Getting a microbicide into the field in South Africa: What would it take?*

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* This research was commissioned by the International Partnership for Microbicides (IPM). The findings do not necessarily reflect IPM's views.
Background

• IPM contracted HDA, SFH and GAF to perform a study on access to microbicides in South Africa

• This was done through document reviews, informant interviews and stakeholder workshops
Focus areas

- Regulatory approval
- Requirements for importation
- Policy and decision-making processes
- Financing
- Procurement

- Local manufacture and commercial distribution
- Distribution channels, logistics and distribution
- Marketing, communication and branding
- Community preparedness: are communities ready for microbicides?
Key Findings 1 – Delays are real!

- Delays in registration with the MCC may be a key impediment
  - Even “fast track” registration can take up to a year, unclear what products can be fast tracked. Cost data are becoming important!
- Manufacture takes time to scale up
- While the Department of Health can make funding available, there will have to be a process of decision making and application within government
- Even if the DOH is committed and provides funding for a microbicide, procurement, training and distribution can add further delays to microbicide access.
Key Findings 2: There are also opportunities

- South Africa has a strong Regulatory Body (The MCC) that could be used by other countries in the region
- There are 2 manufacturers in South Africa that could manufacture a microbicide for the country and the region, and the South African government has financing tools to support them
- South Africa already funds a large HIV programme ($350 million per year), and would be willing to include microbicides into this funding envelope. It would help if the product was researched and manufactured in South Africa!
- We already have experience of segmenting the condom market to get maximum distribution of a product – private, public and socially marketed products
- South Africa has an active media environment with multiple programmes focusing on HIV prevention
But remember….

- The best microbicide with the best access plan will not change all the underlying societal issues that make this epidemic such a challenge.

- So, we still need prevention messages and to challenge unequal gender relationships, and strengthen health systems.
Recommendations

• A lot of the detailed planning needs to wait until a microbicide candidate shows efficacy

• However, we can and should:
  ✚ Ensure that clinical trials are rigorous, and also look at cost-effectiveness and acceptability
  ✚ Strengthen regulatory bodies
  ✚ Keep our governments up to date on developments
  ✚ Start negotiating with manufacturers
  ✚ Try and get consensus within the scientific community
  ✚ Look at alternative distribution channels
  ✚ Start to examine models of microbicide manufacture, financing, cost–effectiveness, that will allow informed decision making when the results of clinical trials are known

• All this is necessary if we don’t want excessive delays
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