Marketed Vaginal Products as Microbicides: A Strategy in India

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Project Overview

PATH is developing a microbicide for use in India from a product already marketed in the country. PATH's microbicide development is driven by three priorities:

1. **Decrease time to market.** A good product available soon is better than the best product not available until later.
2. **Introduce a product that is free of the stigma associated with prevention or treatment of HIV and other sexually transmitted infections (STIs).** Research indicates that a woman seeks her husband's approval before using a vaginal product and that male partners will not permit their wives to use a microbicide with an STI/HIV indication.[1]
3. **Collaborate with a commercial partner.** A commercial partner is essential for efficient formulation and clinical development, regulatory approval, manufacturing, distribution, and marketing of the product.

Focus on India

Outside of South Africa, no country has more cases of HIV infection and AIDS than India.[2] Nearly 4 million Indians are living with HIV/AIDS, and 25 million infections are possible by 2010.[3] With a population of more than 1 billion people, a high prevalence of STIs, and a low rate of condom use, India is poised for an explosive increase in the number of cases of HIV/AIDS in the years to come. Women have an urgent need for health products that will reduce the transmission of STIs and HIV. India was also a practical choice for this project because:

- India has excellent pharmaceutical manufacturing and distribution capabilities.
- Many vaginal, skin, and mucosal products are currently marketed in India.
- Microbicide-related activities are in progress in India.

Project Strategy

Based on our priorities and focus on India, PATH's strategy is to:

1. **Start with products already marketed in India.**
2. **Introduce a microbicide using an "escalating claim" strategy.**
3. **Use benchmarking criteria to select leads for advancement.**

Using Marketed Products

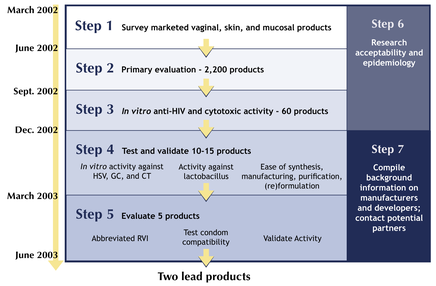
PATH surveyed more than 2,200 vaginal, skin, rectal, ear, oropharyngeal, buccal, dental, nasal, and antiseptic products in India to determine whether any could be used to prevent HIV and/or common microbial infections.

PATH started with already marketed products because:

- These products are already formulated, manufactured, and distributed, and commercialization mechanisms are in place to facilitate access.
- Safety and efficacy data are available, which enable quicker entry into clinical trials.
- Some women may be familiar with the product, and acceptability information may be available.

Compounds identified as nontoxic and potentially active against HIV were tested for *in vitro* anti-HIV and cytotoxic activity. Additional biological tests assessed activity against herpes simplex virus; *Neisseria gonorrhoeae; Chlamydia trachomatis; lactobacilli;* and sperm. Additional tests assessed rabbit vaginal irritation (RVI) and latex condom compatibility.

Summary of Selection Process:



"Escalating Claim" Strategy

The escalating claim strategy is an approach whereby prevention products will be introduced into the Indian market in a stepwise fashion. Product development for prevention of vaginal infections and HIV will be conducted in parallel. The initial indication will be for vaginal health to prevent common vaginal infections, such as bacterial vaginosis and/or vulvovaginal candidiasis. Subsequent claims will be for the prevention of HIV and possibly other STIs.

This strategy has critical advantages:

- It paves the way for a successful anti-HIV microbicide by:
  - Raising awareness of prevention products among Indian women.
  - Increasing the field's understanding of distribution, access, and consumer acceptability.[4]
  - Avoiding stigma, so that products are more acceptable to the general population.
- It improves commercial viability by:
  - Reducing the risk to a commercial partner.
  - Enabling a "first claim" product to be marketed quickly.
- It improves public health through reducing the disease burden of vaginal infections.

Because the microbicide is being developed for the Indian market, the development and regulatory plan is based on the Indian regulatory authority. Local regulatory authorities will evaluate the microbicide from the perspective of their own risk/benefit assessment, and on the basis of the needs of the Indian population.

Benchmarking Criteria

Although technical criteria are paramount, PATH also took commercial parameters into account in the selection process. These include time to market, cost, and market potential. PATH's two lead products are benchmarked against the following criteria:

- **Efficacy**
- **Safety**
- **Ease and cost of formulation, manufacturing, and scale-up**
- **Time to market and cost**
- **Market potential and public health impact**
- **Interest to pharmaceutical companies**

Conclusion

PATH selected microbicide leads from currently marketed products on the basis of both technical and commercial selection criteria. The "escalating claim" strategy provides the means to reduce risk and attracts commercial partners whose involvement from the start of the development process is integral to an efficient project timeline, optimized product development, and successful marketing.

References

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This study was supported by the Bill & Melinda Gates Foundation.

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