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

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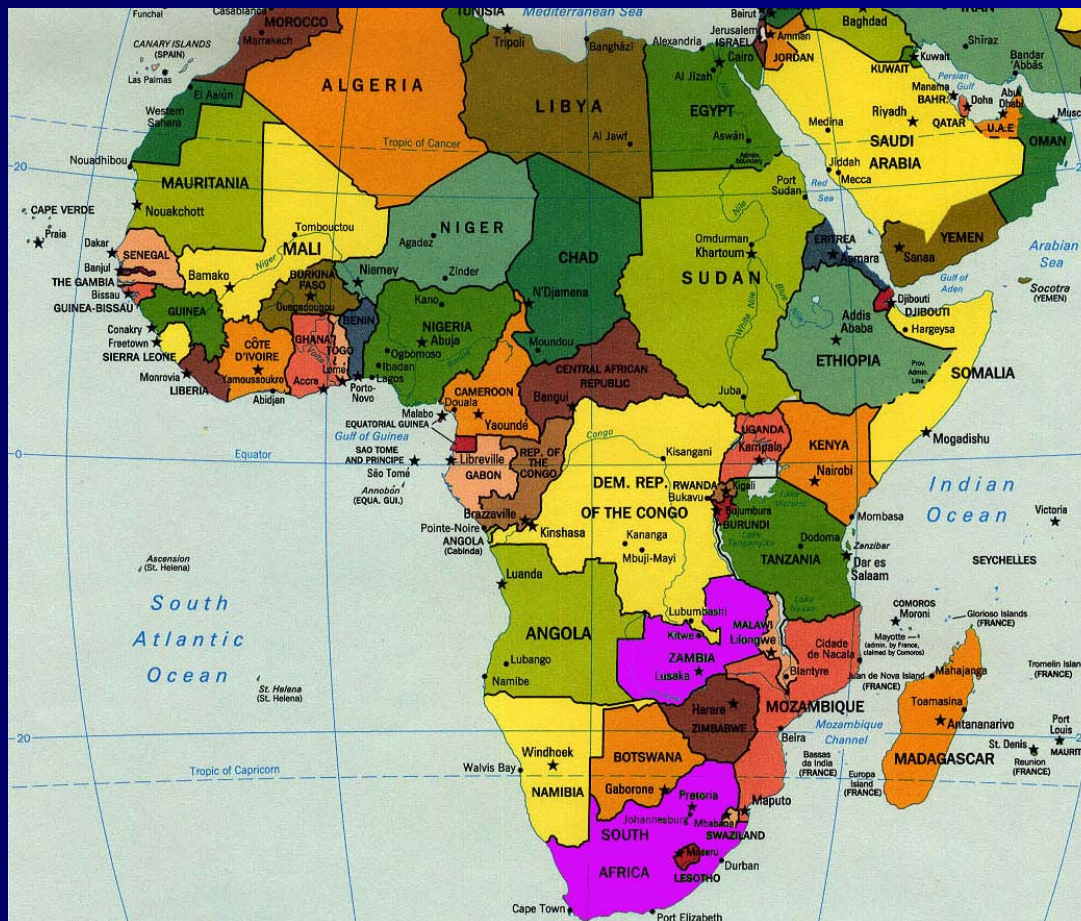
This research was commissioned by the International Partnership for Microbicides (IPM). The findings do not necessarily reflect IPM's views.



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



Regulatory Approval

- 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 may 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)

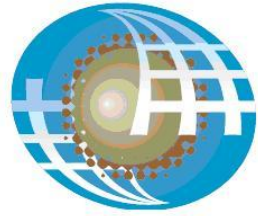


- Continue to conduct relevant social science research to inform clinical research and focus advocacy, communication and marketing strategies, for example:
 - Sexual practices (e.g., dry sex, anal sex, acceptability of lubricants, violence, etc.)
 - Sexual debut, promiscuity, potential disinhibition
 - 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



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Thank You

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