

A framework for future microbicide access in developing countries

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Planning for Access

The International Partnership for Microbicides [IPM] is an international not-for-profit organisation dedicated to preventing HIV transmission by accelerating the development and availability of safe and effective microbicides for use by women in developing countries.

Supporting 'access' to future microbicides is an integral part of IPM's mission. IPM has developed a framework and timeline to guide, coordinate and sequence activities contributing to future 'access.' The framework emphasises that supporting developing country access will require contributions from a wide range of stakeholders including researchers, product developers, manufacturers, distributors, policy makers, NGOs, donors and communities.

Defining 'Access'

A number of frameworks exist that define 'access' to health commodities.^{1,2} Summarising these, access to microbicides can be defined as getting a **high quality and effective product that women want to use:**

- to the right place
- in the right quantity
- in the right condition
- at the right time
- with the right service and support
- at the right cost

To ensure that these conditions are met, an access framework needs to address several dimensions that have both user and supply side aspects. These include:

Availability: sufficient *supply* of quality product is required to meet user *demand* - which itself needs to be generated.

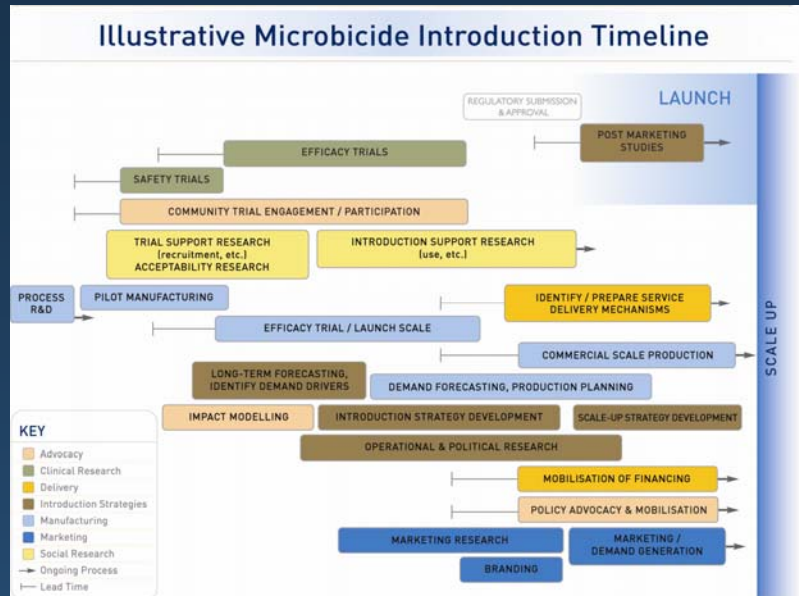
Accessibility: effective channels are needed to distribute products and service points geographically close enough to intended target populations.

Acceptability: the *product and the way in which it is provided* need to be acceptable to end users and to policy makers and gatekeepers (e.g. health professionals) that control product availability.

Affordability: the cost of the product and the programme required to deliver it must be affordable and sufficient financing (public and/or private) must be available.

In addition, to have a health impact, microbicides must be **appropriately used** as part of personal and programmatic strategies to prevent HIV transmission. This requires that policy makers can make informed decisions about the use of microbicides *as part of HIV strategies* and that women and their partners can equally decide on if, how and when to use microbicides to reduce their risk of HIV transmission.

These dimensions make clear that access is a theme running throughout the development and introduction process. The foundation of access is early acquisition of intellectual property rights for drugs under development, which makes their availability guaranteed before large development funds are spent. Access considerations must also be taken into account during design (e.g. ensuring acceptability and affordability), through to clinical testing (e.g. how to use microbicides), manufacturing (e.g. supply and affordability), introduction and scale up (e.g. targeting, demand generation, distribution and financing).



An Access Timeline

The timeline in the figure above illustrates the range of parallel activities that are required to bring a microbicide from early clinical research through to launch and initial scale up. Although the process is represented linearly here, in practice feedback loops operate between a number of activities – for instance, forecasting iteratively building on market research and the generation of clinical trial data. Equally, knowledge generated for one microbicide must inform the design and selection of the next generation of products.

Activity sequencing, timely mobilisation of constituencies and the ongoing development of an evidence base to inform stakeholder decision making are all strongly emphasised in product introduction frameworks.³ The timeline in the figure above highlights the importance of these steps for microbicides. It also demonstrates the move from strategic (e.g. long-term forecasting) to concrete planning and implementation as information improves on likely product profiles (e.g. efficacy, cost, etc) and acceptability with the progress of clinical trials and marketing research.

Access Scenarios

In addition to understanding the components of access and the timing of activities needed to develop and introduce a microbicide, identifying likely introduction scenarios can guide effective planning and establish realistic expectations for the success of initial introduction.

IPM has commissioned research exploring lessons learned from reproductive health commodities to guide scenario planning for microbicide introduction.⁴ Drawing on this and other research, key lessons include:

- Clinical trials are key to building developing country and community experience and support for microbicides - supporting active country partner participation is crucial.
- Introduction will be staggered by and within countries – even 'rapid' introduction and scale up product use takes considerable time.

- Demand generation activities are essential and must address specific local contexts.
- Strategic selection of countries/sites for launch is important to demonstrate success from which to scale-up.
- Establishing realistic criteria for assessing the success of initial introduction is crucial to sustaining momentum for scale-up.
- Microbicide introduction and use **must** be strategically considered as part of HIV and broader health strategies.

Next Steps

The access framework and timeline provide a helpful guide for IPM's work planning, research agenda, policy development and strategic partnership activities.

The framework also provides a basis for working with stakeholders in the microbicide field and for identifying the types of partnerships needed for product development, manufacturing, introduction and planning that support the goal of ensuring access to future microbicides for women in developing countries. Work already underway includes a consultation in August 2006 on the modelling of microbicide introduction strategies at a country level.

IPM will continue to use and adapt the framework to guide future work and collaboration.

References:

- [1] See WHO Access to Essential Medicines Framework www.who.int/medicines
- [2] See John Snow International Deliver Project- "6 Rights Framework" www.isi.com/JSIInternet/Publications/healthlogistics.cfm
- [3] 'Strategic Approach to Strengthening Reproductive Health Policies and Programmes' WHO www.who.int/reproductive-health/strategic_approach/index.htm
- [4] Brown, G. Raghavendran, V. Walker, S. "The Introduction of Contraceptive Technologies: Lessons for Microbicide Access": Forthcoming