

## **Position of REDLA+ on procurement generic and copied versions of antiretroviral medications**

The **Latin American Network of People Living with HIV/AIDS** (REDLA+) issues the following statement (\*) on purchasing and distributing non-brand name antiretroviral drugs\*\* or pharmaceutical products (ARVs) for treatment of HIV/AIDS (brand name drugs are also known as innovator or original drugs):

### **Considering that:**

1. Life, health, access to scientific and technological advances, and egalitarian treatment are human rights that states and governments must guarantee for persons living with HIV/AIDS (PLWHA), as expressed in: national constitutions; the Universal Declaration of Human Rights, the American Declaration of the Rights and Duties of Man; the International Covenant on Economic, Social and Cultural Rights; the American Convention on Human Rights; and norms on the defense of human rights such as the Declaration on Human Rights of PLWHA, signed in England in 1990.
2. According to legal national and international norms states and governments have the duty to protect the health care of citizens living with HIV/AIDS; national government agencies are compelled to establish mechanisms for strengthening their budgets for the implementation of national HIV/AIDS policies in order to guarantee the rights to life, health, access to scientific and technological advances, and the non-discrimination of PLWHA.
3. States and governments (in the context of their role as decision makers) lack information on the manufacture and quality control of innovator, generic and copied drugs in Latin America and the Caribbean.
4. Quality controls (bioequivalence and bioavailability) must be done on every pharmaceutical product or medication; these controls guarantee that pharmaceutical products or medications are effective, safe and capable of producing therapeutic effects (preventive and/or curative) against human ailment(s), symptom(s), illness or disease.
5. **Bioavailability** is the exact quantity of active ingredient in an orally-administered 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 (between an innovator drug and a generic or copied drug) containing the same active ingredient in the same quantity, have the same form, and are administered by the same means and in the same dosage, such that they present a bioavailability so similar that it would be possible to predict that the therapeutic effects of both drugs would be essentially identical.
6. Manufacturers of innovator, generic, and copied drugs have commercial interests.
7. The inappropriate use of the term “generic medication” to refer to copies or similar versions of medications, as well as the problems being created by some medications lacking demonstrated therapeutic equivalence.

(\*) Unofficial translation of the June 2003 Spanish language document, “Posición de Red Latinoamericana de Personas Viviendo con VIH/SIDA (REDLA+) frente a la adquisición de medicamentos antirretrovirales de versión genéricos y copias”.

8. The possibility of creating differences between persons living with HIV/AIDS due to their having ingested different types of medications: innovator, generic or copied drugs.
9. The lack of scientific recommendations and technical publications on alternative treatment in regards to failure of generic medications schemes .
10. Following various consultations with experts and as a result of our experience, ethics, and disinterested commitment to the wellbeing of the community of PLWHA in Latin America and the Caribbean, we wish to share the following document describing the institutional and consensual position of REDLA+ on procurement.

This document seeks to establish and clarify the following points:

- A. A drug is only a **generic** drug, and can only be called as such, if it is “interchangeable”. For this to be the case, the drug must have successfully passed tests to show its therapeutic equivalence. With regard to antiretroviral drugs, each medication must have successfully passed clinical tests (in vivo) for, and must bear certification of its bioequivalence in accordance with international guidelines (where this certification is based on the results of the aforementioned clinical tests).
- B. If a drug, once manufactured (also called the completed pharmaceutical product) has not passed or gone through the clinical laboratory tests (in vivo phase) to certify its bioequivalence and bioavailability, it can only be considered a **similar or copied** medication. Its quality and the possible adverse effects it can produce in people remain unknown, as do its actual therapeutic effects and effectiveness in treating HIV/AIDS.
- C. Completed drugs or pharmaceutical products that have been shown to be pharmaceutically equivalent through the appropriate testing methods but have not been shown to be therapeutic equivalent, cannot be considered to be generic drugs, and must be considered similar or copied drugs.
- D. We consider that any PLWHA who is administered similar or copied drugs is participating in a test or clinical trial. A clinical trial is a scientific method for studying in various phases (studies done with cellular cultures, animal studies, and small consenting groups of human beings) the effectiveness, quality, possible adverse effects and interactions of a medication. Before administering the drug, national health authorities must explain and notify PLWHA, clearly and equitably, about the characteristics of the drug in question and of any subsequent alterations done to it. If the PLWHA involved agree to participate in the clinical trial, they must give their signed informed consent to be part of the test or clinical trial in accordance with the Declaration of Helsinki on Human Experimentation. These clinical trials must be done under conditions respectful of the fundamental rights of persons and of the ethical criteria that guide biomedical research involving human beings.
- E. Prescribing medications or pharmaceutical products that have not passed the quality tests (bioequivalence and bioavailability) cannot be considered part of a treatment plan, but must instead be considered part of a test or clinical trial.

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F. Certification of quality, proof of quality, and good manufacturing practices, must follow the completion of a pharmaceutical product, and each of the forms it takes in the country where it will be consumed. Manufacturing certificates for the active ingredient in a medication (chemical compound that brings about a therapeutic effect and thus reduces or eliminates symptoms, illness or disease) do not free producers and/or buyers of their responsibilities, such as their duty to do quality tests on completed pharmaceutical products aimed at human consumption.

G. The national public health authority or the public health authority of each country has the responsibility to act on the implementation, follow-up, and control of quality tests. It cannot delegate this responsibility for any reason to a private entity or to an international agency. The national authority is responsible for information on whether a product is an innovator/original drug, generic/interchangeable drug, or similar/copied drug and for information on the nature of the drug's therapeutic and adverse effects.

H. The Declaration of Commitment on HIV/AIDS, signed by the States and Governments of Latin America and the Caribbean during the United Nations General Assembly Special Session (UNGASS) states:

“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...”

**Thus, the Latin American Network of People Living with HIV/AIDS (REDLA+) agrees that:**

- a. **REDLA+** will support, only and exclusively, the distribution of antiretroviral medications shown to be therapeutically equivalent and to bear scientific certification to that effect. This requirement applies to innovator products and generics that have successfully passed tests of bioequivalence and bioavailability.
- b. **REDLA+** will support, only and exclusively, the distribution of generic antiretroviral medications if the abovementioned tests have been done and if their outcomes are periodically and randomly made available at purchase and/or procurement points.
- c. **REDLA+** will keep a critical eye on the distribution of brand name and generic antiretroviral medications.

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- d. **REDLA+** will support, only and exclusively, universal access to treatment for PLWHA according to criteria of equity and the same treatment for everyone of the highest quality (known and proven). There are no moral or ethical arguments for justifying substandard treatment for PLWHA.
- e. **REDLA+** exhorts governments to formulate or adapt their drug regulation legislation, including guaranteeing follow-up on quality control processes throughout the manufacturing, distribution, storage, and dispensing stages of medications. The requirement of guaranteeing follow-up on quality control processes does not only apply to completed pharmaceutical products. It applies throughout the steps Good Manufacturing Practices require, and it must be implemented in accordance with the policies the World Health Organization (WHO) recommends.
- f. **REDLA+** will denounce policies, government officials, organizations, and businesses that engage in practices that are illegal, conflict with ethics, or promote partial information on our own treatment.
- g. **REDLA+** promotes and demands that PLWHA be treated only and exclusively with drugs and treatment plans that have been clinically shown to be the most effective.
- h. **REDLA+** will promote tests and clinical trials on humans that meet all the ethical criteria, including the process of informed consent. In situations of extreme necessity, such as PLWHA experiencing resistance to proven treatment plans or drug combinations, we will support treatment plans that, for example, involve “compassionate access”.
- i. **REDLA+** satisfies its mission of exclusively promoting the quality of life of PLWHA.
- j. **REDLA+** declares it does not have conflicts of interest with the pharmaceutical industry and with health care systems and their clients. We declare having no interest whatsoever in the results of conflicts, negotiations, purchases, or national, regional or international bids, except for those specified in our bylaws .
- k. **REDLA+** exhorts the pharmaceutical industry to develop policies with social content that take into consideration the lives of people and that do not alone prioritize commercial earnings made from the sale of the pharmaceutical products people living with HIV/AIDS consume.

**REDLA+** considers that universal access to treatment, which includes ARVs (among other things, and care for all PLWHA who need them can and must be achieved through commitment , ethics, science, rigor, and adherence to existing legal norms in the countries of Latin America and the Caribbean. We, PLWHA, do not wish to be the ones in our countries, to have our bodies again used, to test the effectiveness or ineffectiveness of ARVs.

**Havana, Cuba, April 2003**

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**REDLA+, the Latin American Network of People Living with HIV/AIDS**, is composed of networks, groups, and associations of people living with HIV/AIDS. It has representatives or “Focal Points” in Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominican Republic, Uruguay, and Venezuela.

The above statement from **REDLA+, the Latin American Network of People Living with HIV/AIDS**, is the result of a consensual agreement among all the Focal Points of **REDLA+**. In addition, more than 7,900 members of **ESVIHSIDA** ratified the statement at the May 2003 **ESVIHSIDA** Discussion Forum.

The signatories\*\*\* to the above statement from **REDLA+** are as follows:

- Pastor Padron Bucarano / Integrante de GPSIDA, Villa Clara, Cuba
- Perceval Carvalho / Natal, STV Brasil - Sociedade Terra Viva, Brasil
- Sergio / RNP+ Brasil
- Georgina Gutiérrez Alvarado / Coordinadora del Programa de Mujer y SIDA en Salud Integral para la Mujer (SIPAM, A.C.); y Vanguardia Mexicana de Personas Afectadas por el VIH/SIDA (VANMPAVIH), México
- Rosalinda Hernandez M. / Jefa Programa Nacional VIH/SIDA, Secretaría de Salud, Honduras
- Roberto Viñuela / Presidente Asociación Redes Nueva Frontera, Argentina
- Maria Fernanda Macedo / Brasil
- Raymundo Sandoval / ProPositivo del Centro de Derechos Humanos, México D.F., MÉXICO
- Fausto Paez / Director Ejecutivo LATITUD 0° MOVIMIENTO LGBT ECUATORIANO, New York, USA
- Javier Leonardo Varón
- Martín de Jesús García Lira / Candidato para Diputado Federal por el Distrito 14 de Guadalajara, Jalisco, México.
- Gustavo Adolfo Campillo Orozco / Presidente de Fundación Positivos por la Vida; Miembro de CONASIDA, Medellín, Colombia
- Gabriel Borges Gutiérrez / Coordinador General – Presidente de la Delegación de PVVs, Buenos Aires, Argentina
- Lázaro Rodríguez Corrales / Coordinador GPSIDA, Coordinador de Líneas de PVVs, Voluntario de ONUSIDA en Pinar del Río y Miembro del Equipo Nacional de PVVs, Cuba
- David Mauricio Quintero / Fundacion Manos Fraternas Y FUNPPREVESS
- Cristina Calderón / Guatemala
- Julio Palma G. / Centro de Apoyo CAPVIH, Chile
- Maria Beatriz Dreyer Pacheco / RNP+/POA Rede Nacional de Pessoas Vivendo com HIV/Aids - Núcleo Porto Alegre – Brasil; Membro do MLCM+
- Patricia Pérez / Secretariado Regional América Latina de la ICW+
- Arturo Vazquez Razo / Cord. Grupo de Autopoyo, Chiapas, México
- Aroldo Enrique Pinedo Lanao / Director Ejecutivo de Fundación Manos Amigas , Santa Marta, Colombia
- Psic Andres Costilla Castro / Consejo Directivo de FRENPAVIH AC y Director General de APLCS AC, México
- Aldo Araujo / Director del Movimiento Homosexual de Lima (MHOL), Perú

\* REDLA+ is the acronym for the Spanish language name of the network, “Red Latinoamericana de Personas Viviendo con VIH/SIDA”. The acronym has not been translated for the sake of avoiding confusion.

\*\* The terms “drug” and “medication” are used interchangeably.

\*\*\* All details related to the signatories have been left in the original Spanish to facilitate contacting them directly.

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