Draft document, date: August 2004

Position of the community-based networks of Latin America and the Caribbean regarding the procurement of the following types of antiretroviral drugs: certified generic, patent-protected registered trademark, and copied/similar.

The undersigned community-based networks of Latin America and the Caribbean, issue the following statement on the purchase and distribution of non-brand name pharmaceutical (considered innovator or original) antiretroviral medication (ARVs) for the treatment of HIV/AIDS infection:

Considering:

1. That life, health, social security, access to the advances of science and technology and egalitarian treatment are human rights that states and governments must guarantee for people who live with HIV/AIDS (PLWHA), as expressed in: national constitutions; the Universal Declaration of Human rights; the American Declaration of Rights and Duties of Man; the International Pact on Economic, Social and Cultural Rights; the American Convention on Human Rights; the Declaration of Human Rights of PLWHA signed in England in 1990; the 1994 Paris AIDS Summit Declaration; the United Nations Millennium Development Goals, and the 2001 Declaration of Commitment of the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS.

2. That in the region of Latin America and the Caribbean (LAC) there are currently more than two million people living with HIV/AIDS; more than 200,000 people are becoming infected with HIV every year; in 2002 more than 100.000 people died mainly due lack of antiretroviral medication and timely comprehensive care; and at the present time, large numbers of people living with HIV/AIDS (PLWHA) in several countries do not have access to ARVs.

3. That national and international legal norms express that states and governments must develop concrete interventions for disease prevention, health promotion, health recovery, rehabilitation and for coordinating the health of their citizens living with HIV/AIDS; that national governmental organizations are obligated to implement mechanisms to strengthen their budgetary capacity in a timely fashion to implement national HIV/AIDS policies. The aims of these policies are to guarantee the right to life, health, social security, development, work, access to the advances of science and technology, and freedom from discrimination. National governmental organizations are also obligated to implement mechanisms that offer maximal social coverage to PLWHA and vulnerable populations.

4. That several LAC region countries already have universal access to antiretroviral treatment, and some of them, have even made important advances to increase the level of health care provided. Universal access to ARVs has been achieved in countries like Brazil, due to reduction in the price of ARVs, through

strategies that have included local production of generics, use of commercially-protected innovator (or brand name) medications, and generally, through generic competition. Other advantages obtained are the significant savings on drugs for opportunistic infections, improved hospital care, and an increase in specialized personnel.

5. That HIV and AIDS have stopped being costly diseases. The price of medication and laboratory tests has decreased drastically in the last five years. These price drops facilitate access for all countries.

6. That regarding the agreement on the Trade-related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization and the Doha Ministerial Declarations on public health, combined with the obligations indicated in item 3 above, countries have the right to produce legislation to guarantee access for all their citizens to public health and social security, including PLWHA, by means of compulsory licensing, local manufacturing and parallel importation of good quality medication at lowest possible price (including ARVs and other medicines used for HIV/AIDS care).

7. That there is a lack and/or absence of truthful scientific or technical information from states and governments--as part of their responsibility for the public's health and in their capacity as decision-makers--on quality control of generic or copied medication in the LAC region. Manufacturers of innovator, generic, copied, falsified, adulterated, or re-packaged drugs have commercial interests. There are people and companies with only business-oriented interests (They consider only the costs in the relation between costs and benefits, and place opportunism before the quality and effectiveness of products and before the health of PLWHA).

8. That in all the countries of the Region governments and universities with expertise in the area must execute all quality controls on specific generic and innovator drugs (in accordance with our social, economic and regional realities) with the goal of guaranteeing the effectiveness and safety of the medication in the event of any human ailment, symptom, illness or disease.

9. That the World Health Organization (WHO) and the Pan-American Health Organization (PAHO), the 3 x 5 Initiative, the United Nations Fund for Children (UNICEF), several departments of Doctors without Borders, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and other institutions have established regulations that guarantee norms of good drug manufacturing and that they have certified some laboratories of the LAC region in this respect.

10. That several LAC region governments, with the support of Doctors Without Borders, the Clinton Foundation, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and several LAC non-governmental organizations already have scientific information that has been validated by comparative testing of treatment with generic ARVs with innovator ARV drugs in thousands of PLWHA. Years after initiating

antiretroviral treatment, the following was noted: an increase of the total number and proportion of CD4, a decrease in viral load, an improvement in the clinical and overall state of patients, reduction in incidences of opportunistic infections and cancers, and the same side-effects at the same frequency and level of adherence to medicines. These studies demonstrate that the medicines compared are bioequivalent.

11. That bioavailability is defined as the exact quantity of active ingredient in a medication that will reach the bloodstream and the time it takes to do so from the moment of ingestion. Bioequivalence is the degree of similarity or comparison between two drugs, usually between an innovator drug and another drug (generic or copied) containing the same active ingredient in the same quantity, with the same form, and administered by the same means and in the same dosage.

12. That some manufacturers of generics, patent-protected innovator drugs, and copied drugs have commercial and political interests.

13. That drugs that fail to satisfy quality controls create serious health problems and risks for PLWHA. Lack of adherence to medications due to changes in presentation can lead to viral resistance, irreversible therapeutic failure, damage to health, and finally to death.

14. That given our various consultations with specialists on infectious diseases and HIV/AIDS, our experience, our sense of ethics, and our disinterested commitment for the well-being of the community of PLWHA in the LAC region, we wish to share the following document on the institutional and consensual position of the community-based networks of the LAC region.

This document tries to establish and clarify the following points:

A. A medicine is only generic and can only and exclusively be referred to as such when he it is bioequivalent. The WHO, PAHO and other similar entities have established guidelines for the accreditation of a generic version of a medication, through quality controls done in certified laboratories, i.e., laboratories set up for the purpose of quality control and capable of accrediting medications. Some of the controls which a medication must pass successfully are: good norms of manufacturing, a controlled study in several countries of the region comparing PLWHA on treatment with specific generics and PLWHA on innovator medications, and/or the test of bioequivalence. The results of the controls must be available to the public according to international directives.

B. Once a drug has been manufactured (also called finished pharmaceutical product) if it has not been approved or submitted to the quality controls and/or the certifications mentioned above, it can only be considered a similar medicine or a copy. This is the case because there is no information on the possible adverse effects that can occur in patients or on the therapeutic effects and efficacy for treating HIV/AIDS.

Until such medications are certified or have passed established and standardized quality controls they should not be used for PLWHA. The certificates referred to as quality certificates, quality tests, and good manufacturing practices will have to be the result of the finished product, *and* for each one of the versions in which the same drug appears in the country in which it will be consumed. That the active ingredient in a drug (chemical compound that causes the therapeutic effect that reduces or eliminates the symptom, illness or disease) has manufacturing certification does not release the manufacturers and/or buyers of that finished product of their responsibilities to test its quality for human consumption.

C. We consider that only certified generic drugs or innovator drugs should be administered to any PLWHA. It is not ethical according to the Declaration of Helsinski and to medical deontology to administer medicines that do not have the aforementioned certification. We do not accept that drugs be administered if their quality has not been proven. To do so would be a violation of our right to health and life.

D. Quality certification for drugs must be applied to finished products and must be maintained during the procurement period.

E. National sanitation authorities, the WHO, PAHO and other international institutions charged with the health of PLWHA in the world have the responsibility to take action to implement, certify and follow up on drug quality control by creating laboratories that satisfy international standards for those purposes. Each sub-region of LAC should have its laboratory devoted to drug analysis. Likewise, inter-country support should be promoted so that countries can rely on laboratories for quality control analysis (in the form of a local, regional or international service) while new laboratories are to be created. It should be an obligation to disseminate the information obtained from drug quality control studies in an efficient and timely fashion to all involved entities.

F. That the lack of speed and clarity in the laws on processes for drug registration in our countries make it difficult for generic medication at more competitive prices to enter the market. The abovementioned laws must incorporate the unrestricted control of the quality of drugs (generic or innovator) as health public health goods.

G. Free trade agreements threaten the ability of generic drugs to compete freely on the market and can impose restrictions on governments that prevent access. Countries that enter into these negotiations must respect at minimum the outcomes of the DOHA accords.

H. It is necessary that at level of the WHO and PAHO, states and non governmental organizations a network be established to monitor prices and qualities in order to avoid monopolistic practices and the commercial practices of drug distributors that increase prices.

I. The Declaration of Commitment on HIV/AIDS, signed by the States and Governments of the LAC region during the United Nations General Assembly Special Session (UNGASS) states the following:

> "By 2003, ensure that national strategies, supported by regional and international strategies, are developed in close collaboration with the international community, including Governments and relevant intergovernmental organizations, as well as with civil society and the business sector, to strengthen health-care systems and address factors affecting the provision of HIV- related drugs, including anti-retroviral drugs, inter alia, affordability and pricing, including differential pricing, and technical and health-care system capacity. Also, in an urgent manner make every effort to provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections, and effective use of quality-controlled anti-retroviral therapy in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance; and to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs…"

J. That the WHO and PAHO participate strongly in drafting commercial bilateral or multilateral agreements so as to preserve the terms of the Declaration of Doha and that they publicly assume the defense of these terms.

To this effect the aforementioned community-based networks of Latin America and the Caribbean agree that they:

a. Will support only and exclusively the distribution of ARVs (innovator drugs and generics certified by PAHO/WHO, the Global Fund and other agencies) the quality of which has been shown and certified.

b. Will support only and exclusively the distribution of ARVs, innovator or generic, insofar as the tests referred to in this document have been made and their results have been made available regularly and at random at purchasing or procurement points.

c. Will only and exclusively support universal access to treatment for PLWHA under the equity-based criterion: the highest quality treatment (known and proven) available to all. There are no arguments that can justify, morally or ethically, that there be different standards of treatment for PLWHA.

d. Will denounce policies, civil servants, organizations and companies that engage in illegal or unethical practices that promote partial information, bad information and disinformation regarding treatment for PLWHA.

e. Will promote and demand that PLWHA be treated only and exclusively with innovator and/or generic medicines and treatment plans that have been clinically demonstrated to be the most effective.

f. Will promote clinical tests or tests on humans that correspond to all the ethical criteria, including the informed consent process. In case of extreme necessity, such as compassionate access for PLWHA, we

will promote treatment plans for those who have experienced resistance to proven drugs and drug combinations.

g. Fulfill one of their objectives: the exclusive promotion of the quality of life of PLWHA.

h. Declare being free from conflicts of interest in relation to pharmaceutical industries and to health systems and their users. We declare to have no interest whatsoever in the results of conflicts, negotiations, purchases, or litigation (national, regional or international), except for what our statutes specify.

i. Insist that manufacturers of innovator drugs and manufacturers of certified generic drugs provide differential pricing to government institutions and NGOs working in the LAC countries and that these aforementioned manufacturers reduce their prices to guarantee universal access in the region to HIV drugs and drugs to treat opportunistic infections.

j. Demand the governments of the Region maintain their constitutional obligation to guarantee health and life over any commercial interest. That they provide universal, continuous and free access to ARVs for those persons who need them, and that they resist commercial pressures of whatever origin that could impact the capacity of maintaining the quality of life of the millions of PLWHA in the LAC region.

k. Exhort governments to formulate and/or to adapt their laws on medicine on drug regulation, including guaranteeing follow up on quality control processes during the manufacturing, distribution, storage and dispensation phases of all medications (not only for finished products). This also applies to all the steps governed by good manufacturing practices (of clinics and laboratories), in accordance with the policies the WHO recommends.

l. Demand that governments of the region create reference laboratories to carry out quality controls for any pharmaceutical product. Similarly, we ask the WHO and PAHO to motivate, promote and provide technical assistance for the creation of these laboratories in LAC.

m. Are committed to fomenting citizen's watchdog groups and social control on these issues in the region. This is an URGENT and IMPORTANT matter, as such action would allow us to engage in follow up of processes, information seeking, denouncing problems and continuity of processes. Such action would also allow us to make our demands sustainable in these processes and to foment processes for technology transfer.

n. We demand the WHO improve its processes for the prequalification of antiretroviral drugs and that it effect secure and reliable inspections of those research institutions with which pharmaceutical companies

contract for bioequivalence studies. With such measures the WHO would avoid having to make inconclusive statements and public declarations or to provide incomplete information on bioequivalence tests done on ARVs that had previously been granted prequalification certification. All this is to provide assurance to citizens regarding medications that may have obtained approval to be consumed.

o. Demand the WHO/PAHO guide the 3x5 initiative in each one of the LAC countries of region LAC, summoning the different national actors for discussion and decision-making processes.

p. Demand the WHO/PAHO and governments implement processes for pharmaceutical vigilance, which includes creating committees in which the community sector participates.

q. Consider that universal access to treatment and care for all PLWHA who need them, including access to ARVs (among other necessities), can and must be obtained with commitment, ethics, science, seriousness and attachment to the existing legal norms in LAC countries. We consider that the reductions in ARVs occurring in many countries of the region place the lives of PLWHA in danger and pose a danger to public health. For these reasons we exhort governments, pharmaceutical companies and the WHO/PAHO to take concrete and speedy action to avoid that new reductions.

The community-based networks of Latin America and the Caribbean refuse that the effectiveness or lack of effectiveness of antiretroviral drugs be tested on the bodies of PLWHA in our countries.

Signatories to the document:

- **Asociación por la Salud Integral y la Ciudadanía de América Latina, ASICAL)**
- **Comunidad Internacional de Mujeres que viven con HIV, Secretaria Regional para América Latina y el Caribe de ICW+**
- **Consejo Latinoamericano y del Caribe de ONGs con Servicio en HIV/AIDS (LACCASO)**
- **Movimiento Latinoamericano y del Caribe de Mujeres que viven con HIV/AIDS (MLCM+)**
- **Red de Reducción del Daño (RELARD)**
- **Red de Trabajadores Sexuales de Latinoamérica y el Caribe (REDTRABSEXLAC)**

- **Red Latinoamericana de Personas que Viven con HIV/AIDS (REDLA+)**

Latin America and the Caribbean, August 2004