

An Open Competition Model for Regional Price Negotiations Yields Lowest ARV Prices in the Americas

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Summary

The shift from a country by country approach in price negotiations to a sub-regional approach has resulted in a rapid decrease in HIV/AIDS Antiretroviral (ARV) prices in Latin America and the Caribbean. Through the regional Accelerated Access Initiative in the Caribbean and Central America, ARV costs have been reduced to US\$ 1,100 – US\$ 1,600 per year per patient. The development however of an open competition based model for regional price negotiations by ten other Latin American countries (June 2003) has yielded the most significant reductions in the region, with costs reduced from US\$ 5,000 to US\$ 400 per patient per year through the source selection of prequalified generics.

Introduction

In 1996, triple therapy of HIV/AIDS was initiated using Protease Inhibitors (PI) in combination with Nucleoside Reverse-Transcriptase Inhibitors (NRTI) in what would become known as Highly Active Antiretroviral Therapy (HAART). With the advent of HAART powerful medical tools have become available radically changing the outlook for persons living with HIV/AIDS (PLWHA). Significant reductions in HIV mortality have been achieved in countries of medium to high income where access to comprehensive care for HIV is considered universal¹. In addition HAART generates savings through reductions in hospitalization costs and health systems operation, maintaining family income², and facilitating continued economic development by allowing PLWHA to return to a productive working life.

Nonetheless antiretroviral drugs remain inaccessible for the vast majority of PLWHA living in countries of average and low income. As drug prices remain excessively high, developing countries struggle to incorporate triple therapy into national health budgets as competing demands draw upon limited resources.

The Accelerated Access Initiative (AAI), a partnership created in May 2000 with the participation of WHO, UNICEF, UNFPA, World Bank, UNAIDS and five pharmaceutical manufacturers of ARV (Boehringer Ingelheim GmbH, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., Inc. and F. Hoffmann-La Roche Ltd.) was established to address the issue of lack of affordability of HIV medicines, and to develop a partnership that would work to increase access to HIV/AIDS care in developing countries³. The initiative sought to broker commitments from countries to implement plans and improve access to ARV treatment, and from companies to offer reductions in the price of ARV based on scale-up proposals.

Between May 2000 and June 2002, 5 countries in Latin America and the Caribbean (Barbados, Chile, Jamaica, Trinidad and Tobago) participated in the AAI receiving significant reductions in the price of ARV from participating manufacturers. During the same time period it was recognized that too few countries were benefiting from the reduced prices offered through the AAI because of lack of adequate funding and resources, weak health systems and labor intensive processes necessary for brokering agreements on a country by country basis⁴. A sub-regional approach to accelerating access to ARV was therefore proposed, involving countries of geographical proximity and with a tradition of inter-country and/or sub-regional cooperation.

Methods

The first countries in the region of the Americas to develop a sub-regional approach to accelerating access to ARV were the countries of the Caribbean. In February 2002, representatives from CARICOM countries met with the partners of the AAI to reach agreement on the principles of a sub-regional approach, highlighting similarities within the region in the status of the HIV epidemic and the response of the countries, as well as the importance of mobile populations between countries. In the months that followed, Caribbean countries developed a proposal for Accelerating Access to Care and Treatment in the Caribbean⁵ that would form the basis for sub-regional discussions with the partners of the AAI. In July 2002, representatives from the Caribbean nations reached an agreement with the pharmaceutical companies participating in the AAI, during the XIV AIDS Conference,

Barcelona, resulting in significant price reductions for ARV in the region.

As Caribbean countries completed negotiations, Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama) initiated a similar sub-regional process within the framework of the Declaration of Central American Presidents, Madrid, May 2002, to “*implement a sub-regional approach that will accelerate access to comprehensive care, including ARV therapy*”⁶. The approach would build on commitments made by the countries through the regional meetings of the Ministers of Health (COMISCA) and other sub-regional bodies. Similar to the Caribbean process, a series of sub-regional technical meetings were held with participation of all the countries, to propose a sub-regional response that would accelerate access to care and treatment. A framework proposal was presented to the companies participating in the AAI in January 2003, and based on the proposal, Central American countries negotiated price reductions *en bloque* for ARV.

It is to be noted that Central American countries added a new dimension to the sub-regional negotiation not present in the Caribbean process. A number of Central American countries expressed interest in using generic ARV, particularly generics assessed against international quality norms, and certified by WHO as suitable for procurement by UN agencies⁷. Accordingly in January 2003, during the AAI negotiations, the Ministers of Health from Central American countries initiated a dialogue with the representative of the association of manufacturers of generic ARV, and received information and price offers for WHO prequalified generics.

As the Central American process was developing, ten other countries in Latin America came together to initiate a third regional initiative to reduce the price of ARV and HIV diagnostic tests. This initiative was developed by the Ministers of Health in the Andean countries (Bolivia, Chile, Colombia, Ecuador, Peru and Venezuela) and extended to include the participation of Argentina, Mexico, Paraguay and Uruguay, within the context of a regional political mandate to expand care and treatment in participating countries⁸. Again, a number of technical meetings were held to examine in-depth the status of HIV epidemic in the countries and to review the country and regional response to care and treatment of PLWHA.

The preparatory process for the negotiation developed by the 10 countries in Latin America included a number of distinctive elements not seen in the Central American and Caribbean negotiations:

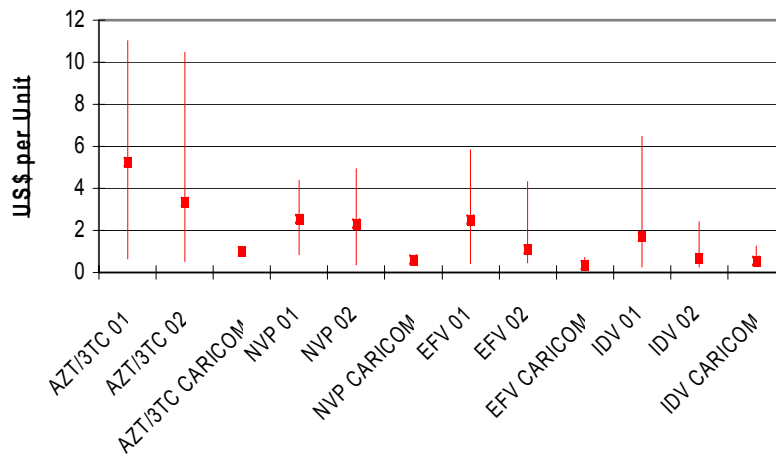
negotiations would be based on price alone and not on other conditions stipulated within the framework of the AAI, and quality criteria (for product and manufacturer) based on WHO standards would be determined in order to identify appropriate qualified suppliers of ARV and diagnostics for participation in the regional negotiation. The process culminated in a round of price negotiations held in Lima, Peru, June 2003, between the Ministers of Health from participating countries and representatives of 9 manufacturers of HIV diagnostics and 16 manufacturers of ARV. The negotiation resulted in the signing of a Statement of Intent between the 10 countries and 8 suppliers of ARV including both originator and generic manufacturers (Abbott Laboratories, Cipla Ltd., Combinopharma S.A., Laboratorios Filaxis S.A., Ranbaxy Laboratories Ltd., Richmond S.A., Laboratorios Rontag S.A. and Refasa (one product)).

Results

The three sub-regional rounds of ARV negotiations held in Latin America and the Caribbean in 2002 and 2003 display a number of similarities. A firm political commitment was achieved on the part of the countries participating in each of the processes as witnessed by the level of debate and subsequent resolutions adopted in regional and sub-regional meetings of the Ministers of Health and the health sector. Technical frameworks for each of the negotiations were developed based on an analysis of the epidemiological situation, access to comprehensive care and treatment, and health service capacity required to expand comprehensive care. Similarly, technical meetings in each sub-region facilitated the development of a negotiation strategy by technical teams designated by the Ministers of Health, facilitating the pooling of objectives. In each negotiation, sub-regional and regional networks of people living with HIV/AIDS were involved to ensure transparency. The negotiations were directed by the Ministers of the countries, while regional mechanisms were used to coordinate the organization and facilitate the negotiations (CARICOM Secretariat in the Caribbean, SISCA in Central America and ORAS for the 10 Latin American countries). Each process received technical support from PAHO/WHO and UNAIDS. Finally, manufacturers of ARV displayed a firm commitment to work with countries and participate in the negotiations, to facilitate improved access to ARV.

However, each process had distinctive characteristics that would contribute to the level of price reduction achieved. Caribbean countries negotiated with manufacturers of originator ARVs through the Accelerated Access Initiative resulting in reductions in the cost of

treatment from US\$ 10,000 to US\$ 1,100 – 1,600 per patient per year for a first line treatment of AZT/3TC + NVP or EFV (Graph 1). Although Central American countries also negotiated with brand manufacturers through the AAI and achieved the same prices as Caribbean countries, the discussions initiated with manufacturers of prequalified sources of ARV including generic manufacturers would mean that Central American countries could pay significantly less per year for the same regimens using generics (US\$ 500 for AZT/3TC + NVP, US\$ 800 for AZT/3TC + EFV (originator)).



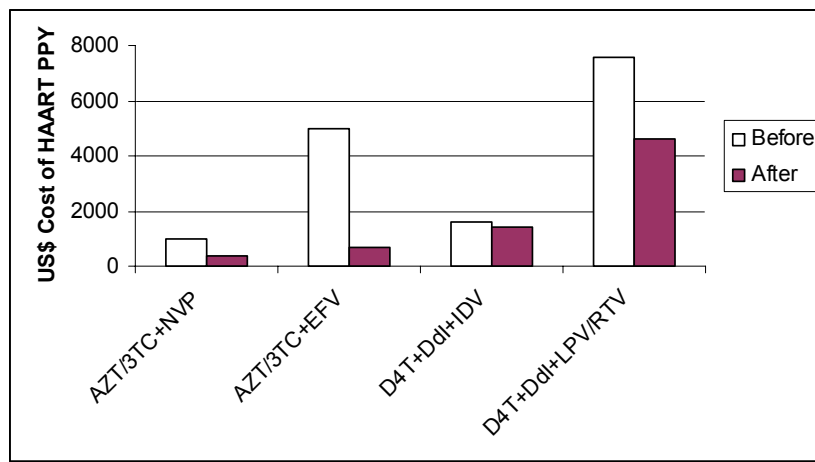
Graph 1: US\$ cost range and median cost per unit of ARV (AZT/3TC, NVP, EFV and IDV) in Caribbean countries in 2001 (01), beginning of 2002 (02) and following the CARICOM negotiation (CARICOM).

The most significant price reductions were however achieved by the 10 Latin American countries that developed the negotiation process based on price alone, defining quality criteria for the prequalification of suppliers participating in the negotiation (Graph 2). Following the negotiation, the cost of triple therapy was reduced in the order of 30 – 92%, from US\$ 1,000 to US\$ 400 per year using pre-qualified generic sources of AZT/3TC + NVP, and more significantly from a US\$ 5,000 to US\$ 700 using prequalified generic sources of AZT/3TC + EFV.

Conclusions

Sub-regional negotiations in the Americas with the participation of neighboring countries, countries with a tradition of cooperation and facing similar challenges in scaling-up the response to HIV/AIDS, have led to significant price reductions in the annual cost of HAART in recent years. Uniform sub-regional prices have been negotiated in three

sub-regions including 30 countries and inter-country cooperation has been strengthened building on the regional response to HIV/AIDS. Although significant sub-regional price reductions have been attained through the Accelerated Access Initiative, the greatest ARV price reductions have been achieved through the negotiation developed by the 10 Latin American countries based on the principle of price and quality, and not on other conditions relating to acquisition and use of ARV essential medicines. In defining the quality criteria applicable for source selection of ARV, the countries have increased the number of source options available to include prequalified ARV generics, resulting in considerable potential savings: in closing remarks at the 10-country negotiation in Lima Peru, the Ministers of Health indicated that the cost savings achieved through the sub-regional negotiation would permit the treatment of an additional 150,000 persons living with HIV/AIDS in the region.



Graph 2: Average cost (US\$) of ARV triple therapy per patient per year (PPY) in the 10 Latin American countries pre and post negotiation

The first steps have been taken to improve access to ARV in the Americas, but a great deal remains to be done in order to achieve equitable access. Countries must build the capacity of the health services to expand access to diagnostic and care services. Human resource capacity must be strengthened and capacity currently available must be used in a manner that is rational. Drug supply systems must be developed to ensure continuity in drug supply, and drug regulatory capacity must be strengthened to ensure that quality is never compromised. Political commitment must remain steadfast and additional financial resources must be mobilized and brought to bear, not only for the development of systems and services, but also to tackle

the silent problem of stigma and discrimination. Through a comprehensive approach countries can achieve universal access to lower cost HAART for those who are in need, this within the paradigm of strengthening and scaling-up the response to HIV/AIDS.

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