



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



## **45th DIRECTING COUNCIL**

### **56th SESSION OF THE REGIONAL COMMITTEE**

*Washington, D.C., USA, 27 September-1 October 2004*

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*Provisional Agenda Item 5.5*

CD45/10 (Eng.)

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### **ACCESS TO MEDICINES**

#### **Promoting Access to Strategic Public Health Supplies**

1. Expanding access to essential medicines and other critical public health commodities is a global priority and must be viewed within the context and recognition of the importance of the right to health for all.\* The attainment of the global mandates presented through the United Nations Millennium Declaration, September 2000, and the identification of two priority public health targets (on the one hand HIV/AIDS, malaria, and other major diseases, and on the other the reduction of child mortality), will require access to essential public health supplies. In addition, Target No. 17 of the Millennium Development Goals explicitly highlights the need to “provide access to affordable essential medicines in developing countries.”
2. Between 1997 and 2003, it is estimated that the number of persons having access to essential medicines increased globally from 2.1 billion to 4 billion. Despite this significant improvement, approximately 2 billion, or one-third of the world’s population still does not have access to affordable quality medicines: only 27% of TB patients have access to Directly Observed Therapy, Short-course (DOTS) even though a six-month drug treatment can cost as little as US\$ 10, and less than 53% of persons living with HIV/AIDS in the Region of the Americas have access to antiretroviral therapy (ART), despite significant reductions in the prices of antiretrovirals during the last three years.
3. The number and variety of other medicinal products, and especially blood products, diagnostics, and vaccines being produced at the global level continues to increase. But in many developing countries within the Region, essential medicines and other public health supplies are not readily available, or if available not affordable to the

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\* WHO Statement to the UN Commission on Human Rights, Agenda Item 10, Economic, Social, and Cultural Rights, Geneva, April 1, 2003.

poorest segments of the population. Inadequate financing and financing systems result in inequitable access, and poorly developed supply systems hinder continuity in product availability. In addition, inadequate capacity in product assessment and regulation and irrational commodity use often means that access to quality products cannot be ensured.

4. Tackling the complex issue of access to public health supplies, with focus on priority diseases, is becoming ever more urgent in the Region of the Americas, and requires a new and intensified effort. The approach must address the principal dimensions and determinants of access; build on existing strategies, initiatives, and mechanisms; involve the participation of all stakeholders in the provision and use of essential public health supplies; ensure transparency in decisions and processes adopted to promote access; and ultimately strengthen the public health system, services and essential functions.

#### **Challenges for PAHO in Access to Public Health Supplies**

5. The challenges facing Member States in improving access to essential public health supplies lie principally in important areas of selection of quality products, financing and procurement, cost containment and intellectual property regulation, and supply management. The selection of essential public health supplies is often not based on rational criteria resulting in the availability and use of inappropriate commodities. Sources of commodities are often selected based on price alone, and without appropriate consideration of product quality and quality assessment of manufacturers and suppliers.

6. Price information is often not readily available to facilitate referencing in procurement, and there is insufficient information on pricing policies and methodologies being applied. Too often essential drugs are inaccessible to the poor because of high price: differential pricing policies are not necessarily equity-based.

7. Due consideration has not been afforded to the importance of supply management systems, forecasting, programming and planning in ensuring the continued availability of public health supplies.

8. There is insufficient information available to countries with regard to cost containment methods, processes and options in the implementation of provisions and safeguards provided for in intellectual property regulation. Within the framework of recent World Trade Organization meetings some countries are taking steps to facilitate the export of low cost essential medicines used in the treatment of priority diseases and the modification of laws governing intellectual property. As regional and bilateral trade agreements continue in the Americas, the level of consultation with and participation of the health sector in negotiation processes has been limited. As a consequence, public health interests may not be adequately represented. More information is required on the

impact of trade agreements on access to medicines, and on the effect of adopting provisions that are more restrictive than those presented in TRIPS.

9. Mechanisms and options for the financing of essential public health supplies in the Region vary considerably but little has been documented concerning options and best practices by resource setting. It is recognized, however, that essential public health commodities can consume as much as 25% of household expenditure in some countries in the Region. Furthermore, data from PAHO Health Accounts and National Health Accounts 2003 indicates that medicines account for on average 35% of household health expenditure in the region, with some countries reporting average household health direct expenditures as high as 50 – 60% for medicines (Table 1).

**Table 1: Percentage Distribution of Direct Household Health Expenditures in 5 Countries in the Region of the Americas**

Country	% of Household Health Expenditure (Direct)				
	Year	Consultations	Drug	Hospital Diagnostics	Other
Argentina	1996-97	47	53	...	...
Bolivia	1997	18	58	...	24
Ecuador	1995	19	54	13	14
El Salvador	2001	12	68	19	1
Panama	1997	16	34	36	14

Source; Table A.6 (III) PAHO Health Accounts and National Health Accounts, 2003.

10. Although multisource drugs are used widely in the Region, regulatory definitions vary widely between countries hindering the rapid registration among Member States. Few countries in the Region have effectively implemented generic policies with strong regulatory requirements in combination with incentives for the development of the generic markets, acceptance, and rational generic drug use, hindering access to the most cost-effective public health commodities required for the provision of primary care.

11. Processes developed and implemented to promote access to essential public health supplies in the region need to be more transparent; the lack of information concerning the regulation and benefits of generic medicines results in low levels of public acceptance; lack of transparency in prescribing and dispensing practices may mean that consumers often have to spend more from out-of-pocket expenditure to access essential public health commodities.

12. Although pooled procurement of vaccines has been effective in the Region, other initiatives for pooled procurement have had limited success to date due to factors such as political and financial commitment, harmonization of quality criteria and inadequate joint programming and planning.

### **Elements of the PAHO Response in Promoting Access to Public Health Supplies**

13. The Essential Medicines, Vaccines, and Health Technology Unit, within the Area of Technology and Health Services Delivery (THS/EV), under the Office of the Assistant Director, promotes, coordinates, and implements technical cooperation activities aimed at strengthening national and regional capacity to improve accessibility, rational use, and regulation of essential medicines, and quality laboratory/blood services. Country offices provide direct technical cooperation in this area, specific to the needs of the country and with the support of THS/EV. Within its scope of work, THS/EV coordinates technical cooperation in access to essential public health supplies used in the delivery of health services. Interarea and interinstitutional cooperation are promoted to ensure that core areas of work are coherent with the overarching objectives of the priority regional programs such as HIV/AIDS, TB, and malaria; other priority emerging noncommunicable diseases; and the development of primary health care in the Region.

14. PAHO has contributed to improving access to quality medicines in Member States through the regional program of work in medicines. Countries receive support in developing pharmaceutical policies that promote principles of equitable access, and use tools to measure the policy performance. PAHO acts as the Secretariat of the Pan American Network for Drug Regulatory Harmonization (PANDHR), a highly participative and operational association of drug regulatory authorities and other stakeholders in the Region working to harmonize standards in key areas such as Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), bioequivalence, and quality control of pharmaceuticals amongst others. Through joint programs with other partners, the rational use of drugs is promoted including greater access to scientific and patient information. Capacity in monitoring access to medicines and other supplies is being developed through the implementation of indicators. PAHO/WHO Collaborating Centers continue to work actively in pharmaceutical policies, rational drug use, commodity supply management as well as in monitoring the impact of TRIPS and other trade agreements on access to medicines. The program of work in medicines is guided by the WHO Medicines Strategy, adapted to the needs and specificities of PAHO Member States.

15. In 2000, PAHO established at the request of Member States the Regional Revolving Fund for Strategic Public Health Supplies (Strategic Fund) to support countries in the source selection and access to priority medicines used in HIV, TB, malaria, and leishmaniasis. The Fund aims to facilitate the procurement of low-cost

priority essential public health supplies and at the same time build capacity in drug supply management and procurement programming and planning. One-third of PAHO Member States have signed agreements for participation in the Strategic Fund, and even if the use of the Fund as a procurement mechanism has been limited to a few countries to date, the potential of the fund as a regional supply mechanism for priority public health commodities is recognized within the context of PAHO support to Global Fund recipient countries as well as countries participating in key global initiatives such as 3 by 5. As at the end of 2003, countries participating in the fund have used the mechanism to purchase \$14 million of essential public health supplies.

16. Within the framework of the PAHO/WHO Expanded Program for Immunization, PAHO provides support to Member States in the selection, procurement, supply, and use of vaccines through the PAHO Revolving Fund for Vaccine Procurement (EPI Revolving Fund), managed by the Unit of Immunizations (FCH/IM). The EPI Revolving Fund was established in 1979 with an initial fund capital of \$1 million for the procurement of 5 vaccines. In recent years the product profile has expanded to 14 vaccines, and 35 countries in the Americas are using the Fund to purchase these products. Fund capital is reported at \$29 million with orders exceeding \$145 million administered by the fund on an annual basis. Further support is provided to Member States to strengthen capacity in the quality assessment of vaccines in use throughout the Region.

17. As the Region moves towards the 100% screening of blood transfusions for HIV, HCV, HVB, and other transfused infections, technical cooperation is provided to countries in the selection, supply, and use of diagnostics and other medicinal products derived from blood directly through the regional program and/or through collaborating and specialized sub-regional centers. The availability and use of diagnostics is improved through the work program in developing clinical and public health laboratory networks and the development of diagnostic procedures for priority diseases.

### **Proposed Principal Lines of Action for a PAHO Work Program in Essential Public Health Supplies, Access, and the Strategic Fund**

18. Based on the core competencies of PAHO, focusing on the countries as primary recipients and partners in technical cooperation and recognizing the multiplicity and capacity of actors and stakeholders in the field, a focused approach is proposed to improve access, and in particular, the availability and affordability of quality public health supplies in the Region. The approach aims to focus on determinants of access and address key issues in the selection and supply of public health commodities in priority diseases, building on the comparative advantage that PAHO has in key areas, and identifying networks and partners to share experience and build capacity in other areas. The strategy will complement work currently being executed in pharmaceutical policy and by PANDHR, will be integrated with the program of work in key initiatives such as

the 3 by 5, and with other non-communicable disease programs such as diabetes, hypertension, chronic renal disease and others.

19. Four principal strategic lines of action are proposed:

- Promoting coherent generic drug policy as a means to increase the availability and use of quality essential medicines. The strategy proposes to build on the principal advantage presented by generics, namely as cost-effective medicines in the delivery of health care, through the exchange of experience in generic policy in the region, the development of the regulatory framework and approaches to promote increased availability and the rational use of generic drugs. A more profound discussion is required on what we understand by the term 'generic', with focus on quality criteria, options and practices in generic medicines regulation, and the impact of the regulatory system on public acceptance. The assessment and promotion of incentives to increase the availability and affordability of generics, as well as incentives aimed at the prescriber and user to improve acceptance, will provide countries in the region with options in the development and implementation of policy.
- Developing cost containment strategies for Essential Public Health Supplies, with focus on two areas: pricing and intellectual property. In the area of pricing, the strategy proposes the development and implementation of approaches for measurement, dissemination of pricing information, assessment of the impact and use of pricing information and transparency, the role of competition, pricing methodologies, as well as options and practices in price control. In the area of intellectual property, the work of the Commission on Intellectual Property Rights, Innovation and Public Health, established by WHO in February 2004 will be drawn upon. An evidence based approach is to be developed, assessing the regulation of intellectual property in countries of the region against the requirements and safeguards provided for in TRIPS, and reviewing the impact on access to medicines in these countries. Technical and policy support will be provided, on request from a Member State, in order to take full advantage of the flexibilities provided by TRIPS and the 30 August 2003 decision from the General Council of the World Trade Organization in relation to public health problems. Information exchange will be facilitated to assess the impact of other regional and bilateral trade agreements in the Americas on access to medicines.
- Strengthening public health commodity supply systems to ensure continuity and availability. A review of drug supply management core components, from selection through procurement, stock forecasting and facilities management to distribution and use, will permit the assessment of practices and the identification of options by resource setting and health system structure. Country support in

elements of supply management will strengthen capacity at the national level, to ensure continuity in product availability.

- Strengthening regional pooled procurement mechanisms, such as the PAHO Strategic Fund, established in 2000, in the supply of low-cost quality essential public health supplies. The development of the fund will strengthen capacity in procurement, programming and planning at the country level, lead to economies of scale through the consolidation of requirements, and promote continuity in supply through the development of the cyclical procurement system. The operational framework for the Fund will be reviewed including the development of a country advisory mechanism for the Fund, and a strategy for the generation of Fund capital developed.

#### **Action by the Directing Council**

20. The Directing Council is invited to consider the report and the annexed resolution recommended by the Executive Committee.

Annex



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



## 134th SESSION OF THE EXECUTIVE COMMITTEE

*Washington, D.C., USA, 21-25 June 2004*

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CD45/10 (Eng.)  
Annex

### ***RESOLUTION***

#### ***CE134.R6***

#### **ACCESS TO MEDICINES**

#### ***THE 134th SESSION OF THE EXECUTIVE COMMITTEE,***

Having considered the report of the Director on Access to Medicines (Document CE134/12),

#### ***RESOLVES:***

To recommend to the Directing Council the adoption of a resolution along the following lines:

#### ***THE 45th DIRECTING COUNCIL,***

Having considered the report of the Director on Access to Medicines (Document CD45/10);

Bearing in mind that access to medicines and other critical public health supplies is a global priority, mandated through the United Nations Millennium Declaration;

Taking into account the insufficient and inequitable access to essential medicines and other public health supplies that exist in countries of the Americas, not only for products required in the treatment of HIV/AIDS, TB, and malaria, but also products used in the prevention and treatment of noncommunicable diseases, such as diabetes, hypertension, cancer, renal insufficiency, and other diseases of public health significance;



Considering the challenges that Member States face in addressing the problem, in particular, in the selection of quality products, financing, procurement, cost containment, intellectual property regulation, and supply management; and

Acknowledging the achievements of countries in the Americas in developing medicines policy based on principles of safety, quality, and efficacy, and in collaborating to develop regulatory capacity in the Region through fora, such as the Pan American Network for Drug Regulatory Harmonization,

***RESOLVES:***

1. To urge Member States to:
  - (a) assign priority to the issue of access to medicines and essential public health supplies, addressing the determinants of access at the national level with special focus on poor and marginalized populations;
  - (b) develop generic drug policies as a means to increase the availability and affordability of essential medicines, ensuring product quality and safety through effective regulation and promoting rational use through incentives aimed at both providers and users;
  - (c) continue to implement a broad range of cost containment strategies for essential public health supplies to maximize efficiency and resource utilization, and to monitor and evaluate the impact of such strategies on price and access;
  - (d) implement in the Region of the Americas Resolution WHA57.14 of the Fifty-seventh World Health Assembly, specifically to adapt national legislation in order to maximize the flexibilities contained in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and to encourage that bilateral trade agreements take into account the Doha Ministerial Declaration on the TRIPS Agreement and Public Health;
  - (e) acknowledge the importance of supply management in ensuring continuity in access to medicines and essential public health supplies, and to strengthen accordingly pharmaceutical supply management systems.
2. To urge the Director to:
  - (a) support the development of networks and partnerships with the active participation of key stakeholders to implement a program of work promoting the development of generic drug policies in the Region, the development and

- monitoring of cost containment strategies in accordance with applicable international laws and agreements and the strengthening of supply management capacity;
- (b) continue to strengthen the Regional Revolving Fund for Strategic Public Health Supplies as a procurement mechanism in support of the technical program of work in promoting access to medicines in the Region.

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