

8 March 2016

## ***South African Advocates' Statement on Dapivirine Ring Results***

***On this International Women's Day and amid great excitement South African PrEP advocates welcome the results from the ASPIRE and Ring Study and call for rapid action from International Partnership for Microbicides (IPM), the developer of the microbicide vaginal ring technology, and the South African Government to take concrete steps to adopt and implement this HIV prevention option for women.***

The results of two ring trials, ASPIRE and the Ring Study, announced at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, US on Monday 22 February are a remarkable advance in microbicide research and provide the potential to bolster HIV prevention efforts in South Africa and the sub-Saharan region at large. This is yet another exciting development after a pill that prevents HIV acquisition – daily oral PrEP – was approved by the Medicines Control Council late in 2015.

Both dapivirine ring trials showed a significant reduction in HIV infections among women who used the vaginal ring – inserted for a month – containing the ARV dapivirine, and they also established that the ring is safe to use. To note, like oral PrEP, for it to work one needs to use it. In the two sister studies, the reduction in HIV infections was greater among female trial participants who were over the age of 21 years who used the ring most consistently, but there was little or no reduction in HIV infections among women 18 – 21 years old.

We are pleased that Dr Aaron Motsoaledi, South Africa's Minister of Health, welcomed these results and also mentioned that every advance in science that empowers women to protect themselves from the HIV virus should be considered for rapid adoption and implementation. This is a critical need, especially given that women in our country are in urgent need of a tool they can use to protect themselves from HIV as they continue to be infected at alarming rates. One third of the almost 1,000 new HIV infections per day in South Africa are among young women aged 15 – 24. The overall infection rates among women in both studies – up to 4.5 to 6.1 percent – illustrate the need for new options for women. As PrEP advocates working very closely with civil society we rally behind the Minister of Health and we would like to see the following concrete steps taken without delay:

- Research institutions, International Partnership for Microbicides (IPM), Microbicides Trials Network (MTN) and civil society should work together to disseminate the study results to all relevant stakeholders and in the process, ensure that the stakeholders' suggestions, recommendations and input on the next steps are sought.
- IPM and MTN with the government's support, should conduct follow up social-behavioural and biological studies to find out why women below 21 years old did not benefit from this prevention tool.
- We support IPM's intention to immediately seek regulatory approval to licence the vaginal microbicide ring.
- Alongside this, we commit ourselves to backing up IPM's and MTN's plans to conduct open label extension studies to assemble additional information to inform the potential rollout of the intervention in the real world.
- We would also like to urge the South African government to move beyond the approval of PrEP to actually ensuring its rapid rollout, particularly among women.

We are aware that implementing these concrete steps will take time and should therefore begin as quickly as possible. It is exciting that science has afforded us yet another option for women to use to discretely prevent HIV. We strongly call for no delays in ensuring the dapivirine ring moves through the processes needed to determine if it can be made available in real life settings. At the same time, the critical acceleration of PrEP for women and others at significant risk of HIV must continue. The country cannot for any reason afford to waste time in taking these new prevention options forward.

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