Scaling-up access to medicines: challenging, overcoming the obstacles

Jorge Bermudez (Presentation at the ICTSD-UNAIDS Policy Dialogue - UNCTAD XI, Sao Paulo, BRAZIL, 17 June 2004)

Initially, to take into account recent lessons learned in Brazil, we must consider the main principles of the Brazilian National Health System, which has been built over the last 15 years and include universal access to care, it is strongly based on Alma Ata Declaration and Primary Health Care, also guided by WHO guidelines. It considers Health as a citizenship right and State duty and has an adequate legal framework ensuring that right and the principles of universality, integrality, equity, decentralization and social control.

At the same time, recent Ministry of Health guidelines that are being enforced by the new Government since last year (2003) include:

- Expansion of access to health services and actions, including pharmaceutical care, ensuring quality;
- Intensification of endemic diseases control and strengthening of health surveillance actions;
- Formulation and implementation of a Human Resources policy;
- Strengthening of the democratic management of the system.

Regarding scaling-up of access to medicines, a very comprehensive framework has been settled, including the establishment of a written National Medicines Policy and the revision of the Essential Medicines List every two years; the decentralization of basic pharmaceutical care; the establishment of the new Regulatory Agency and the Generic Medicines Law; a comprehensive procurement system which includes central procurement as well as decentralized purchasing by different cathegories; IPR regulation, especially ensuring access to ARV within the National STD/AIDS programme; and economic regulation of the pharmaceutical sector. State manufacturing of generic ARV ensures sustainability of universal access to care for PLWHA.

The National School of Public Health working closely with the WHO as a Collaborating Centre for Pharmaceutical Policies, we have been involved in data collection in Latin America and the Caribbean regarding the WTO TRIPS Agreement monitoring and its implications on access to medicines. We have especially surveyed the inclusion of the TRIPS Agreement safeguards or flexibilities in the different countries national IPR legislation. In particular, addressing if the national legislations, all of them recently updated, have included compulsory licensing, parallel imports, early working option (Bolar provision) and the conditions where compulsory licenses may be granted; at the same time, taking Brazil as an example and figuring the patent claims that have been filed by country of origin, as well as the impact of patent protection on the country balance of trade, we conclude that countries are not taking full advantages of the TRIPS safeguards and they still may improve their legislations in order to achieve better public health outcomes.

The generic medicines increasing market share and the recent process of price negotiation that the Ministry of Health implemented with three pharmaceutical companies which were responsible for 63% of the expenditures for ARV for the universal access policy were also addressed in this presentation.

Finally, recent and relevant initiatives were highlighted which surely were decisive factors scaling-up access to medicines in developed countries. Among the most remarkable we may include:

- The South Cone Region (MERCOSUL, Bolivia and Chile) Joint Medicines Policy in 2000, which included main concerns with the impact of IPR in access and prices of medicines in the Region;
- The G-15 (Group of 15) Brasilia Declaration in June 2002, expressing concern with the same issue;
- India-Brazil-South Africa (IBSA) Dialogue Forum Trilateral Commission addressing the issue of IPR and stating that all the flexibilities provided by the WTO TRIPS Agreement must be included in the national regulatory frameworks, as well as no TRIPS-Plus provisions must be accepted;
- UNDP project on IPR and Development of capacity to increase access to medicines;
- Technical assistance network for national responses to HIV/AIDS in Latin America and the Caribbean;
- Several recent PAHO initiatives for discussions related to IPR and access to medicines in the Region.

Finally, consideration was made regarding the recent 57th World Health Assembly held last May 2004 and the approval of the Resolution on Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS, which included a specific mention which urges Member States to encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration. Mentioning the United Nations High Commission on Human Rights, emphasis was stressed on the fact that Health Right as a human right involves access to health services, prevention, care and therapies, thus including access to medicines.

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