International Cooperation Programme

For HIV and AIDS Prevention and Control Activities For Other Developing Countries

Brazil, June 2002
Introduction

The Brazilian Ministry of Health, by means of the Ministerial edict published in the Official Gazette of the Union dated 22 May 2002, brought into existence the International Cooperation Programme for HIV and Aids Prevention and Control Activities for Developing Countries.

The main objective of this Programme is to provide funds for the establishment of 10 pilot projects to the annual value of R$ 250,000 (US$ 100,000) each, in technical assistance and antiretroviral drugs manufactured in Brazil by government owned laboratories, directed towards HIV and Aids carriers in relatively less developed countries. Other initiatives covered by the offer, apart from the donation itself, are human resources training in clinical management and the logistical aspects of antiretroviral drug distribution. Projects which have as their aim the creation of a favourable environment for local manufacture of such medical products will also be taken into consideration. See below information regarding ARV drugs produced locally by official public laboratories.

Drug

ZIDOVUDINE Caps 100MG
ZIDOVUDINE Oral Solution
ZIDOVUDINE Injectable Solution
ZIDOVUDINE + LAMIVUDINE Tab 300+150MG
DIDANOSINE Tab 25MG
DIDANOSINE Tab 100MG
DIDANOSINE Powder for Oral Suspension
ZALCITABINE Tab. 0.75MG
LAMIVUDINE Tab 150MG
LAMIVUDINE Oral Solution
ESTAVUDINE CAP.30MG
ESTAVUDINE CAP.40MG
ESTAVUDINE Powder for Oral Suspension
INDINAVIR Caps. 400MG
NEVIRAPINE Tab 200MG
Background

The Brazilian government’s decision to offer technical assistance and appropriate medical drugs for setting up projects aimed at treatment for carriers of HIV and AIDS is in line with two basic objectives. On the one hand, recent resolutions and statements undertaken and made by the international community, with the determined encouragement of the Brazilian delegations, have finally made way for an admission that it is necessary to expand access to medicines to deal with AIDS. For its part, the present leadership position that Brazil has assumed has in fact led to generation of a substantial increase in the number of requests on the part of institutions and non governmental organizations from a range of different countries for Brazil to take more incisive action in the sense of broadening the offer of antiretroviral drugs to the remaining millions of carriers who to date have failed to obtain access to such drugs. It is also worth noting that Brazil integrated several years ago the local production of essential medicines, including antiretrovirals, into its national public policy. In this perspective, Brazil has been providing universal and free of charge access to anti-AIDS drugs to all those in need for about 11 years. Currently, more than 115 thousand patients make use of these drugs. In fact, this policy is a true outcome of the strong mobilization of the Brazilian society and, to respond to its demands, the Government adopted a number of strategies, among them the local production, by public official laboratories, of generic versions of the drugs distributed in the public health system.

Besides this domestic issue, Brazil has been very active in advocating greater access to medicines all over the world. It is of crucial importance the fact that Brazil has publicly offered, for over two years now, to transfer the technology for ARV production to other developing countries, an offer that has been reiterated directly to the governments of several countries in the region. In this regard, elapsed more than 2 years, no country has taken any initiative to make good on this offer. It is also worth noting the crucial role Brazil has played in the international scenario to guarantee the adoption of several decisions in favor of public health at a global level:
1) approval of Resolution 33/2001 at the 57ª Session of the United Nations Commission on Human Rights, establishing that access to anti-aids medicines is a basic human right;

2) approval of the Brazilian proposal at the May 2001 World Health Assembly, that highlights the importance of increasing the availability of affordable medicines to all those affected by the disease;

3) approval of the Declaration of Commitment on HIV/AIDS at the United Nation General Assembly Special Session on HIV/AIDS, which recognizes the necessity of adopting an integrated approach between prevention, treatment and protection of human rights as the sole way to effectively counter the spread of the epidemic;

4) direct Brazilian involvement at the Global Fund to fight AIDS, TB and Malaria, fighting for equal participation between rich and developing countries in its main decision-making body, the Board of Directors. The Fund also publicly assumed that it will financially support projects involving distribution of antiretrovirals, what is another important victory for developing countries. The Global Fund recently approved its first round of proposals, consisting of 58 proposals, of which 5 are from Latin America and the Caribbean, that account for a total of US$ 616 million.

5) Approval at the World Trade Organization of the Brazilian proposal according to which nothing in the TRIPS (Trade-Related Intellectual Property Rights) agreement can prevent countries from adopting measures to protect public health;

6) Intense mobilization of the Brazilian technical structure to support various international delegations/missions that have searched for assistance in the field of treatment and care.

This particular initiative aims at strengthening the links of solidarity and friendship that bring Brazil closer to less privileged peoples and also serves to give life to the international alliance which has made it possible for our country to win key victories in international forums such as the World Trade Organisation, the United Nations Human Rights Commission and others.

In addition to the foregoing points, pilot projects of this kind also fulfil the important role of expanding and acting as a catalyst for internal demand for high quality low cost generic antiretroviral drugs in those countries where the treatment of HIV and Aids carriers has been seen to be effective. This spin-off demonstration effect serves to bring on board the interest of the local public administration in the whole issue of HIV and Aids as well as
encouraging the commitment by the international community to aim for reductions in the prices of antiretroviral drugs which are currently manufactured and sold under patent protection and which could have beneficial results for Brazil’s own policy regarding the control of HIV and AIDS.

**Operational Aspects**

The pilot projects proposed could be drawn up, presented and implemented in partnership with governments, United Nations agencies, non-governmental organisations, universities and official bi-lateral cooperation agencies. Coordination if this particular initiative is under the auspices of a Working Group within the Brazilian Ministry of Health.

The submission of project proposals to the Brazilian authorities requires the completion of the Project Submission. Directions on how requesting institutions should complete this form in detail are included in a separate Instructions Guide. In order to secure best advantage form the allocation of resources available for this Programme within the Ministry of Health’s budget, a total of 8 minimum criteria shall be observed as far as project proposals are concerned, as follows: (1) the size and impact of the epidemic in the country concerned (2) the level of social and economic development of the country (3) the availability of additional “own” or external resources (4) the potential or not for the future rapid growth of the epidemic (5) the technical quality of the proposal submitted (6) the degree of political commitment to controlling the epidemic (7) the availability of a counterpart resource on the part of the requesting institution and/or the requesting government, and finally (8) the outlook for the longer term sustainability of the proposed project.
Criteria Needed For Submission Of Proposals

1. Size and impact of the epidemic
   Those countries which at the time of the selection process are most deeply affected by the HIV and Aids epidemic will take priority.

   Measuring and Indicators: the effect of the HIV and aids epidemic will be measured on the basis of rates of prevalence and incidence as published officially by governments concerned and by international organizations such as UNAIDS.

2. Economic and social development of the country
   Low purchasing power certainly impedes the development of an appropriate response to the epidemic. AIDS itself creates a vicious circle between death, loss of the useful work force of a country, a weakening of the public social protection networks, a fall off in demand for goods and services and a downturn in economic growth levels - all these factors accentuate further the poverty already suffered by populations and contributes towards lowering the capacity of countries and whole societies to find adequate responses to the epidemic. Interventions in the treatment field are able to interrupt this process and can help to slow or to break the vicious circle.

   Measuring and Indicators: Indices to help calculate economic and human development such as the GDP per capita (expressed in US dollars), the country’s HDI (Human Development Index) of the United Nations, the Gini Coefficient (to identify countries with a high level of income inequality) and the proportion of the population of a particular country living beneath the poverty line (wherever available).

3. Availability of own or external resources
   The Brazilian Programme will prioritize those countries with the least ability to attract own additional resources or resources for external funding sources such as bilateral cooperation agencies, civil society organizations and multilateral international bodies. In this way, the pilot projects which will be implemented in countries where severe restrictions on budgets prevents the
earmarking of more substantial funds for controlling HIV and Aids will be eligible.

Measuring and Indicators: Criteria to be used will be the percentage of the national health budgets allocated to activities in the HIV and Aids field; the existence of other projects backed by international aid; the amount (expressed in US dollars) on a per capita basis received as the result of international aid, in accordance with the methodology employed by the World Bank.

4. Potential for rapid growth of the epidemic

The Brazilian Programme will focus especially on those countries which present fast growing epidemiological trends. The funds to be allocated to each pilot project are relatively small and are basically to be viewed as having strategic use, particularly on account of the knock-on demonstrative effect that the projects can have and the resulting possibility of other processes with similar objectives being got off the ground as a result of these efforts. This criterion must not be viewed separately, but jointly with Criterion 1 above.

Measuring and Indicators: in view of the above, national and/or international indicators related to epidemiological trends, size of most vulnerable population groups, prevalence of risk factors and the size of internal and cross border migration.

5. Technical quality of the proposals submitted

To combat HIV and Aids effectively means more than dealing with a series of merely technical questions. A large dose of political commitment is a vital component in the anti-epidemic battle and this involves a countrywide national counterpart effort comprising policies which give priority to an integrated approach, bringing together prevention, care and protection of the human rights of persons living with HIV and Aids. Those pilot projects which incorporate integrated public policies, which do not discriminate against the most vulnerable population and which encourage the active participation of organizations representing civil society, will be given preference. These criteria are based upon Brazil’s experience in the building of an effective and genuinely productive response to the HIV/Aids epidemic.

Measuring and Indicators: An analysis of the current situation to be submitted as condition number 3 (see below) for agreements to be finalized, analysis of the project proposal.
6. Political commitment of the local government to control of the epidemic

In order to close cooperation agreements with government bodies it is necessary for the counterpart to possess some degree of effective commitment to engage in the battle against the epidemic and not restrict its approach to good verbal intentions, but rather show what concrete action has been taken to date. Failing this commitment, a dependency relationship can be involuntarily established which can prevent the Selection Committee from perhaps bringing to a close a given project even when this is considered to be the correct action to take, especially in those cases involving the delivery of antiretroviral drugs to the relevant recipient body.

Measuring and Indicators: An analysis detailing current and recent policies carried out in the fight against the Aids epidemic, the amount of funding allocated to this etc.

7. Counterpart of the requesting institution and/or government

The literature referring to international cooperation lays stress above all on the need to make the availability of a counterpart a condition of whatever accord is reached between the parties. This is especially the case for projects where the executing body forms part of the apparatus of the state. The need for counterpart is justified on the following grounds: (a) to establish a feeling of co-responsibility for the good management of resources and to ensure a meaningful evaluation of the results achieved by a given project (b) to act as an incentive for ongoing sustainability of the project (c) to act as an internal pressure mechanism to correct internal policy. The existence of counterpart will not however represent a criterion for ultimate approval of a given project but it will be considered an indicator of social and/or political commitment and will as a result be an advantage when the project proposal is being evaluated for selection. Regardless of the amount of counterpart involved, this will be taken into consideration by the Selection Committee.

8. Level of sustainability of the proposal

The pilot projects in no way are intended to replace responsibility for treatment of people living with HIV and Aids in developing countries. The intention is to help projects to get underway or to bolster efforts being made nationally to treat such people. The initiatives undertaken within the context of this Cooperation Programme must establish how long the project will last as well as the manner in which it is proposed to achieve the sustainability of the pilot project.
The Selection Committee will monitor the implementation process of each pilot project by means of Progress Reports which shall be submitted on an annual basis. Impact assessment studies will be carried out every two years. In the event that the particular pilot project is assessed negatively, the Selection Committee will reserve the right to cancel or not to renew support for any current project. Thus the counterpart must furnish guarantees that it will continue providing care including the provision of antiretroviral drugs to all those patients benefited by the project in the event of the project being discontinued. The counterpart will also be required to demonstrate how it proposes to do this.

Finally, we should like to stress that the agreements may be renewed by common accord between the signatory parties and renewal will be dependent on securing the results foreseen for the pilot projects and presented in relevant end of year reports.
Conditions required for drawing up agreements

1) To show interest in participating in the Programme by writing to the Brazilian Embassy in your country and/or to contact the Advisory Unit for International Affairs of the Brazilian Ministry of Health. This can be done by contacting Sr. João Alberto Dourado Quintaes, whose official address is Esplanada dos Ministérios Bloco G, sala 433, CEP 70048-900 Brasília - Distrito Federal- Brasil
   Tel. (+55 61) 315 2813. 223 5089
   (+55 61) 224 0014

2) To complete in full the relevant Form for Presentation of Project Proposals

3) To demonstrate capacity in resources management

4) To show commitment with controlling the HIV/AIDS epidemic in your area.
Instructions For Completing Proposal Application Form

The application form connected with proposals to be submitted under Brazil’s “International Cooperation Programme for HIV and Aids Prevention and Control Activities for other Developing Countries” is the only method by which government or non governmental organizations can participate in the selection process organized under the auspices of the Brazilian government. It is essential therefore that any request for a project made to our government must, in all circumstances, be made on the above-mentioned application form. The form can be sent if necessary together with a covering letter explaining the background to the project application, in order to enable the Brazilian authorities to give due consideration to the request. The project will be judged on its technical merits by a Selection Committee comprising professionals from a number of different areas of the Ministry of Health. The need demonstrated by the requesting country for the introduction of a national response to the epidemic will be fully taken into consideration by the group of experts. Each proposal must plan to run for a minimum of one year and the project concerned can be extended for one further year depending on an assessment of the results of the project as well as on the political and financial circumstances prevailing in the Brazilian government at the time.

We must stress that the form must be filled out in full. It must also be legible and be submitted in clear language. Detailed replies to all the items on the form must be provided without fail. In this way, detailed relevant data required by the Brazilian authorities will be available to the Selection Committee, which will be in a meaningful position to judge the proposal on the grounds of its overall consistency. In the event of additional information being required under any of the different items (and for which there is no space) you should provide this information through, for example, the electronic medium or by appending extra pages to the form. This is perfectly acceptable, providing the annexes are sent in clear language and with appropriate numbering referring specifically to the various items to which they refer on the application form.
How To Complete Each Of The Items On The Form

Item 1 - The requesting institution

Completing this item is of fundamental importance to enable our Selection Committee to obtain an understanding of the type of institution which is making the application for a project, and for the Brazilian authorities to obtain an overall impression of the size of the project and its real potential. In effect, our assessment of the type of requesting institution will determine whether the description given of the proposed project by the applicant fits the requesting institution’s proper remit. Therefore it is very important to enter the name of the institution concerned in the item space reserved for this, as well as clearly naming the official address of the institution’s headquarters. This should be the address which appears in all the legal and juridical documents relating to the said requesting institution. If the institution has a “made-up” name this can be put under the item “description of project”, in the event of this being useful for enhancing understanding of what the actual project is about. It must be emphasized that as far as the remaining items concerning identification of the address of the institution and of those responsible for running it, if correct and appropriate information is not provided this could well result in the Brazilian authorities being unable to establish adequate contact with the requesting institution.

Item 2 - Type of requesting institution and its attributions in the field of STD, HIV and Aids

In this item, a brief description of the requesting institution must be given. This should cover for example the size of the institution, the number of people working for it, the coverage of the institution’s activities (on a national, regional or local level), the number of medical appointments attended to by the institution, other bodies with which the institution has formed partnerships (whether they be technical, scientific, political or other). Under this item information should also be provided related to the sources of the funding employed in the development of the activities referred to as being carried out by the said institution.
In addition to a description of the activities effected by the requesting institution, activities in the fields of STD, HIV and Aids must be described in particularly full detail. Activities by the institution in the fields of care, treatment and epidemiological surveillance concerning STD, HIV and Aids, must be described under this item.

**Item 3 - Person responsible for the request**

In this item, the full name of the person responsible for completing the form must appear and that of the person with whom the Brazilian government may need to make contact in the case of any queries arising from the details given on the submitted form. This will be the one and only individual responsible for liaison at this stage between the Brazilian authorities and the requesting institution. Complete contact details of this person must be provided in order to enable easy and quick contact to be made with the institution by representatives of the Brazilian Government.

**Item 4 - Size and impact of the epidemic in the country of the requesting institution and within the region covered by the project**

Under this heading, the epidemiological picture of Aids in the particular country and in the region covered by the Project must be described. Data concerning the incidence of Aids, and information available about the most commonly recurrent sexually transmitted diseases, must be given. Information under this item must also take into account data concerning the social, and economic impact of the Aids epidemic in general as well as the effect of the epidemic on families, plus an analysis referring to the numbers of children made orphans as a result of the epidemic both on a countrywide basis and in the region covered by the project.

**Item 5 - Potential for rapid spread of the epidemic both in the country concerned and in the region covered by the project.**

An analysis of the main determinants for the rapid spread of the epidemic nationally and in the region covered by the project should be made under this item. The data provided should include for example information referring to the social, economic, epidemiological situation in the country and the region concerned and other information about the vulnerability of the population to the Aids epidemic. The latter should include questions such as gender issues, illegal drug use and local specific cultural peculiarities, all of which must be outlined so that a proper assessment can be made about the likelihood or not of a rapid spread of the epidemic.
**Item 6 - Socio-economic and demographic details about the country of the requesting institution** (for example, to specify the position of the particular country in the Human Development Index (HDI) and its Gross Domestic Product (GDP))

All the socio-economic and demographic details available on the country must be entered under this item. It is hoped in this way to obtain a description of the level of social and economic development of the country in question. These details are essential to better understand the context in which the Aids epidemic is developing in the requesting country. This information will make it possible for the Brazilian government to meet the particular objectives of its "Programme", the main one of which is to attend to the needs of developing countries in this particular field. It is therefore extremely important to give details about for example the position of the country on the Human Development Index (HDI) and the per capita Gross Domestic Product (GDP), expressed in US dollar terms. A description of the Gini Coefficient is also required, vital for identifying those countries with high levels of inequality. It is also important to provide information about the percentage of the population of the country living below the poverty line. All the above data must be accompanied by details regarding the respective sources from which the information was collected.

**Item 7 - Objectives of the proposal**

Under this item the general and specific aims of the project must be described, drawing particular attention to the main problems to be dealt with by the project. Within the general objectives, a description must be provided of those problems of greater importance, while the details of specific objectives must include those that are adduced to be important for attaining the general objectives.

**Item 8 - Justification**

Under this item must be provided any data which could assist in understanding the special relevance of the project proposal. All the factors concerned with the elaboration of the project which could be relevant in the building of an effective national and/or regional response to the Aids epidemic should be mentioned. Details must also be provided about the most significant matters to be dealt with by the project, in particular those which could lead to the creation of a more propitious atmosphere for bringing the epidemic under control.
**Item 9 - Description of the project**

Under this item, all the information concerning proposals for carrying out the project's activities must be outlined. The main objective of this description should be to provide clear and coherent information for people who probably possess little or no information about the social, cultural or epidemiological situation in the country or the region where the project will be developed. A brief description of the local Health System and the interface that the proposed project is likely to have with the System should also be described. All the interfaces, partnerships and institutional liaison contacts needed for successfully taking the project forward must be mentioned under this item, in order to provide a comprehensive view of what the proposed project actually consists of.

**Item 10 - Institutional Counterpart**

The institution must give complete details about its “own” financial (and/or other) resources that will be earmarked for implementing the project. The existence of counterpart resources shall not represent any criteria for actual approval of the project, but the fact of their existence will however be taken into consideration as an indication of the institution's social and/or political commitment and, as such, it will be an advantage in the course of the process of selection by the Brazilian authorities. Regardless of the value of this counterpart, it will be taken into account by the Selection Committee.

**Item 11 - Sustainability**

It is not the intention of the Brazilian Programme to meet the needs for ARV treatment of the people living with HIV and Aids in the country or the region of the requesting institution. The aim is to either to help get underway or to give support to national efforts aimed at treating such people. In this respect, it is important to stress that the requesting institution must define and make absolutely clear the appropriate measures which will be taken to ensure ongoing sustainability of the various activities to be undertaken under the proposed project - especially those related to treatment. The aim is to ensure that at the conclusion of the project local institutional capacity exists for ensuring longer term sustainability of the group of activities.

**Item 12 - Results to be achieved by the project**

The requesting institution must submit a range of indicators so as to permit an effective analysis and evaluation of the progress of the project. The extension of the agreement for a second year of the project will depend on a
carefully detailed and periodic analysis which will be carried out by Brazilian professional involved with the "Programme". Indicators for the evaluation of the impact of the project therefore need to be drawn up and described.
Project Proposal Application Form

1. REQUESTING INSTITUTION

Name: __________________________________________
Address: _______________________________________
City: __________________________________________
Country: _______________________________________
Telephone: _____________________________________
Fax: ______________________ E-Mail: ______________

Name of person responsible for institution:
Type of Institution: ________________________________
Institutional relationship: __________________________

2. Features of the institution and attributions in the field of
STD/HIV and Aids

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3. PERSON RESPONSIBLE FOR THE REQUEST

Name: ___________________________________________________________
Position: _________________________________________________________
Address: _________________________________________________________
City: _____________________________________________________________
Country: _________________________________________________________
Telephone: _______________________________________________________
Fax: _________________, e-mail: ________________________________

4. Size and impact of the epidemic in the country and in the region covered by the project

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5. Potential for rapid growth of the epidemic in the country and in the region covered by the project

6. Socio-economic and demographic data on the country (please specify the position of the country on the HDI, and its GDP)
7. Objectives of the proposal:
   General Objectives:

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   Specific Objectives:

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8. Justification

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9. Description of the project:

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10. Institutional counterpart

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11. Sustainability conditions

12. Results to be achieved by the project
EDICT No. 949 OF 22 MAY 2002

The Minister of State for Health, using his attributions and considering that the Aids pandemic has affected in particular the least privileged countries in Africa, Asia, Latin America and the Caribbean, which have been able to mount only a minor or restricted response;

the experience and the successful results achieved by Brazil in the integrated activities related to treatment and prevention;

Brazil's commitment to use cooperation as a valuable instrument with which to exercise international solidarity.


does hereby resolve:

Nº 949 - Art. 1º to establish the international Cooperation Programme for activities for the control and prevention of HIV for developing countries;

Art. 2º- to make available technical support and funds to the value of R$ 2.500.000,00 for carrying forward the objectives of the aforementioned programme of the Ministry of Health;

Single paragraph. The Ministry of Health shall fund the setting up of 10 pilot projects to the value of up to R$ 250.000,00 annually per project aimed at the prevention and treatment of carriers of HIV in other developing countries. The projects to consist of:

I - human resources training and training in clinical management, plus the donation of antiretroviral drugs furnished by Brazilian public government run laboratories;

II - drawing up and implementing said projects in partnership with governments, UN system bodies, civil society organizations and technical cooperation agencies;
III – examining proposals for transfer of production and distribution logistics technology regarding antiretroviral medicines produced in Brazil by public laboratories;

Art. 3º - To set up a committee to define criteria, coordinate the selection, implementation and evaluation processes concerned with the pilot projects.

Art. 4º- To designate as members of the Committee the following representatives of the Ministry of Health:

a) Platão José Erwin de Souza Lima Fischer-Puhler – Minister’s Cabinet Office
b) Cláudio Duarte da Fonseca – Secretary for Health Policies
c) Gonzalo Vecina Neto – National Health Surveillance Agency
d) Paulo Roberto Teixeira – National STD and Aids Coordinating Office;
e) João Alberto Dourado Quintaes – Advisory Unit for International Health Affairs.

Art. 5º This Edict will take effect from the date of its publication.