibly compromised vials was subsequently conducted by Sahpra.
- The heberon drugs were still not accounted for in the inventory system at the date of our report. The payment was subsequently correctly accounted for and this amount was disclosed as irregular expenditure.
- The department had not yet obtained approval from the relevant authority to use the drugs except for 10 vials that were re-authorised in October 2020. This non-compliance has resulted in a material irregularity (MI).

# Material irregularity on importation of Heberon drugs

## Importation of unregistered drugs without approval from regulating authority

- The department did not obtain approval from the South African Health Products Regulatory Authority (Sahpra), as required by MCSA regulation 6.2, before importing the unregistered drug Heberon® Alfa R (Heberon) into the country. The department procured 970 895 vials of Heberon from a Cuban supplier between 27 April 2020 and 17 August 2020. Sahpra re-authorised the use of only 10 vials of Heberon on a single patient on 5 October 2020. Sahpra has granted no further approvals. The department currently has approximately 970 885 vials that are not approved for patients. The outstanding approval, together with the approaching expiry dates of March and April 2022, will most likely result in the department not administering some or all of the remaining drugs. Therefore, the non-compliance has resulted in a likely material financial loss of R260 342 813 to the department.
- The accounting officer (AO) was notified of the MI on 13 August 2021. On 28 September 2021, the AO responded and indicated that the department was in the process of appointing an Clinical Research Organisation to assist in obtaining approval from Sahpra for the research trials.

## Recommendations:

**In addressing the material irregularity the AO must implement the following:**

- The AO must prevent the likely financial loss from occurring
- The AO must determine the officials responsible for importing drugs without approval from the regulating authority and causing the likely financial loss to the department.
- Appropriate disciplinary actions must be taken against responsible officials within reasonable time.
- If any losses are suffered, the AO must determine if any officials are liable by law, for purposes of recovery.

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