Approve Truvada to be used as Oral Pre-exposure Prophylaxis for HIV Prevention in South Africa

Contact

John Mutsambi, <u>JohnM@tbhivcare.org</u>, 082 258 1238 Ntando Yola, <u>ntando.yola@hiv-research.org.za</u>, 021 650 4223 Brian Kanyemba, Brian <u>Kanyemba@hiv-research.org.za</u>, 021 650 4223 Yvette Raphael, <u>yvetteraphael8@gmail.com</u>, 0734653515

We, the signatories of this petition, call on the Medicines Control Council to approve the licensure of Truvada (already licensed as HIV treatment) to be used as Pre-exposure Prophylaxis (PrEP), in South Africa. Oral PrEP is a new HIV prevention tool, which if taken correctly and consistently, can prevent HIV infection in both men and women by more than 90 per cent. This proof of evidence comes from several clinical trials, some of them conducted in South Africa. For this reason, we strongly feel that Truvada should be licensed as PrEP and then should be made available to all those at high risk for HIV who desperately need this prevention tool where others are failing. To do so would be in alignment with WHO's forthcoming guidelines, recommending PrEP for all those at risk.

It is quite disheartening to know that PrEP is near and yet so far, due to regulatory hurdles. We are concerned that the continued delay in making PrEP accessible to those who need it most infringes on the fundamental rights of individuals who could benefit from it. Delaying the licensure of Truvada as PrEP, is resulting in more HIV infections that could be averted, holding back efforts to curb the further spread of HIV. In 2013 alone, almost 400,000 people seroconverted in South Africa. We urgently need PrEP as an additional option in our HIV prevention toolbox.

As HIV prevention advocates, we observe and acknowledge that our country has scored remarkable successes in fighting HIV and AIDS. We need to build upon these successes by taking advantage of new innovations like PrEP which will help us to bend the curve in the HIV epidemic in South Africa—preventing new infections and subsequently saving on treatment costs. Approval and implementation of Truvada as PrEP, will further support the National Department of Health's priority which is now in line with UNAIDS targets 90:90:90. It will be increasingly hard to achieve this priority if we don't stop new infections. In the absence of an effective vaccine, PrEP is one of the ways we can stop new infections. If immediate action is not taken to make Truvada as PrEP available, this will continue to haunt our collective conscience in years to come, knowing we could have averted massive numbers of new infections and saved on costs of lifetime ARVs and sickness. The time is now appropriate for regulatory action.

Call To Action

At the 7th South African AIDS Conference held in Durban from 9-12 June 2015, the voices of people demanding the approval and rollout of Truvada as PrEP were loud and clear. We therefore request that you:

- Place high priority on fast-tracking and approving Truvada as PrEP and recognize the urgency and ethical imperative of making this prevention tool available.
- Engage stakeholders, including civil society, on the status, plans and timeline for approval in an ongoing and transparent manner.

We further request that this petition be responded to in a timely manner.

Please sign below to ask the Medicines Control Council to approve the licensing of Truvada for PrEP as soon as possible.

Thank you