



## Press release

### Medicines Control Council approves fixed-dose combination of tenofovir disoproxyl fumarate and emtricitabine for pre-exposure prophylaxis of HIV

**From: Registrar of Medicines, Medicines Control Council**

Date: 3 December 2015

**Release:**

At its 75<sup>th</sup> meeting on 27-28 November 2015, the Medicines Control Council (MCC) approved the use of the fixed-dose combination of tenofovir disoproxyl fumarate and emtricitabine to include pre-exposure prophylaxis of HIV (also referred to as PrEP).

As the use of the fixed-dose combination of tenofovir disoproxyl fumarate and emtricitabine represents a departure from the usual use of these antiretrovirals for the treatment of HIV infection, the MCC has also requested the applicants to implement a risk management plan, which requires applicants to provide prescribers with a detailed information pack, to gather data on adverse effects, and to report these to the MCC at 6-monthly intervals.

**Notes:**

1. The Medicines Control Council (MCC) is responsible for regulating all medicines and medical devices in South Africa by ensuring that they meet standards of efficacy, safety and quality. The MCC operates in terms of the Medicines and Related Substances Act (Act 101 of 1965), the Regulations issued in terms of that Act, and associated guidelines.

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