

Microbicides are products being developed to reduce the transmission of HIV and other sexually transmitted infections. They are being developed in a variety of forms, such as topical gels, creams, tablets, films, oral pills, alone or in combination with cervical barriers, rings, condoms, and ancillary devices.

RESEARCH AND DEVELOPMENT

Currently 13 microbicide candidates are in various stages of clinical development, and over 50 products are being tested pre-clinically. Results from the Phase 2/2B PRO 2000 and BufferGel® trial will be available in early 2009, and the Phase 3 PRO 2000 trial and the Phase 2B Tenofovir trial expect to release results by 2010. New products regularly move into clinical trials with advances in HIV research and lessons learned from previous product testing.

Current Microbicide Candidates

<u>Candidate</u>	<u>Current Status & Phase</u>
PRO 2000	Ongoing - Phase 3
Tenofovir gel	Ongoing - Phase 2B
PRO 2000/BufferGel®	Ongoing - Phase 2/2B
VivaGel®	Ongoing - Phase 1/2
Dapivirine	Ongoing - Phase 1
Ethanol in Emollient Gel	Ongoing - Phase 1
UC-781	Ongoing - Phase 1
BufferGel®	Planned - Phase 3
Invisible Condom™	Planned - Phase 2/3
CAP Vaginal Soft Tablet	Planned - Phase 1
PC-815	Planned - Phase 1

Effectiveness trials: Phase 2/2B - Phase 3 trials involve a microbicide given to large groups of people to confirm its effectiveness against HIV and other STIs, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used

Safety trials: Phase 1-2 trials test a microbicide in a small number of people to determine its safety, evaluate side effects, and provide preliminary data of effectiveness.

Planned trials: These trials are planned for a variety of reasons, such as awaiting funding, completing country-specific approvals, finalizing trial protocol, or completing safety profiles prior to further clinical research.

CURRENT APPROACHES IN MICROBICIDE RESEARCH: A, B, AND C

A Antiretrovirals: Many of these microbicide candidates are already used in HIV therapy. These microbicides would specifically target HIV. Tenofovir gel is an antiretroviral product in late-stage effectiveness testing. Other products in the pipeline include dapivirine, PC-815, and UC-781.

B Behaviors: Research has revealed that not everyone is able to use a microbicide immediately before a sexual act. Developers are now investigating microbicides that could be used daily, before, or after sex to eliminate some adherence issues in clinical trials and upon product roll-out.

C Combinations: Some microbicide candidates are combinations, meaning combinations with other microbicides or combined with a novel delivery mechanism. These include a diaphragm pre-coated with a microbicide, a drug-filled intravaginal ring, and ARV-based products with other drugs.

THE MACRO OF MICROBICIDES

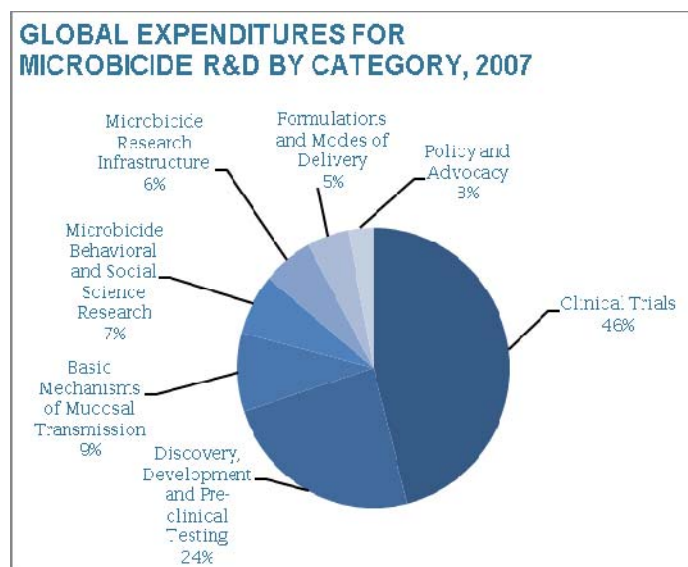
FUNDING

In 2007, public sector investment in microbicide R&D accounted for 90% of the combined global funding for microbicide research, development and advocacy. The United States continues to maintain the largest presence in public sector funding for microbicides, providing 62% (US\$139.8 million). European national governments and the European Commission together accounted for 26% (US\$59.6 million).

Source: HIV Vaccines and Microbicides Resource Tracking Working Group. *Sustaining the HIV Prevention Research Agenda: Funding For Research and Development of HIV Vaccines, Microbicides, and Other New Prevention Options 2000-2007*. 2008.

TABLE 5. ANNUAL INVESTMENT IN MICROBICIDE R&D 2000-2007 (US\$MN)

	2000	2001	2002	2003	2004	2005	2006	2007
Public sector								
US	34.6	61.3	75.3	78.8	92	101.6	129.7	139.8
Europe	0.7	0.4	5.1	10.6	29.9	30.3	56.3	59.6
Other	0.3	<0.1	0.2	0.9	2.0	10.5	4.7	3.4
Multilaterals	<0.1	0.3	0.4	<0.1	0.2	0.2	1.4	0.2
Total public	35.7	62.0	81.0	90.2	124.2	142.6	191.2	203
Philanthropic sector								
Total philanthropic	29.4	3.4	24.8	16.9	18.1	21.3	26.2	19



For further information on microbicides and HIV prevention, please visit www.microbicide.org. Contact the Alliance for Microbicide Development at alliance@microbicide.org.

POLICIES THAT IMPACT MICROBICIDE DEVELOPMENT

On 30 July 2008 President Bush signed into law a 5-year reauthorization of the President's Emergency Plan for AIDS Relief (PEPFAR). The act contains new language that puts a greater emphasis on development and deployment of microbicides as a means of preventing the spread of HIV. **For the first time, the development of microbicides is included as one of the stated purposes of US efforts to address the AIDS epidemic.** The Act mandates that the US Government's 5-year strategic plan for HIV/AIDS should "expand and accelerate research on and development of" prevention methods, including enhanced interagency coordination, staffing, and organizational infrastructure dedicated to microbicide research. Specifically, the Director of the Office of AIDS Research at the National Institutes of Health is directed to expedite implementation of the federal plan to develop microbicides, in coordination with the Global AIDS Coordinator, the US Agency for International Development, the Centers for Disease Control and Prevention, researchers, and advocates.