MEDIA RELEASE

SAHPRA Announces Approval of Breakthrough Treatments for Children with HIV

Embargo: Immediate release

Pretoria, 23 June 2022 – SAHPRA has registered a new "sweet-tasting" combination antiretroviral treatment for infants and young children with HIV. This treatment comes in granules that can be sprinkled on soft food or dissolved in milk or water. Furthermore, this treatment does not require refrigeration.

The "4-in-1" formulation approved by SAHPRA with the trade name Quadrimune has been developed by the non-profit entity, Drugs for Neglected Diseases initiative (DNDi), and Cipla.

Unlike the traditional protease inhibitor-containing paediatric ARV formulations, this new treatment combines the antiretrovirals abacavir, lamivudine, lopinavir and ritonavir in a novel manner of administering it to children and infants.

SAHPRA has also registered dolutegravir dispersible tablets for children with HIV by Macleods (Trade names - Syromak 10 ODT and Kovasyp 10 ODT) and Mylan (trade names - Odinstri and Ristegra dispersible tablets). This comes after the recent registration of dolutegravir dispersible tablets for this cohort by the innovator company GSK (Tivicay) which paved the way for the registration of generic medicines.

"These new treatment regimens for infants and children with HIV heralds a huge breakthrough. The formulations are also recommended by the World Health Organisation (WHO). SAHPRA is committed to enabling access to innovative health products that work well and that adhere to the tenets of safety, quality and efficacy," indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

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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 (Act No 101 of 1965, as amended) as well as the Hazardous Substances Act (Act No 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.

Notes to Editors:

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

Should you request an interview for television, please send your request to media@sahpra.org.za and copy yuveng@sahpra.org.za. Include your discussion points in your request.