

■ Access to drugs



■ UNAIDS
■ Technical update

■ October 1998

At a Glance

- Living with advancing HIV infection is complicated with a variety of symptoms and medical conditions, many of which are manageable with drugs. The classes of drugs most important to persons living with HIV are:
 - anti-infective agents to treat or prevent opportunistic infections;
 - anti-cancer drugs to treat malignancies such as Kaposi sarcoma and lymphoma;
 - palliative drugs to relieve pain and discomfort, both physical and mental;
 - antiretrovirals to limit the damage that HIV does to the immune system.
- Access to even the most basic of these drugs is seriously lacking in many parts of the world. The most important obstacle to access is affordability but legal, infrastructural, distribution and cultural factors are also serious impediments. The influence of each of these factors is different from country to country, just as frequencies of diseases also vary greatly.
- As HIV/AIDS is quite recent in medical history, most drugs created especially to treat the HIV infection and its related diseases are proprietary and therefore expensive.
- Improving access to drugs for people living with HIV presents challenges on a variety of levels. Most countries face the following challenges to some degree: limited financial resources; problems with prioritization of drug needs; inadequate health care infrastructure; inadequate distribution and administration systems.
- Ensuring better access to drugs on a global level demands new relationships and alliances at international, country and local level. Responses that are proving useful in various parts of the world include:
 - including care of people living with HIV or AIDS as part of national strategic planning;
 - improving methodologies for rational selection of AIDS-related drugs, including creation of national essential drug lists;
 - improving affordability through actions such as: negotiation with pharmaceutical companies for better prices; competitive procurement through generic tendering and therapeutic class tendering, local production; working with private sector drug distributors in order to reduce the mark-up on price between the supplier and the consumer;
 - ensuring physical availability of drugs through actions such as: group purchasing arrangements by groups of people living with HIV; facilitating supply of priority HIV-related drugs through NGOs; involving local associations of pharmacists and licensed drug sellers in promoting safe dispensing; strengthening regulatory control of drug registration, quality assurance and drug outlets.
- While responsibility for deciding how to allocate public funds rests with the government, based on the public health and economic context of the country, experience shows that the challenges of access to AIDS-related drugs can best be met when the government enters into partnerships with other sectors. Strengthening the role of persons living with HIV in care partnerships is of central importance in this. The role includes advocacy for building political commitment, providing information to aid in the process of prioritization, and finally in advising on delivery and administration of drugs.
- At the same time, strategic partnerships are necessary at international level. UNAIDS is currently working with its Cosponsors and several multinational pharmaceutical companies to improve access to drugs for persons living with HIV.

UNAIDS *Best Practice* materials

The Joint United Nations Programme on HIV/AIDS (UNAIDS) is preparing materials on subjects of relevance to HIV infection and AIDS, the causes and consequences of the epidemic, and best practices in AIDS prevention, care and support. A *Best Practice* Collection on any one subject typically includes a short publication for journalists and community leaders (Point of View); a technical summary of the issues, challenges and solutions (Technical Update); case studies from around the world (*Best Practice* Case Studies); a set of presentation graphics; and a listing of key materials (reports, articles, books, audiovisuals, etc.) on the subject. These documents are updated as necessary.

Technical Updates and Points of View are being published in English, French, Russian and Spanish. Single copies of *Best Practice* materials are available free from UNAIDS Information Centres. To find the closest one, visit UNAIDS on the Internet (<http://www.unaids.org>), contact UNAIDS by email (unaids@unaids.org) or telephone (+41 22 791 4651), or write to the UNAIDS Information Centre, 20 Avenue Appia, 1211 Geneva 27, Switzerland.

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This document was developed in close collaboration between UNAIDS and the Action Programme on Essential Drugs of the World Health Organization (WHO). Both programmes acknowledge the comments of the Office of HIV/AIDS and Sexually Transmitted Diseases of the WHO.

Background

While people living with HIV infection or AIDS may live many years before their infection leads to secondary diseases and eventually AIDS, survival with advancing HIV infection is complicated with symptoms and medical conditions. Many of these symptoms and conditions, and the advance of HIV itself, are manageable with drugs. However, access to even the most basic of drugs is seriously lacking in many parts of the world.

The World Health Organization (WHO) estimates that over one-third of the world's population has no guaranteed access to essential drugs. There are various reasons for this lack of access. Worldwide, the most important is affordability (drugs cost more money than is available to pay for them) but legal, infrastructural, distribution and cultural factors are also serious obstacles. The influence of each of these factors is different from country to country, just as frequencies of diseases also vary greatly.

Among its activities aimed at improving drug access in developing countries (including technical services such as help in drug procurement and performance of needs estimates), WHO has drawn up a Model List of Essential Drugs, which is updated every two years. The tenth list (1997) has 308 priority drugs that provide safe, effective treatment for the infectious and chronic diseases which affect the vast majority of the world's population. The drugs are selected on the basis of cost-effectiveness within each drug class (e.g. of the dozens of penicillins only eight appear on the Essential Drugs list).

With WHO's encouragement, more than 140 countries have developed their own national essential drug lists taking into account local needs, costs and available resources. (For more information see WHO's *The use of essential drugs* in the Selected Key Materials.)

The drug needs of people living with HIV

Drug access issues related to HIV infection are especially complex because HIV gradually destroys the body's immune system, which normally defends the body against

a multitude of invaders. When this defence system is weakened, even relatively weak invaders may attack successfully, and cause diseases that would otherwise be rare.

Table 1 shows a list of the diseases (both opportunistic infections and malignancies) that are most often reported among people living with HIV/AIDS.

These diseases occur in different combinations and at different rates among people living with HIV/AIDS in different parts of the world. For instance, PCP is more frequent in industrialized countries while tuberculosis is more frequent in developing countries. Such epidemiological differences mean that the mix of drugs for treating diseases and symptoms in one location may be different from that in another location. (For more information see the

Technical Update on *Opportunistic diseases and AIDS*.)

The affordability gap

Affordability is not the only reason that people cannot obtain the drugs they need, but it is probably the single most important one. Over 80% of the world's current 30 million people living with HIV live in sub-Saharan Africa, where the average health expenditure per capita ranges from under US\$ 10 in the poorest countries to around US\$ 200 in the richest. In these and other developing countries, treatments for opportunistic infections such as cryptococcosis and candidiasis and antiretroviral therapy may be beyond the financial means of public health systems and of most individuals.

Price is an important part of affordability. Drug prices depend

Table 1. Global frequency rates of HIV-related opportunistic infections and malignancies

Infection or malignancy	Average frequency
Oral candidiasis	53%
<i>Pneumocystis carinii</i> pneumonia (PCP)	24%
Tuberculosis	22%
Oesophageal candidiasis	21%
Cytomegalovirus disease	21%
Kaposi sarcoma	15%
Toxoplasmosis	11%
Cryptococcosis	9%
Cryptosporidiosis	8%
Herpes zoster	7%
Systemic herpes simplex	7%
<i>Mycobacterium avium</i> complex infection	4%
<i>Salmonella</i> septicaemia	4%
Histoplasmosis	4%

Note: *Aspergillosis, isosporiasis, nocardiosis, leishmaniasis and penicillinosis* were also reported, and on average had a rate of less than 4%.

Table adapted from WHO's "Standard treatments and essential drugs for HIV related conditions: Access to HIV-related drugs" (DAP/97.9)

Background

on many factors, but one of the most important is whether the drugs are *proprietary* (still new and under patent) or *generic* (not under patent, and therefore sold at a price closer to the cost of production). Because of their high price compared to generic drugs, proprietary drugs are not usually included on the World Health Organization's List of Essential Drugs (only 10% of the list is currently proprietary), nor on national lists developed by individual countries.

As HIV/AIDS is quite recent in medical history, most of the drugs created especially to treat HIV infection and its related diseases are proprietary. This renders their treatment less affordable than that of other diseases.

Gaps in supply and distribution

When ability to purchase drugs is low, it is often not profitable for drug suppliers to offer their products at all, no matter how great a need there is. This is especially true for proprietary drugs. However, some generic drugs with important benefits for people living with HIV are also not consistently available even when they appear on the WHO's Essential Drugs list.

For example, in a 1995 survey of 13 main international providers of generic drugs by Management Sciences for Health (MSH) identified a number of serious gaps (see *International Drugs Price Indicator Guide* in Selected Key Materials). Out of these 13 providers, only four offered codeine tablets while none offered morphine, either for oral or intravenous administration, for basic pain relief. None offered pentamidine for treatment of PCP; none offered doxorubicin, bleomycin, or vinblastine (and only 4 offered vincristine) to treat Kaposi sarcoma; none offered calcium folinate (leucovorin) to combat

the side-effects of pyrimethamine treatment for toxoplasmosis. The study also found that too few galenic forms were offered, making intravenous treatment and the treatment of children difficult. For example, no pediatric formulations of antituberculosis drugs were offered by any of the 13 suppliers surveyed by MSH.

Another gap in coverage comes from the fact that some generic drugs of great benefit to people living with HIV are not on the WHO Essential Drugs list. Examples include lope-ramide and diphenoxylate, two drugs used to alleviate intractable chronic diarrhoea (a very frequent complication of advanced HIV infection) and methadone, used in the management of drug dependence. Fortunately, loperamide was still supplied by some generics suppliers in spite of its absence from the list.

Tables 2 to 5 provide a brief look at drugs that offer significant benefits to people living with HIV and lists indicative wholesale prices, whether the drugs are proprietary, and the main obstacles to their availability and use. The tables are not meant to be used as definitive sources of pricing information (such data are constantly being updated in catalogues) but as a means of illustrating the supply side of the access to drugs question. The tables cover:

- *Anti-infective agents*: Table 2 lists some of the drugs most in demand to treat or prevent opportunistic diseases. Almost half are proprietary, with prices as high as several thousand dollars per year for treatment or prophylaxis, and many are not widely available in developing countries. As well, some are both difficult to administer (i.e. requiring highly trained medical staff or expensive equipment) and to monitor.
- *Anti-cancer drugs*: Table 3 lists drugs used to treat two of the most frequent malignancies in people

living with HIV/AIDS, Kaposi sarcoma and lymphoma. Although generics exist, availability is low.

- *Palliative drugs*: Table 4 lists drugs needed to relieve pain and discomfort, both physical and mental, and other symptoms in people living with HIV/AIDS. Even though most of the symptoms listed can be treated or alleviated with essential drugs, access to palliative care is hampered by limited availability of major analgesics (e.g., codeine, morphine and pethidine). As well, some cheap and effective palliative drugs are classed as illegal narcotics and thus are not listed, even if the palliative benefits at a late stage of disease outweigh the risk of addiction.

- *Antiretrovirals*: Table 5 lists drugs that combat HIV, a retrovirus, and thereby limit the damage that the virus does to the immune system. All are proprietary, all are very expensive, and all must be used in combination in order to be effective (see WHO's *Guidance Modules on Antiretroviral Treatments* in the Selected Key Materials).

Background

Table 2. Anti-infective agents frequently needed by people living with HIV/AIDS

Indication	Drug	Wholesale price* (in \$)	Status	Obstacle
Cytomegalovirus (CMV) disease	Ganciclovir IV (treatment)	959 /14 days	Proprietary (P)	\$, A, M, O
	IV (prophylaxis)	(12 358 /year)		
	Oral (prophylaxis)	(21 968 /year)	P	\$, M, O
	Cidofovir IV treatment (alternative to ganciclovir)	2236 /14 days		\$, A, M, O
	Foscarnet IV treatment (alternative to ganciclovir)	(29 071 /year)	P	\$, A, M, O
		1159 /14 days		
Herpes zoster	Aciclovir 800 mg/day oral	170 /7 days	Off patent, but no generic yet listed	\$, O
Extensive herpes simplex	Aciclovir 800 mg/day; injection	1283 /10 days	P	\$, O
	Foscarnet (alternative to aciclovir for prophylaxis)	(18 148 /year)	P	\$, A, M, O
MAC	Azithromycin	923 /year	P	\$, O
	Clarithromycin	1860 /year	P	\$, O
	Rifabutin	3175 /year	P	\$, O
Microsporidiosis	Albendazole	0.0267/tablet		Generic (G)
PCP	Pentamidine	Not listed	G	O
	Trimethoprim-sulfamethoxazole concentrate for IV administration	611 /21 day treatment	G	\$, A, M, O
Systemic mycosis	Itraconazole	7441 /year	P	\$, O
	Fluconazole	5506 /year	P	\$, O
	Amphotericin B	15.90 /day	G	\$, A, M, O
		656 /42 days		
Thrush	Ketoconazole 200 mg tablet(PO)	0.40 /tablet	G	\$
	Miconazole gel (PO)	0.02 /mg	G	
	Nystatin suspension	0.05 /ml	G	
	Nystatin tablet (PO)	0.07 /tablet		
Toxoplasmosis	Clindamycin	4411 /year	G	\$
	Sulfadiazine tablets	1.59 /day	G	O
		(507 /year)		
Tuberculosis prophylaxis	Isoniazid 300 mg/tablet	5.15 /year	G	
Tuberculosis treatment	Anti-TB drugs	15-45 / treatment course	G	

* Source: *International Drugs Price Indicator Guide*, 1996. Proprietary drugs as listed in British Hospital Formulary. Prices converted at £ 1 = US\$ 1.59

Symbols: \$ = high price, I = international regulations limit distribution, A = administration to patients is difficult, M = monitoring of patients is difficult, E = generic, but not on WHO Essential Drug List, O = not offered on market.

Background

Table 3. Anti-cancer drugs frequently needed by people living with HIV/AIDS

Indication	Drug	Wholesale price * (in \$)	Status	Obstacle
Kaposi sarcoma	Adriamycine (injectable)		Generic	O, A, M*
Kaposi sarcoma	Bleomycin (injectable)	25.84/15 units	G	O, A, M*
Kaposi sarcoma	Vinblastine (injectable)		G	O, A, M
Kaposi sarcoma	Vincristine (injectable)	3.97/vial	G	O, A, M
Lymphoma	Methotrexate (PO)	0.12	G	O

Table 4. Drugs for palliative care frequently needed by people living with HIV/AIDS

Symptom	Drug	Wholesale price* (in \$)	Status	Obstacle
Allergy, anxiety, itching (treatment with antihistaminics)	Promethazine injection	0.1364/2 ml	Generic	
	Promethazine suspension	0.0060/ml	G	
	chlorpheniramine tablet	0.0030/tablet	G	
	chlorpheniramine injection	0.1443/ml	G	
Anxiety, convulsions	Diazepam, oral and injection	0.003/5 mg tablet; 0.0447/5 mg ampoule		
Convulsions	Sodium valproate 200 mg/tablet	0.0265/tablet	G	
Depression (treatment with anti-depressants)	Amitryptiline 25 mg tablet	0.0063/tablet	G	
	Amitryptiline 10 mg tablet	0.006/tablet	G	
Diarrhoea	Loperamide 2 mg tablet	0.0065/tablet	G	E
Drug addiction	Methadone	Not listed	G	I, O
Epilepsy, convulsions	Carbamazepine	0.0304/tablet		
Hypersecretion	Anticholinergics e.g. atropine	0.1165/0.5 mg/ml ampoule		
Itching skin rash	Calamine lotion	0.0023/ml		
Nausea	Anti-nausea products e.g. meclorpramide	0.0055/tablet	G	
Pain, cough, diarrhoea	Codeine 30 mg tablet	0.03/tablet	G	I, O
Severe anxiety, psychosis, intractable hiccups (treatment with neuroleptics)	Chlorpromazine 100 mg	0.00216/tablet	G	
	Haloperidol 1.5–2.0 mg tablet	0.0057/tablet		
Severe pain	Pethidine 50 mg ampoule (oral and injection)	0.266/ampoule	G	I, O
Severe pain	Morphine oral solution 10 mg/5 ml injection 10 mg/1 ml ampoule	Not offered	G	I, O I, M, O

* See footnote to Table 2

Background

Table 5. Antiretrovirals for treatment of HIV/AIDS

Drug	Wholesale price* (proprietary) (in \$)	Obstacles
Delarvudine	266	\$ A, M, O
Didanosine	186	\$ A, M, O
Efavirenz	about 360**	\$ A, M, O
Indinavir	450	\$ A, M, O
Lamivudine	230	\$ A, M, O
Nelfinavir	559	\$ A, M, O
Nevirapine	248	\$ A, M, O
Ritonavir	668	\$ A, M, O
Saquinavir	572	\$ A, M, O
Stavudine	243	\$ A, M, O
Zalcitabine	207	\$ A, M, O
Zidovudine	287	\$ A, M, O

* Estimated cost to a pharmacist in the United States for a 30-day supply (cost to patient will be higher, depending on mark-up). Source: *Red Book, 1997*, quoted in *American Family Physician, 57*(11): 2791

** Dupont-Merck Press Release, September 1998

The Challenges

Improving access to drugs for people living with HIV presents challenges on a variety of levels. Most countries face the following challenges to some degree, though the mix and intensity of each challenge varies from country to country.

Cost of treatment

The cost of drugs poses the greatest single challenge to individuals and to health-care systems. Although the price of the most expensive proprietary drugs (such as triazole antifungals, drugs to treat MAC and CMV infections, and antiretrovirals) will likely decrease in the years to come through the effects of competition and expiring patents, many products will probably remain financially out of reach for the majority of people living with HIV/AIDS.

Rational selection of drugs by health sector

Rational selection of a cost-effective list of drugs requires not only knowledge of drug prices and applications, but also of the health sector's capacity to use those drugs efficiently. Even before these questions are asked, however, decision-makers need detailed knowledge about morbidity (i.e. symptoms and diseases) among people living with HIV/AIDS. This is difficult when the health sector faces problems such as: limited diagnostic capacity; inadequate record-keeping; data collection focused on reportable conditions and hospitalized patients (this tends to under-report less severe conditions and those that occur among outpatients).

Inadequate health-care infrastructure

In some countries, health-care infrastructure (chiefly the physical infrastructure of health-care facilities, both public and private) is too sparse to ensure adequate usage of drugs *even if these drugs were to be imported at no cost*. It will be a challenge in each country

to objectively assess and prioritize the possible medical and public health interventions in the existing infrastructure (as well as to assess country's needs), and to decide where it should be strengthened or expanded.

Distribution and administration

As with infrastructure, many countries do not have adequate distribution systems or sufficient trained personnel to permit drugs to get to the people who need them. Improvements may be required in a variety of areas including transport systems, drug handling, stock control, and record-keeping.

Rational drug use by care providers and clients

Proper use of most drugs for HIV requires training and information for doctors, nurses, pharmacists, and other care providers. It also requires knowledgeable clients since about 70 to 80% of health care takes place in the household rather than in hospitals or clinics, with people making their own decisions about which drugs to use. In many settings, however, reliable information is not available and drug use may therefore be strongly influenced by uninformed friends and relatives, traditional healers and unqualified entrepreneurs.

Political commitment

The priority given to AIDS-related needs in national policy and health budgets is partly the result of analysis, taking into account factors such as prevalence of HIV, its impact on society, and other important needs faced by the country. However, it is also highly dependent on how much of a voice people infected or affected by HIV (i.e., not just people living with HIV but their families, friends and support network) have in the decision making process. In the

absence of pressure from them it is likely that their needs will be given a low priority. This is a particular challenge in places where the social consequences of disclosing HIV infection are onerous, and where independent political advocacy is difficult.

Ethical considerations about rationing scarce drugs

Since full access to all drugs needed by people living with HIV is not realizable in the short term in the vast majority of countries, some types of drugs will need to be rationed. This inevitably gives rise to both practical and ethical questions. For instance, what criteria will be used to decide whether an infected person receives treatment or not? (For further information see module 9 of the WHO *Guidelines* listed in the Selected Key Materials.)

The Responses

"It is my hope that this 12th World Conference will mark the time when the global community commits itself to closing this AIDS gap. Now is the time for us to embrace a new realism and a new urgency in our efforts. Let's stop waiting for a perfect strategy that will assure universal access to all drugs in the future. Rather, let us do what we can do to improve access to care today, even as we commit ourselves to do better tomorrow."

– Peter Piot, Executive Director, UNAIDS, 1998

The enormity of the task before the global community in ensuring better access to drugs demands new relationships and alliances at global, country and local levels. It also requires both a short-term and long-term perspective for action. In the short term, there is a great deal of problem-solving and technical consultation to be done. In the long term (but beginning with planning and negotiations now), access to drugs for HIV/AIDS and related illnesses provides an opportunity to improve the quality of care through strategic alliances.

The following are some elements that reflect an emerging consensus among UNAIDS and its partners, and shared thinking about responses.

Ensure that care of people living with HIV is part of national strategic planning

When the need to care for people living with HIV is acknowledged, the question of providing the services and goods to deliver care becomes part of the political agenda and addressed as part of the national strategic planning process.

It is important that all key stakeholders—from people living with HIV, their families, their care providers, the national pharmaceutical sector, multinational pharmaceutical companies, to governments and international agencies—be involved in this process. (For more information, see UNAIDS' publication *Guide*

to a Strategic Planning Process for a national response to HIV/AIDS.)

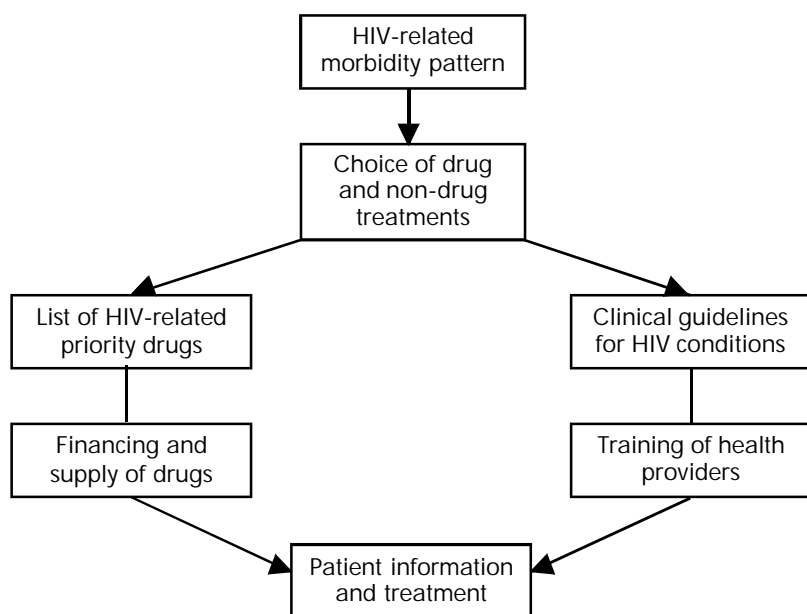
Selection of drugs

Drug selection is a task that must include the Ministry of Health, NGOs providing care, groups of people living with HIV involved in care, doctors and the private sector. Decisions will be based on a wide variety of questions and criteria such as:

- the frequency of HIV infection in the population
- the frequency of specific diseases and symptoms among people living with HIV/AIDS;
- the efficacy and safety of different treatment options;
- other benefits that the drug might provide, in addition to the primary user (i.e., treating TB as an opportunistic disease prevents the emergence of new cases of TB among close contacts of treated patients);
- availability and cost of the drug;
- availability of diagnostic, treatment and storage facilities and relevant trained staff.

Figure 1 below shows a model for drug procurement and service implementation developed by the WHO Action Programme on Essential Drugs. As the model

Figure 1. HIV-related morbidity pattern should guide local selection, training, supply and drug use



Source: WHO/DAP

The Responses

makes clear, establishing morbidity patterns is the first step in the process, from which all other steps must follow.

Improving affordability

Once drug needs and costs have been determined, the goal of improving affordability can be pursued through two major approaches. The first approach is to decrease drug costs. Strategies to reduce source prices paid to producers and importers include combinations of the following:

- Collection of information on drug prices and sources. This information helps in price negotiations and in locating new supply sources. (*The International Drug Price Indicator Guide* published by Management Sciences for Health (see Selected Key Materials) is an excellent resource for prices of generic drugs from non-profit suppliers and international procurement agencies.)

- Negotiation with pharmaceutical companies for favourable prices. Examples of successful negotiations for bulk purchases of antiretrovirals include those by the governments of Brazil, Thailand and Uruguay, and the UNAIDS Access to HIV-Drugs Initiative.

- Competitive procurement through tendering for generic drugs and by therapeutic class. In Thailand, the price of zidovudine is lower than in most other markets, probably because an international tender for this drug was open to manufacturers of generics (allowing the manufacturers an agreed profit margin).

- Direct price control through cost-plus pricing, reference pricing, or other forms of price control.

- Local production in places where real production costs are lower and quality can be maintained. For proprietary drugs, this requires licensing from the patent holder.

The second approach concerns private sector drug distributors, and aims to reduce the mark-up on price between the supplier and the consumer. Actions to control mark-ups include:

- removing import and value-added taxes;
- minimizing the number of wholesalers (distributors) and limiting their margins (or changing from a fixed percentage to a flat service fee);
- moving from pharmacy charges (dispensing margins) based on a fixed percent of drug costs to the more current system of a fixed professional fee.

Increasing financial resources for HIV-related drugs

Even if prices are reduced funds are still needed. Financing strategies should be based on a careful consideration of the major drug-financing alternatives which include:

- *public financing*;
- *health insurance*;
- *financing by NGOs*, groups of people living with HIV and community organizations, solidarity funds and other private voluntary mechanisms;
- *donor financing*: with some exceptions bilateral and multi-lateral donors are turning more toward funding basic health sector reforms, and away from individual diseases and funding of recurrent costs such as drugs. Convincing arguments must be put forward to secure significant levels of funding;
- *development loans*: over the past decade World Bank lending for health has increased dramatically. Pharmaceutical lending is over US\$ 300 million per year with an emphasis on providing drugs in support of broader development goals and very cost-effective drugs such as those for tuberculosis.

Ensure physical availability of drugs

Supply strategies must be closely linked to financial strategies and must recognize the unique features of HIV treatment. Most countries rely on a mix of public, private, and often NGO drug supply systems. Different strategies are needed for the different sectors.

Where there is a demand, the private sector is usually efficient in making drugs available—at least in urban areas. But common problems with private sector distribution include misleading and unethical promotion, irrational prescribing and self-medication, high prices, purchase of small quantities by consumers, and sometimes poor drug quality. Action to promote access through private and NGO sectors includes:

- organization of group purchasing arrangements by groups of people living with HIV and supply of priority HIV-related drugs by existing NGO essential drugs supply services;
- involvement of local pharmacy associations and associations of licensed drug sellers in promoting safe dispensing and appropriate advice, especially for specialized HIV-related drugs;
- strengthened regulatory control of drug registration, quality assurance and drug outlets;
- initiation of local partnerships with industry to self-regulate drug promotion, oversee quality in the distribution chain, and ensure availability of priority drugs.

Understanding local needs and capacities

Many significant non-monetary barriers to access—stigmatization, inefficient or unfriendly health care staff, popular acceptance of incorrect information leading to “irrational” treatment-seeking behaviour, etc.—exist at the local level. Often the full extent of these

The Responses

barriers is unknown, as is the extent to which available treatment resources remain untapped or underutilized (see Van der Geest in the Selected Key Materials.)

Improved knowledge about the treatment needs of people living with HIV/AIDS, their knowledge of and access to HIV-related drugs, drug stocks and ordering patterns of local commercial suppliers, and the existing and potential capacity of the local health system, are important parts of increasing access.

UNAIDS and WHO are working together to develop rapid assessment tools to collect such information using standard techniques of qualitative research in communities in Malawi. Assessment will be followed by a closely monitored implementation phase.

Creation of partnerships for care

Responsibility for decisions regarding the allocation of *public* funds rests with the government, based on the public health and economic context of the country.

But, it is clear from the challenges that increasing access to drugs by

persons living with HIV or AIDS will be impossible if the efforts come only from the government.

Strengthen the role of people living with HIV/AIDS in care partnerships

One of the great lessons of the first two decades of the pandemic has been the essential role of advocacy by people living with HIV in advancing effective responses to the epidemic. This is as true of efforts to increase access to drugs as it is in promoting public awareness and prevention. Action by people living with HIV/AIDS has helped bring about a number of advances including:

- the wide availability of triple antiretroviral therapy in industrialized countries and Brazil;
- accelerated approval of new drugs by the Food and Drug Administration in the USA;
- the AIDS Act in Argentina, which obliges the health system to provide treatment for HIV/AIDS.

However, in less well-developed countries, activism by people living with HIV has been much less.

This has a variety of explanations, including the basic struggle for

day-to-day survival and the late diagnosis of HIV infection, by which time the prospects for survival are limited.

Strategic partnership building at international level

Several organizations in the UN family—notably WHO, UNICEF and the World Bank—have for many years had both individual and joint programmes to increase access to basic drugs in various parts of the world. As mentioned earlier, the WHO Action Programme on Essential Drugs (DAP) and UNAIDS are currently developing a joint UN action plan to improve access to drugs for people living with HIV/AIDS.

In addition, UNAIDS is working with several multinational pharmaceutical companies in a series of pilot projects in developing countries to improve access to drugs for people living with HIV/AIDS (see Box), and intends to initiate discussion with other partners.

HIV Drug Access Initiative

In the pilot phase of UNAIDS' initiative to improve access to HIV-related drugs in developing countries, four developing countries will adapt their health infrastructures to ensure effective distribution and use of the HIV/AIDS-related drugs. At the same time, participating pharmaceutical and diagnostic companies will subsidize purchases of these drugs.

To date five companies—Bristol Myers Squibb, Glaxo Wellcome plc, F. Hoffmann-La Roche Ltd., Organon Teknika and Virco N.V.—have confirmed their intention to participate in the Initiative. Discussions are also continuing with others, and the Initiative is open to all those interested in participating.

The pilot phase will be conducted in Chile, Côte d'Ivoire, Uganda and Viet Nam, allowing evaluation of the Initiative in a variety of geographical, social, and economic situations. In each country, two new entities will be created:

- a national HIV/AIDS drugs advisory board, under the Minister of Health, composed of representatives of the local medical, public health and HIV/AIDS communities;
- a non-profit company to act as a clearing house for placing orders for bringing drugs into the country, as well as the channel for subsidies from the companies. The company will be funded by participating pharmaceutical companies.

Levels of subsidies will be negotiated by each company in discussions with country officials, taking into account the nature of the drugs to be purchased as well as the economic and epidemiological situation of the country.

Selected Key Materials

Chaudhury R (ed). *International experience in rational use of drugs* (vol. 2.) Bangkok: College of Public Health, Chulalongkorn University. Articles collected under auspices of UNESCO, including discussion of essential drug programmes in India, Myanmar, Thailand, Zimbabwe.

Dormont PJ (ed). *Prise en charge des personnes atteintes par le VIH*, 1996 edition. Paris: Flammarion, 1996. Practical, comprehensive guide to management of HIV. Published with support of Ministry of Labour and Social Services, and widely distributed to physicians in France.

Essential Drugs: WHO Model List, in *WHO Drug Information*, 12(1), 1998.

Hardon A, Van der Geest S, Geerling H & Le Grand A. *The provision and use of drugs in developing countries. Review of studies and annotated bibliography*. Amsterdam: Het Spinhuis Publishers, 1991. Overview (163 pages) of availability and rational use of drugs by region and country. Analysis of obstacles, research gaps, recommendations.

International conference on national medicinal drug policies: the way forward (conference

proceedings). Supplement to *Australian Prescriber*, 1997; 20. Examples of drug policies around the world, including access to medicines and rational use of drugs. 272 pages.

Management Sciences for Health. *International Drug Price Indicator Guide*. Boston: Management Sciences for Health, 1996. Updated annually, with text in English, French, Spanish. Drugs are sorted alphabetically and by therapeutic category.

Management Sciences for Health. *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals (2nd edition)*. Boston: Kumarian Press, 1998. Comprehensive manual with practical case studies on all aspects of drug selection, procurement, distribution and use.

Nine Guidance Modules on Anti-retroviral Treatments. Geneva: WHO, 1998. Also available on the Internet at <http://www.who.ch/asd/arv/index.htm>

Steward GJ (ed). *Managing HIV*. Sydney: The Australasian Medical Publishing Company, 1996. Complete 208-page overview of HIV medicine and clinical practice, written for primary care doctors with the information needed to work with specialists.

Anon. The importance of pharmaceuticals and essential drugs programs. In: *Better health in Africa: experience and lessons learned*. Washington DC: The World Bank, 1994. pp 67–84. Suggests that drugs needed to treat 85% of common illnesses, including expanded treatment of STDs, could be covered by annual per capita cost of US\$ 1.60—less than current spending by some African countries. Since drug coverage is reduced by inefficiencies and waste, management should be a government priority.

Van Praag E, Fernyak S, Katz AM (eds). *The Implications of anti-retroviral treatments*. Geneva: WHO, 1997. Conclusions of informal consultation held to discuss latest antiretroviral therapies and aspects of their use, cost, and long-term effectiveness.

WHO. *Health reform and drug financing*. Geneva: WHO, 1998. WHO/DAP/98.3. Overview of major sources of drug financing: public financing, drug insurance, user charges, voluntary and local financing, donor financing and drug donations, and development loans. Also discusses affordability for consumers and cost control.

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