

Preparing for Microbicide Access and Use: Policy Priorities

Elizabeth McGrory
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Overview

Why address access now?

Dimensions of access

- Acceptability and use
- Supportive environment
- Availability
- Affordability
- Regulatory approval and licensing

Priorities for action

Why address access now?

“Access” central to ultimate goal of reducing HIV/AIDS transmission

Effectiveness trials beginning

Few products reach developing countries until 10+ years after introduction in West

Expectation that products demonstrated to be safe and effective will be made available quickly

- Urgent need
- Public investment
- Clinical testing
- Access to treatment

Acceptability and Use

Women and men want to use microbicides, and know how to use them properly

- Products meet user needs; are easy to use
- Informed choice; potential users can decide if microbicides appropriate
- People who want to use microbicides understand how to do so correctly

Acceptability and Use

- Prioritize user perspectives in product development
- Explore ways to communicate complex concepts
- Develop and test model materials and program approaches for product introduction
- Consider introduction strategies that build on staying healthy and pleasurable aspects of sex

Supportive Environment

Microbicides actively supported as key strategy for HIV and STI prevention

- Social and policy environment supports microbicide use
- International agencies actively promote microbicide development and introduction; resource for national programs
- Microbicides adopted by policy makers as part of a comprehensive HIV/ STI prevention program

Supportive Environment

- Increase awareness of microbicides
- Identify and address concerns of policymakers, providers, potential users
- Develop model national frameworks for introduction, promotion, financing, and delivery
- Continue analysis to demonstrate potential impact of microbicide introduction

Availability

Microbicides easily available to users

- Microbicides available in range of outlets convenient to different potential users
- Efficient, effective, reliable distribution systems within countries
- Reliable supply globally and nationally
 - Financing
 - Logistics
 - Manufacturing

Availability

- **Examine existing systems and programs:**
 - Service delivery and consumer education
 - Procurement
 - Logistics
 - Manufacturing and packaging
- **Strengthen and/or plan for new systems**
- **Demand projection**
- **Learn from other products; be creative**

Affordability

Cost is not a barrier to microbicide use

- Microbicides priced at level users can afford
- Product and distribution costs as low as possible
- Subsidies/financing mechanisms to ensure sustainable supply
- Overall revenues make product commercially viable

Affordability

- Microbicides on international agenda re: financing for health
- Price guarantees for public funds for R&D and clinical trials
- Tiered pricing; product differentiation
- Manufacturing, packaging, distribution, purchasing
- Donor commitments
- Ongoing analyses to assess market viability

Regulatory Approval and Licensing

Microbicides are approved and licensed by relevant authorities rapidly and efficiently

- Regulatory authorities have information and procedures to approve and license microbicides
- Minimize delays due to differences in requirements between countries/regions
- Develop national and international systems and protocols to monitor product quality and use

Regulatory Approval and Licensing

- Develop guidance document on scientific requirements for regulatory review
- Encourage regional collaboration to establish guidelines and review based on risk/benefit
- Specify and prepare for local trials or bridging studies
- Continue work with FDA and EMEA to prepare for rapid review
- Develop common application formats

Priority Activities...

- Conduct policy research in key countries to establish framework for “microbicides preparedness”
- Establish technical working group, including public and private sectors, to specify policy, legal, fiscal, and monetary measures to ensure microbicide access
- Continue international and regional efforts to outline regulatory processes and requirements

...Priority Activities

- Step up efforts to raise profile of microbicides on the “Global Stage”
- Form strategic alliances for common goals; draw in new expertise

Implications for Product Development

To ensure microbicide access and use, a range of initiatives concurrent with product development, starting now

Decisions regarding product development and testing should explicitly consider implications for future access and use

R&D guided by accessibility priorities in addition to scientific imperatives

Why address access now?

Smart thing to do

- Expand constituency and resources
- Opportunity to systematically prepare for access
- Build on international attention to public health goods for vulnerable populations
- Coverage drives impact

Why address access now?

Right thing to do

- Urgent need
- Access should drive agenda, especially given public sector investment
- Requires careful preparation and investment
- Product that does not reach people at risk will not save lives

Thanks to

Access Working Group

Geeta Rao Gupta, Co-Chair

Lori Heise

Quarraisha Abdool Karim

Susan Perl

Jeffrey Spieler

Consultants

Jane Rowley

Roy Widdus