Joint Advocacy on HIV/AIDS Microbicides, Treatments and Vaccines

Developing an Agenda for Action

CANADIAN HIV•AIDS LEGAL NETWORK
RÉSEAU JURIDIQUE CANADIEN VIH•SIDA

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Prepared by
John Godwin
for the
Canadian HIV/AIDS Legal Network

For further information about this publication, please contact:

Canadian HIV/AIDS Legal Network
Tel: +1 (514) 397-6828
Fax: +1 (514) 397-8570
Email: info@aidslaw.ca

Further copies can be retrieved at www.aidslaw.ca
or ordered through the
Canadian HIV/AIDS Information Centre
Email: aidssida@cpha.ca

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Please also see the accompanying document Joint Advocacy on HIV/AIDS Microbicides, Treatments and Vaccines: Statement of Commitment to Building a Comprehensive Global HIV/AIDS Response.

Ce document est également disponible en français.
Éste documento también está disponible en español.

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Background

In November 2003, the Canadian HIV/AIDS Legal Network convened a global consultation of advocates and experts working in the fields of microbicides, treatments and vaccines in Montreal, Canada. The meeting was the first occasion at which advocates from the three fields had the opportunity to meet and exchange views on current policy priorities and advocacy efforts.

Discussions at the consultation were based on a detailed Background Paper (available on the Legal Network's website at www.aidslaw.ca).

Advocates attending the consultation agreed that there are significant benefits to be gained from working more closely together in pursuing advocacy goals in a range of areas. To inform and encourage collaboration, advocates agreed that a document should be prepared that outlines key issues and sets out areas for action. They also agreed that a statement of commitment should be drafted, and circulated for endorsement by civil society groups, in order to inform and encourage collaboration between advocates working in these three fields.

The Canadian HIV/AIDS Legal Network undertook to produce those resources.

This document, *Developing an Agenda for Action*, sets out the key issues described in the Background Paper and a Plan of Action listing advocacy challenges discussed at the consultation. The objective is to introduce, to a wider global audience, the rationale for collaboration between advocates in these three fields and the key current priorities for advocacy.

The accompanying document, the joint *Statement of Commitment to Building a Comprehensive Global HIV/AIDS Response*, has also been circulated and is open for ongoing endorsement by civil society groups engaged in advocacy in one or more of the areas of microbicides, treatments and vaccines.

The international consultation in November 2003 was co-organized by the Canadian HIV/AIDS Legal Network, the AIDS Law Project (South Africa) and the International Council of AIDS Service Organizations. The consultation was co-hosted by UNAIDS, WHO-UNAIDS HIV Vaccine Initiative and IAVI. Financial support for the participants from developing countries was provided by the Canadian International Development Agency. Additional financial support was provided by Health Canada and the International Partnership for Microbicides.

Key messages

HIV microbicides, treatments and vaccines are not in competition. Rather, they are complementary components of a comprehensive approach to combating HIV/AIDS.

HIV microbicide, treatment and vaccine advocates share the common goal of the full realization of the human right to health of all people living with and affected by HIV/AIDS.

To achieve this goal, advocates are pursuing common policy objectives relating to research and access issues. Key advocacy aims include:

- Increasing research efforts relating to therapeutic, diagnostic and preventive products for use against HIV/AIDS in resource-poor settings.
- The rapid expansion of access to HIV/AIDS treatments and prevention in low- and middle-income countries.
- Ensuring that rapid and equitable access to new HIV therapeutic, diagnostic and preventive products occurs as new products become available.

Advocates from the fields of HIV/AIDS microbicides, treatments and vaccines have agreed to collaborate on a range of policy issues that support their common research and access agendas. These issues include funding, clinical trials, community mobilization, patents, pricing, liability, regulatory issues, manufacture, delivery and national plans.

A Plan of Action also included in this booklet sets out strategies to address these issues. The Plan demonstrates that action can be taken by advocates at national, regional and international levels to promote this evolving agenda.

Introduction

In the past, the fields of microbicides, treatments and vaccines have often been positioned as competitors rather than collaborators. Advocates from the three fields have pursued their objectives largely independently from each other.

Treatment advocacy has worked to a very different timeframe as compared to vaccine and microbicide advocacy. Whereas treatment advocacy has been focused on meeting the immediate and urgent need of scaling up access to existing microbicide, treatment and vaccine advocates have argued for research efforts that require sustained investment for decades to come.

To an extent, competition between the fields has arisen as a result of an environment of chronic under-funding. In recent years there has been growing awareness that competition is counterproductive and that advocacy could be strengthened by aligning efforts and joining forces in advancing key policy areas. It is not anticipated that the three advocacy fields will become integrated, and differences in emphasis and approach can be expected to remain. But increasingly advocates are keen to explore those policy areas where their interests converge, rather than dwelling on their differences.

It is hoped that, through collaboration, advocates can make better use of advocacy resources by sharing skills, expertise and access to information. Combining the strengths of the three fields can be used strategically to increase political influence. Advocates are working in complex, difficult and sometimes demoralising areas. Collaboration provides a context for providing mutual support and encouragement for this essential work, and presents opportunities to generate a shared vision and sense of hope and purpose for advocacy efforts.

This document describes the reasons why developing a common advocacy agenda is emerging as a priority for advocacy organisations from the HIV microbicide, treatment and vaccine fields. It describes the main features of each advocacy field, the reasons that advocates have identified for seeking to work together, the shared policy concerns of advocates, and the ways in which these issues can be taken forward through collaborative advocacy.

About the three fields

Microbicides advocacy[1]

Microbicide advocates are seeking support for a product category that is not yet available. The word 'microbicide' refers to a range of products that share the common characteristic that the product prevents the sexual transmission of HIV and other sexually transmitted infections (STIs) when applied topically to the vagina or rectum. A microbicide could be produced in many forms, including gels, creams, suppositories, films, or as a sponge or ring that releases the active ingredient over time.

Microbicides are predominantly being developed for use by women, but they could also be used rectally by men. Microbicide advocates emphasise that many women do not have the social or economic power necessary to insist on condom use, or to abandon partnerships that put them at risk. Microbicides would have the capacity to empower women, particularly if they can be used without requiring the cooperation of women's sexual partners.

Many substances are being tested to see whether they help protect against HIV and other STIs, but no safe and effective microbicide is currently available to the public. However, there are almost sixty potential products being investigated, including at least eleven that have proven safe and effective in animals and that are now being tested in humans. If one of these products proves successful and investment is sufficient, a microbicide could be available in five to seven years.

The primary concern of microbicide advocacy is to expand research and development efforts. Funding for microbicide research has been at very low levels compared to treatments and vaccines. At this stage, research funding is being sought primarily from governments and philanthropic donors rather than industry. Industry has demonstrated little interest in the field.

Advocates are involved in issues regarding the conduct of clinical trials of microbicides, such as ethical safeguards and the challenges of conducting trials in developing countries. Advocates are also raising awareness about the measures that will need to be taken to ensure that microbicides are accessible to those who need them without delay once a safe and effective product is found.

There are a growing number of organizations involved in microbicides advocacy, including the Alliance for Microbicide Development, the Global Campaign for Microbicides, Family Health International, the International Partnership for Microbicides, and the International Working Group for Microbicides.

Treatments advocacy

The primary concern of treatment advocates is to secure sustainable supplies of affordable antiretroviral therapies (ARVs) and other medicines for poor communities across the world. It is now widely recognised that provision of ARVs is an effective option for treating HIV/AIDS in resource-poor settings, and there is a humanitarian and legal imperative to make treatments accessible globally without further delay.

Current priorities of treatment advocates include:

- Promoting access to affordable generic medicines, including fixed dose combination ARVs
- Seeking the development of cheaper, simpler treatment regimens, monitoring tools and diagnostics, including new doses and new regimens to facilitate long term global access and use
- Training of staff in HIV/AIDS treatment issues
- Community mobilization to support activism and promotion of treatment literacy among communities of people living with HIV/AIDS

[1] This section draws from the website of the Global Campaign for Microbicides (www.global-campaign.org/about_microbicides.htm).

- Building health care delivery systems, including clinical and laboratory infrastructure and local community health centres with the capacity to deliver ARVs
- Removing barriers to access to medicines created by pricing policies, trade agreements and intellectual property laws.

The context for treatment advocacy is currently being influenced by the WHO's 3 by 5 Initiative, which issued a global call to action on treatments in 2003. The 3 by 5 Initiative is seeking to ensure that three million people in the developing world have access to ARVs by the end of 2005.

Examples of some of the key civil society organisations working to improve treatment access are: Consumer Project on Technology, Global AIDS Alliance, Health Action International, Health GAP, International HIV Treatments Access Coalition, Médecins Sans Frontières, Oxfam, Clinton HIV/AIDS Initiative, Treatment Action Campaign (South Africa), the Pan African HIV/AIDS Treatment Access Movement and the Thai Treatment Action Group. There are many other national and local treatment advocacy organizations.

Vaccines advocacy

HIV vaccine advocates argue that current prevention efforts are proving insufficient to stop the spread of HIV. They point to the success of past immunisation campaigns for other viruses that have had dramatic public health benefits to mount the case for escalation of efforts to find an HIV vaccine.

The main objective of HIV vaccine advocates is to secure increased support for research into preventive HIV vaccines. Vaccine research has gathered pace since 2000 but no breakthrough is imminent. Advocacy suffered a setback in 2003 when the first vaccine candidate to go through Phase III clinical trials failed to demonstrate efficacy.

There are about thirty preventive HIV vaccine candidates in clinical trials. Advocates are seeking to galvanise public and political support for the long term research effort that is required to find a suitable vaccine. A preventive HIV vaccine is still many years away.

The direction of vaccine research suggests that the first HIV vaccines are likely to be only partially efficacious. Early vaccines may have the effect of reducing the level of HIV in the blood to very low levels, rather than providing absolute protection from infection. People who received such a vaccine prior to being infected may not go on to experience severe HIV illness and may be less likely to pass the virus on to others.

The current agenda of vaccine advocates includes:

- Accelerating vaccine research, through greater public sector support and incentives for private-sector involvement in R&D;
- Protecting the rights of trial participants, including through involving and educating communities in the planning and implementation of clinical trials; and
- Measures to prepare for global vaccine access. Advocates point out that people in the developing world have experienced delays of a decade or longer before receiving other vaccines after they have been licensed for use in wealthy nations. To prepare for rapid access to an HIV vaccine, advocates are supporting the expansion of existing immunisation programs for other diseases and seeking to bolster vaccine manufacturing capacity.

Major organizations involved in HIV vaccine advocacy include the International AIDS Vaccine Initiative (IAVI), the AIDS Vaccine Advocacy Coalition (AVAC) and the African AIDS Vaccine Programme (AAVP). There are also many other national and local organizations involved in vaccine advocacy.

Why work together?

We need new treatment and prevention options

A unifying factor for advocates from the three fields is their commitment to broadening the range of options available to fight HIV/AIDS. Education and behavioral risk reduction do work as prevention strategies, but face ongoing challenges, such as the impact of gender power imbalances on restricting women's choices, and restrictions on the availability of male and female condoms and clean injecting equipment. In the treatments field, side effects and drug resistance are a reminder that we need better ways to manage HIV disease. Cheaper and simpler options are urgently required to facilitate treatment scale up in resource-poor settings.

Research and development (R&D) efforts in the microbicide, treatment and vaccine fields could deliver powerful new tools for fighting the epidemic. From this realisation emerge two broad aims common to microbicide, treatment and vaccine advocates:

- To accelerate progress in developing new products and approaches for fighting HIV; and
- To ensure that interventions that are safe and effective against HIV/AIDS are made available and accessible without undue delay to those in greatest need.

The prevention-care-treatment continuum

Underpinning a common agenda is the prevention-care-treatment continuum. This concept recognises the importance of building a comprehensive response to HIV/AIDS, and that prevention, care and treatment strategies are closely inter-related.

Treatment supports prevention. There is evidence that providing ARV treatments has the effect of reducing the stigma associated with AIDS. Making treatments available also provides a powerful incentive for people to present for HIV testing. Voluntary uptake of testing supports behavioural prevention. Further, where treatments are available, HIV rates may be reduced due to the lowering of viral load in individuals on treatment, which makes the transmission of HIV less likely.

Vaccine and microbicide advocates point out that the relationship of vaccines and microbicides to treatments is also mutually reinforcing. The conduct of large vaccine and microbicide clinical trials in developing countries presents opportunities to build health care infrastructure, train staff, and expand treatment services for communities that are hosting trials. Similarly, treatment access involves investments in health infrastructure and training that can enhance capacity to trial and eventually deliver vaccine and microbicide products. Treatment access programs strengthen the health sector, as health care workers gain skills and communities gain confidence in health services. A strong health sector that is accessible to and supported by local communities is important for trialing and delivering new prevention products.

Furthermore, some microbicide, treatment and vaccine products are by nature or effect closely related. For example, research into preventive vaccines is leading to trials of therapeutic vaccines which may be suitable for use in treating people living with HIV. Also, some microbicide candidates are being investigated that incorporate ARVs to enhance protection. ARVs are being used as a prevention tool in a variety of contexts, including post exposure prophylaxis and in preventing mother-to-child transmission. Trials are underway to test the use of ARVs by people who are not infected but belong to high risk populations, so as to investigate whether, like a vaccine, ARVs may provide a level of protection against infection.

A human rights-based approach

A human rights-based approach provides a conceptual framework for linking advocacy agendas. The three fields share the common goal of realizing the human right to the highest attainable standard of health of all people living with or affected by HIV/AIDS. Responses to the epidemic should be framed in the context of this right and other human rights recognised by international law that are related to health, such as the right to life, non-discrimination, privacy, work, social security, education and information, freedom of movement and the right to share in scientific advancement and its benefits.

The relevance of a human rights framework to the pursuit of a comprehensive treatment and prevention agenda was explored in detail by an International Consultation on HIV/AIDS and Human Rights convened by the UN in 2002.[2] The Consultation found that prevention, treatment, care and support are mutually reinforcing elements of a comprehensive approach to HIV/AIDS. This approach implies a right to access ARVs and other medicines, diagnostics and related technologies as well as a right of access to HIV prevention technologies including condoms, lubricants, sterile injection equipment, and, once developed, safe and effective microbicides and vaccines. Based on international human rights law and principles, universal access requires that these goods and services "not only be available, acceptable and of good quality, but also within physical reach and affordable for all."[3]

The Consultation recommended that governments "move as quickly and effectively as possible, towards realizing access for all to HIV/AIDS prevention, treatment, care and support at both the domestic and global levels. This requires, among other things, setting benchmarks and targets for measuring progress."[4]

Important aspects of a rights-based approach include:

- Attention to those populations most vulnerable to ill health
- An emphasis on participation of communities in decisions affecting their rights and a commitment to transparency and accountability to communities in decision making processes
- The universality of rights, which means that health services should be accessible without discrimination and that issues of gender equity must be addressed
- The responsibility of governments to transfer the benefits of scientific progress to assist less wealthy nations in realizing the right to health
- The central role of governments in respecting, protecting, and fulfilling human rights, including the right to health.

The expert meeting that preceded the preparation of this document (Montreal, November 2003) concluded that advocacy would be assisted by the preparation of a formal statement that presents the link between human rights and the obligation to build a comprehensive HIV/AIDS response. To this end, the meeting participants agreed to publish and promote a Statement of Commitment. *The Statement of Commitment to Building a Comprehensive Global HIV/AIDS Response* sets out elements of a comprehensive response in detail, and is available as a companion resource to this document.

[2] See *HIV/AIDS and Human Rights International Guidelines, Revised Guideline 6, Third International Consultation on HIV/AIDS and Human Rights* New York & Geneva: OHCHR & UNAIDS, 2002.

[3] Ibid at 14.

[4] Ibid, Recommendation (b), at 15.

What are the most important issues?

Funding of global health

Funding of global health is strongly skewed in favour of the needs of rich markets. Advocates have a common interest in advocating for a better global funding deal for health services and health research that is responsive to the needs of poor communities, rather than market driven.

Enhanced support from donors to sustain the operation of the Global Fund to Fight AIDS, TB and Malaria (GFATM) is a key common priority of advocates. The GFATM provides a significant opportunity to redress global health funding inequities. GFATM is supporting a range of treatment access initiatives, and plays a critical role in supporting WHO's 3 by 5 Initiative. The strengthening of primary health sectors through GFATM-supported projects can have significant benefits for microbicide, treatment and vaccine fields, by supporting current access efforts and providing a stronger foundation for delivery of new products as they become available.

The GFATM does not fund R&D. It is necessary that governments and private donors make contributions to the GFATM, but to do so does not mean that enough has been done by donors to address HIV/AIDS needs. Advocates have a common interest in persuading donors that they must also increase their support for basic research and HIV-related product development initiatives.

Developing countries require increased resources to finance basic health services from aid grants and debt relief. Recognising this, advocates from the three fields have restated the imperative that donor countries meet the UN target of increasing donor governments' levels of Official Development Assistance to 0.7% of their Gross National Product and to enhancing and expediting debt cancellation with a view to supporting domestic HIV/AIDS responses in developing countries.

To inform advocacy on funding issues, advocates need to collaborate in maintaining up-to-date cost estimates for overall R&D needs, and the costs associated with expanding the capacity of countries to deliver health products (new infrastructure, staff training etc). Advocates also need to map resource flows so that they can argue for resources to be directed in a more targeted way. This can help to ensure that existing delivery capacity is better utilized and that priority is given to building capacity where the need is greatest.

Clinical trials

Expanding the capacity of countries to conduct clinical trials is a high priority for advocates from the three fields. This issue is particularly pressing for prevention trials, which require thousands of volunteers. Building trial infrastructure is becoming of more central importance as more prevention products move into large scale phase III trials. Building trial site capacity in developing countries will also facilitate trials of treatment strategies designed specifically for resource-poor settings.

Common challenges involved in conducting trials include ethical issues and community preparedness for trials. Prevention and treatment trials face common volunteer recruitment and retention challenges. Advocates have developed expertise in new mechanisms for community participation in trial processes that could be shared, such as developing locally owned Participants' Bills of Rights. There are common needs relating to training to support community participation in advisory, ethical monitoring and management structures. Communities would benefit from more integrated approaches to community education about the nature of different prevention and treatment products being trialed.

Much work has been done in the last few years to define ethical issues involved in conducting research in developing countries. Efforts are required to further develop ethical practices and standards that take into account local cultural contexts. Issues to be considered include informed consent, confidentiality, compensation, use of placebos in trials, and the standard of care for any trial participants who require HIV-related treatment and care. Mutual benefits would be gained from sharing approaches adopted in prevention and treatment trials to resolving these issues.

An issue being confronted by all three fields is the impact on behaviour of the introduction of new products. There is a concern that people may increase their risk taking behaviours if they know that they have access to treatments or a vaccine, or if they are using a microbicide. If this is a common behavioural response, it would reduce the benefits of these products to fighting the epidemic.

Complex issues will arise, for example, in ensuring that people maintain safe behaviours after they receive an HIV vaccine that only provides partial protection from infection, or in ensuring that use of microbicides is not accompanied by a reduction in the use of condoms. Advocates have a common interest in social research accompanying clinical trials that increases our understanding of risk taking behaviours. This research is essential to inform decisions about licensing new products and so that educational strategies can be developed to counter any adverse behavioural consequences of the introduction of new products.

Pricing of health products

Advocates are seeking to define pricing policies that maximise access to needed health products. 'Equity pricing' has been adopted as a term to describe the policy of setting prices at the lowest possible level for poor markets. Implementing equity pricing for health products would support treatment scale up and provide a framework for access to HIV vaccines and microbicides. An equity pricing approach should be designed to ensure sustainability of affordable supplies, rather than being based on ad hoc donations. The aim should be to achieve prices for developing countries that are not more than the marginal costs of production.

Pricing policies need to be placed in the context of a range of policy options that can be used to achieve affordability of medicines. Making generic medicines more widely available and legislated price controls may be more effective than relying on brand name drug companies to voluntarily set prices at lower levels. Options that should be considered include compulsory and voluntary licensing of medicines and negotiating for bulk supplies of generic medicines at discounted prices.

Structures need to be put in place to enable countries with similar needs and buying power to negotiate good prices when procuring health goods. Establishing bulk procurement mechanisms for ARVs is an important strategy to keep prices down. Multilateral agencies such as WHO, GFATM and the World Bank are facilitating and financing bulk ARV procurement. Lessons from these approaches can be used to inform bulk procurement of vaccines and microbicides as they become available.

Advocates also need to support price transparency, through advocating for a mandatory system for the monitoring and reporting of global prices of therapeutics, diagnostics and preventive technologies for HIV/AIDS.

Intellectual property

Flexible patent rules that encourage generic competition and which are responsive to the health and development needs of poor countries are a common goal of advocates.

A priority issue raised by advocates is the need to ensure that international agreements relating to patents and related issues enable countries to access generic medicines for public health purposes. Such agreements include the World Trade Organization's (WTO) TRIPS Agreement,[5] and bilateral, regional and multilateral trade agreements. The WTO's Doha Declaration[6] in 2001 stated the principle that the TRIPS Agreement should be interpreted in a way that promotes access to medicines for all. However, there are many issues that remain unresolved regarding the implementation of this principle.

For example, countries that do not have domestic capacity to manufacture generic medicines face difficulties in importing generic medicines. Although a process has been established by the WTO to facilitate importing, the process requires the cooperation of exporters. For the system to work, countries with the capacity to export generic medicines need to legislate to allow licenses to be granted that permit exports and that are not subject to the veto of a patent holder. There are concerns that the current process is not workable and equitable, and that streamlined procedures are required.

Another current issue of concern is the 2005 deadline by which many low and middle- income countries are required by WTO rules to include TRIPS standards of intellectual property protection within their domestic laws. There are concerns that this requirement will have the effect of reducing access to medicines if manufacturing of generic ARVs is restricted.

Some trade agreements are undermining the ability of countries to access generic medicines by including requirements that are additional to those required under WTO rules. These are known as 'TRIPS plus' provisions. 'TRIPS plus' provisions restrict the capacity of generic providers to compete with brand name pharmaceutical manufacturers by requiring high levels of data protection, data exclusivity and patent protections. These provisions can result in exclusion of generic competition in developing countries for extended periods. Advocates are concerned that bilateral and regional trade agreements that incorporate 'TRIPS plus' provisions create a hostile environment for developing countries seeking affordable access to new therapeutic and preventive products.

Developing countries should have the freedom to choose an intellectual property system which best meets their development objectives. The trend towards harmonising the international patent system could result in high standards of patent protection which may not be suitable for them, and which result in highly priced health products.

Some advocates are investigating new options such as open collaborative intellectual property models. Approaches whereby discoveries are openly shared to encourage further innovation have been adopted, for example, in SARS research and the Human Genome project. There are lessons to be learnt from these experiences for HIV research.

Enhancing research and development

Injecting substantial new public funds into research and development (R&D) would provide immediate benefits for the three fields. Public bodies play very significant roles in basic research, and support product developers through funding clinical trial networks and assistance with product manufacturing. However, considerable R&D expertise is located within the private sector. The private sector has been particularly reluctant to invest in products such as microbicides designed for use in resource-poor settings, on the basis that there is insufficient profit incentive. Public Private Partnerships (PPPs) are used as a strategy by vaccine and microbicide advocates to harness private sector expertise for product development. Benefits could flow from advocates developing best practice in such areas as input by communities from the global South in partnership arrangements, and accountability and transparency mechanisms.

[5] WTO Agreement on Trade Related Aspects of Intellectual Property Rights.

[6] Declaration on TRIPS Agreement and Public Health, Doha: WTO 2001.

Advance purchase commitments are another policy option being examined by advocates as a possible way to provide an incentive to stimulate private sector investment. Public sector pre-commitments to purchase bulk quantities of vaccines, microbicides or treatments could provide an incentive for private sector investment in product development. However, issues remain unresolved as to how such schemes might operate in practice.

Exposure to liability risks has been an issue of concern mostly to the vaccines field. Liability concerns are a barrier to private sector involvement in research and development in litigious environments. Advocates have focused on identifying opportunities to advance 'no fault' compensation models. These models provide compensation for vaccine related injuries from a central fund, while reducing the exposure of vaccine manufacturers to the risk of liability. Microbicide advocates are also concerned about liability risks that may deter private sector interest in their field. Some advocates argue that Governments should indemnify manufacturers from liability arising from use of HIV prevention technologies provided that there has been no negligence.

In addressing liability issues, it is important to ensure that trial participants' rights to compensation are not unduly eroded, particularly where trial participants are relatively powerless, which may often be the case in poor communities.

Regulatory issues

The streamlining of regulatory requirements is important to reduce delays in approving clinical trials and licensing new products.

Most developing countries have only limited regulatory infrastructure. Lack of regulatory capacity means that approval of products is often heavily influenced by the decisions of the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA). Expanding regulatory capacity would facilitate local decision-making about hosting clinical trials and expand each country's ability to conduct safe and ethical trials. Countries with similar epidemics could benefit by pooling their regulatory expertise and linking approval processes.

Advocates have pointed out that a partially effective HIV vaccine or microbicide might not be approved by regulators in the US or Europe, because the efficacy level is considered too low to provide public health benefits. The product could nonetheless be appropriate for use in countries with rapidly emerging or more widespread epidemics. Regulatory pathways need to be defined for products that are designed specifically for use in the developing world.

Advocates are assessing the impact of harmonization of regulatory requirements. Harmonization involves the adoption of common approaches by regulators on approaches to determining safety, efficacy, and quality. Harmonization of regulatory standards and processes needs to strike an appropriate balance between quality control concerns and the need for health products to be affordable and accessible. WHO prequalification of therapeutics (such as fixed dose combination ARVs) and vaccines is providing developing countries that do not have strong regulatory capacity with a reliable process to assess products. The WHO prequalification scheme should be expanded to support treatment scale up and because it may prove a useful process for future HIV vaccines and microbicides.

Manufacturing

Lack of manufacturing capacity can delay products reaching markets in poor countries. Meeting global needs for vaccines and microbicides will require substantial private and public sector investments in manufacturing. The importance of investing in manufacturing has become clear as the focus of product development has shifted to small biotechnology companies and non-profit organizations, which have little manufacturing capacity. The public sector needs to demonstrate a willingness to assist the private sector in managing the risks involved in creating sufficient capacity to meet projected global demand for new products.

There is a common interest, among the fields of microbicides, treatments and vaccines, in mobilizing support from major global funders, and through additional financial mechanisms, for investment in manufacturing facilities. Advocates need to define a broad range of innovative and flexible financial incentives to support investment in manufacturing, including targeted loans, government grants and contracts, and incentives for technology transfer to the global South. This task would be assisted by assembling an overview of the manufacturing processes and associated costs for the microbicide, treatment and vaccines fields, and mapping and analysing existing manufacturing capacity and resource flows against these needs.

Delivery

Improving delivery systems for existing treatments and vaccines is key to preparing for delivery of new products. Building community health systems to support delivery of existing treatments prepares the way for delivery of new products. Delivery issues for vaccines and treatments will likely overlap given the involvement of medical staff in prescribing and administering products. Microbicides are more likely to be available over the counter and at a broad range of community sites.

The usual pattern has been for rich countries to enjoy access to new health technologies years in advance of developing countries. This is not acceptable, especially in the case of pandemics such as HIV/AIDS. Policy makers need to address delivery issues well in advance, by considering public sector involvement in distribution, guidelines for approval of partially effective products, and promotion of products to communities and health professionals.

There are intersecting issues for the different products regarding the need for health promotion messages that educate communities about the health benefits of each product. Communities will need to understand the implications of use of partially effective vaccine and microbicide products, and the need to sustain condom use and other prevention strategies. Advocates recognize the importance of moving towards integrated community education approaches. These could be piloted in settings where products are anticipated to be trialled concurrently. Education could address the mutually supporting relationship of microbicides, treatments and vaccines issues specific to partially effective products.

Community mobilization focused on treatment activism in countries such as Brazil and South Africa has helped to provide a social climate in which access to treatments is seen as a human right. The continued vibrancy of this movement is important to provide a supportive context for rapid delivery of new products such as vaccines and microbicides. Community mobilization in support of expanded access is vital to the successful uptake of new therapeutic and preventive products.

National plans

The development of National HIV/AIDS Plans is a key strategy for ensuring public and political support for microbicides, treatments and vaccines. National plans are also important accountability mechanisms and can be used to hold governments to account for national budgetary allocations to HIV treatment and prevention, research efforts and the strengthening of health delivery systems.

National plans should set out a comprehensive approach to HIV/AIDS. Plans should define an integrated package of measures, including treatments, voluntary counselling and testing, education, harm reduction, condom distribution, care and support, blood safety, research issues (including new therapies, diagnostics, microbicides and vaccines), and efforts to address stigma, discrimination, gender inequalities and other social, cultural and legal factors that drive the epidemic.

Important elements to be incorporated into national planning include:

- A human rights framework
- Commitment to the participation of community representatives, including people living with HIV/AIDS, in developing and monitoring national plans
- Recognition of the link between prevention and treatment, and promotion of the prevention-care-treatment continuum.

Advocates also noted that it is important to ensure that the role of research and access initiatives within national responses is given explicit support by agencies funding national strategies, including national governments and bilateral and multilateral funders.

A Plan of Action for advocates

At the meeting preceding the development of this document (Montreal, November 2003), advocates agreed to develop a common Plan of Action to guide collaborative efforts. They discussed a draft of such a plan. The draft was revised and then distributed to microbicide, treatment and vaccine advocates for further comment before being finalized for inclusion here.

This Plan of Action is intended to encourage collaboration by setting out a broad range of actions that are required in order to advance the common agendas of advocates working in the fields of microbicides, treatments and vaccines. It is intended to educate people working in the three fields about the breadth of advocacy and policy actions that global experts from these fields have identified as common priorities.

The Plan of Action can be used as a point of reference for advocates and policy makers worldwide. It is intended for people working at local, national, regional or international levels, and in all sectors, including advocates and policy makers located in community, not-for-profit, public sector or industry bodies. It is acknowledged that the policy agenda is rapidly evolving and that advocacy priorities will need to be adjusted as new developments occur. It is hoped that presenting an agenda of issues that are currently considered priorities across the three fields of microbicides, treatments and vaccines will assist advocates in aligning their efforts towards shared objectives.

It should be noted that the Plan of Action has not been formally agreed to by any advocacy organization. No attempt has been made to assign responsibilities for any of the specific actions. Timeframes for completion of actions are not defined, and no attempt has been made to rank the priorities. To be applied in practice, more detailed planning and collaboration would be required by the advocates who wish to take up aspects of the Plan. In its current form the Plan of Action does, however, provide a framework for advocates to conduct such further planning, within the context of their own resources and strategic priorities.

GOAL

The full realization of the human right to the highest attainable standard of health for all people living with and affected by HIV/AIDS.

AIMS

- **Expanded research and development (R&D) efforts relating to therapeutic, diagnostic and preventive products for use against HIV/AIDS in low and middle-income countries.**
- **Rapid scale up of access to HIV/AIDS treatments and prevention in low and middle-income countries.**
- **Preparation for rapid and equitable access to new HIV/AIDS therapeutic, diagnostic and preventive products.**

Objective 1: Global Funding

An improved global funding environment for HIV/AIDS that supports collaboration between the prevention and treatment fields, and that provides a supportive context for advocacy.

1.1 Build activists' capacity for collaborative, mutually supportive advocacy within the global funding environment.

- Develop shared understanding amongst advocates of the nature and priorities of the microbicide, treatment and vaccine fields and their respective resource needs
- Develop shared understanding of the overall funding required to build and sustain a comprehensive global response to HIV/AIDS, which includes antiretroviral (ARV) treatments, treatments for opportunistic infections (OI) and sexually transmitted infections (STI), and new HIV prevention technologies, as well as resources for testing, education, harm reduction, condom distribution, care and support, blood safety, and efforts to address the gender inequality, stigma, and various forms of discrimination that both fuel the epidemic and are reinforced by it.

1.2 Lobby donor governments and foundations to support the Global Fund to Fight AIDS, TB and Malaria (GFATM) at levels proportionate to each donor's resources.

- Advocate for national contributions to the GFATM at a scale appropriate to meet the global growth in demand for resources, and in amounts proportionate to the relative size of each country's economic wealth.

1.3 Investigate new models for financing treatment scale up and procurement of vaccines and microbicides.

- Build on the financing strategies used to support WHO's 3 by 5 Initiative to finance access to prevention as well as treatment
- Examine the use of GFATM and World Bank financing mechanisms.
- Examine the implications of new development financing initiatives (e.g., the UK proposal for an International Finance Facility to support achievement of the Millennium Development Goals).

1.4 Assess the potential role of advance purchase commitments in stimulating R&D relating to vaccines and microbicides.

- Examine lessons to be learnt from the use of purchase guarantees for vaccines and treatments for anthrax, smallpox and other communicable diseases as part of US biodefense policy.

1.5 Promote debt cancellation that frees up debt repayments so that the funds can be invested in building the health systems of low income countries.

1.6 Examine the impact of major bilateral HIV programs and GFATM disbursements on integrating treatment and prevention strategies.

1.7 Lobby donor governments for increased funding of basic research and product development initiatives aimed at addressing the health needs of the global South.

1.8 Develop cost estimates for meeting global HIV R&D needs.

- Promote collaboration among the Alliance for Microbicide Development (AMD), the International AIDS Vaccine Initiative (IAVI), the Global Campaign for Microbicides (GCM), UNAIDS, WHO and other agencies involved in developing cost estimates so that an accurate overall estimate of costs can be assembled and progressively updated as needs change.

1.9 Develop cost estimates for expanding the capacity of low- and middle-income countries to deliver health products (e.g., through new infrastructure, staff training etc).

- Map resource flows so that existing capacity can be better utilized and capacity can be rapidly expanded in areas where needs are greatest.

1.10 Examine the viability and utility of a multilateral mechanism to enhance global health R&D funding.

- Investigate use of trade agreements to share the costs and benefits of R&D more equitably.
- Investigate options for a treaty or convention on health R&D.
- Investigate the viability of new health R&D fund or sub-fund within GFATM.

Objective 2: Clinical trials

Expanded clinical trial capacities in the global South

2.1 Advocate for increased quality and quantity of clinical trial capacities in the global South.

2.2 Encourage transparency and collaboration between trial sponsors in planning and implementing clinical trial programs.

2.3 Develop new models for running concurrent, complementary microbicide, treatment and/or vaccine trials.
- Advocate for trial networks to better coordinate and maximize synergies between microbicide, treatment and vaccine, trials.

2.4 Promote best practice models for community participation infrastructure for prevention and treatment trials e.g., community advisory boards, participatory research and other models.

- Scrutinize community involvement aspects of clinical trial initiatives.

2.5 Promote training for communities and trial staff on ethical, legal and human rights issues common to microbicides, treatments and vaccines.

- Facilitate South-South learning on these issues including informed consent, confidentiality, compensation and standard of care.

2.6 Cooperate in providing education to community groups about new prevention and treatment products being trialled in their communities.

- Promote the rights of people living with HIV/AIDS and vulnerable communities to be involved in debates and decisions.
- Develop independent resources for use in promoting community involvement at trial sites.

2.7 Advocate for social, behavioural and epidemiological research in the South that supports both prevention and treatment trials and that supports efforts to prepare communities to gain maximum benefits from new products and technologies as they become available.

2.8 Develop a comprehensive model for provision of enhanced prevention, treatment and care at vaccine and/or microbicide trial sites that addresses treatment for breakthrough infections among trial participants as well as the HIV needs of communities within which trials take place.

2.9 Advocate for regulators in the global North and South and product developers to support post-marketing studies to assess the long term risks and benefits of use of new products in different settings.

2.10 Explore strategies to lower the cost to those conducting trials of insuring trial participants.

Objective 3: Pricing of health products

Reduction in the prices of health products in low and middle-income countries

3.1 Implement equity pricing for medicines as a global norm, to support HIV/AIDS treatment scale up and to provide a framework for access to HIV vaccines and microbicides.

- Ensure that equity pricing arrangements are transparent and sustainable, and offer the lowest possible price (e.g., marginal cost of production for least developed countries).
- Ensure that differential pricing between rich and poor markets does not result in poor communities in high-income countries being unable to afford medicines.

3.2 Increase the options available to governments for controlling prices, including equity pricing, generic competition, legislated price controls and bulk procurement.

3.3 Encourage approaches to intellectual property (e.g., voluntary and compulsory licensing) that facilitate price reductions through increasing competition between generic and brand name medicines.

- Advocate for countries to make full use of flexibilities in the WTO TRIPS Agreement or other agreements in order to promote access to medicines for all.

3.4 Oppose bilateral and regional trade and investment agreements that restrict the capacity of governments to control prices so as to ensure affordability of health products.

3.5 Establish bulk procurement mechanisms for HIV medicines, thus also providing a model for bulk purchases of prevention products.

- Advocate for sustainable financing arrangements for procurement (e.g., through GFATM, WHO or the World Bank).
- Explore applicability to the prevention field of lessons learnt from procurement strategies adopted by the 3 by 5 Initiative, the Clinton Foundation HIV/AIDS Initiative, and procurement of treatments and vaccines for other diseases (e.g. Medicines for Malaria Venture, Global Alliance for Vaccines and Immunization) .

3.6 Argue for greater transparency in pricing through mandatory systems for reporting prices of drugs, diagnostics and preventive technologies, and the costs of production.

3.7 Conduct research into the role of markets, competition and price controls in reducing prices and increasing access to treatments and vaccines.

3.8 Remove tariffs and duties on essential health products in developing countries where they have the effect of increasing prices.

Objective 4: Intellectual property

Removal of intellectual property barriers to access to HIV therapeutic and preventive products

4.1 Ensure that trade and investment agreements maximize countries' capacities to pursue public health objectives.

- Oppose bilateral and regional trade agreements containing 'TRIPS plus' provisions that restrict the capacity of generic providers to compete with brand name pharmaceutical manufacturers by requiring high levels of data protection, data exclusivity and patent protections, or that place limitations on the use of public health safeguards such as compulsory licensing, parallel importing or other exceptions to patent protection.

4.2 Promote the flexible implementation of TRIPS requirements.

- Monitor and evaluate the impact of the 2005 deadline for TRIPS compliance for some low- and middle-income countries.
- Advocate for countries with the capacity to export generic pharmaceuticals to enact legislation allowing TRIPS compliant exports to developing countries, in full compliance with the letter and spirit of the “Doha Declaration” on TRIPS and Public Health (November 2001) and without adding 'TRIPS plus' features.
- Assess whether the WTO decision of 30 August 2003, permitting countries with manufacturing capacity to compulsorily licence pharmaceuticals for purposes of exporting generics to countries lacking manufacturing capacity, is workable and equitable from the perspective of low- and middle-income countries, and advocate for the WTO to adopt streamlined procedures and implement a more lasting solution that better responds to health needs.
- Promote use of compulsory and voluntary licensing to increase generic competition.

4.3 Scrutinize the impact of the draft Substantive Patent Law Treaty, and other initiatives aimed at international harmonization of patent laws, on affordability of medicines and preventive technologies.

- Advocate to ensure that the flexibilities that are currently available under the TRIPS Agreement are not eroded as a result of patent harmonization moving to higher and stricter standards of patent protection.

4.4 Advocate for governments to support innovative use of open collaborative intellectual property models for stimulating HIV/AIDS product development.

Objective 5: Research & development (R&D)

Enhanced R&D initiatives directed at the priority health needs of the global South, and measures aimed at stimulating research and development of HIV-related products

5.1 Support community education to improve understanding of the research process, basic HIV/AIDS information, and the risks and benefits of products (e.g., through promoting treatment and prevention literacy).

5.2 Develop monitoring and evaluation frameworks on HIV/AIDS-related R&D.

- Develop indicators that measure overall R&D funds invested in HIV microbicides, treatments and vaccines, as well as progress in transfer of skills and technology, and investments in research infrastructure in the global South.
- Advocate for incorporation of R&D indicators into follow-up of the UNGASS Declaration of Commitment and the UN's Millennium Development Goals.

5.3 Examine viability and utility of a multilateral mechanism to address the failure of R&D to adequately address health needs of the global South, including a new trade framework or a treaty/convention to enhance global health R&D efforts towards neglected diseases and HIV/AIDS.

5.4 Argue for increased public sector commitment to product development, through innovative partnerships (e.g., the Drugs for Neglected Diseases Initiative model), and increased public sector commitment to basic research and clinical trial networks.

5.5 Develop principles to inform public-private partnerships (PPPs) for R&D regarding:

- input from communities and people living with HIV/AIDS
- conflict of interest issues, particularly where not-for-profit NGOs partner with private corporations
- accountability and transparency
- measuring effectiveness of different models against the goal of development and delivery of products to equitably address health needs.

5.6 Formulate a package of legislative incentives to promote public sector roles in research programs and to stimulate private sector involvement in areas of health R&D where the market fails to provide sufficient incentives e.g., through fast-track regulatory approval, waiver of licensing fees, and similar measures.

5.7 Assess the effectiveness of tax credits in stimulating R&D on HIV medicines, microbicides and vaccines, including enhanced R&D tax credits that attract investment in small biotechnology companies.

5.8 Propose models to reduce the likelihood that exposure to expensive lawsuits will deter investment in developing new prevention technologies in wealthy countries. Advocate for law reform that reduces the exposure of manufacturers and product developers to the risk of liability for using HIV prevention products, provided that:

- high safety requirements are maintained by regulatory authorities that oversee clinical trials and license products, and
- people who use products are able to access reasonable compensation should they suffer harm through 'no fault' compensation schemes, whereby people who suffer injury are able to access compensation from a fund without having to establish that the manufacturer's negligence caused their injury.

5.9 Explore the public interest case for governments to provide indemnities from liability to product developers and manufacturers of vaccines and microbicides in wealthy countries, based on the potential of vaccines and microbicides to stem the global epidemic.

Objective 6: Regulatory issues

A regulatory environment that promotes rapid appraisal of products in the development stage or for licensing, while ensuring that appropriate safety, efficacy and quality standards are maintained

6.1 Advocate for investment that strengthens the capacity of Southern regulatory authorities.

6.2 Advocate for increased transparency of regulatory procedures and improved accountability to communities affected by regulators' decisions.

6.3 Advocate for the expansion of the role of WHO and Northern regulatory authorities in supporting and building the capacity of Southern regulators in relation to safety, efficacy and quality issues relating to trials and licensing of products in developing countries.

6.4 Advocate for the expansion of the WHO's pre-qualification system to support access to quality assured treatments, diagnostics and prevention technologies.

6.5 Promote the creation of regional regulatory advisory bodies for countries with similar public health needs.

6.6 Advocate for WHO to:

- expand its technical assistance on regulatory issues
- develop and promote guidelines for regulatory requirements on safety, efficacy and quality for HIV products
- work with regulatory authorities in the South to develop regional advisory roles
- adopt a more proactive, urgent role in addressing regulatory issues.

6.7 Ensure that national planning considers funding, coordination, and technical training for regulatory review, and the possibility of regulatory review in collaboration with regional advisory entities.

6.8 Ensure that any harmonization of regulatory standards takes into account access and equity issues and strikes an appropriate balance between quality control concerns and the need for health products to be affordable and accessible.

Objective 7: Manufacturing

Expanded capacity to manufacture new and existing health products and technologies for the leading causes of sickness and death in the developing world

7.1 Assemble an overview of the manufacturing processes and associated costs for the microbicide, treatment and vaccines fields, and map and analyze existing manufacturing capacity and resource flows against these needs.

7.2 Define a broad range of innovative and flexible financial incentives and options to support investment in manufacturing capacity, including targeted loans, government grants and contracts.

7.3 Advocate for increased public sector investments in manufacturing facilities in the South so as to ensure strong manufacturing capacity for public sector needs.

7.4 Create incentives for North-South and South-South technology transfer to develop sustainable manufacturing capacities.

Objective 8: Delivery

Delivery systems established to accelerate rapid access to, and use of, needed health products

8.1 Support the rapid establishment of sustainable health systems infrastructure to support delivery of antiretrovirals and other medicines and to prepare for delivery of new therapeutic, diagnostic and preventive technologies.

- Advocate for investments in laboratory and clinical infrastructure.
- Promote sustainable strategies for staff training and development that address the drain of skilled health sector staff away from developing countries.

8.2 Develop strategies to mobilize communities and providers through integrated community education programs that address the mutually supporting relationship of treatments, vaccines and microbicides.

- Ensure that issues regarding appropriate use of partially effective prevention products are addressed in community and provider education.
- Ensure that education initiatives explain, in any given case, why it may or may not be appropriate to use products in developing countries that are not approved for use in countries in the North, taking into account different exposure patterns, risk/benefit factors, pre-qualification processes or other factors.

8.3 Conduct social, economic and epidemiological research to assess need and demand for treatments, vaccines and microbicides in different settings, and to explore behavioural responses to new products.

- Invest in social research to assess and understand how new technologies are introduced into communities and networks, how they are used in different settings, and how new health technologies can best be introduced so that they can be used to maximize their positive impact.

Objective 9: National contexts

National Plans that support product development and access for treatment and prevention.

9.1 Advocate for national HIV/AIDS plans and strategies that explicitly adopt a human rights framework and that promote the prevention–care–treatment continuum as part of a comprehensive and integrated approach to HIV/AIDS.

- Plans should address access to treatments, and the role the nation can play in relation to microbicides and vaccines, as well as voluntary counselling and testing, education, harm reduction, condom distribution, care and support, blood safety, and efforts to address stigma, discrimination and gender inequality.

9.2 Develop minimum standards against which advocates can hold governments to account for national budgetary allocations to HIV/AIDS treatment and prevention, research efforts and the strengthening of health delivery systems.

9.3 Promote the involvement of people living with HIV/AIDS and civil society groups in the development, content, implementation and monitoring of national plans.

9.4 Develop checklists of essential items relating to R&D and access as an evaluation and accountability tool for assessing National Plans (e.g., community involvement, ethical review, regulatory issues).

9.5 Ensure that vaccine, microbicide and treatment trials and access initiatives are given explicit support by national budgetary processes, and by agencies funding national strategies including bilateral funders, the World Bank, and the GFATM.

- Engage with donors and countries preparing applications for funding to assess opportunities for funding access initiatives such as community preparedness for trials, and community education on HIV literacy, the clinical research process, treatments and prevention technologies.

Objective 10: Advocacy coordination

Improved communication and strategic coordination between advocacy organisations

10.1 Promote the Statement of Commitment to a comprehensive global HIV/AIDS response amongst advocacy groups and the wider research, health and development sectors.

10.2 Promote collaboration among treatment and prevention activists at global, regional and national forums, and present key advocacy messages through consensus statements.

10.3 Develop links between microbicide, treatment and vaccine activists and advocacy organisations working at local, national, regional and global levels.

Opportunities for advocacy on the elements of the Plan of Action

This section provides a list of actions that could be taken on a collaborative basis by advocates. They are actions that each field may be pursuing independently, but where there may be advantages gained by aligning efforts and thereby combining the political power of the three movements. For this agenda to be realised, links between advocates working at national, regional and global levels need to be actively fostered. This underscores the need for advocacy organizations to integrate collaboration into their forward planning. The accompanying document, the joint *Statement of Commitment to Building a Comprehensive Global HIV/AIDS Response*, is one resource to assist advocates in understanding the areas of common interest and the value of collaboration.

Links also need to be made with advocates working on broader health, development and rights issues. Many of the issues confronting HIV/AIDS advocates intersect with concerns of advocates working on globalization, fair trade and social development issues. Collaboration with advocates working outside of the HIV/AIDS sector on topics such as the impact of trade and investment agreements and World Trade Organization practices, sexual and reproductive rights, and development financing options, to name a few, could be beneficial to HIV/AIDS advocacy.

Global and regional actions

Opportunities for advocates to collaborate at the global and regional levels include:

WHO and the GFATM

Advocates should collaborate in liaison with WHO and the GFATM (Board members and Partnership forum) regarding priority actions required to achieve the objectives of the 3 by 5 Initiative. The sustainability of GFATM and the success of the 3 by 5 Initiative are critical issues for advocates. Common priorities can also be presented to the WHO Commission on Intellectual Property Rights, Innovation and Public Health.

UNAIDS and the UN General Assembly

Advocates should highlight policy priorities to inform the periodic assessment by the UN General Assembly of progress in meeting the targets set in the *UN Declaration of Commitment on HIV/AIDS*. Countries have committed to reporting their progress using UNAIDS indicators. Advocates can recommend more precise indicators to measure progress in R&D and access measures. To inform their critique, advocates can access copies of past country reports on the UNAIDS website.

G8 Summits

Advocates should coordinate their efforts to communicate priorities to the annual G8 Summits and to advocate for Summits to result in concrete global health policy outcomes.

World Health Assemblies

The annual global meeting of the World Health Assembly provides an opportunity to seek backing for new multilateral initiatives to address access and R&D priorities. For example, in the past treatment advocates have lobbied at Assemblies to seek support for an international treaty on health R&D.

UN Millennium Project

The UN Millennium Development Goals (MDGs) are highly significant in informing the priorities of donors. The UN's recommended strategies for achieving the Goals will influence the major global bilateral and multilateral agencies. The MDGs are the central point of reference for discussions around financing development. An opportunity to shape UN action

[7] E.g., see: *The protection of human rights in the context of human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS)*, Resolution 2003/47; Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria, Resolution 2004/26; and The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Resolution 2004/27.

on the MDGs is by way of influencing the UN's Millennium Project, which has issued detailed reports on HIV/AIDS and access to medicines. The Project is due to provide policy recommendations in a report to the UN Secretary-General by 30 June 2005. Advocates could collaborate in providing input to the Project and other ongoing work by the UN related to the MDGs.

UN Commission on Human Rights

Advocates can seek to influence debates and resolutions of the Commission on Human Rights relating to HIV/AIDS and other relevant UN human rights mechanisms. The Commission meets annually Geneva. The Commission has the power to request countries to report periodically on HIV/AIDS issues, such as progress in promoting and implementing the International Guidelines on HIV/AIDS and Human Rights, and in implementing measures to expand access to HIV/AIDS medicines in developing countries.[7]

UN Special Rapporteur on the Right to Health

The UN Special Rapporteur on Health is conducting a three year investigation on the human right to health until 2005. Advocates should present their advocacy priorities to the Rapporteur to support his work, which informs the work of UN agencies and the Commission on Human Rights.

International and Regional HIV/AIDS Conferences

Progress in achieving the objectives of this Plan of Action can be reviewed at annual microbicide, treatment and vaccine conferences, the bi-annual International HIV/AIDS Conference, and regional conferences. These meetings provide an opportunity to publicize and build support for a consensus agenda on R&D and related access issues, and to develop regional networks of microbicide, treatment and vaccine advocates to foster collaboration. The media attention that conferences attract offers an opportunity for joint media work on issues of agreed priority.

Global and regional meetings

Advocates can present common priorities to influence the health and development agendas of regional political fora, such as

- World Trade Organisation and Member delegations
- World Economic Forum
- World Social Forum
- Association of South East Asian Nations (ASEAN) summits
- African Union, Southern Africa Development Community, Economic Community of West African States
- Latin American summits
- European Union summits
- Regional trade blocs

Influencing research and clinical trial networks

Advocates can collaborate in liaison and advocacy with researchers and trial managers through networks such as

- Networks established by the European and Developing Countries Clinical Trials Partnership (EDCCTP)
- Networks funded by the US NIH Comprehensive Program of Research on AIDS
- Other regional research networks e.g., African AIDS Vaccine Program
- HIV Vaccine Trials Network
- HIV Prevention Trials Network

National and local actions

Opportunities for collaborative action at the local and national levels include:

- Presenting concerns to national research agencies such as Medical Research Councils
- Feeding priorities into national health and development planning processes
- Presenting priorities and checklists to the National HIV/AIDS Council or equivalent bodies
- Raising concerns with local and national political leaders, including trade, justice and health ministries
- Bringing treatment, microbicide and vaccine advocates together at the national level to review domestic priorities and community mobilisation strategies
- Planning joint community education efforts
- Encouraging liaison and exchange of lessons learnt between staff involved in prevention and treatment trials
- Encouraging liaison between domestic clinical trial initiatives to support collaboration in community preparedness and education efforts
- Initiating collaborative national campaigns on issues such as support of the GFATM and fair outcomes for health from trade agreements
- Presenting priorities to advocates working nationally on broader health, development, trade and globalization issues
- Establishing bilateral links with advocates in similarly placed national contexts

Glossary of acronyms

AMD	Alliance for Microbicide Development
ASEAN	Association of South East Asian Nations
AVAC	AIDS Vaccine Advocacy Coalition
ARVs	Antiretroviral therapies
EDCCTP	European and Developing Countries Clinical Trials Partnership
EMEA	European Medicines Evaluation Agency
FDA	US Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunization
GCM	Global Campaign for Microbicides
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
IAVI	International AIDS Vaccine Initiative
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
MMV	Medicines for Malaria Venture
MTCT	Mother-to-child transmission of HIV
MDGs	United Nations Millennium Development Goals
NIH	US National Institutes of Health
OIs	Opportunistic infections
R&D	Research and development
STI	Sexually transmitted infection
TRIPS	World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United National General Assembly Special Session
WEF	World Economic Forum
WHO	World Health Organization
WTO	World Trade Organization

Sources of further information

Publications

Access Working Group of the Microbicide Initiative. *Preparing for Microbicide Access and Use.* Microbicide Initiative of the Rockefeller Foundation, 2002.

AVAC. *How Do You Fight a Disease of Mass Destruction?* New York: AVAC, 2003.

Avrett S. *HIV Vaccines for Developing Countries: Advancing Research and Access* Montreal: Canadian HIV/AIDS Legal Network 2003.

Collins C, S Avrett. HIV Vaccines: Current challenges and future directions, *Canadian HIV/AIDS Policy & Law Review* 2002; 7(1):1, 20-25.

Committee on Economic Social and Cultural Rights. *General Comment 14: The Right to the Highest Attainable Standard of Health* Geneva: UN, 2000 Doc.E/C, 12/2000/4.

Ethical Considerations in HIV Preventive Vaccine Research: UNAIDS Guidance Document. Geneva: UNAIDS, 2000.

Global Advocacy for Microbicides: A Call to Action. New York: Microbicide Initiative and Global Campaign for Microbicides, 2002.

Global Mobilization for HIV prevention: A Blueprint for Action Global HIV Prevention Working Group, July 2002.

Gross M, M Johnston. HIV vaccines and topical microbicides: a complementary combination *Microbicide Quarterly* 2003; 1(1): 5-9.

Gross M, M Johnston. HIV vaccines and topical microbicides: a complementary combination Part 2: shared regulatory considerations *Microbicide Quarterly* 2003;1(2):8-12.

HIV/AIDS and Human Rights International Guidelines, Revised Guideline 6, Third International Consultation on HIV/AIDS and Human Rights. New York & Geneva: OHCHR & UNAIDS, 2002.

Hunt P. *Report of the Special Rapporteur on the Right to Health, Report to the 59th Session of the Commission on Human Rights,* Geneva: United Nations OHCHR, February 2003.

IAVI. *A New Access Paradigm: Public Sector Actions to Assure Swift, Global Access to AIDS Vaccines, IAVI Access Project White Paper* New York: IAVI, 2001.

Mobilization for Microbicides: the Decisive Decade. New York: Microbicide Initiative of the Rockefeller Foundation, 2002.

Preparing for Microbicide Access and Use. New York: Microbicide Initiative of the Rockefeller Foundation, 2002.

Promoting Development and Delivery of Preventive Medical Technology To Fight AIDS, Malaria and TB: Legislative Proposals for Consideration. AVAC, IAVI, GCM, IPM, Alliance for Microbicide Development, Gay Men's Health Crisis, Malaria Vaccine Initiative, Alan Guttmacher Institute, Sequella Global Tuberculosis Foundation, March 2003.

Report of the Commission on Macroeconomics and Health: Investing in Health for Economic Development. Geneva: World Health Organization, December 2001.

Stone A. Microbicides: a new approach to preventing HIV and other sexually transmitted infections *Nature Reviews* 2002;1:977.

The Case for Microbicides: A Global Priority(2nd ed). New York, London: Population Council, IFH 2001.

The Ethics of Research Related to Healthcare in Developing Countries. London: Nuffield Council on Bioethics, 2002. (available at www.nuffieldbioethics.org/publications).

UN General Assembly Special Session on HIV/AIDS. *Global Crisis-Global Action: Declaration of Commitment on HIV/AIDS.* New York: June 2001.

Wilson P et al. *Interim Report of Task Force 5 Working Group on HIV/AIDS.* New York: UN Millennium Project, 2004.

Websites

AIDS Vaccine Advocacy Coalition	www.avac.org
Alliance for Microbicide Development	www.microbicide.org
Canadian HIV/AIDS Legal Network	www.aidslaw.ca
Consumer Project on Technology	www.cptech.org
Drugs for Neglected Diseases initiative	www.dndi.org
Family Health International	www.fhi.org
Global Campaign for Microbicides	www.global-campaign.org
Health Global Access Project (Health GAP)	www.healthgap.org
International AIDS Vaccine Initiative	www.iavi.org
International Council of AIDS Service Organizations	www.icaso.org
International Family Health	www.ifh.org.uk
International Partnership for Microbicides	www.ipm-microbicides.org
International Treatment Access Coalition	www.itacoalition.org
MSF Access to Essential Medicines Campaign	www.accessmed-msf.org
Treatment Action Campaign (South Africa)	www.tac.org.za
Joint United Nations Programme on HIV/AIDS	www.unaids.org
WHO-UNAIDS HIV Vaccine Initiative	www.who.int/hiv-vaccines
WHO 3 by 5 Initiative	www.who.int/3by5

HIV/AIDS Microbicides Treatments and Vaccines