## SAHPRA's position on anti-cancer medications in South Africa

**Embargo: Immediate release**

**Pretoria, 15 July 2025** – The South African Health Products Regulatory Authority (SAHPRA) was notified of the *Lancet Global Health 2025; 13: e1250,* an investigational study and its findings on substandard anti-cancer medications in Sub-Saharan African countries, including Ethiopia, Kenya, Malawi, and Cameroon. This study did not include South Africa. The seven (7) medicines/dosage forms mentioned in the study are *cisplatin, oxaliplatin, methotrexate, doxorubicin, cyclophosphamide, ifosfamide, and leucovorin*. The specific brands mentioned/shown in the article are neither registered nor marketed in South Africa.

SAHPRA, in terms of the Medicines and Related Substances Act 101 of 1965, as amended, and its General Regulations, requires medicines marketed in the country to meet prescribed requirements and adhere to set standards. Every batch of medicine produced must undergo testing to ensure that the integrity of the product is consistent with approved specifications before the release for sale, and imported medicines must additionally comply with the Guideline for Post-Importation Testing.

SAHPRA commenced internal processes to verify whether any of the South African-registered cancer medicines with the mentioned Active Pharmaceutical Ingredients (API) might have been affected or implicated. The cancer products registered and marketed in South Africa were not implicated/affected by the investigational study and its findings on substandard anti-cancer medicines. SAHPRA conducts risk-based post-market surveillance (PMS), sampling, and testing on high-risk medical products.

**SAHPRA is satisfied that the marketed and registered cancer medicines meet the appropriate specifications; therefore, no substandard cancer medicines were detected.**

"SAHPRA is committed to the three pillars of quality, safety, and efficacy. I am satisfied that our rigorous regulatory processes have borne fruit and that all patients, especially cancer patients, can rest assured that their health and well-being are not compromised," indicated SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

**ENDS**

**Issued by:**

Dr Boitumelo Semete-Makokotlela

**CEO: South African Health Products Regulatory Authority**

boitumelo.semete@sahpra.org.za

**For further enquiries/information contact:**

**SAHPRA media contact:**
Yuven Gounden
Cell: 083 297 1214
E-mail: yuveng@sahpra.org.za

**Notes to Editors:**

SAHPRA will post this media release on its website. Navigate to the News section on the website.

Should you wish to request an interview, please send your request to media@sahpra.org.za and yuveng@sahpra.org.za

**Updates on vaccine registration can be accessed here:**

*Vaccines - News and updates (sahpra.org.za)* - https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/

**About SAHPRA:**

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act,101 of 1965, as amended, as well as the Hazardous Substances Act, 15 of 1973.

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.