SOUTHERN AFRICAN HIV CLINICIANS SOCIETY
Tel: +27 11 728 7365 • **Fax:** +27 11 728 1251 • **Web:** www.sahivsoc.org • **NPC** 1998/020881/08
Suite 233, Private Bag X2600, PostNet, Killarney, Houghton, 2041

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SAHCS letter of concern for delayed access to the paediatric formulation of dolutegravir 10 mg dispersible tablet

Since 2018, dolutegravir (DTG)-based antiretroviral treatment (ART) has been the preferred first line treatment regimen in the World Health Organization guidelines for adults and children with HIV and has been adopted into South African guidelines for adults since November 2019.[1,2] DTG-based regimens have been proven to be superior to prior recommended lopinavir/ritonavir (LPV/r)-based regimens in children due to the improved palatability, fewer side effects and drug interactions, and high genetic barrier to drug resistance.[3-8] South Africa's 2023 ART guidelines expanded the indications for DTG by recommending that all children from 3 kg and 4 weeks of age should be started or evaluated for switching to a DTG-based regimen using the dispersible paediatric DTG (pDTG) formulation.[1]

In May 2023, the South African National Department of Health released Circular 1 of 2023 "Guidance of the rollout of new ART treatment regimen for adults and children as introduced in the National Consolidated ART Guidelines".[9] This circular highlights the need to achieve the UNAIDS 95-95-95 targets with an emphasis on improving viral suppression (the percentage of which is 34% in children compared to 92% in adults)[10] by getting paediatric patients on to a DTG-based regimen facilitated by the introduction of pDTG tablets. However, also stated is that there should be a phased approach in implementation to avoid wastage and expiry of the ARVs used in previously recommended regimens. For paediatric patients this would relate mostly to LPV/r stocks. The circular further states that for paediatric patients, priority in transition to a DTG-based regimen should be given to children newly initiated on ART or not virally supressed on non-DTG regimens but that children who are stable on non-DTG regimens should be retained on their current regimen until depletion of LPV/r stocks. It does not include paediatric patients on TB treatment for which the addition of ritonavir is required for children treated with LPV/r solution in order to overcome drug interactions. Ritonavir powder sachets are frequently unavailable and add significant complexity to ART for young children and their caregivers which negatively impacts adherence and viral suppression rates.

Despite DTG-based regimens proving superior and being incorporated into international and local guideline recommendations, uptake of pDTG among infants and children weighing less than 20 kg has remained low in South Africa.

The Southern African HV Clinicians Society (SAHCS) would like to take this opportunity to express its concern about restricted access for most paediatric patients to pDTG. With knowledge of DTG-based regimen superiority and palatability, transition to DTG-based regimens should not be delayed based on LPV/r stock levels. We would like to encourage both National and Provincial departments of Health, with support from SAHCS, to make accessible pDTG 10 mg to all paediatric patients living with HIV, including children on TB treatment. Certainly, young children requiring rifampicin-based TB treatment as well as antiretrovirals should be prioritised for pDTG dosed twice daily.

Paediatric and Adolescent Committee

Southern African HIV Clinicians Society (SAHCS)

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