Microbicide Access Forum

Mexico City: August 3 2008

Meeting Report

ACKNOWLEDGEMENTS

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EXECUTIVE SUMMARY

The second Microbicide Access Forum held in Mexico City, Mexico, on 3 August 2008 helped advance the way forward for microbicide access by bringing together more than 40 representatives from microbicide development, government, research and science, HIV/AIDS advocacy, the pharmaceutical industry and reproductive health to evaluate the current state of access planning, and draw on lessons learned from the introduction of health technologies in developing countries.

Hosted by the International Partnership for Microbicides, Population Council and World Health Organization, with funding from the US Agency for International Development and European Community, the event was held in advance of the XVII International AIDS Conference.

Forum participants assessed recent progress in microbicide development and new data on microbicide acceptability. Preliminary findings from a recent mathematical modeling study conducted by The London School of Hygiene and Tropical Medicine designed to forecast the impact of microbicide introduction in India and South Africa were discussed. The research clearly illustrates how factors such as efficacy, distribution channels and speed of regulatory approval could act together to play a critical role in determining eventual microbicide uptake.

Participants also explored the pharmaceutical industry's experience introducing antiretroviral therapy in developing countries, with a focus on the crucial role partnerships play in providing access to new products.

Recent efforts to introduce Human Papillomavirus (HPV) vaccines for preventing cervical cancer into public health programs were also examined along with the criteria policymakers use at the country level to decide whether and how to introduce new health products.

Forum participants reached consensus on the need for further effort in the areas outlined below:

- Supporting efforts to build capacity for regulatory oversight in developing countries as well as efforts to harmonize guidelines for clinical trial and marketing approval applications;
- Continuing to develop and strengthen partnerships for access with key stakeholders including governments, civil society, private sector and multilateral agencies;
- Building capacity for social science research and examining under-researched topics such as the social context of microbicide use and demand;
- Exploring financing options for microbicide introduction and scale-up programs;
- Developing product-specific introduction plans with strategies for manufacturing, financing, distribution, marketing and evaluation, and tying timing to progress in clinical trials;
- Finding opportunities to meaningfully engage civil society while managing expectations about the likely timelines for microbicide access.

The Microbicide Access Forum is an annual event that provides an opportunity for stakeholders to share information, discuss current issues and examine new evidence to plan for the future introduction and use of microbicides. The first forum was held in Nairobi in 2007.

This report includes a summary of the meeting sessions, agenda and participant list. Presentations from the meeting are available online at: http://www.ipm-microbicides.org/ensuring_future_use/english/2008_microbicide_access_forum.htm.

1. Update on Microbicide Development: Zeda F. Rosenberg, IPM

Summary

- *HIV prevention landscape*: Recent disappointing results from HIV prevention trials are a stark reminder that drug development is a difficult and unpredictable process, and that the majority of drugs that enter the clinical trial process fail. This is especially true for a new class of drugs like microbicides.
- *Early and next-generation microbicides:* Next-generation microbicides are in different stages of preclinical and clinical development. Unlike early-generation microbicides, these antiretroviral (ARV)-based compounds are specific to HIV and highly potent. They also more easily lend themselves to long-acting formulations such as gels, rings, films and tablets and therefore not coitally-dependent. Resistance is a possible issue with ARV-based microbicides that must be investigated further in clinical studies.
- *Microbicide development process and criteria for moving forward*: Drugs that act earlier in the HIV life cycle are preferred for use as microbicides. At each stage of development, IPM's approach is to advance the best-in-class drugs to the next stage. At the preclinical stage, the drug's toxicity, potency, ease of manufacture and intellectual property status are assessed. During the clinical phase, drugs are evaluated on the basis of pharmacokinetics, safety and acceptability. Top candidates move into clinical safety and efficacy trials, where they are evaluated on all these factors as well as efficacy in HIV prevention.
- *Intellectual Property*: IPM and others in the microbicide field have been successful in obtaining non-exclusive, royalty free licenses from several pharmaceutical companies to develop antiretroviral compounds as microbicides for use in developing countries. These licenses allow for distribution on an affordable basis.
- *Pathway to Access:* Securing favorable intellectual property agreements and conducting robust clinical trials are critical in the pathway to access. Conducting ethical and rigorous clinical trials are a pre-requisite for obtaining licensure to market the product. The work of microbicide developers in strengthening research capacity to conduct clinical trials will pave the way to support access programs in the future. Ultimately, it will take a major effort on several fronts, including demand forecasting, manufacturing, marketing, mobilizing financing and garnering political support, as well as the contributions of a range of public and private sector partners to make access to microbicides a reality.

Discussion

- *Access timelines:* Timelines are difficult to predict because of the risk inherent in drug development. Trials of two early-generation microbicides are expected to declare results in 2009. If proven successful, they could be licensed in a few countries by 2010-11. A next-generation candidate, Tenofovir, is in a proof-of-concept trial that is scheduled to complete by 2010. A second confirmatory study of the compound is expected to begin next year and complete by 2012. Several other candidates are in earlier stages of clinical and pre-clinical development.
- *Regulatory requirements for efficacy/ resistance/ safety*: Since no microbicide has been licensed for marketing in any country, it is difficult to predict what efficacy/ safety profile would be considered acceptable for a microbicide. National regulatory authorities have the mandate to evaluate a compound, and based on the compound's risk/benefit profile in the context of the country's population, make a decision on marketing authorization.
- *Resistance*: Questions related to the issue of HIV drug resistance have been discussed since the first considerations of ARV-based vaginal microbicides. Specifically, questions regarding the risk for selection and transmission of HIV drug resistance through microbicide use have been raised. For example, what is known about the risk for the transmission and selection of HIV drug resistance through use of microbicides? Specifically: could a vaginal microbicide select for HIV strains that are resistant to the drug (or drug class) in women who are already infected and are

using the product? HIV-infected women may be either unaware of a pre-existing HIV infection (incorrect use of a preventative microbicide) or have become HIV infected while using the microbicide (microbicide failure or inconsistent use). Additionally, could drug-resistant virus (from the male) override the barrier of an effective microbicide? In summary, resistance is an important issue that requires careful study and further evaluation during the development and clinical testing of ARV-based microbicides.

- *Geographic prioritization for access*: Microbicides would initially be introduced in the communities that hosted clinical trials. This is an ethical requirement in that communities that contribute to research should be prioritized to receive its benefits. These communities are also best placed for early introduction programs because they are familiar with the product and its use. The next tier of priority is other communities in the countries that hosted trials, followed by other, high-need countries.
- *Managing expectations*: Grassroots mobilization efforts need to consider that a microbicide may not be available in the very near future and that expectations among potential users must be tempered to match these timelines.

2. Introducing and Scaling Antiretroviral Therapy in Developing Countries- Lessons from the Pharmaceutical Industry: Jon Pender, GlaxoSmithKline and Ben Plumley, Tibotec Pharmaceuticals Ltd.

Summary

- *Barriers to access in the developing world:* Scarce funding, lack of healthcare workers and inadequate infrastructure pose huge barriers in providing quality healthcare in the developing world. As a result, access to essential medicines in Africa is less than 30%.
- *Partnerships are key:* Delivering access requires the cooperation of many stakeholders. The right partners will have complementary core competencies, recognize common objectives and tackle difficult issues (such as intellectual property) upfront. An effective governance structure, transparency and accountability are essential components of a good partnership.
- *Market preparedness is vital*: This will include demand forecasting, establishing distribution systems, securing the supply chain, influencing public health strategy, engaging in dialogue at the highest levels, and securing funding.
- *Regulatory approval can be a major rate-limiting factor:* Many under-resourced developing countries look to the regulatory opinions of the World Health Organization (WHO) or agencies in developed countries to guide their decisions. WHO has a prequalification program that offers opinions on the safety, acceptability and efficacy of new drugs, and is highly regarded as a measure of quality in many developing countries. The European Medicines Agency has introduced a regulatory mechanism, called Article 58, through which it would provide an opinion on drugs that are intended for use outside European markets only. This mechanism could also prove relevant for microbicides since these drugs are being developed primarily for developing country use.
- *Cause for pragmatic optimism:* Despite hurdles, the AIDS treatment field has seen many successes on the access front. Microbicide access may face a greater burden of stigma and taboo, because it will deal directly with sexual behavior and gender dynamics. However, with rigorous advance planning, challenges can be overcome and widespread access to microbicides can be a reality.

Discussion

- *Need for regulatory harmonization*: Drug developers could benefit greatly from greater regulatory harmonization across countries. The example of southern African countries adopting vaccine guidelines developed by South Africa was cited as a model. WHO could play a key role in facilitating harmonization efforts.

- *Need to increase capacity of WHO and national regulatory authorities*: Donor agencies need to increase funding for building regulatory capacity in developing countries. This could take the form of direct funding to national regulatory authorities and/or funding for WHO to help facilitate capacity building.
- *Need for regulatory guidelines*: Since microbicides are a new class of product, the regulatory pathway for licensure is untested. In the past, country guidelines have been subject to changes due to staff turnover. WHO can play a role by convening national regulatory authorities to agree on a set of harmonized guidelines.
- *Over-the-counter vs. prescription only*: It was agreed that microbicides, whether it be early or next-generation candidates, will likely not be approved for marketing as over-the-counter in the initial stages. In the case of ARV-based microbicides, it is also possible that regulatory agencies might require pre-prescription HIV screening due to concerns about resistance.

3. Interim Lessons from HPV Vaccine Introduction: Olga Georgina Montana M, Mexico National Center for Gender Equity and Reproductive Health, Ministry of Health; and Timothy Farley, World Health Organization

Summary

- *Status of HPV vaccine introduction:* HPV is a very common sexually transmitted virus that causes 99.7% of all cervical cancer cases. Two vaccines that provide protection against the two HPV strains most commonly associated with cervical cancer have recently become available. These vaccines were developed by Merck and GlaxoSmithKline (GSK) and have been licensed in over 120 and over 50 countries respectively. While public sector rollout has begun in many developed countries, developing countries are lagging despite the fact that cervical cancer is the leading cause of cancer deaths in women in developing countries.
- *Access challenges in developing countries:* The HPV vaccine costs approximately US$120 per dose in developed countries. Although the manufacturers have agreed to reduced prices for developing countries, international subsidies will still be needed to make the vaccine widely and equitably available. Financing from the Global Alliance for Vaccines and Immunization (GAVI) and the Pan-American Health Organization (PAHO) revolving fund will be critical for HPV vaccine access. However, financing is only one challenge. The acceptability of vaccinating preadolescent girls for a sexually transmitted infection and the difficulties in reaching this group remain challenges that need addressing.
- *Lessons for microbicides:*
  - Design trials capable of demonstrating efficacy, effectiveness, safety and acceptability
  - Identify suitable, sustainable and relevant financing mechanisms
  - Develop guidelines and policy recommendations for product use and programming
  - Ensure awareness and commitment at the highest levels (regional and international)
  - Develop research programs to inform policy and programs (bridging studies to assess acceptability, safety in different populations, factors impacting consistency of use etc.)
- *Experience of Mexico:* Cervical cancer is the second leading cause of cancer death among women in Mexico, and is associated with poverty, lack of schooling, residency in rural areas and lack of access to health services. A cost-effectiveness study by the Mexican Ministry of Health indicated that at US$20 per dose, a vaccine in combination with screening programs could prove cost effective. However, price poses a barrier as do other competing priorities, and the Ministry has decided to prioritize access to the vaccine among vulnerable populations with poor access to health services in order to maximize cost-effectiveness. The vaccine was included in the Government's list of basic drugs, and a public tender has been issued. (Merck and GSK have recently responded with price offers of US$44 and US$42 per dose, respectively.) The case study of HPV vaccine introduction in Mexico offers lessons on how government programs have to

balance decisions about introducing a new product against competing priorities such as other immunizations or the improvement of screening programs.

Discussion

- *Pricing*: Public pressure will be key in addressing pricing issues for new drugs and vaccines. While financing mechanisms such as GAVI have contributed to tackling the price barrier facing low-income countries, the challenge of middle-income countries that are unable to afford public sector access remains. Pricing should be less of an issue for the microbicides field because the public sector has underwritten the majority of microbicide development costs. Additionally, licensing agreements like IPMs' have built in flexibility in setting prices in low-income countries, as well as middle-income countries like India and South Africa. Other product development teams also have preferential pricing arrangements for public sector distribution in developing countries.
- *Educating policy makers*: Policy makers need to be updated about new technologies well in advance of expected registration, so they can consider the inclusion of the new product within their budget and program cycles.

4. Acceptability Studies' Contribution to Microbicide Access: Youssef Tawfik, IPM

Summary

- *Domains of enquiry:* Acceptability research investigates user experience and preferences with regard to product characteristics, effect on sexual relationships, male partner involvement, potential for covert use, concerns about side effects and delivery systems. Findings from acceptability studies have relevance for upstream research and development efforts (e.g. formulation preferences) as well as downstream marketing and delivery planning efforts.
- *IPM studies:* Three market research studies assessing the acceptability of microbicide formulations among women and their sexual partners in Africa are either complete or underway. In 2005, IPM investigated the acceptability of gels with differing viscosities among women and their male partners in Kenya, South Africa and Zambia. A vaginal ring acceptability study is ongoing in South Africa and Tanzania. A third study is planned in Burkina Faso, Mozambique, Tanzania and Zambia to investigate preferences regarding vaginal tablets, gel capsules and films. The studies' findings are helping determine which formulations IPM pursues further. Results will be disseminated widely to other microbicide developers and stakeholders.
- *Population Council studies:* A study to assess the acceptability of a placebo vaginal gel and inert vaginal ring is planned in Africa. The study will also investigate various self-reporting methods and recruitment strategies. Clinical trials of three different contraceptive vaginal rings are also underway or planned, that will provide information about the acceptability of ring formulations among women in the populations where they are tested. The studies include a Phase 3 trial in the North America, Latin America, Europe and Australia (ongoing); a Phase 2 trial in Latin America and North America (ongoing), and a Phase 3 trial in Asia (planned).
- *Areas for future research:* Condom migration, the impact of partial efficacy and the role of male partners in determining product acceptability were identified as areas where further research is needed.

Discussion

- *Covert Use:* Studies conducted by the Microbicide Development Programme (MDP) and the Population Council indicate that women generally prefer to let their partner know if they are using a microbicide. A Population Council study showed that a majority of participants disclosed their enrollment in a trial to their male partners. Acceptability to the male partners was a very important factor in continued and consistent use of the product. In Uganda – in findings from a MDP study – disclosure about gel use and trial enrollment has helped women negotiate condom use with their male partners.

- *Translating Findings:* Experiences recorded within the controlled context of a clinical trial may not necessarily predict how a product would be used when available in the market. However, they can offer some preliminary assessments to guide access planning efforts.

5. The Public Health Impact of Microbicides: Results from Recent Mathematical Modeling Studies- Charlotte Watts and Lilani Kumaranayake, London School of Hygiene and Tropical Medicine

Summary

- *Study objectives*: The objectives of the study were to estimate the impact of microbicide introduction on the HIV epidemic in southern India and South Africa; explore how microbicide impact can be influenced by product efficacy and use, introduction strategy, level of population uptake, speed of product approval, and restrictions on product delivery; and estimate the cost and cost-effectiveness of different distribution scenarios.
- *Scenarios:* The mathematical model used for estimating microbicide impact employed scenarios with different assumptions about HIV-efficacy per sex act, percentage of sex acts covered by microbicides, and the effect of microbicide introduction on condom use. The modeling considered several introduction strategies, including the distribution of microbicides to all sexually active women, distribution to female sex workers only and population wide distribution with enhanced provision to youth.
- *Results of Impact Study:* Preliminary results suggest that the highest impact in southern India would be achieved through distribution to female sex workers when the product has high preventive efficacy, high consistency of use, and achieves quick approval and high levels of uptake. In South Africa, the model predicts highest impact with population wide introduction of a product that sees high levels of uptake, and that is highly efficacious, used consistently and approved quickly.
- *Cost/ Cost-Effectiveness:* Preliminary results predict that the most cost-effective scenarios in India will be a targeted distribution to female sex workers (this is also the scenario that achieves highest impact). The South Africa results are to be reported at a later stage.
- *Dissemination*: Final results of the studies will be disseminated in journals and other publications by the end of 2008.

Discussion

- *Role of modeling studies:* Modeling studies can examine the impact of various introduction scenarios on different epidemics and different populations. Results can be used with funders, regulatory agencies and other stakeholders to make the case for microbicides. For example, the potential impact of microbicides could be used to make the case for sustained funding and the impact of delays in licensure could be used with regulatory agencies to advocate for expedited review of marketing applications.
- *Cost-effectiveness vs. impact:* While universal coverage is desirable, resources for access programs could be limited. In this scenario, identifying the most cost-effective interventions will help program managers achieve the highest impact, and make the case for scaling up of targeted programs and eventually, universal access.

6. Service Delivery and Demand Challenges in Introducing New Health Products: Helen Rees, Reproductive Health and HIV Research Unit; and Bernice Heloo, Society for Women and AIDS in Africa

Summary

- *WHO conceptual framework for contraceptive introduction:* Aspects to consider when introducing a new health product into an existing health system include: profile of potential users

and their needs; product profile including safety, efficacy, side effects etc; availability of other options; and the capacity of the health system to absorb a new product.

- *Introduction takes time*: Uptake rates for new products depend on many factors, including price, political context and distribution channels. A typical product uptake curve, based on past experiences from the introduction of other products, indicates a pattern of initially slow uptake, followed by a rapid scale-up phase and then a less rapid maturation phase. In the public sector in developing countries, coverage of 50-60% has taken up to 30 years in the case of many products. Coverage of 70% seems to be the upper bound in most cases. In comparison, uptake through the private sector in developed countries has typically been more rapid.
- *Lessons from the female condom:* The female condom (FC) introduction in South Africa, Zimbabwe, India and Ghana provide several lessons for microbicides. Transferable lessons from female condom introduction include the effectiveness of targeting niche populations; importance of reliable and consistent supply, the value of using multiple information and distribution channels; understanding gender dynamics and their impact on product use; developing male buy-in; and building support among important opinion leaders. Finally, experience indicates the utility of not overselling a product and transparently communicating the product's risks and benefits.

Discussion

- *Positioning:* Products will need to be positioned differently with audiences and markets. For instance, according to research conducted in South Africa, women's empowerment resonated as a product benefit to potential microbicide users, but not by women living with their partners. On the other hand, working women tended to react positively to messaging about sexual pleasure.
- *Role of competition:* It was noted that marketing of one brand can have a positive influence on sales of competing brands. Similarly, competition among various microbicide brands could have a multiplier effect on overall microbicide uptake.

7. Key Themes and Next Steps: Martha Brady, Population Council; Manju Chatani, African Microbicides Advocacy Group; and Debrework Zewdie, World Bank

Summary and Discussion

- *Need for regulatory strengthening and harmonization*: Weak regulatory capacity in developing countries as well as the lack of clear regulatory guidelines increases the uncertainty inherent in drug development. WHO can play a coordinating and facilitating role in strengthening and harmonizing regulatory systems.
- *Financing*: The availability of international financing to support the introduction of microbicides will be critical to the success of introduction efforts, as has been evidenced in the introduction of several other health commodities.
- *Meaningfully engaging civil society*: Prematurely mobilizing grassroots support can create expectations which my be difficult to deliver on, based on the timing and phasing of product development. However, in the long-term, civil society has an important role to play in creating demand and facilitating access.
- *Expanding the role of social science research to prepare for access*: As the microbicide field gets closer to licensed products, marketing, product positioning and public education will become increasingly important. Systematically and strategically using social science research can help to understand product acceptability, adherence, use and context of use.
- *Developing a specific introduction plan*: Closer to licensure, there will be need for a product-specific introduction strategy that identifies countries and locations for initial introduction as well as strategies for manufacturing, financing, distribution, community engagement, marketing and evaluation. Timing will depend on progress in clinical trials.

Annex I: Agenda

TIME	TOPIC	PRESENTER / MODERATOR
7:30– 8:30	Breakfast and Registration	
8:30 - 8:45	Welcome and Forum Objectives	Dr. Susana Prudencia Cerón, Mexico National Center for Gender Equity and Reproductive Health, Ministry of Health Dr. Kim Dickson, World Health Organization
8:45 – 9:30	Update on Microbicide Development • *New scientific developments since last forum* • *Discussion*	Dr. Zeda Rosenberg, International Partnership for Microbicides
9:30 – 10:30	*Challenges and Lessons Learned from Introducing Relevant Health Products - I* Introducing and Scaling Antiretroviral Therapy in Developing Countries • *Pharmaceutical industry experience: policy, price, supply, logistics* • *Discussion*	Panel: Dr. Jon Pender, GlaxoSmithKline Mr. Ben Plumley, Tibotec Pharmaceuticals Ltd. Moderator: Dr. Thomas Mertenskoetter, International Partnership for Microbicides
10:30 – 10:50	Break	
10:50 – 11:50	*Challenges and Lessons Learned from Introducing Relevant Health Products - II* Interim Lessons from HPV Vaccine Introduction • *Role of the World Health Organization in supporting national policy development and setting international guidelines: HPV vaccine case study* • *Introducing new commodities into national programs: Mexico's experience with the HPV vaccine* • *Discussion*	Presentations: Dr. Timothy Farley, World Health Organization Dr. Olga Georgina Martinez and Dr. Susana Prudencia Cerón Mireles, Mexico National Center for Gender Equity and Reproductive Health, Ministry of Health Moderator: Ms. Sarah Goltz-Shelbaya, Cervical Cancer Action

TIME	TOPIC	PRESENTER / MODERATOR
11:50 – 12:30	Acceptability Studies: Contribution to Microbicide Access • *Recent microbicide acceptability studies* • *Discussion*	Presentations: Dr. Youssef Tawfik, International Partnership for Microbicides Moderator: Dr. Sandy Garcia, Population Council
12:30 – 13:30	Lunch	
13:30 – 14:45	The Public Health Impact of Microbicides: Results from Recent Mathematical Modeling Studies • *Potential public health impact of microbicide introduction* • *Cost implications* • *Discussion*	Presentations: London School of Hygiene and Tropical Medicine Team
14:45 – 15:45	Service Delivery and Demand Challenges in Introducing New Health Products • *Service delivery of reproductive health products* • *Community demand* • *Discussion*	Panel: Dr. Helen Rees, Reproductive Health and HIV Research Unit Ms. Bernice Heloo, Society for Women Against AIDS in Africa Moderator: Dr. Kim Dickson, World Health Organization
15:45 – 16:00	Break	
16:00 – 17:00	Open Discussion	Moderator: Ms. Manju Chatani, African Microbicides Advocacy Group
17:00 – 17:15	Conclusion and Way Forward	Ms. Martha Brady, Population Council
17:15 – 17:30	Closing Remarks	Dr. Debrework Zewdie, World Bank

Annex II: Participant List

	Name	Organization	Position	Country	Email
1	Dr. Sharon Abbott	Population Council	Associate	USA	sabbott@popcouncil.org
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