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Approval of Tenofovir in children age 2-12 years: Implications for South African clinicians

In January, the U.S. Food and Drug Administration (FDA) approved tenofovir disoproxil fumarate (TDF) for use in paediatric and adolescent patients aged 2 -12 years. The agency approved new paediatric formulations of 150 mg, 200 mg and 250 mg for children aged 6-12, and an oral powder formulation for children aged 2-5.

In South Africa, a paediatric formulation of TDF has not yet been approved by the Medicines Control Council (MCC). Our current first line regimen for children includes abacavir, which is potent and has a low toxicity profile in our population. TDF has been associated with both increased renal toxicity and decreased bone mineral density (BMD) in HIV-infected patients; data on its use in paediatric populations is limited. Given the potential risks, the routine use of TDF in children aged < 15 years should not be implemented until there is safety data available for our population and a paediatric formulation is approved in South Africa.

However, TDF may be used in younger patients if there is a definite indication, including resistance to all NRTI's other than TDF, or active hepatitis B co-infection. For all patients on TDF, renal function (GFR) and serum PO₄ monitoring is required at 1 and 3 months, and thereafter at 6 monthly intervals, and if available DEXA scans at baseline and thereafter at 6-12 month intervals.

If you have any questions about using TDF in a specific paediatric patient, please contact the Health Care Worker Hotline at 0800 212 506. If you have general questions about TDF dosing and monitoring in patients under age 16, please contact child_adolescent@sahivsoc.org . We will share further data and information on TDF use in paediatric populations with you as it becomes available.

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