Acknowledgments

This Plan of Action was developed as part of a project of the Canadian HIV/AIDS Legal Network entitled *HIV/AIDS Treatments, Microbicides and Vaccines: Developing an Agenda for Action*. The Project aims to explore common policy objectives of the three fields and promote coordinated advocacy efforts.

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A revised Plan was distributed in the first quarter of 2004 to treatment, microbicide and vaccine advocates for further comment. The Canadian HIV/AIDS Legal Network thanks the participants in the expert consultation for their input on the draft Plan, and the members of the reference group, who reviewed a further draft.

John Godwin drafted the Plan of Action and edited revisions. David Patterson was the Project Manager.

Other documents produced by the Project are:
• A Background Paper
• An Issues Paper
• A Statement of Commitment

More information on the Project can be obtained from the Legal Network’s website: www.aidslaw.ca

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Ce document est également disponible en français.
Este documento también está disponible en español.
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Purpose of this Plan of Action

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 treatments, microbicides 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 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 treatments, microbicides 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 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 Context**

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 the capacity of advocates for collaborative, mutually supportive advocacy within the global funding environment.
   - Develop shared understanding amongst advocates of the nature and priorities of the vaccine, microbicide and treatment 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 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 such as the UK proposal for an International Finance Facility.

1.4 Assess the potential role of advance purchase commitments in stimulating R&D relating to vaccines and microbicides.
   - Assess 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 relief 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 (new infrastructure, staff training etc).
   - Map resource flows so that resources are directed to ensure existing capacity can be better utilized and to rapidly expand capacity 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: National contexts**

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

2.1 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 that 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.

2.2 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.

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

2.4 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).

2.5 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 3: Research & development (R&D)**

**Enhanced R&D initiatives directed at the priority health needs of the global South**

3.1 Develop monitoring and evaluation frameworks on HIV/AIDS-related R&D.
   • Develop indicators that measure overall R&D funds invested in HIV vaccines, microbicides and treatments, 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.

3.2 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.
3.3 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.

3.4 Develop principles to inform public-private partnerships (PPPs) for R&D regarding:
- input from Southern 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.

Objective 4: Clinical trials
Expanded clinical trial capacities in the global South

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

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

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

4.4 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.

4.5 Promote training for communities and trial staff on ethical, legal and human rights issues common to treatments, microbicides and vaccines.
- Facilitate South-South learning on these issues including informed consent, confidentiality, compensation and standard of care.

4.6 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.

4.7 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.

4.8 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.

4.9 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.

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

Plan of Action for Joint Advocacy on HIV/AIDS Treatments, Microbicides and Vaccines
Objective 5: Pricing
Reduction in the prices of health products in low and middle-income countries

5.1 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.

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

5.3 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.

5.4 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.

5.5 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).

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

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

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

Objective 6: Intellectual property
Removal of intellectual property barriers to access to HIV therapeutic and preventative products

6.1 Ensure that trade and investment agreements maximize countries’ capacities to pursue public health objectives.

- Oppose bilateral and regional trade agreements imposing ‘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, and that place limitations on the use of public health safeguards such as compulsory licensing, parallel importing or other exceptions to patent protection.

6.2 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 medicines 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.

• Promote use of compulsory and voluntary licensing to increase generic competition.

6.3 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.

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

Objective 7: Liability
Increased capacity of governments and communities to assess the acceptable risks and benefits associated with use of therapeutic and preventive technologies

7.1 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).

7.2 Propose models that 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.

7.3 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 unique potential of vaccines and microbicides to stem the global epidemic.

Objective 8: Legislative incentives
An enabling legislative and fiscal environment to stimulate HIV product development

8.1 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.

8.2 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.
**Objective 9: Regulatory issues**
A regulatory environment that promotes rapid appraisal of products in the development stage or for licensing, whilst ensuring that appropriate safety, efficacy and quality standards are maintained

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

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

9.3 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.

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

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

9.6 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; and
   - adopt a more proactive, urgent role in addressing regulatory issues.

9.7 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.

9.8 Ensure that harmonization of regulatory standards (e.g., through the ICH process) 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 10: Manufacturing**
Expanded capacity to manufacture new and existing health products and technologies for the leading causes of sickness and death in the world’s poorest countries

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

10.2 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.

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

10.4 Create incentives for North-South and South-South technology transfer to develop sustainable manufacturing capacities.
**Objective 11: Delivery**

Delivery systems established to accelerate the rapid access to and use of essential health products

11.1 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.

11.2 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 explains 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.

11.3 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 12: Advocacy coordination**

Improved communication and strategic coordination between advocacy organisations

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

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

12.3 Develop links between vaccine, microbicide and treatment activists and advocacy organisations working at local, national, regional and global levels.
Opportunities for advocating the Plan of Action

Global actions

Advocate priorities to:

- WHO 3 by 5 Initiative
- WHO Commission on Intellectual Property Rights, Innovation and Public Health
- UNAIDS
- G8 meetings
- World Health Assemblies
- UN Millennium Project
- UN Commission on Human Rights and relevant UN human rights mechanisms
- UN Special Rapporteur on the Right to Health
- World Trade Organisation and Member delegations
- World Economic Forum
- World Social Forum
- GFATM Board members and Partnership Forum

Feed priorities into the process for the annual assessment by the UN General Assembly of progress in meeting the targets set in the UN Declaration of Commitment on HIV/AIDS.

Review progress in achieving the objectives of this Plan of Action at annual vaccine, microbicide and treatment conferences, and at the bi-annual International AIDS Conference.

Regional actions

Present common priorities to

- Regional political fora e.g., ASEAN, African Union, and Latin American Summits
- Regional HIV/AIDS conferences
- Regional research networks e.g., the African AIDS Vaccine Programme, the European and Developing Countries Clinical Trials Partnership (EDCCTP)
- Regional trade blocs e.g., at WTO meetings

Develop regional networks of treatment, microbicide and vaccine advocates to foster collaboration.

National actions

- Present R&D concerns to national research agencies e.g., Medical Research Councils
- Feed priorities into national health and development planning
- Present priorities to the National HIV/AIDS Council or equivalent body
- Raise concerns with national political leaders, and trade, justice and health ministries
- Bring treatment, microbicide and vaccine advocates together at the national level to review domestic policy priorities and community mobilisation strategies
- Encourage liaison between domestic clinical trial initiatives to support collaboration in community preparedness and education efforts
- Establish bilateral links with advocates in similarly placed national contexts
- Present priorities to advocates working nationally on broader health, development, trade and globalization issues
Glossary of Acronyms

AMD    Alliance for Microbicide Development
ARV    Antiretroviral
ASEAN  Association of South East Asian Nations
EDCCTP European and Developing Countries Clinical Trials Partnership
GAVI   Global Alliance for Vaccines and Immunization
GFATM  Global Fund to Fight AIDS, Tuberculosis and Malaria
GCM    Global Campaign for Microbicides
ICH    International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IAVI   International AIDS Vaccine Initiative
MMV    Medicines for Malaria Venture
OI     Opportunistic infections
R&D    Research and development
STI    Sexually Transmitted Infections
TRIPS  World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights
UNAIDS United Nations Joint Programme on HIV/AIDS
UNGASS UN General Assembly Special Session
WEF    World Economic Forum
WHO    World Health Organization
WTO    World Trade Organization