

Issues Paper

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Treatments Access in the Asia/Pacific Region

Introduction

At the Barcelona AIDS Conference in July 2002, the World Health Organisation set a goal of providing treatment to 3 million people living with HIV in the developing world by 2005. Realistically, this goal seems unattainable. This paper intends to provide an overview of the issues which require rapid resolution if communities in our region are to make greater headway in making progress towards this ambitious goal.

There have been many local success stories in treatment access, but thus far, there are no stories of significant national scale-up. There are many small scale solutions being proposed, both programmatic and policy, for increasing treatment access – but is this enough? There may be upcoming progress in Thailand where the combination of government leadership, a national health-care scheme, a strong CBO/NGO movement, and availability of some generic antiretroviral treatments (ARVs) may see a significant number of Thais gain access to ARVs. Can this be replicated?

AFAO believes that engagement of influential decision-makers and policy-makers on the issues outlined below will be critical to the future of treatment access in our region.

1 Resources

1.1 How can access to ARV treatments be funded in the Asia Pacific region?

Issue

- Most countries in the region require major investment in health infrastructure to support expanded ARV treatment access
- Low income countries are unable to afford universal access to ARVs from domestic health budgets
- Do countries receiving Global Fund grants invest in infrastructure or ARVs?

Threat

- The major European and North American bilateral funders have focused their efforts in Africa
- Low income countries lack internal budgetary capacity



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- Middle income countries lack political will and funds are diverted to areas such as defence

Possible solutions

- Analysis of opportunities presented for expanding support provided by
 - Global Fund
 - Asian Development Bank and World Bank financing programs
 - Japan
- Lobbying on debt relief and collaboration with the Jubilee campaign
- Support of the Global Fund, and within that, support for proposals that include strong treatment access components

2 Procurement and distribution

2.1 How do countries develop and negotiate ARV procurement plans?

Issues

- Through what structures are drugs provided in each country?
- Are drugs provided free or at minimal cost by the government?
- Are brand name drugs or generics used in the country? If generics are used, are generic prices significantly lower than brand name prices?
- How is drug purchasing done? Through country level agreements or institution-by-institution?
- What are the ramifications of TRIPS and patent laws in each country?
- How can drug pricing be made more transparent so that countries can negotiate purchases on the basis of an open market?

Threats

- National governments may not be willing to use mechanisms under TRIPS to produce or import generic drugs for fear of economic and political reprisal from western governments or because of WTO negotiations.
- Research-based pharmaceutical companies are negotiating contracts for the supply of ARVs, presumably with the strategic goals of maximising market share and revenue.

Possible solutions

- A regional survey of patents legislation lead by an international agency or a regional NGO
- Purchasing and TRIPS /patents assistance to governments on a systematic basis (e.g., MSF comparative pricing tables made more universal; TRIPS-analysis provided centrally)
- Fast tracking the regional implementation of WHO's global ARV bulk procurement scheme

2.2 How do countries devise an effective ARV Distribution Plan?

Issue

- ARV regimens are dependent on the capacity of individual countries to deliver them. The issues involved include: maintenance of supply,

storage and refrigeration, and the capacity and ability of medical practitioners for distribution.

Threats

- ARV treatments are available but cannot be delivered routinely, systematically and appropriately to patients

Possible solutions

- Countries will have to tailor their solutions to their respective capacities
- Dissemination of information on models of successful pilot distribution programs (eg Haiti, Khayelitsha - Capetown)

3 Standard of care

3.1 Achieving the best 1st line and 2nd line ARV combinations

Issue

- The combinations of ARVs that are known to be most effective are currently not available in most of the Asia Pacific region because some individual drugs are under patent and not available for inclusion in generic combinations

Threat

- Rapid development of toxicities (nevirapine rash, lipodystrophy, etc.) from suboptimal combinations could undermine:
 - patient confidence in ARV treatment (particularly in context of high levels of stigma and discrimination)
 - governments' commitments to supporting widespread ARV access programs

Weakness

- No international agency or body is taking on responsibility for analysing possible solutions and negotiating with the major brand name pharmaceutical industry

Possible solution

- An international agency should be created, or an existing one persuaded, to take on this task
- A single pill, once-a-day ARV regimen should be developed through co-operation between manufacturers eg, voluntary licensing of brand name components to generic manufacturers

3.2 What minimum level of patient monitoring is required?

Issue

- Elaborate high-tech monitoring performed in rich countries is not feasible

Possible solutions

- Rapid research is needed to clarify what level of monitoring is required (simple monitoring techniques could include monitoring weight gain or the presence of opportunistic infections).
- The Thai Government Pharmaceutical Organization is developing a very cheap (US\$5) CD4 test.
- The Brazilian generic industry is aiming to develop cheaper diagnostics.
- Training and education is needed in the region with healthcare professionals so that they can deliver the most effective patient monitoring considering the resources that are available to them.

Weakness

- A funder for this research and activities has not been identified

3.3 What measures can be put in place to support best possible adherence to ARV regimens?

Issue

- Low adherence to ARV regimens can lead to drug-resistance.

Threat

- In the West primary health-care providers and advisors are doctors, specialists or HIV clinics. In some countries in the region, there is a different model and advice may be provided by those without formal medical training. In South India, they are referred to (not always negatively) as “quacks”; in Thailand, drugs are often dispensed through neighbourhood pharmacies without advice or consultation with a medical professional.

Possible solutions

- Adapting adherence support mechanisms to individual country’s existing pharmaceutical provision at the local level.
- Action research with people living with HIV/AIDS which fosters adherence at the local level

3.4 How can we ensure a sufficient body of qualified and trained HIV health care workers?

Issue

- In many countries there are insufficient health care workers to prescribe ARVs and monitor patients.
- Best practice in prescribing and patient care is constantly evolving as new medicines become available
- In countries where health care system are not properly resourced few or no opportunities exist for ongoing training

Threat

- Efforts to establish standards for staff qualifications and staff/patient ratios will be difficult in a region which is so diverse
- Stigma and discrimination may lead to health care workers avoiding working in the field.

Possible solutions

- Countries conduct national audits of human resource needs to support ARV scale up
- Pharmaceutical companies invest in a regional program for medical practitioner HIV education
- Resourcing of the production and distribution of treatment information resources by PLWHA/community groups
- Inclusion of PLWHAs on staff may help in quality of treatment and care

3.5 How can quality assurance in generics manufacture be enhanced?

Issue

- Although initial quality assurance checks have indicated that generic manufacturers in India and Thailand are producing drugs that meet required guidelines, ongoing quality assurance is needed

Threat

- Poor quality drugs will not be effective, harming individual's health and undermining confidence in ARV treatments.

Possible solutions

- Using Australian/EU quality assurance mechanisms to support quality assurance checks for generic HIV/AIDS drugs
- Expansion of the WHO's pre-qualification system for ARV manufacture.

3.6 How do we ensure that expanded treatment access does not compete with and degrade HIV prevention programs? How do we ensure that prevention programs are expanded as necessary?

Issue

- HIV prevention programs are already inadequate in most countries in the region

Threat

- In rich countries, the availability of ARV was accompanied by a downgrading of HIV prevention programs and commitment to HIV/AIDS programs in general.

Possible solutions

- Meetings or summits that bring together key players working on treatment access with those working on prevention
- Capacity-building workshops for treatment activists that view access to treatment within a comprehensive national response to HIV/AIDS that does not separate treatment from prevention.

4 Leadership and advocacy

4.1 How do we skill up treatment advocates and build the capacity of community organizations?

Issue

- The involvement of affected communities will be vital to the effective design and implementation of ARV access programs

Threat

- Most NGOs and CBOs in the region are weak and lack skills for treatment advocacy.
- Many PLWHA organisations are losing key activists to AIDS because of lack of access to treatment

Possible solutions

- Regional workshops to build advocacy skills
- Country specific Treatments Access Plans incorporating participation of people living with HIV/AIDS

4.2 How do we support provision of ARVs to community activists?

Issue

- Community activists are dying through lack of treatment

Threat

- Some western organisations are reluctant to get involved in direct provision of drugs to activists in the region because they worry about questions such as: who should get them first? How do we decide who to provide the drugs to? Can we supply them on an ongoing basis?

Possible solutions

- Questions of sustainability are not as important as many used to think. The priority is to begin a program and then find ways to support it.
- Donation programs and buyer's clubs which make drugs more affordable for key activists should be supported
- Work should be done on both a regional and a national basis.

4.3 How can we engage employers in ARV provision?

Issue

- How can the private sector be engaged to increase treatment access? What are their obligations to provide ARV to employees and their families, and how long can this provision be guaranteed?
- Do AusAID and development NGOs provide treatment to local employees? Would AFAO provide treatment to those involved in AFAO funded projects?

Threat

- Employers may fear that they will be obliged to provide treatment to employees on a lifetime basis, and may not have the resources to do so.

Possible solutions

- Work with AusAID and ACFOA to develop standards and programs for treatment provision to local employees
- International corporate employers to initiate models along the lines of those adopted by Heineken and AngloAmerican
- Pursue collaborations with organisations that deal with workplace issues (eg, Global and Regional Business Coalitions and the ILO) to raise this issue
- Persuade the Australian Government to provide a leadership incentive program for the private sector

5 Research and development

5.1 How do we support introduction of generic competition whilst retaining incentives for research-based pharmaceutical companies to continue HIV treatment research?

Issue

- A total shift to generic manufacturing leaves brand name pharmaceutical companies with only rich country markets, reducing their incentives for ongoing research and development in HIV therapies

Threats

- Research into new HIV therapies is significantly diminished

Possible solutions

- A high-level, negotiated resolution which retains incentives to research-based pharmaceutical companies to continue to invest in HIV R&D.
- Creative use of voluntary and compulsory licensing models
- Cooperative efforts to prevent reimportation of generics to rich markets

5.2 How can research priorities be adjusted to enhance regional treatment access?

Issues

Clinical

- When should patients commence ARV therapy? Are there considerations specific to regional contexts which justify departure from ARV clinical guidelines used in Australia, the US and Europe? eg What is the optimal dose for average bodyweight of the various Asian peoples?
- With limited resources, should ARV provision be given priority over and above prophylaxis for Opportunistic Infections?
- What are the implications of HIV treatments for co-infection with TB, malaria and other diseases endemic to the region?

Social and behavioural

- What effects will the availability of ARVs have on behaviour?

- Will ARV provision increase demand for testing, reduce stigma and increase access to prevention?
- Are there culturally specific aspects of health seeking behaviours eg Asian men's reluctance to attend clinics for non-symptomatic conditions.
- What is the role of traditional and complementary therapies in various regional contexts?

Possible solutions

- Support for representation of people with HIV and HIV affected communities on bodies setting local research priorities
- Investment in capacity of research agencies to pursue locally determined priorities
- Raising the importance of investment in new clinical, social and behavioural research to support treatment scale up at appropriate fora eg, Asia Pacific Leadership Forum.