

HIV/AIDS Treatments and Australia's Aid Program

“Australia is aware of the importance of access to essential medicines for developing countries. Many governments in our region are starting to consider new AIDS treatments in national programs of prevention, care and treatment. Australia has already been working to strengthen the capacity of health care systems in many countries. We are willing to support, through our aid program, research and trials to help countries assess alternatives for introducing new HIV/AIDS treatments.”

In addition we are working with the World Trade Organisation, World Health Organisation and other international forums to improve access to essential drugs. We are willing, if requested, to help developing countries draft intellectual property legislation that enables them to implement the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and thereby to facilitate access to lower-cost HIV/AIDS medicines in health emergencies.”

*- Minister for Foreign Affairs,
Hon Alexander Downer MP,
speaking at the Asia-Pacific
Ministerial Meeting on HIV/AIDS
& Development, 10 October 2001*

Executive Summary

The affordability and availability of HIV/AIDS treatments, particularly antiretroviral drugs (ARVs), is improving in many developing countries. With increasing international interest in implementing expanded responses to the global epidemic, many countries will seek to introduce these treatments increasingly as part of their response to the crisis of HIV/AIDS. However, ARVs require a sound health infrastructure and careful management and monitoring if effective treatment is to be sustained and drug resistant strains of HIV/AIDS are to be avoided. This will present significant challenges for the primary health care systems in much of our region.

In response, Australia is willing to support Asia-Pacific partner governments' requests for research and trials to help countries assess alternatives for introducing new HIV/AIDS treatments. Such activities would usefully complement existing AIDS projects. Research and trials can help develop options for the possible broader integration of ARVs into national HIV/AIDS programs, and may provide models for scaling up by partner governments in the longer term. Activities might include support for trials of ARVs for the prevention of mother-to-child-transmission, or trials to establish protocols governing the introduction of expanded treatments in resource-poor settings, or for post-exposure prophylaxis. Support for collaborative approaches between the public and private sectors may also be appropriate. Requests will need careful assessment to ensure issues of effectiveness and sustainability are addressed, within the context of existing national or donor-funded HIV/AIDS programs.

While much debate currently focuses on ARV treatments, provision of less sophisticated drugs to treat opportunistic infections (OIs) could also make a significant contribution to quality of life in developing countries. This approach should be encouraged in discussion of HIV/AIDS treatments.

Australia has committed to providing support to Asia-Pacific governments requesting assistance to implement the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), thus enabling them to take TRIPS-consistent action to secure access to lower-cost treatments. In dealing with such requests, it will be important to involve appropriate legal expertise to ensure that any legislation that is proposed is TRIPS-consistent and meets the particular country's need in terms of facilitating access to treatments.

While HIV/AIDS drugs are important, they can only form a part of the overall national and international response to HIV/AIDS. Other aspects such as education, early prevention, community-based care and development of health care systems are vitally important and require priority attention by national governments and the international community. Australia's continuing programs in these areas will help ensure that any future treatment initiatives can be implemented effectively.

The rapidly changing environment around this issue will require AusAID to continually monitor international developments closely, both bilateral and multilateral. This will require policy dialogue with partner governments and international agencies as appropriate. Desks and posts should monitor developments in this area and liaise with the HIV/AIDS Taskforce as required.

CONTENTS

<u>INTRODUCTION</u>	2
<u>HIV/AIDS AND AUSTRALIA'S AID PROGRAM</u>	2
<u>Primary health care setting</u>	2
<u>Current practice on HIV/AIDS treatments</u>	2
<u>RECENT INTERNATIONAL DEVELOPMENTS</u>	3
<u>Innovations in Treatment</u>	3
<u>Reductions in Cost</u>	4
<u>Increased international political action</u>	4
<u>CHALLENGES FOR INTRODUCING ANTIRETROVIRAL THERAPY</u>	5
<u>POLICY RESPONSES</u>	6
<u>Trials and research</u>	6
<u>Opportunistic Infections</u>	7
<u>Continuing support for prevention and primary health care</u>	7
<u>Support for Intellectual Property Legislation</u>	7
<u>Need for continuing review</u>	8
<u>KEY REFERENCES</u>	8
<u>ATTACHMENT A - Treatment Options for HIV/AIDS</u>	9
<u>ATTACHMENT B - Managing the delivery of antiretroviral therapy</u>	10
<u>ATTACHMENT C - Guidelines on Key Elements of Care and Support</u>	11
<u>ATTACHMENT D – Accelerating Access Initiative</u>	12
<u>ATTACHMENT E – DOHA Declaration on TRIPS and Public Health</u>	13

INTRODUCTION

Following the Minister's policy announcement of October 2001, this paper presents an analysis of issues concerning the availability and provision of HIV/AIDS treatments, particularly antiretroviral drugs (ARVs), through Australia's aid program. The paper first provides background on the Government's policy on HIV/AIDS and the aid program. It then considers recent developments that have prompted international debate on access to essential AIDS drugs, and the challenges facing the introduction of antiretroviral treatments in developing countries. . It concludes by presenting policy responses for the aid program concerning the availability and provision of HIV/AIDS treatments.

HIV/AIDS AND AUSTRALIA'S AID PROGRAM

Primary health care setting

2. Australia's health policy for the aid program seeks to improve the health of the poor by focusing on primary health care (AusAID 1998). Primary health care is a comprehensive health systems approach, developed in partnership with governments and communities, which covers prevention, health promotion, treatment, and rehabilitation. In HIV/AIDS, our objectives are to help partner countries in addressing prevention, treatment and care, and the social and economic impact of HIV/AIDS (AusAID 1999). The aid program advocates a multisectoral response to HIV/AIDS because the epidemic is not just a health crisis; interventions to counter the epidemic need to consider the complex causes of the epidemic, many of which are exacerbated by poverty.

3. Health interventions in relation to HIV/AIDS need to be considered within this context. For an aid program focused on providing health that benefits the poor, it is important that health interventions are assessed as cost-effective in reducing the diseases of poverty. Specific health interventions need to be assessed against competing alternatives to determine the optimal allocation of limited health resources.

4. HIV/AIDS stretches the resources of the health sector: it increases the number of people seeking services, and health care for AIDS patients is more expensive than for most other conditions. In this context, developing countries face a number of difficult policy tradeoffs. These include focusing on preventing HIV infection versus treating AIDS cases; treating AIDS versus treating other illnesses; and allocating health spending against spending for other objectives. For the aid program, the most positive and cost-effective contribution in countering the advance of the HIV/AIDS epidemic, particularly in populations experiencing a nascent HIV epidemic, is to ensure that prevention campaigns are expanded to cover populations at risk.

Current practice on HIV/AIDS treatments

5. Prevention campaigns are most effective when supported by HIV/AIDS treatment, care and support within a comprehensive prevention/treatment continuum, particularly as the epidemic advances. For example:

- Prevention campaigns create demand for testing services, that in turn require counselling services that can help people living with HIV/AIDS (PLWHA) take action to prevent further HIV infections, e.g. by practicing safe sex.
- HIV transmission rates can be reduced by treating sexually transmitted infections.

6. The aid program provides support for treatment and care within a primary health care framework that prioritises cost-effective interventions that include treatment for common opportunistic infections, palliative care and home-based care. A classification of the different types of health interventions for managing HIV/AIDS-related illnesses is provided at **Attachment A**.

7. However, to date the aid program has not provided support for treatments that fall outside a primary health care framework because of the expensive drugs and sophisticated health infrastructure required to sustain those treatment regimens. The use of antiretroviral drugs require careful management and monitoring. Issues such as compliance with treatment regimens, the management of side-effects and the dangers of drug-resistance need careful handling. A brief outline of the infrastructure defined by WHO as required for effective management of the delivery of ARV therapy is provided at **Attachment B**.

8. This position is consistent with guidelines issued by the WHO and UNAIDS that identify three different classes of treatment, care and support services that countries can deliver according to the availability of resources and the level of sophistication of health infrastructure (contained at **Attachment C**). Public health systems should try to ensure universal access to the essential package of service before directing resources towards providing partial access to the expanded and advanced package of services.

RECENT INTERNATIONAL DEVELOPMENTS

9. Recent developments have renewed interest in the future possibility of including antiretroviral therapy and expanded drug treatments for opportunistic infections within a primary health care approach.

Innovations in Treatment

- In the absence of a cure or vaccine against HIV/AIDS, the development of ARV drugs has been the major recent achievement in treatment of HIV/AIDS. ARV therapy is not a cure, but it delays the progression of HIV/AIDS for many years. Since the introduction of highly active antiretroviral therapy (HAART) in developed countries in the mid 1990s, HIV infection is increasingly being dealt with in the West as a treatable, chronic condition requiring lifelong treatment.
- Studies have also demonstrated that effective ARV treatment of HIV positive people lowers the viral load of infected people that may in turn reduce the likelihood of transmitting infection to others.
- Some middle income countries have introduced HAART within nationally funded programs – Brazil on a large scale, Thailand and Costa Rica on a more modest scale. Recent trials conducted in Haiti have explored issues for the possible use of HAART in resource-poor settings with limited health infrastructure. Research in

India, Kenya and Senegal has also been examining the management of ARV treatment regimes.

- New approaches are being developed which offer the possibility of less demanding treatment regimes (e.g. single tablet triple therapy, in place of complex regimes of multiple daily medications) or less strict requirements for management and monitoring (e.g. symptomatic diagnosis and a DOTS-HAART approach along the lines of the Directly Observed Treatments Short-Course (DOTS) approach being promoted by WHO for tuberculosis.)

Reductions in Cost

- The price of ARV therapy has fallen in some developing countries by more than 90% during 2001, from about US\$10,000 patient/year to US\$500 patient/year. The price reductions are the result of agreements negotiated in the context of increased competition (actual or potential) from the manufacturers of generic drugs, increasing calls in multilateral fora for improved access to drugs, demonstrations of global citizenship by pharmaceutical companies, and cooperative international frameworks such as the UNAIDS Accelerating Access Initiative (see below).
- Some developing countries in the Asia-Pacific, such as Thailand and Vietnam, are considering following the lead of Brazil and India in establishing or expanding their domestic capacity for manufacture of lower-cost generic ARVs.
- Some pharmaceutical companies have also started announcing major price reductions in certain countries of drugs used to treat opportunistic infections. For example, in June 2001 Pfizer announced it would provide 50 low-income countries with unlimited supplies of the drug Diflucan, used to treat cryptococcal meningitis, at no cost.

Increased international political action

- Interest in the question of access to AIDS drugs, particularly by advocacy groups, increased substantially during 2001 resulting in renewed debate on what essential service delivery packages ought to comprise.
 - : In July 2000, participants at the XIII International AIDS Conference (Durban, South Africa) highlighted global inequities in access to essential AIDS drugs. Following the conference, activists united to form the Global Treatment Access Campaign to promote access to essential medications for HIV and other diseases, focusing on "exorbitant drug prices and crippling debt."
 - : In Australia, Medecins Sans Frontieres and Oxfam have campaigned publicly and lobbied Ministers directly on improved access to essential drugs, particularly in the leadup to the WTO Ministerial Conference in Doha in November 2001.
- The international community has expressed increasing interest in funding an expanded response to the HIV/AIDS epidemic that may include some funding for antiretroviral therapy.

- : In May 2000, the UNAIDS/WHO initiative, *Accelerating Access*, was established to help countries implement comprehensive packages of care for PLWHA that would include, where possible, access to antiretroviral drugs. As at November 2001 some 72 countries have expressed interest in assistance through this initiative, though only three in the Asia-Pacific region (Malaysia, Vietnam, Thailand). For further detail, see **Attachment D**.
- : In July 2000, G8 member countries announced a major communicable diseases initiative that included targets to reduce the burden of malaria and tuberculosis by 50% and HIV/AIDS by 25% within 10 years.
- : In October 2000, Dr Brundtland, Director General, WHO announced Massive Effort, an initiative targeting diseases of poverty including malaria, HIV/AIDS, tuberculosis and other childhood diseases.
- : In June 2001, the UN General Assembly adopted the Declaration of Commitment on HIV/AIDS that called for expanded responses for HIV/AIDS prevention, care, treatment and support.
- : In June 2001, the UN Secretary General announced the establishment of the Global Fund for AIDS, Tuberculosis and Malaria (GFATM). The outcome of the first round of country proposals submitted in March 2002 will indicate the extent to which antiretroviral therapy will be supported within an expanded package of health interventions to counter the epidemic.
- : In November 2001, the WTO Ministerial Conference in Doha agreed the Declaration on the issue of intellectual property and public health (Attachment E). The declaration was welcomed as an important demonstration that the WTO can respond to the genuine concerns of developing countries on public health issues. It reinforced the flexibilities in the TRIPS Agreement, such as parallel importation and compulsory licensing, which help developing countries gain access to affordable medicines.

CHALLENGES FOR INTRODUCING ANTIRETROVIRAL THERAPY

10. Until recently, the prohibitive cost of ARV treatments precluded any real efforts by developing countries to introduce these drugs into national responses on any significant scale. The downward pressure on prices has encouraged consideration of bulk purchase and distribution of ARVs. Brazil, with its major program of ARV provision through the public health system, has provided a possible example for other countries to consider. However, though the price of ARVs is becoming a lesser factor, other economic and technical issues remain outstanding.

11. Even with the prospect of ARV prices dropping to US\$500 or below, this cost is still substantial for developing countries. Recognising that lifelong treatment is required, a major recurrent budget allocation would be required for every patient every year. The drug cost alone would quickly consume major proportions of health budgets. Sustainability of future supply also needs to be considered as countries cannot necessarily rely on the current price cuts offered by drug companies being maintained indefinitely. In addition to the direct cost of the treatments, other costs must also be taken into account, such as operational costs for delivery of the necessary treatment, testing and monitoring, associated material costs for clinical supplies such

as diagnostic tests, and research costs to monitor the effectiveness of HAART in-country. Establishing ARV programs may also be less effective in countries where social discrimination against PLWHA discourages participation in such treatment regimes.

12. In low-income countries, there would also be significant costs associated with improving health infrastructures to the point where it would be possible to support the provision of antiretroviral therapy and expanded treatments for opportunistic infections. Before antiretroviral treatments are introduced, WHO recommends a range of conditions be in place, such as testing and counselling services, diagnostic capacity, laboratory services, drug supply systems, training for health professionals, and regulatory mechanisms. Otherwise, there is high risk in the absence of effective monitoring of treatment regimens that drug-resistant strains of HIV will emerge, negating the efficacy of existing AIDS drugs.

13. Nevertheless, many developing countries will wish to make ARVs available for the benefit of their HIV-positive populations. Some countries may seek support through the Global Fund for AIDS, TB and Malaria. Therefore, research and trials are needed to test different approaches for possible scaling up in the longer term and to inform the possible broader integration of ARVs into national HIV/AIDS programs.

POLICY RESPONSES

Trials and research

14. Australia has indicated its willingness to support requests for research and trials to help countries assess alternatives for introducing new HIV/AIDS treatments. Such trials may include:

- use of ARVs to prevent vertical HIV transmission from mother-to-child. This is an area where UNICEF is involved in several countries (e.g. PNG, Vietnam) where opportunities may exist for collaboration
- trials to establish protocols governing the introduction of ARVs and/or expanded treatments for opportunistic infections in resource-poor settings. This may involve time-limited trials in specific geographic areas, looking for example at use of single table triple therapy or DOTS-HAART approaches to management of
- use of ARVs for post-exposure prophylaxis, covering groups such as healthcare workers or rape victims.

15. Requests for assistance will need careful assessment with regard to effectiveness and sustainability. Particular attention would be required to issues such as:

- the ability of the partner country to effectively administer the trial and to sustain the future supply of ARVs
- the place of such ARV trials within the partner government's broader policies and priorities on primary health care and HIV/AIDS prevention
- the involvement and ongoing support available from technical agencies such as UNAIDS, WHO or UNICEF
- integration of trials with other donor support for HIV/AIDS activities, particularly major Australian projects.

16. Support for collaborative approaches between the public and private sectors may also be appropriate. In particular, dialogue with the pharmaceutical industry may be required given their key role.

Opportunistic Infections

17. Most international debate has focussed on the pricing and provision of ARVs. However, in developing countries, the disease burden on people with AIDS arises primarily from common infections and their complications: tuberculosis, diarrhoea, pneumonia, candida, meningitis and parasitic infections. Treatment of many of these opportunistic infections (OIs) is generally successful with antibiotics that are relatively effective and affordable in most countries. The distribution and effective use of such drugs in-country is also likely to present fewer logistical problems.

18. While ARVs dominate much of the current discussion, provision of drugs for OIs can also make a significant contribution to quality of life in developing countries. If partner governments, international agencies, NGOs or pharmaceutical companies approach desks or posts with proposals for ARV distribution, AusAID should take the opportunity to broaden discussions to include consideration of whether support for provision of drugs for OIs may be justified.

Continuing support for prevention and primary health care

19. While HIV/AIDS drugs are important, they can only form a part of the overall national and international response to HIV/AIDS. Other aspects such as education, early prevention, community-based care and development of health care systems are equally important and require priority attention by national governments and the international community. Australia's continuing programs in these areas will help ensure that treatment initiatives can be effective, for instance through:

- strengthening health infrastructure to support the provision of primary health care in relation to HIV/AIDS including, for example, disease surveillance, health worker training, and drug procurement and distribution systems.
- expansion of the provision of treatments for opportunistic infections, palliative care and home-based care within a primary health care approach: including, for example, the DOTS approach for tuberculosis, and treatments for STIs.
- engagement with the Accelerating Access Initiative to assist countries in the Asia-Pacific region to introduce comprehensive packages of care for people living with HIV/AIDS.

Support for Intellectual Property Legislation

20. Looking beyond the health sector, other factors also impact on the availability of HIV/AIDS treatments. For example, the prevailing intellectual property legislation in any given country will influence its access to affordable medicines.

21. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) makes provision for member states to put in place measures to enable the production or importation of lower-cost drugs in certain circumstances, such as health emergencies. Flexibilities in the TRIPS Agreement, such as parallel importation and compulsory licensing, can help developing countries gain access to more affordable

medicines. This was reinforced in the Declaration on TRIPS and Public Health from the WTO Ministerial Meeting in Doha in November 2001 (**Attachment E**).

22. Australia fully supports the effective implementation of the health provisions in the TRIPS Agreement. In October 2001, Minister Downer announced that Australia is willing, if requested, to help developing countries draft intellectual property legislation that enables them to implement TRIPS and facilitate access to lower-cost HIV/AIDS medicines in health emergencies.

23. Australia already provides support to countries on matters of intellectual property legislation and TRIPS, through IP Australia, AusAID, DFAT and Attorney General's Department. Following the Minister's announcement, further requests may be received for assistance relating more specifically to HIV/AIDS treatments. When country desks are dealing with these requests, it will be important to involve appropriate legal expertise to ensure that any legislation that is proposed is TRIPS-consistent and meets the particular country's need in terms of facilitating access to treatments.

Need for continuing review

24. The rapidly changing environment around the treatments issue will require AusAID to monitor international developments closely, including shifts in technological, political and economic parameters. For example, the price of ARVs may continue to fall to new levels; international distribution of ARVs or treatments for OIs may be facilitated through the GFATM or other international mechanisms; or medical advances may produce drugs requiring less complex treatment regimes or management requirements. Such developments may bring opportunities for greater integration of treatments into national HIV/AIDS programs.

25. For AusAID's response to remain relevant, policy dialogue will be needed with partner governments and other agencies as appropriate. As a result, desks and posts involved with HIV/AIDS activities will need to monitor HIV/AIDS treatment issues in their partner countries and regions, and alert the HIV/AIDS Taskforce to any relevant policy developments or emerging proposals.

KEY REFERENCES

- Ainsworth, Martha et al (2000) "Breaking the Silence: setting realistic priorities for AIDS control in less-developed countries", in *The Lancet*, vol. 356, July 2000
- AusAID (1998) *Health in Australia's Aid Program*
- AusAID (1999) *Guide to HIV/AIDS and Development*
- <http://www.globaltreatmentaccess.org/>
- UNGASS (2001) *Declaration of Commitment on HIV/AIDS*
- UNAIDS (2001) *Accelerating Access to HIV/AIDS-Related Care: Third Meeting of the Contact Group*
- Sachs, Jeffrey et al (2001) *Consensus Statement on Antiretroviral Treatment for AIDS in Poor Countries by Members of the Faculty of Harvard University*
- WHO (2000) *Key Elements in HIV/AIDS Care and Support*
- WHO (2000) *Safe and Effective Use of Antiretroviral in Resource-Constrained Settings*

ATTACHMENT A - TREATMENT OPTIONS FOR HIV/AIDS

Basic Opportunistic Infections. In developing countries, the disease burden on people with AIDS arises primarily from common infections and their complications: tuberculosis, diarrhoea, pneumonia, candida, meningitis and parasitic infections. Treatment of these infections is generally successful with antibiotics that are cheap, effective and affordable in most countries. WHO's Model List of Essential Drugs provides a reference guide on safe and effective treatments that should be available worldwide: several new AIDS drugs are yet to be added to this list.

Palliative Care. In many developing countries, palliative care that seeks to alleviate symptoms rather than treat causes of diseases is the most common treatment available to people living with HIV/AIDS. Examples of symptoms managed by palliative care include pain, rashes, diarrhoea, fever, cough, nausea and shortness of breath.

Community-based Care. Community-based care involves caring for people either at home or as outpatients. Patients and their carers require strong support from primary health care clinics, including access to essential drugs and home care training.

Advanced Opportunistic Infections. Other HIV-related infections and cancers, such as toxoplasmosis, pneumocystis carinii pneumonia, cytomeglovirus, cryptococcosis, atypical mycobacteria, Kaposi's sarcoma and lymphoma, that require more expensive treatments. These infections are often more difficult to diagnose and are usually life threatening if not treated.

Antiretroviral therapy. The use of antiretrovirals is seen as an important factor in reducing the impact of HIV/AIDS in developing countries. Antiretrovirals have been acknowledged as having the potential to reduce the transmission of HIV from mother to child by up to 50%. They can also reduce opportunistic infections among people with HIV/AIDS.

Antiretrovirals are available in 3 types: non-nucleoside reverse transcriptase inhibitors, (nevirapine, efavirenz, delavirdine); nucleoside analogues reverse transcriptase inhibitors (zidovudine, didanosine, zalcitabine, stavudine, lamivudine, abacavir) and protease inhibitors (saquinavir, ritonavir, indinavir, nelfinavir, amprenavir). These drugs are usually taken in combination of three or more of two different types, known as triple or combination therapy or Highly Active Anti-Retroviral Therapy (HAART).

Source: WHO (2000) Key Elements in HIV/AIDS Care and Support

ATTACHMENT B - HEALTH INFRASTRUCTURE: MANAGING THE DELIVERY OF ANTIRETROVIRAL THERAPY

Antiretroviral therapies are complex to manage and monitor. Health practitioners providing these treatments are required to have access to tests for viral load and CD4 counts as well as training in understanding when and how to use these drugs, assess their impact, and monitor outcomes. People using these treatments are required to comply with complex regimens of many pills, where some drugs must be taken with or without food and at regular intervals for an indefinite period. Strict adherence to these regimens is essential to avoid drug resistance and the possibility of the virus replicating and changing. These treatments can also have severe side effects and the combinations of drugs may need to be changed from time to time to reduce these effects and to maintain their potency to suppress viral activity in the body.

Infrastructure for effective health care includes adequate technical staff and health care facilities such as clinics and laboratories. To manage the use of antiretrovirals trained clinical staff are required for diagnosis, counselling and monitoring of these treatments. In addition, laboratory services are needed for testing viral load and CD4 counts. Reliable supply and distribution systems also need to be in place to ensure that the supply of these treatments can be sustained. Many countries do not have the adequate infrastructure necessary and require substantial improvements to their systems in order to provide effective management of these treatments.

WHO recommends the following conditions are in place before antiretroviral treatments should be introduced:

- Access to voluntary counselling and testing for support and to enhance compliance to treatments
- Capacity to recognise and manage common HIV-related illnesses and infections
- Reliable laboratory services
- Assurance of an adequate supply of quality drugs, including drugs for treatment of opportunistic infections and other HIV-related illnesses
- Identification of sufficient resources to pay for treatments on a long-term basis
- Information and training on safe and effective use of antiretroviral drugs for health professionals to prescribe treatments
- Establishment of reliable regulatory mechanisms against misuse and misappropriation of antiretroviral drugs

Source: WHO (2000) *Safe and Effective Use of Antiretroviral Treatment in Adults with particular reference to resource-poor settings*

ATTACHMENT C - WHO / UNAIDS GUIDELINES ON KEY ELEMENTS OF HIV/AIDS CARE AND SUPPORT

Table: HIV/AIDS Priorities in Providing Treatment, Care and Support	
Essential package of services	<ul style="list-style-type: none"> ■ HIV voluntary counselling and testing ■ Psychosocial support for PLWHA and their families ■ Palliative care and treatment for common opportunistic infections: pneumonia, oral thrush, vaginal candidiasis and pulmonary tuberculosis (DOTS) ■ Nutritional care ■ Sexually transmitted infections and family planning services ■ Cotrimoxazole prophylaxis among HIV-infected people ■ Recognition and facilitation of community activities that mitigate the impact of HIV infection (including legal structures against stigma and discrimination)
Expanded package of services of intermediate complexity and cost	<p>ALL THE ABOVE PLUS</p> <ul style="list-style-type: none"> ■ Active case finding (and treatment) for TB, including for smear negative and disseminated TB, among HIV-infected people ■ Preventive therapy for TB among HIV-infected people ■ Systemic antifungals for systemic mycosis (such as cryptococcosis) ■ Treatment of HIV-associated malignancies : Kaposi's sarcoma, lymphoma and cervical cancer ■ Treatment of extensive herpes ■ Prevention of mother to child transmission of HIV ■ Post exposure prophylaxis of occupational exposure to HIV and for rape ■ Funding of community efforts that reduce the impact of HIV infection
Comprehensive package of services of high complexity and cost	<p>ALL THE ABOVE PLUS</p> <ul style="list-style-type: none"> ■ Triple antiretroviral therapy ■ Diagnosis and treatment of opportunistic infections that are difficult to diagnose and/or expensive to treat, such as atypical mycobacterial infections, cytomegalovirus infection, multiresistant TB, toxoplasmosis, etc ■ Advanced treatment of HIV related malignancies ■ Specific public services that reduce the economic and social impacts of HIV infection
Source: WHO / UNAIDS (2000) Key Elements On HIV/AIDS Care And Support	

ATTACHMENT D – ACCELERATING ACCESS INITIATIVE

Accelerating Access to HIV Care, Support and Treatment

In May 2000, WHO, World Bank, UNICEF, UNFPA and UNAIDS Secretariat established the Accelerating Access Endeavour to help countries implement comprehensive packages of care for people living with HIV/AIDS.

Countries that wish to significantly expand access to HIV care, support and treatment with assistance from UNAIDS Cosponsors and the Secretariat make formal requests to the UNAIDS Secretariat. As at November 2001 some 72 countries have expressed interest in assistance through this initiative, though only three in the Asia-Pacific region (Malaysia, Vietnam, Thailand). Under the initiative, countries work to establish national action plans that integrate comprehensive care programs into national HIV public health strategies.

The comprehensive package includes: voluntary counselling and testing, prevention and treatment of opportunistic infections, nutrition, health systems capacity, equitable and sustainable financing, and where possible, access to antiretroviral drugs.

In improving access to commodities, Accelerating Access encourages:

- **tiered pricing:** where pharmaceutical companies make long-term commitments to make HIV-related medicines available to developing countries at highly reduced prices
- **competition between suppliers:** where national legislation allows both patented medicines and generic medicines
- **collective purchasing agreements:** where country groupings collaborate to purchase larger volumes of drugs to achieve discounts
- **licensing agreements:** where companies with patent medicines offer licenses to other manufacturers willing to produce for developing country markets at lower cost
- **new funding mechanisms:** where new sources of public and private funding are increased dramatically to help pay for treatment
- **reinforcing and using health safeguards in trade agreements.**

Source: UNAIDS (2001)

ATTACHMENT E – DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
 - (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.