Preparing for Access at the Country Level: Findings from Zambia and South Africa

Rick Hughes, JHPIEGO
Saul Johnson, Health and Development Africa

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

- Present selected highlights and recommendations from the initial Country Preparedness Assessments
Initial Country Preparedness Assessments

- Zambia:  
  - JHPIEGO

- South Africa:  
  - Health and Development Africa
  - Society for Family Health
Outline

- Regulatory approval
- Decision-making, financing
- Manufacture, importation
- Market strategies, distribution
- Community preparedness
- Considerations for trials and research
Pick a country with a strong and reputable DRA for initial registration

Use this regulatory approval to facilitate registration in subsequent countries

Work with people highly experienced with the local decision makers and processes

Educate and advocate with key stakeholders in advance
Regulatory Approval (cont)

- Ensure robust technical data from clinical trials, supported with peer reviewed articles.
- Complement efficacy and safety with additional studies (e.g., cost effectiveness, acceptability).
- Secure fast-track status.
- Position for the least restrictive schedule possible.
Decision-making, Financing

- In any country, strong support from MOH is likely to be critical.
- Identify and educate / advocate with other key stakeholders:
  - e.g., medical council, medical / pharmacy associations, etc.
- SA is an exception in that MOH could largely finance major public sector distribution.
- Donor support will be critical in most countries for public sector distribution and/or for social marketing.
Manufacture, Importation

- In most cases, finished medicinal products are tax and duty free, but some raw materials for local manufacture may not be.
- Once registered and approved, importation does not seem to be a major constraint.
- Some countries have tax structures, incentives, and other considerations that may make local manufacture advantageous.
- Regional manufacture could have an added benefit due to local trade alignments.
Market Strategies, Distribution

- Target multiple channels
  - Public sector
  - Social marketing
  - Private sector
- Integration / complementarity with other prevention strategies & methods
- Scientific profile & registration will determine many opportunities, for example:
  - Community-based distribution
  - Point of use / high-risk sites such as bars, truck stops, etc.
  - Use by women at risk of sexual violence
- Involve communities, civil society, and men
Community Preparedness

- Learn from existing experience with both HIV prevention and woman-controlled products
  - Male condoms, female condoms, OCPs

- Ensure product availability and accessibility is coordinated with demand generation

- Even with a ‘woman-controlled’ microbicide, do not underestimate the role of men
Community Preparedness (cont)

- Concerns over the possible impact on promiscuity, early sexual debut, increased ‘risky’ behavior / sexual disinhibition should be clearly addressed.

- Women’s perceptions of men’s attitudes and preferences may be important.

- Urban and rural communities are likely to have different profiles and require different strategies.
Considerations for Trials and Research

- Safety and efficacy in ‘real use’ situations
- Contraceptive effect, impact on conception and fertility
- Time to onset and duration of effectiveness
- Shelf-life and storage requirements
- Products containing ARVs – potential impact on HIV resistance
- Potential for post-exposure prophylaxis
Considerations for Trials and Research (cont)

- Continue to conduct relevant social science research to inform clinical research and focus advocacy, communication and marketing strategies, for example:
  - Sexual practices (e.g., dry sex, anal sex, acceptability of lubricants, violence, etc.)
  - Sexual debut, promiscuity, potential disinhibition
  - Acceptability of different delivery methods
  - Decision-making and male involvement
  - Contraceptive/fertility preferences
  - Price sensitivity
Summary

- Continue to conduct high-level advocacy and education with stakeholders
- Be careful, however, to coordinate demand generation and supply/access
- Build solid scientific data, backed by publications, for registration
- Gather critical scientific evidence to support product positioning and marketing
- Continue to fund social-science research on relevant issues
Thank You

Rick Hughes, J HPI EGO
Saul Johnson, Health and Development Africa