UNAIDS

Report on the global HIV/AIDS epidemic - June 1998

WHO

REPORT

on the global

HIV/AIDS epidemic

June 1998

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Sorry to have
missed you –
this is our new
Let's in Geneva? Peter

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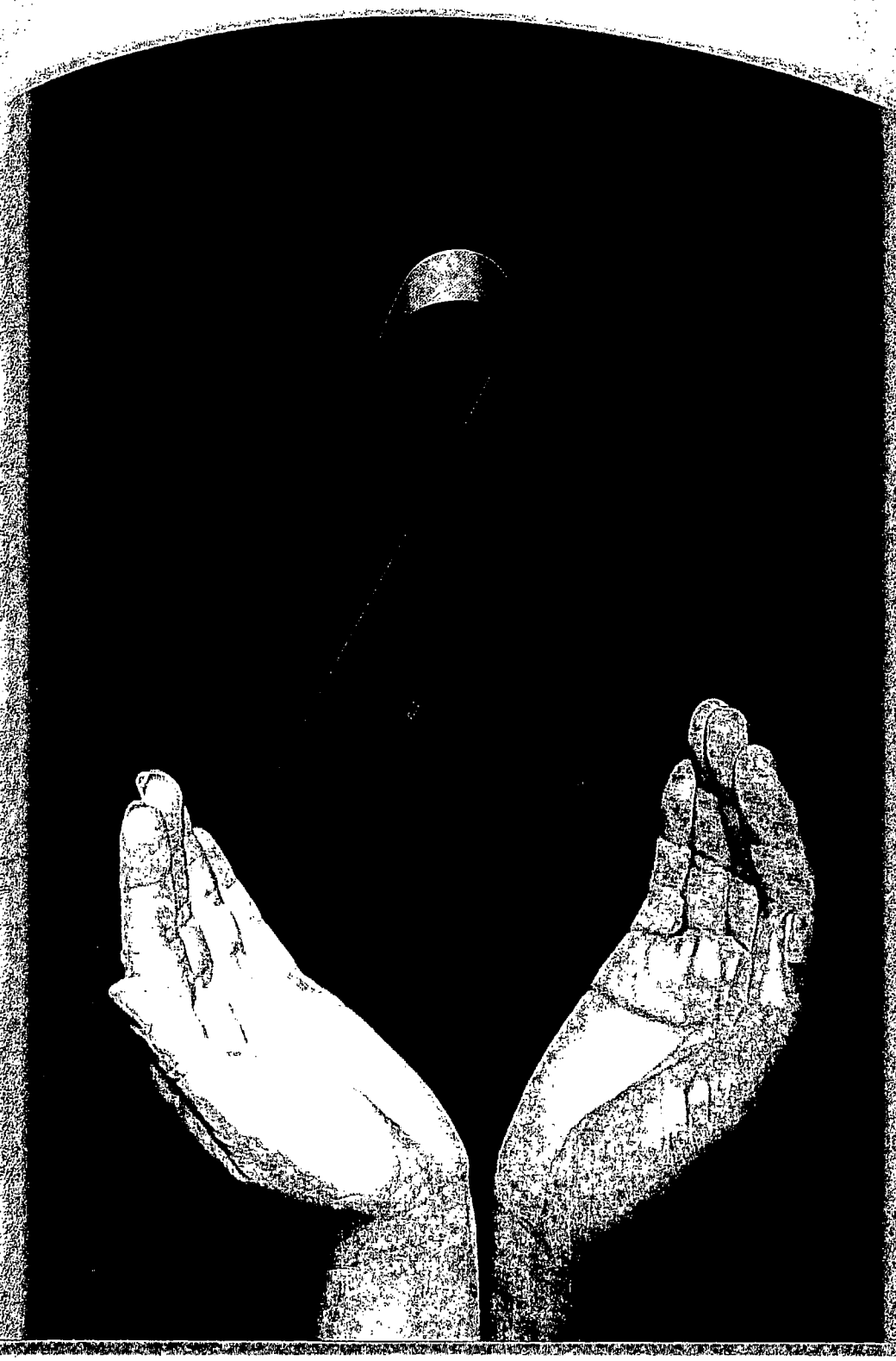

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UNAIDS

JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS

UNAIDS HIV DRUG ACCESS INITIATIVE

Providing Wider Access to HIV-related Drugs in Developing Countries

PILOT PHASE

BACKGROUND DOCUMENT

October 1997

BACKGROUND INFORMATION

INTRODUCTION

UNAIDS and WHO estimate that as of the end of 1996, over 22 million persons were living with HIV with more than twenty million in developing countries. Approximately 1.5 million deaths among adults in 1996 are estimated to be related to AIDS, 90% in developing countries.

The emergence of the HIV/AIDS epidemic together with an increasing number of AIDS cases, raises new challenges, these range from the need to develop effective drugs for treatment to the assurance of an equitable distribution. To ensure that these drugs reach the individual in the community, one is confronted with complex political, economic, social/cultural and technological obstacles which vary in expression from country to country. With the increasing number of patients with AIDS, there is an increasing demand by People Living with HIV/AIDS (PLHA) to have access to HIV-related drugs. For example, in Latin America where access to care is presented as a constitutional right, this created new political and ethical considerations. These considerations have to be reconciled with the technical, financial and social capacities of existing institutions both in the private and public sector. In many developing countries, patients do not have access even to basic treatment modalities for opportunistic infections. For example 80% of HIV/AIDS cases are concentrated in Sub-Saharan Africa with GDP per capita in the range $80-$256, making it doubly difficult to have these drugs available to PLHA. Yet economic arguments alone are not sufficient reason in a democratic state to deny access to those who need it, as these need to be reconciled with issues of social justice and equity. In such an environment new approaches of interaction at global and country level are required, if sustainable solutions are to be found on these issues.

Apart from challenges mentioned above, HIV/AIDS brings new opportunities to this agenda in form of increasing number of Non Governmental Organizations, Community Based Organizations and PLHA who are already opening up new avenues for improving access to care in general and drugs in particular. The increasing number of actors if not properly harnessed and coordinated could result in a fragmented response to the problem. UNAIDS sees its function as facilitator of this process.

BASIC PRINCIPLES

- The responsibility for care and treatment of people with HIV/AIDS rests fundamentally with the government and national public health systems of the countries in which these people live. However, any successful effort to make available HIV-related drugs requires a multipartite approach that effectively engages all parties with an active interest in improving the response to this world-wide health care threat. This is most true in the resource-constrained environments of developing countries.

- A rational HIV strategy in a country should objectively assess and prioritize the available medical and public health interventions in the context of the country's medical and public health infrastructure and needs. The availability of a treatment through public sector financing is dictated by its positive cost-effective clinical outcome which takes

into account realistic medical and public health considerations, especially with sophisticated or demanding pharmaceutical regimens. As public health constraints affect successful use of treatments, they also limit their commercial profile in the same environment.

- Suppliers of HIV-related drugs have sound policy and market-based incentives to facilitate access to their products and services by differentiating or subsidizing their prices to address the varying economic, medical, and public health characteristics of individual countries. An effective price which represents an agreed mutual value between supplier and purchaser will by definition vary according to the economic circumstances in which the product is acquired and its benefit realized.

- Selection of treatments and interventions should be based on the objective assessment of their medical, public health, and health economic merits.

- A multipartite framework which can address HIV treatment access issues on the basis of public health criteria can provide a model that may have applicability beyond HIV field

UNAIDS PRIORITIES.

- Without compromising HIV prevention priorities, the continuous spread of HIV epidemic especially in developing countries is increasing the need for proper HIV care in these countries. Access to HIV-related medicines together with an adequate social support and health care infrastructure for a rational use of these medicines, are the fundamental bases for proper HIV care.

- Access to HIV related drugs as well as STD treatments in developing countries requires a product pricing which is in accordance with the economic reality of the country. Specific mechanisms should be set up to facilitate such pricing and ensure a rational use of drugs.

- Such mechanisms should make HIV-related drugs available for purchase through public or private funds. The allocation of public funds rests with the government of the country and is based on the public health and economic context of the country.

- While implementing such mechanisms in countries where health care infrastructure is reasonably adequate, it is essential to keep strengthening the infrastructure within the country as well as in other countries to create a favourable setting for a wider access to HIV-related drugs.

- To implement mechanisms for access to HIV-related drugs without disrupting or altering existing Essential Drugs Programmes

- To provide the appropriate information and training to health workers and communities and foster the establishment and improvement of an adequate medical information system.

- To ultimately make HIV/AIDS and STD drugs available in each country.

RATIONALE FOR CHOOSING THE INITIATIVE

While the objective is to improve access to HIV-related drugs in developing countries, it should be kept in mind that each developing country is unique especially in the context of HIV/AIDS. There is a wide difference in their systems, economic capacities, HIV prevalence, cultural and geographical contexts. Therefore, the obstacles to drug access vary widely between countries and there is no single solution for all developing countries.

For example, the presence of an adequate health care infrastructure, together with a rational prescription of drugs in many South American countries makes the focus of these countries on negotiating bulk purchase prices by pooling their orders, an adequate and successful method for improving access to HIV-related drugs. In other countries, the health care infrastructure is so limited that it does not allow an adequate distribution and prescription of drugs even if these drugs were to be provided at no cost.

This Initiative creates through flexible mechanisms, a link between interested parties, private drug providers, health system, communities and patients. It will address the obstacles and weaknesses at any level: pricing, distribution, health care centres, drug dispensation etc... Without pretending to provide a unique solution to all problems, this Initiative is meant to address the needs of a large number of countries.

The pilot phase will be implemented in countries where the health care infrastructure is reasonably developed or may only require moderate strengthening to allow rapid implementation and results. These results will identify specific prerequisites for improving access to HIV-related drugs and will provide recommendations on how to strengthen the health care infrastructure to ensure these prerequisites.

DESCRIPTION OF THE INITIATIVE

The purpose of the Initiative is to create an appropriate environment for a long term collaboration between the pharmaceutical companies and health care providers in the country, where the companies can provide securely HIV/STD-related drugs in line with their affordability in the country and where health care providers can make these drugs available to the patients within optimal standards of care and with a rational prescription policy. To reach this goal, the Initiative will test and evaluate mechanisms to supply drugs at subsidized prices and to ensure an adequate health care infrastructure with an adapted distribution system.

THE HEALTH CARE INFRASTRUCTURE

AT NATIONAL LEVEL: The Advisory Board

It is of critical importance to have a well coordinated HIV-related National Drug Policy which takes into consideration drug supply mechanisms as well as health care delivery systems. Even if drugs are made available at the lowest prices, patients who are most in need would not be able to benefit from them without an adequate HIV-related National Drug Policy which will ensure targeted supply as well as a rational prescription and use of the drugs.

The HIV-related National Drug Policy will be determined by the Ministry of Health based on the recommendations of an Advisory Board established in the context of this Initiative, unless there is another existing body which could ensure the role of the Advisory Board.

Role of the Advisory Board

The Advisory Board has the responsibility of recommending HIV-related National Drug Policy as well as ensuring the functionality of the health care infrastructure. The Advisory Board is under the authority of the Minister of Health.

The functions of the Advisory Board will be:

- To determine HIV-related National drug policy which includes recommendations on technical aspects of the epidemic including currently available therapies and clinical management of HIV infection, as well as the establishment of a list of the HIV related drugs needed which is adapted to the local context..

- To estimate the needs of the relevant country for HIV-related drugs. The drugs will be supplied preferably but not exclusively through the financial mechanism proposed below which consist of a Non-Profit making Company (NPC). The procurement could be made through the NPC or from other sources, both for the public funds or privately funded purchases. The NPC will act as a normal supplier with no exclusivity rights.

- To determine and recommend to the government, policy for the public sector in relation to the rationale of prescription, usage and distribution of drugs supplied through the Non-Profit making Company, in the local context of the epidemic.

- Some opportunistic infections as well as antiretroviral therapy require sophisticated diagnosis and management facilities. Without basic facilities, including well trained health workers, the rational prescription of drugs cannot be ensured. The Advisory Board will establish the minimum requirements of health care centres to qualify them for selection as centres where the rational prescription and use of the drugs can be assured It is anticipated that there will be minimal requirements for 2 levels of health care settings; first level and referral centres.

- To select the qualifying centres where the drugs will be made available, and to communicate the list of qualifying centres to the NPC Manager and the central distribution point.

- To set objective criteria of the profile of patients who will participate in the pilot project. Such criteria will include restrictive prescription indications to balance the clinical relevance with the availability of the drugs and resources.

- To recommend over time an action plan for improvement of the health care infrastructure where necessary in order to make the HIV/AIDS drugs more widely accessible in the country.

- To determine and recommend regulations concerning privately funded purchases and the proper usage of drugs supplied through the Non-Profit making Company.

The Advisory Board consisting of no more than 10 members, will be established and appointed by the Ministry of Health in collaboration with and will have the following members:

- Representatives of the Ministries of Health, and other relevant Ministries such as Planning and Finance in the Pilot country.
- Representative of UNAIDS through the UN Theme Group on HIV/AIDS
- The National AIDS Programme Manager as well as representatives of relevant AIDS authorities in the countries.
- Representatives of the NGOs who are involved in HIV/AIDS care.
- Clinicians and public heath persons from the academic sector who are knowledgeable in HIV/AIDS epidemic and clinical management of HIV infection.
- Representatives of People Living With HIV/AIDS.
- The Manager of the Non-Profit making Company (as observer and liaison person)

AT HEALTH CARE DELIVERY LEVEL: Qualified health care centres

The health care centre will receive drugs only if it meets qualification criteria as set by the Advisory Board. Qualification criteria will include:

- Well trained doctors and other health workers
- Good clinical facilities for diagnosis and management
- Standard laboratory facilities
- Social support
- Drug dispensation facilities

Each qualifying health care centre, whether first level or referral will be given a single procurement number by the Advisory Board which authorises the centre to purchase the type of drugs according to its qualification. The products will be supplied to this procurement number from the central distribution point.

At the health care centre, drugs will be dispensed against a medical prescription issued by one of the centres qualified physician. All qualifying centres will be required to keep proper prescription and dispensing records in accordance with normal professional practise. Stock management programmes including anonymous data on patient number, prescriber's code and drug name will be provided and standardized by the pilot project.

Drugs supplied through the NPC will be made available in at least 2 levels of Health Care settings including, first level and referral settings. Basic drugs will be made available at both levels, however, more sophisticated drugs and drugs which require a more sophisticated management will be made available only at the referral level.

INFORMATION AND TRAINING STRATEGIES

Appropriate information and training strategies will be developed by the Ministry of Health and the National AIDS Programme, in accordance with the recommendations of the Advisory Board. Such strategies will target doctors and other health workers as well as patients and communities. The communities will play an active role in dissemination of relevant information.

The companies will continue to provide information and material as per their usual practice.

COMMUNITY INVOLVEMENT

The communities will play an essential role in the Initiative. Communities and NGOs which are involved in health care delivery systems will be encouraged and assisted to have their health care centres qualified by the Advisory Board.

NGOs and communities will play a crucial role in counselling and psycho-social support provided to the patients in all health care centres involved in this Initiative. NGOs and communities will be also involved in delivering targeted prevention and care messages to patients and the general population.

THE FINANCIAL MECHANISM

It is clearly acknowledged that the new HIV-related drugs, mainly antiretrovirals, are beyond the means of most developing countries where over 90% of people with HIV live. The issue of affordability in these countries is linked to the combination of high drug costs and high HIV prevalence rates in these countries. This combination widens the gap between the high financial requirements at the national level and the modest financial capacities of the country whatever the sources of funds. While considerable efforts are being developed to prevent HIV transmission and therefore reduce HIV prevalence, it is essential to address the other determinant of affordability and find mechanisms to reduce drug costs.

When drug costs are in line with the local needs and country's ability to pay, access to these drugs will be maximized. It is therefore conceivable that a patient in Uganda whose income is lower than a patient in the USA or Europe should pay less for antiretroviral therapy or other costly HIV-related medicines. The same economic concept applies at the national level since the national health expenditures in both the public and the private sectors are by far lower in developing countries than in developed countries.

On this basis, the financial mechanism proposed in this Initiative may enable pharmaceutical companies to provide HIV-related drugs to developing countries at country-specific subsidized prices. The price levels will be defined separately and independently by each company, following individual discussions with the country officials, taking into account the nature of the drugs to be purchase as well as the economic and epidemiological situation of the country. The financial mechanism proposed will have no exclusivity rights. The suppliers as well as the purchasers have the choice to order drugs through the mechanism or from other sources.

The Financial Structure

A financial structure will be established in each pilot country to ensure coordination of the anticipated financial transactions without compromizing international competition and open market rules. It will also ensure appropriate and timely supply of drugs as requested by the country.

The financial structure will be a Non-Profit making Company through which any pharmaceutical company willing to participate in this Initiative will channel supplies. The Non - Profit making Company (NPC) will be registered under the laws of each country in which it is to be established. It will be a small structure with a manager and an administrative assistant/secretary. The administrative and operating costs of the NPC will be covered by the participating companies. All companies may participate in the Initiative and cosponsor the NPC.

Drugs will be purchased by the NPC only from the pharmaceutical companies who are willing to participate in this Initiative, and who contribute to the administrative cost of the NPC. These drugs will be supplied to the purchasers within the country at lower prices which are subsidized through the NPC.

The companies will continue to ensure direct responsibility and liability for their respective products.

Donors will not be requested to subscribe directly to the NPC; they will be requested by the country to support the programme by making donor funding available to the government and health care providers in the particular country.

Role of the financial structure (i.e. NPC)

- To liaise with the Advisory Board and the Ministry of Health on the likely demand of products, in accordance with the National Drug Policy.

- To negotiate orders of the products with the relevant pharmaceutical companies for the government and health care settings, in accordance with the recommendations of the Advisory Board.

- To arrange the supply of products to be ordered from the relevant pharmaceutical company.

- To arrange the provision of adequate funding for these orders through the NPC mechanism and to make the appropriate payments to the supplying companies.

- To discuss on an on-going basis the subsidies to be received from the supplying companies.

- To administer the flow of funds into and out of the NPC in accordance with the standards required by the Board of Directors and the Auditors.

Role of the auditors

The accounts of the NPC will be edited annually by a recognized international firm of auditors. The resultant annual report will be public and made available to UNAIDS, the participating companies, and the government of the country concerned.

Another confidential report which details the financial transactions by company will be produced and disclosed to the Board of Directors only. Any participating company may have access to its relevant section of the detailed report. This procedure will ensure confidentiality in accordance with competition rules of open-market economy.

THE DISTRIBUTION MECHANISM.

Products will be delivered by the pharmaceutical companies through the NPC to either a central distribution point, which could be the Government Central Medical Stores, or directly to the health care centres.

THE PILOT PHASE

The Pilot Project will be applied by country and will consist of 2 Phases, and will have a duration of 4 -5 years from start up.

PHASE I: IMPLEMENTATION OF THE PILOT PHASE.

The first phase will cover the initial projects in the Pilot Countries until the schemes are functioning correctly and efficiently. This process is expected to last 2 - 3 years.

It is of critical importance to ensure a sustainable access treatment to the patients who will participate in the pilot phase of the Initiative, during as well as after the pilot phase. Therefore, the participating companies should ensure that those patients who participate in the pilot phase will continue to have access to their usual drugs at the subsidized prices after the completion of the pilot phase. The National Authorities are also expected to assure sustainability of the programme with regard to these patients.

An evaluation of the structure of the Initiative and its mechanism will take place at the end of the first year to determine the difference between the theoretical design and the practical implementations.

The purpose of the first year evaluation is to establish the best and most practical methods for the implementation of such an Initiative in other countries.

A further evaluation at the end of year 2 will establish how well the whole scheme has functioned and has made the drugs accessible. This evaluation will provide the first concrete results with regard to the real impact of the Initiative on access to HIV-related drugs in developing countries. An action plan for the expansion phase will be established on the basis of this evaluation.

PROGRAMME FOR THE IMPLEMENTATION OF THE PILOT PHASE.

It is envisaged that the Pilot Projects will be implemented in the following programme:

A preliminary visit of UNAIDS team will be made to each Pilot Country, during which an assessment will be made of the tasks and activities which must be completed to ensure the successful establishment of the Pilot Programme.

The existing levels of the required infrastructures will also be evaluated in these preliminary visits.

The UNAIDS team will facilitate the implementation of the Pilot Phase for its full duration of 2 years.

It is envisaged that an experienced Project Manager will be recruited in the pilot country to supervise the start up of the Pilot Projects

The initial tasks of the Project Management team are as follows:

- An initial stock level of needed products will be established in each qualifying centre which will be funded by either public funds or in arrangement with the pharmaceutical companies. This initial stock will primarily be required to service the purchases which will be made by non state funded individual patients.
- Assist the Advisory Board in the selection of clinics on the basis of a proposal which describes clinical and lab facilities as well as an inventory of health workers and doctors in each clinic. Once selected, a list of doctors and their authorised signature should be available.
- Hold training workshop of health workers
- Prepare and distribute patient information chart and prescription format
- Provide with appropriate training stock management software for drug dispensation at the clinic.

SELECTION OF PATIENTS

The pilot phase may not be able to give access to HIV-related drugs to all patients who need them, due the high number of patients and insufficient health care infrastructure and financial resources. It is therefore of critical importance that the pilot phase provides access to those patients most in need.

Rigorous and objective selection criteria will be established in each pilot country through a large consensus process involving government officials, people living with HIV, clinicians, ethicists, religious groups and others. Some of the criteria will rely on clinical guidelines but other criteria will be established to ensure that those who are most in need will benefit from the Initiative. The Advisory Board will have the responsibility to implement such criteria and ensure that they are applied.

EVALUATION PROCESS

UNAIDS will be responsible of the evaluation process at the end of the first and second year as mentioned above.

<u>The subsidy mechanism</u>

All financial transactions of the NPC will be evaluated in terms of their efficiency and ease of application.

<u>Distribution system</u>

All ordering and dispensation procedures will be evaluated in terms of their efficiency and applicability. Issues such as stock management and warehousing and storage efficiencies will be assessed. The critical assessment will determine whether drugs were:

a) provided in a timely fashion after receipt of orders
b) dispensed correctly to the designated clinics

The Advisory Board

Applicability and relevance of the recommendation of the Advisory Board with regard to the National drugs Policy for HIV/STD will be evaluated. Subsequently, a strategy to increase the number of qualified centres will be determined.

Referral settings

The standard of care will be evaluated according to the spectrum of diseases managed within the clinic, both from the diagnosis and therapeutic standpoints.

A qualitative evaluation of the rationale of prescription with regard to the indication, dosage and duration of treatment will be carried out.

Patient compliance will also be assessed on a qualitative basis, through a study undertaken by social scientists, to determine compliance rates as well as the factors which influenced compliance. The results will be available with suggested solutions.

Selection of patients

UNAIDS will assist in the selection process of health care centres and patients. The evaluation will focus on the profile of patients selected with respect to their clinical stage as well as their social and geographic distribution.

UNAIDS RELEASE OF BEST PRACTICES GUIDELINES.

On completion of the evaluations of the Pilot Projects UNAIDS will prepare a guideline of best practices which will be made available to the Governments of those developing countries who wish to implement similar programmes.

PHASE II: WIDENING THE ACCESS

The experiences and results of Phase I will help in setting up an action plan for widening access to HIV-related drugs in the same country as well countries other than the pilot countries. The phase II will focus mainly on strengthening the infrastructure in the countries to allow more and more health centres to qualify and ensure an appropriate distribution of health centres in accordance with the geographic and epidemiologic needs. The phase II will be a progressive and ongoing phase. An evaluation at 3-4 years will be planned.

The main objective will be to optimize the number of centres qualified for treatment of HIV infection, opportunistic infections and STDs under this Initiative. Such optimisation may require an improvement of health care infrastructure.

The results of the phase I will be consolidated in a Best Practice model which will be made available to any country willing to improve access to HIV-related drugs through this Initiative.

COUNTRIES SELECTED FOR PILOT PROJECT IMPLEMENTATION.

The countries which have been selected to host Pilot Projects are:

UGANDA

COTE D'IVOIRE

VIETNAM

CHILE

CRITERIA FOR SELECTION OF PILOT COUNTRIES

In selecting the countries in which Pilot Projects will be implemented, the following criteria were considered:

- Political and social stability.
- Political commitment to respond to the HIV/AIDS epidemic.
- Political commitment to care and support of people with HIV infection.
- Active National AIDS Programme.
- Well established Public Health platform.
- Facility to implement and evaluate the pilot phase and collect clear and unbiased results. This requires the absence of programmes which may give confounding data.
- Geographical distribution of countries.
- High HIV prevalence or high HIV incidence.
- Existing health care infrastructure in relatively low income economy.

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