



**INTERNATIONAL**  
**PARTNERSHIP for**  
**MICROBICIDES**

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

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Presentation to Microbicide 2006 Conference

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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

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- 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

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- 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!

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- 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 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

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- 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....

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- 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

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- 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

# Thanks

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