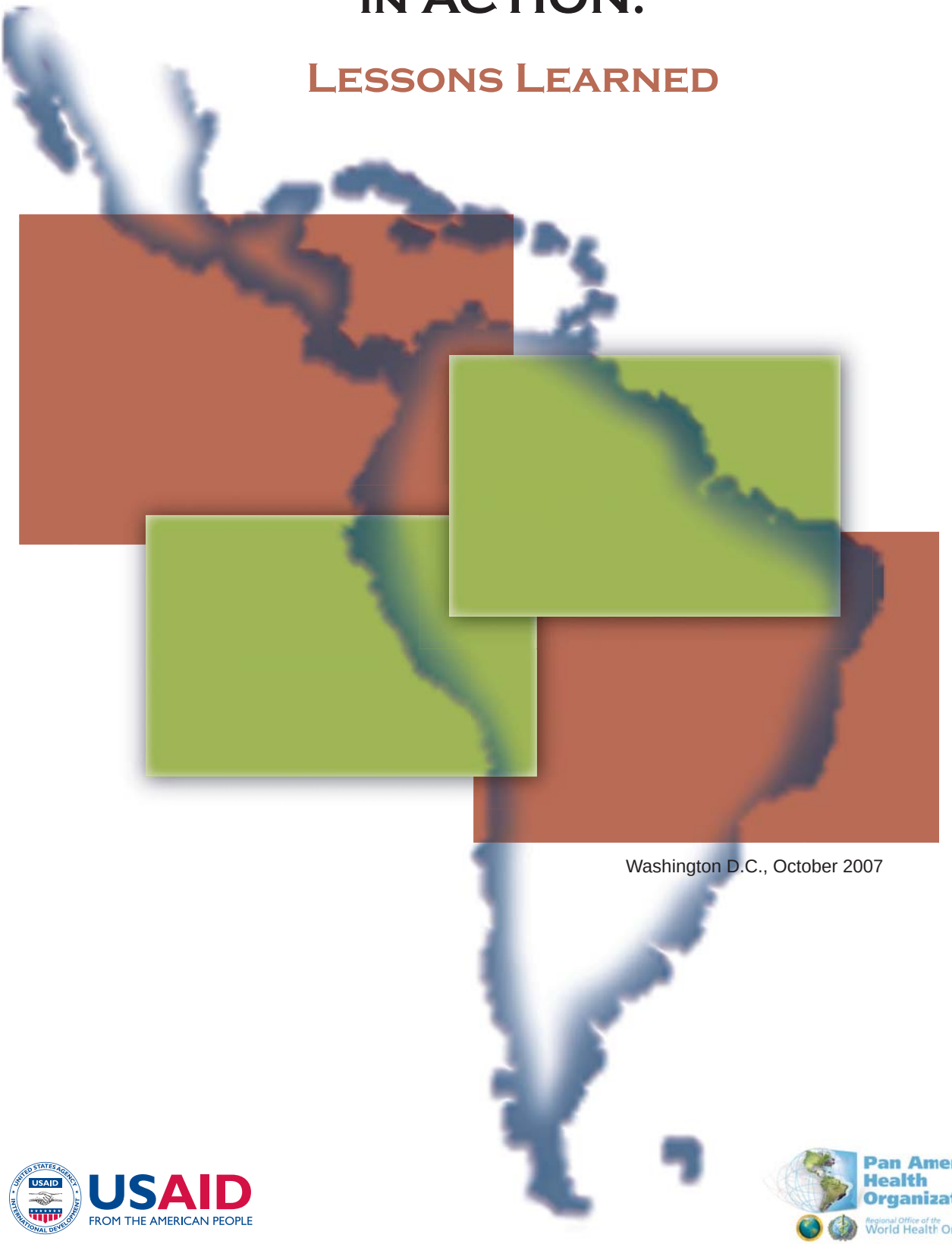
THE STEERING ROLE OF THE NATIONAL HEALTH AUTHORITY IN ACTION:

Lessons Learned



Washington D.C., October 2007

USAID
FROM THE AMERICAN PEOPLE

Pan American Health Organization
Regional Office of the World Health Organization

ISBN 978 92 75128466

Washington DC, October, 2007

This publication was produced by the Health Policies and Systems Unit, Health Systems Strengthening Area (HSS/HP) of the Pan American Health Organization/World Health Organization (PAHO/WHO). This publication was made possible through support provided by the Office of Regional Sustainable Development, Bureau for Latin America and the Caribbean, U.S. Agency for International Development (USAID), under the terms of Grant No. LAC-G-00-04-00002-00. The opinions expressed in this publication are those of the author (s) and do not necessarily reflect the views of the U.S. Agency for International Development.

The electronic version of this document is available at the Web site for Health Systems Strengthening in Latin America and the Caribbean and can be accessed at *www.lachealthsys.org.* For any questions or inquiries regarding this document, please contact *info@lachealthsys.org*.

The Steering Role of the National Health Authority in Action:

Lessons Learned

Washington D.C., October, 2007

Health Policies and Systems Unit (HP)
Area of Health Systems Strengthening (HSS)
Pan American Health Organization / World Health Organization (PAHO / WHO)

TABLE OF CONTENT

1. Introduction

Since 1997, the Pan American Health Organization/World Health Organization (PAHO/WHO), in coordination with the United States Agency for International Development (USAID), have geared their efforts toward strengthening regional Health Sector Reform (HSR) processes, through the Latin American and Caribbean Regional Health Sector Reform (LACHSR) Initiative.

In 2004, PAHO/WHO and USAID signed a new $20 million agreement to work jointly for a three year period on specific objectives that include four components:

Component 1: Improve *Maternal and Child Health*;

Component 2: Lower the incidence of *Tuberculosis and Emerging Diseases*;

Component 3: Reorient *Health Sector Reform* processes in the countries of the Region toward changes centered on achieving improved levels of health; *strengthen the steering role of the national health authority;* develop the institutional capacity to effectively implement Essential Public Health Functions; and improve health system performance through the development of cross-cutting issues;

Component 4: Strengthening *Health Information Systems.*

The present document is the result of a study conducted within the framework of Component 3: *Health Sector Reform* aimed at strengthening the steering role of the national health authority (NHA).

The main objective of this research was to identify the essential criteria on conduct/lead and regulation/enforcement required for improving the performance and strengthening the NHA's steering role. To this end, the research focused on identifying, selecting, and analyzing experiences that are illustrative and add to the knowledge base of the countries in the Region of the Americas. Identifying essential criteria is a key prerequisite to preparing strategies that lead to institutional strengthening for the effective exercise of the steering role.

2. Rationale

2.1. Phase One: Justification for "Best Practices "

The initial research objective was to present best practices for the effective performance of the *conduct/lead and regulation* dimensions of the steering role in the countries of the Region. As a first step in achieving this objective, it was determined that an exhaustive review of the responsibilities and functions of the national health authority needed to be completed, specifically in the areas of *conduct/lead and regulation*, in order to identify best practices.

Under scrutiny, however, it became evident that the term “best practices” could not be applied to the steering role, since by definition the term sets absolute standards and establishes one given model as the best possible practice, an example to be followed by others. This automatically ruled out the "best practices” approach because applying standardized prescriptions to the steering role in the Region of the Americas is impossible, given the variety of experiences and the different context of each country.

2.2. Phase Two: Justification for “Good Practices ”

Since the term “best practices”" did not reflect the purpose of the document, the concept “good practices” was deemed more adequate. Some definitions of “good practices” adopted by public organizations in the Region include:

> ”A *good practice* is a superior method or innovative practice that contributes to improving the performance of a given process” (official public management glossary in Chile).
>
> “*Good practices* are actions or initiatives with tangible and measurable impact that improve the quality of life of citizens as well as the [health sector] in a sustainable way and that can serve as models that other countries or regions can become familiar with and adapt to their own situation.” (Ministry of Housing; Madrid, Spain)
>
> “*Good practices* may be considered to be the experiences in which processes and behaviors have obtained positive results. ‘Good practices’ are comparable to ‘best practices,’ a term widely used in the United States, which refers to something that has obtained the expected outcomes. In this case, it is regarded as the best possible practice. In other places a ‘good practice’ is defined in a more general way, and is considered to be an approach that is frequently innovative, has been proven and evaluated, and tends to be successful in other contexts. A good practice is an innovation that enables improvement and therefore is or can be a model or standard for a given system. This definition establishes a similarity between a ‘good practice’ and innovation, and in many programs both concepts are similar.” (UNESCO)

Under this approach, the status of the performance of the steering role in the countries of the Region was investigated, with a view toward identifying “good practices” that could serve as examples to other countries. Using this strategy resulted in partial success. Although there are innovative experiences that have resulted in important achievements, many of the experiences compiled on existing efforts that seek to strengthen the steering role cannot necessarily be classified as “good practices.”

2.3. Phase Three: Justification for “Lessons Learned ”

Finally, the concept of “*lessons learned*” was adopted, since it not only allows for the compilation of “*good practices*” and extraordinary efforts — as in the case study of Brazil — but also introduces a degree of flexibility that permits the identification of those strategies that should be repeated in the future.

In other words, assembling and organizing the information and analyzing how the health authorities in the countries of the Region exercise the steering role allowed us

to identify a set of "lessons" resulting from positive experiences, or lack thereof. These are presented together with three case studies that analyze experiences that affect one or more of the elements of the *conduct/lead and regulation* functions.

The present document is divided into three sections: the first section identifies the criteria on conduct/lead and regulation used to analyze experiences in the Region; the second presents three case studies in conduct/lead and regulation; and the third offers a summary of the lessons learned regarding the performance of the conduct/lead and regulations dimensions of the steering role by the health authorities of several countries of the Region.

3. Methodology

3.1. Stages of the Research

The identification of "lessons learned" by the health authorities in the Region when exercising the steering role in the health sector was done in five stages:

i. Definition of the operational criteria in the areas of *conduct/lead and regulation* with the goal of using them as indicators of competence in the performance of the steering role.

ii. Review of the current status of the steering role in the countries of the *Region*, using as a guide the indicators identified.

iii. Identification of country experiences as an example of what constitutes the *steering role in action* in the Region.

iv. Selection of the countries that exhibited the most notable positive experiences and innovative strategies.

v. Preparation of the present document with the lessons learned, a general reference overview, and three case studies.

3.2. Scope of the Study

It is important to clarify that the experiences listed in the present document are not exhaustive, but instead serve as a starting point in documenting some recent trends, approaches, and strategies adopted by the health authorities of the countries of the Americas to strengthen their ability to *lead and regulate* the health sector.

The study is based on an extensive review of the literature and a series of interviews with key stakeholders in the countries, and uses available secondary information. The study is not an attempt to document the status of the steering role in all countries of the Region, nor to present a stagnant view of the steering role of the national health authorities in the countries under discussion. Furthermore, it is important to emphasize that the absence of some countries from the document does not mean that they do not have interesting experiences, but probably that the relevant information is not as accessible as in other countries.

In short, based on the information gathered, the document highlights principal illustrative aspects in specific dimensions of the steering role that deserve attention due to the notable effort that the countries' health authorities have demonstrated in implementing them.

4. Conduct/Lead and Regulation Dimensions

4.1 The Steering Role in Health

The Pan American Health Organization has promoted profound debate and exchange about the conceptualization of the steering role in health.[1] It is now accepted that the steering role constitutes the exercise of public health policy responsibilities and competencies, which cannot be delegated, within the framework of relations between government and society in a modern State. It is the government's responsibility, exercised by the National Health Authority.[2]

The steering role refers to the implementation of decisions and public actions to satisfy and ensure, according the adopted national development model, the health needs and legitimate aspirations of social actors. Consequently, the process of strengthening the steering role must be guided ultimately by the goal of reducing health inequalities within the framework of integrated and sustainable development. Moreover, it must eliminate arbitrary inequalities with regard to access both to personal and non-personal health services and the financial burden assumed in accessing the services.[3]

Acknowledging the fact that different taxonomies may be adopted regarding the steering role, PAHO/WHO proposed grouping the steering role dimensions in six broad areas of institutional responsibility and competencies:

- **Conduct/Lead** refers to the capacity to guide the general health policy and the actions of the health system in each country, and to preserve and improve the population's health.

- **Regulation** and **enforcement** of the health system encompasses the design and enforcement of the health regulatory framework that protects and promotes health.

- **Execution** of **essential public health functions** (EPHFs) refers to the implementation of the indispensable set of actions, under the sole responsibility of the state, which are fundamental for achieving the goal of public health which is to improve, promote, protect, and restore the health of the population through collective action.

[1] PAHO/WHO, "Steering Role of the Ministries of Health in the process of Health Sector Reform ," *XL Meeting of the Directing Council of the Pan American Health Organization*. Document CD40/13 (Washington, D.C., September 1997).

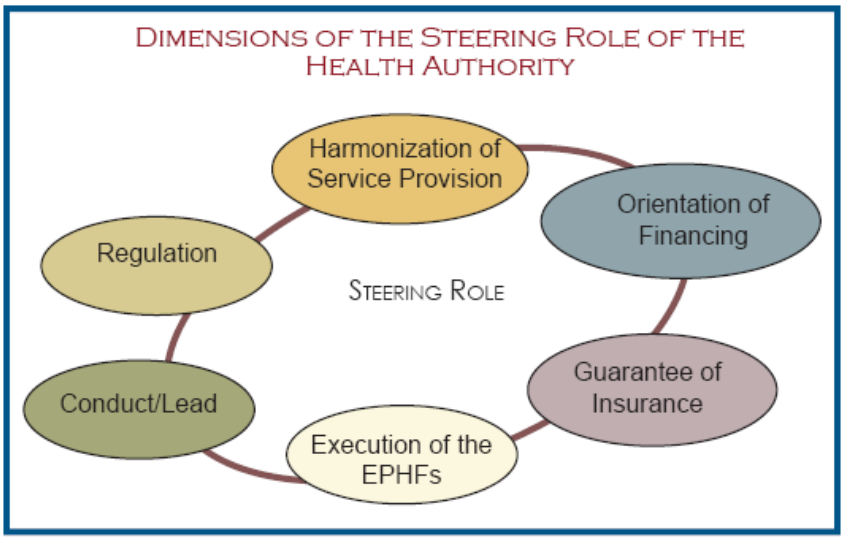
[2] PAHO/WHO, "Final Report," Subregional Meeting on Sectoral Steering Role and Leadership of the Ministries of Health (Guatemala, April 23-24, 1998); Daniel López-Acuna, "The Nature of Health Reform in the Americas and its Significance for PAHO's Technical Cooperation," *Background Paper for the Annual PAHO Managers Retreat* (Washington DC, October 23-24, 2000); PAHO/WHO, "Steering Role of Ministers of Health in the process of Health Sector Reform," *PAHO Annual Managers Meeting* (Washington DC, 23-27 October 2000); PAHO/WHO, "Final Report", Meeting of Experts: Development of the Institutional Capability of the Health Authority to Exercise the Sectoral Steering Role, (Washington DC, June 18-20, 2001); PAHO/WHO, "Final Report," *Meeting of Experts in Steering Role of the Health Sector in Processes of Reform* (Washington DC, June 14-15, 2004).

[3] PAHO/WHO, *Public Health in the Americas: New Concepts, Performance Analysis and Bases for Action*. Scientific and Technical Publication No. 589 (Washington DC: PAHO/WHO, 2000).

- **Orientation of financing** includes the competencies to guarantee, monitor and steer the complementarity of resources from different sources in order to ensure equitable access to health services.

- **Guarantee of insurance** which targets its efforts at guaranteeing access to a health service package for the entire population, or specific plans for special population groups.

- **Harmonization of service provision** is the ability to coordinate various providers and users' groups in order to extend health care coverage equitably and efficiently.



For methodological purposes, the present document will address exclusively the conduct/lead and regulation dimensions, which are considered the two key elements of the steering role.

4.2 Sectoral Leadership

Sectoral leadership or management includes the capacity to guide the sector's institutions and to mobilize stakeholders, organizations, and social groups, in support of the national health policy, with the goal of contributing to greater equity in health and social well-being. Health management is essentially a political process. It is a complex process that ultimately seeks to develop a political, technically consistent, socially ethical, and strategically viable proposal for managing the health sector.[4]

The adequate exercise of *sectoral leadership/management* entails a series of essential steps, which are:

1. Perform an analysis of the health status;
2. Define health priorities and objectives;
3. Formulate, disseminate, monitor, and evaluate health policies, plans, and strategies;

[4] PAHO/WHO, "Methodological Guidelines-Sectoral Analysis in Health: A Tool for Policy-making," Series LACRSS Special Edition # 9, Third Version (Washington, DC.: PAHO/WHO, 2004).

4. Encourage leadership, consensus-building, and mobilization of stakeholders and resources;
5. Foment health promotion, participation, and social control in health;
6. Harmonize international technical cooperation;
7. Ensure political and technical participation in national and sub-regional organizations; and
8. Conduct performance evaluations of the health system, including the measurement of goals and resources used.

4.3 Sectoral Regulation and Enforcement

Sectoral regulation and enforcement encompasses the design of a health regulatory framework that protects and promotes health and the enforcement of such framework. PAHO defines "regulation and enforcement" as the supervision of compliance with health laws and/or regulations aimed at controlling the health risks arising from the environment; the accreditation and quality control of medical services; certifying the quality of new drugs and biological substances for medical use, equipment, and other technologies; and any other activity that involves creating and complying with laws and regulations aimed at protecting public health, as well as promoting healthy environments.[5]

Regulation and enforcement are necessary to guarantee the state a role in organizing the delivery and distribution of health resources, goods, services, and opportunities based on the principles of solidarity and equity. Regulation is a complex process that includes the design and establishment of standards, as well as adopting measures to ensure their effective application. Thus, it is possible to distinguish between the health-related regulatory role, which includes designing and applying the respective standards, and the task of overseeing and controlling these standards.

In general, for a Ministry or Secretariat of Health to exercise its regulatory function with precision, it must have political and public representation, financial stability, technical authority, and must carry out its tasks transparently, subject to public scrutiny.

5. Case Studies

The definition of operational criteria for the conduct/lead and regulation dimensions began with the conceptual framework presented here, breaking down the components listed above into more specific work areas (see Annex I). Once established, these operational criteria became the guide for analyzing and evaluating the steering role in action in the selected countries.

5.1 The Steering Role: Key Component of Health Sector Reform in Costa Rica

Costa Rica is a country that has historically placed high priority on public health development. State policy and a historical commitment to universal health coverage combined with sustained investment in the sector and the delivery of basic social services throughout the 1980s and 1990s has made Costa Rica one of the countries with the best

[5] Directing Council of the Pan American Health Organization, 42. Dec. 15, 2000. More information on the theoretical framework of the steering role may be found at: http://www.lachealthsys.org.

health indicators in the Region, comparable, in many aspects, to that of industrialized countries.[6]

The purpose of the case study presented below is to showcase the achievements and the outstanding challenges for consolidating the steering role of the Ministry of Health. First, the steering role is analyzed within the context of health sector reform. Next, a summary of how the Ministry of Health views its steering role and how the steering functions have evolved in the country is presented. Finally, achievements and remaining challenges are reviewed.

5.1.1. Context of Health Sector Reform

The economic crisis that affected the Region in the previous decades also had a negative effect on Costa Rica. These included problems related to the fiscal deficit, foreign and internal debt, excessive centralization, inefficiency, and bureaucratic growth of the state apparatus, which reduced government contributions to health sector financing.[7] This, in turn, impacted the quality of health services, their coverage, and the level of investment in the sector.

Within this context and due to the country's commitment to public health, the government decided to focus its health sector reform on strengthening the public health system,[8] even though the agenda of existing sector reforms in Latin America at that time reflected a strong trend toward privatization.

A national debate began in the 1990s on possible options to remedy the situation, which culminated in political decisions that affected the Ministry of Health and the Costa Rican Social Security Fund (CCSS). In 1994 important structural reforms in the organization, financing, and delivery of health services began to be implemented. These reforms always maintained the principles and basic values of the Costa Rican society vis-à-vis universal coverage and public financing of the health sector.

As a result, the *Project to Strengthen the Steering Role and the Ministry of Health* was formulated, financed by a loan from the Inter-American Development Bank and formalized under Law 7374 of January 19, 1994. The project's objective focused on supporting the Ministry of Health in assuming an effective steering role in health by transferring direct public health care activities to the CCSS. The goal was to separate the *delivery and financing functions* assumed by the CCSS from the *leadership and regulatory functions* to be implemented by the Ministry of Health, thereby eliminating duplications, particularly in human resources and infrastructure.[9]

At the same time, negotiations were undertaken with the World Bank, which resulted in a loan to support institution strengthening of the CCSS, the development of a new financial resource allocation system, and revision of the health care model.

Redefining the resulting institutional roles within the health system, a product of the reform, required greater ability on the part of the Ministry of Health to exercise its steering role. This included managing the sector, regulating health goods and services, measuring

[6] Ministry of Health of Costa Rica. *Análisis Sectorial de Salud*. Costa Rica, 2002.

[7] Idem.

[8] Mary A. Clark, "Health Sector Reform in Costa Rica: Reinforcing a Public System," Prepared for the *Woodrow Wilson Center Workshops on Education and Health Reform* (Washington, DC, 2002).

[9] World Bank, *Costa Rica-Second Health Sector Strengthening and Modernization Project* (Washington, D.C.: World Bank, 2001).

the performance of essential public health functions, changing health care financing, monitoring insurance, and harmonizing the delivery of services.

5.1.2. The Steering Role within the Context of Health Sector Reform

In 1992, the project to strengthen the steering role and the Ministry of Health established that: "The Ministry of Health must assume the steering role in health, and the CCSS must assume the provision of comprehensive public health services."[10] (See Table 1: Structure of the Health Sector).

Table 1: Structure of the Costa Rican Health Sector

1	The **Ministry of Health** is the steering entity, responsible for setting national policy, regulation, planning, control, and coordination of the overall health strategies in both the public and private sectors.
2	The **Costa Rican Social Security Fund** is the institution that administers health insurance and pensions, in addition to providing health services aimed at prevention, promotion, treatment, rehabilitation, financial protection, and social services for the Costa Rican population.
3	The **National Insurance Institute** is responsible for preventing occupational and vehicular hazards and providing the injured with comprehensive hospital medical services and rehabilitation.
4	The **Costa Rican Institute of Water Supply and Sewerage Systems** is the institution in charge of administering and resolving problems with the potable water supply for household, industries, or other uses, and providing solutions to wastewater and rainwater in the country.
5	The public and private **universities** (in the health area) as teaching institutions have the responsibility of educating and training professionals and technical personnel in the various health disciplines and developing research projects to strengthen and improve health.
6	**Private medical services**, cooperatives, and self-managed institutions provide health services to the population through promotion, prevention, treatment, and rehabilitation activities.
7	The **community** participates in health services through organized groups that determine needs and priorities, direction and control of resources, and manage self-care.

Source: Ministry of Health of Costa Rica, 1992. The Regulations of the National System of Health, Executive Decree 19275-S, establishes the organization of the health sector.

Historically, health care in Costa Rica was divided into two spheres of activity. The first sphere focused on the treatment of diseases and rehabilitation, for which the CCSS was basically responsible. The second included health promotion and disease prevention and was under the responsibility of the Ministry of Health, which offered primary health care services mainly through its network of health posts and centers. These included the primary health care program, the expanded immunization program, the cancer program,

[10] Inter-American Development Bank (IDB). *Program for improvement of health services. Proposal for Loan Number(s) of project*: 711/OC-CR;712/OC-CR;CR0120. (Washington, DC.: Inter-American Development Bank, November 1992).

the tuberculosis program, the public health dermatology (leprosy) program, the public health dentistry program, and the program for control of sexually transmitted diseases.

The reform project emerged in response to a fragmented health care system, the absence of a comprehensive view of the process, increasing health care costs, inefficient administration of resources and growing consumer dissatisfaction.[11] Its fundamental purpose was to correct and improve the operating capacity of health sector institutions and to introduce radical changes to the health services delivery model and to the financing, organization, and operation of the national health system.

With the health sector reform process, the country began to consider changes in the following aspects:[12]

a) ***The Steering Role of the Ministry of Health***. Related to the development, strengthening and modernization of policies, laws, plans, and projects, as well as to mobilizing the stakeholders involved in the social production of health. In order to focus its work on the steering role, the Ministry of Health would transfer its operational functions to the CCSS, which would be responsible for health care and promotion.

b) ***Administrative and Financial Separation of the Pension and Health Systems.*** This separation of both systems was already operating in the country, but measures to differentiate their administration still needed to be adopted. This was to be achieved through the effective implementation of budgetary, legal and administrative standards and practices.

c) ***Separation of Functions related to Financing, Resource Allocation, and Health Services Delivery.*** In this regard, *Management Commitments* were introduced as a result of the reform, in which a separation was established between the service provider (work unit, health center, or hospital) and the buyer of the services (the managerial unit at the central level).

d) ***Operational Deconcentration of Clinics and Hospitals***, in order to provide clinics and hospitals with greater autonomy in managing the budget, procurement, and human resources. Deconcentration was also accompanied by the establishment of health boards, which became auxiliary entities to improve health services, administrative and financial performance, as well as to promote citizen participation. All of this was detailed in Law 7852, which is known as, "Deconcentration of Hospitals and Clinics of the Costa Rican Social Security Fund," of November 30, 1998."

In 1995, the Ministry of Health transferred responsibility for direct public health care to the CCSS, thus taking responsibility for the steering role of the health sector. This transfer allowed the Ministry of Health to concentrate its resources on the tasks of "directing, conducting, monitoring, regulating, and researching health systems development and the health care model," which are all strategic functions of the steering role.

Within this framework, all programs involving direct care to the public, including clinical support services (laboratory, pharmacy, and X-rays), in addition to prenatal and postnatal

[11] Ministry of Health of Costa Rica, op. cit., p. 8.
[12] Edwin Acuña Ulate and C. Fuentes Bolaños, "Salud y desarrollo", *Revistas de Ciencias Administrativas y Financieras de la Seguridad Social* Vol.11, No.1, 2003.

care, family planning, growth and development, and other responsibilities were transferred to the CCSS.[13]

The transfer of services also involved the reassignment of nearly 1600 staff members to the social security institute, whose increased wages meant a cost of more than US$ 36 million for the country. The relocation of human and physical resources, accompanied by an increased allocation of funds for primary care—19% of the budget in 1997 to 22% in 2002—was essential to the successful implementation of the new model,[14] a strategy developed by the CCSS through the organization of health areas and Integrated Health Care Teams (EBAIS).

At the same time, the Ministry of Health focused on performing its strategic role as the sector's steering entity as well as on designing and implementing an organizational restructuring that made exercising these functions possible. The Ministry's strategic functions were defined as: (i) health planning and surveillance; (ii) the definition of policies and inter-institutional coordination; (iii) enforcing compliance with policies and the quality of services; (iv) health promotion; and (v) the protection of public health. Based on these strategic functions, the Ministry's operational functions, organizational structure, financing system, and budgetary structure were carefully designed.

Finally, the Ministry of Health submitted its restructuring proposal to the Ministry of Planning (MIDEPLAN) for approval, which included (i) the institution's functional, structural and organizational profile; (ii) the definition of its mission and vision of its steering role; (iii) the creation of new offices for the performance of the steering functions; and (iv) the preparation of operating manuals for the new post profiles.

5.1.3. Development of the Conceptual Framework of the Steering Role of the Ministry of Health

In light of the challenge of strengthening its steering role, the first step taken by the Ministry of Health was to develop the conceptual framework that defined its steering functions. As mentioned previously, the IDB-financed project on strengthening the steering role and the Ministry of Health focused on this task, with the technical support of PAHO/WHO. Between 1994 and 1995 interdisciplinary technical teams were organized to define the theoretical foundations of the steering role culminating in the development of a roadmap for change that would ultimately lead to a restructuring of the Ministry of Health. This restructuring would allow the ministry to fulfill its new leadership, normative and regulatory responsibilities.[15]

Starting in 1998, with the new organizational structure (See Table 2), the Ministry of Health redefined its work processes, trained its staff members to perform the new functions, and began to develop methodologies, procedures and technical, legal, and administrative mechanisms to meet the challenges posed by the new leadership and management roles in the social production of health.

[13] Through its political and social importance, the Ministry of Health to date maintains the priority programs of food and nutrition, environmental health, and exercises the steering role in these fields. Ministry of Health of Costa Rica. 2002.

[14] With the US$36 million, only US$5.8 was covered by the World Bank Loan for health system reform. The CCSS invested more than $30 million of its own funds to implement the new care model. Ref: World Bank, *Implementation Completion Report on a Loan in the amount of US$22 million to the Republic of Costa Rica for a Health Sector Reform Project.* (Washington, D.C.: World Bank, May 2003).

[15] Ministry of Health of Costa Rica, op. cit.., p. 8.

Table 2: Structure of the Costa Rican Ministry of Health

1	Policy level made up of the Offices of the Minister, Vice Minister, and Chief Administrative Officer, to which Legal Counsel, Internal Auditing, and the Departments of Press, Public Image and Public Relations are linked.
2	Administrative technical level consisting of the General Health Bureau and including the following Offices: Health Surveillance, Health Development, Health Services, Registry and Control, Environmental Protection, Centers for Child Nutrition and Development, Administrative and Information Systems.
3	Deconcentrated level made up of nine Regional Bureaus and 81 Health Steering Areas.
4	Agencies attached: Institute of Alcoholism and Drug-dependency (IAFA) and the Costa Rican Institute for Research and Teaching on Nutrition and Health (INCIENSA).
5	Councils for Sectoral coordination.

Source: Ministry of Health of Costa Rica. *Sectoral Analysis of Health of Costa Rica*, 2002.

A new steering role for the Ministry of Health was thus established, which involved "ensuring the health of the population, establishing conditions that are true to the principles of equity, universality, and solidarity through the exercise of the steering role vis-à-vis individuals and health-related institutions, and executing priority programs, in order to achieve good quality of life for the people and develop the country."[16] Under that mandate, it was determined that the Ministry of Health's *objective* would be to exercise the steering role with regard to the stakeholders involved in the social production of health, promoting their active participation, and guiding their actions toward ongoing development and improvement of the population's health. *Similarly, the steering role was defined as the political capacity to guide and lead the social production of health.*[17]

Similarly, the Ministry of Health established as its **mission** to exercise the steering role through planning and research, health promotion and surveillance, regulation, establishing standards to guide development, and constant improvement in the population's health, through active participation by the various stakeholders.[18]

The definition of the steering functions resulting from the conceptual development processes were modified over time through implementation of actions and by refining and clarifying the elements that comprise it.

5.1.3.1. Framework for Action for the Steering Role

The Ministry of Health determined that the scope of action of the steering role would comprise *strategic functions* and the *sphere of activity of the steering role* as presented below.

- ***Strategic Functions***

- ***Leadership and Management***: This is the most important function of the Ministry of Health. It is a systemic process focused on politically steering and

[16] Ministry of Health. *Marco Conceptual de la Rectoría en Salud*. Working Paper (San José, Costa Rica, 2002).

[17] Idem.

[18] MIDEPLAN, *Proposal to Restructure the Ministry of Health* (San José, Costa Rica, 1998).

operationally and strategically guiding the social production of health. Policy making is the principal product of the leadership function, while management guides the definition and completion of goals related to compliance with the policies.

ii ***Health Surveillance***: This is an ongoing process of identifying, measuring, analyzing, and monitoring the strengths and weaknesses of the health development process.

iii ***Regulation of Health Development*****:** This is the continuous process of designing and implementing mandatory health measures (laws, decrees, regulations, standards, procedures, provisions, resolutions, etc.) that provide guidelines to measure the technical quality and operating capacity of the processes related to the social production of health. Regulation involves constant monitoring, i.e., ensuring that the various stakeholders comply with the health measures that legally govern the processes of social production of health.

iv ***Research and Technological Development*****:** The process of leading, managing, regulating, and monitoring scientific research and technological development in response to specific needs, problems, knowledge gaps, and national priorities in the field of health.[19]

- ***Sphere of Activity of the Steering Role***

It was established that the Ministry of Health would exercise the steering role with regard to individuals and health-related institutions. This includes the following public, private and quasi-public institutions and nongovernmental organizations (NGOs):

- Costa Rican Social Security Fund
- National Insurance Institute
- Costa Rican Institute of Water Supply Systems and Sewerage Systems
- Public and private universities
- Private or cooperative health services
- Municipalities
- Community organizations
- Professional associations
- Other ministries
- Nongovernmental organizations
- Other autonomous and public institutions
- Private entities
- Auxiliary institutions financed wholly or partially with public funds.[20]

Once the strategic functions and sphere of activity had been defined, thus establishing the steering role framework for action, the **strategic objectives** of the Ministry of Health were then developed (See Table 3).

[19] Ministry of Health of Costa Rica, op. cit., p. 8.

[20] MIDEPLAN, op. cit. p. 12.

Table 3: Strategic Objectives of the Ministry of Health

- **Ensure** compliance with the **national health policy** and health plans, programs, and projects.
- **Steer** the **efforts of stakeholders** involved in the social production of health, through leadership and management of strategic planning processes, health promotion, communication, and public health education.
- **Guarantee** that activities related to the delivery of **services to people** meet current technical, legal and administrative **standards** and **regulations**, in order to guide the behavior of social actors and improve health.
- **Guarantee** that activities affecting the **environment** that are directly or indirectly related to public health, meet current technical, legal, and administrative **standards** and **regulations**, through the evaluation and monitoring of these activities, in order to guide the behavior of social actors and improve health.
- **Guarantee** that **products**, **materials** and **equipment** that directly or indirectly affect public health, as well as the **facilities** associated with these products, materials and equipment meet current technical, legal and administrative **standards** and **regulations**, in order to guide the behavior of social actors and improve health.
- **Contribute** to improve the **development** and nutrition of **children** under six years old, with emphasis on those living below the poverty line or in hazardous conditions, through planning, coordination, supervision, and evaluation of actions carried out at the area level and specialized support in nutrition and child development to units of the Ministry of Health and other institutions and organizations.
- **Provide** technical **assistance** to meet the government's targets and objectives with greater efficiency, economy, and effectiveness, providing it with timely information, analysis, evaluation, observations, and pertinent recommendations on operations.
- **Provide legal counsel** to all authorities and levels of the Ministry of Health to ensure that the actions of staff members of the institution are in line with the legal framework.
- **Guarantee** the **allocation** and **efficient** use of institutional and health sector **resources** based on the health policies and the sectoral and institutional plan to contribute to the fulfillment of the steering functions in health and the implementation of programs.
- **Promote** the **integration** and optimal operation of the **subsystems** that comprise the Institutional and Sectoral Information System and its ongoing processes of information gathering, validation, selection, management, processing, communication, and analysis, based on the demands and needs of the users of the system, for the purpose of improving decision-making processes.
- **Guarantee** the prevention, control, and/or eradication of **communicable diseases** and reduce the prevalence of **non-communicable diseases**.
- **Manage** and **steer**, at the **regional level**, the efforts of social actors involved in the social production of health and ensure that the activities, products, and equipment, directly or indirectly related to public health, meet current technical, legal, and administrative standards and regulations, to improve health at the regional level.

Source: Ministry of Health of Costa Rica. *Sectoral Analysis of Health of Costa Rica*, 2002.

5.1.4. Consolidation of the Ministry of Health as the Steering Entity

By 2002, the Ministry of Health had made important efforts in reorganizing its work to respond to the growing demands that are part of being the steering entity of the health sector. The new offices of the Ministry of Health already had the necessary inputs—conceptual, methodological, administrative and legal—to be able to carry out their functions.

In 1999, Law 7927 was enacted, which amended the organic law of the Ministry of Health, and at the end of 2002 the Ministry's organic regulations were approved. Both legal instruments are part of the public health policy that enables the Ministry to act as a steering entity. The Ministry of Health's reports and annual proceedings for these years describe in detail many of the actions implemented to consolidate the process of institutional transformation, which would allow it to adequately perform the steering role. It is worth noting that these actions were multifaceted and involved technical methodologies, legal processes, administrative and managerial steps as well as collaborative negotiations, among others.

Nevertheless, even though many of the changes were already occurring, the Ministry of Health needed sustainable political and financial support to ensure the full implementation of its functional and structural reorganization. A specific area that had fallen behind was regulation.[21] The national development plan (PND in Spanish) presented by the President of the Republic in October 2002 set priorities for the Ministry of Health. They were aimed at modernizing its capacity to manage and exercise the steering role for the sector, with special emphasis on the regulation of services provided by health and related facilities.

Similarly, a PAHO/WHO publication[22] on the progress of the reform states: "…These projects [IDB and World Bank] and their financial assistance ended in 2001, and assessment of the results shows progress in coverage and access to services, as well as improvements in the allocation of financial resources and provider payment mechanisms. However, the results also show that health system reform is still unfinished, since the steering role needs further strengthening to improve the performance of some essential public health functions that are under the responsibility of the health authority, including service management, quality of care, and equitable resource allocation."

In addition, another World Bank report on the closing of the first loan for the health sector in 2003 states: "It is important to provide the Ministry of Health with the opportunity to take advantage of the reorganization in order to improve compliance with new accreditation programs and quality assurance that it has recently developed. […] The Ministry of Health has made great progress in developing accreditation standards. However, its ability to enforce regulation in the sector is weak."[23]

With external financing nearly ending, the government decided to prepare a "second part" for the steering role project, which focused on unresolved issues such as consolidation and other new areas that arose during the project's implementation. Later negotiations with the Banks resulted in new loans for the Project. The World Bank in 2001 approved a second loan in order to support health sector reform, "Health Sector Strengthening and Modernization," which included a component to strengthen the regulatory and institutional

[21] Ministry of Health of Costa Rica, *Estudio para la propuesta del Segundo Préstamo BID-CCSS/MINISTERIO DE SALUD* (San Jose, Costa Rica: Ministry of Health, 2001).
[22] PAHO/WHO, Health System Profiles*: Costa Rica* (Washington, DC: PAHO/WHO, 2002).
[23] World Bank, *Project Appraisal Document on a Proposed Loan in the amount of US$17 million to the Republic of Costa Rica for a Health Sector Strengthening and Modernization Project* (Washington, DC: World Bank, May 2001).

framework of the Ministry of Health. Its aim was to encourage improvements in quality and user rights, as well as in the efficiency and effectiveness of the Ministry of Health as a regulating entity. The principal objective was to have a Ministry that was better prepared and equipped to ensure minimum standards of quality and develop national health policy.

In addition, the national authorities prepared the health sector development program, which was approved by Law 8403 of 2004. The program's first component was "Institutional Strengthening of the Ministry to Exercise the Steering Role." Its objective was to develop new institutional capacities in the Ministry of Health to exercise the steering role, strengthening its strategic and operational ability to expand to the entire country the implementation of the regulatory, inspection and surveillance functions, and the control of health risk factors. It proposed the execution of two specific subcomponents: (i) a pilot program for health management; and (ii) a pilot regulatory program on the quality of food, drinking water, and health facilities of median and low complexity health risk.

This project, which is currently underway, is an attempt to achieve the following results in Costa Rica's 32 poorest regions:[24]

i Thirty-two local steering areas capable of undertaking activities such as monitoring, surveillance and control (MSC) of food and water for human consumption and of health facilities;
ii Risk analysis methodologies and critical control points introduced and evaluated;
iii Four public health policy instruments to define priorities, financing, and health expenditures executed, published and disseminated;
iv Legal standards for the performance of the steering role updated; and
v Project to reform the general health law implemented.

This project has given new impetus to the Ministry of Health's steering role project, which had been in decline in recent years due to lack of financing.

Since January 2006 a set of subprojects have been carried out in tandem, whose purpose is to continue developing institutional capacities for the effective performance of the steering role in health. They are directed at the design, implementation at the deconcetrated levels, and evaluation of public policy instruments.

One of these projects aims to develop a system of satellite health accounts in the country, which will provide information about the structure of expenditures and health sector financing flows. This will give the Ministry of Health evidence to support public health policy-making and to define objective criteria to guide expenditures within the framework of principles that govern the health system and sectoral reform.

Another component is the MSC of food, water for human consumption, and health service facilities, which is very important to improving the regulatory function. This project has two aspects: (i) the central development of the Ministry of Health's institutional capacity to design and evaluate MSC in food, drinking water, and health facilities of median and low complexity and (ii) the development, at the deconcentrated level, of the Ministry's capacity to monitor and introduce MSC instruments for each of these issues. It includes work areas as varied as studies of MSC-related uses and practices, food hygiene; health inspection;

[24] Inter-American Development Bank, *Costa Rica: Health Sector Development, CR-0144. Loan Document* (Washington, DC: IDB, 2003).

health legislation; the training of multiple social actors at all levels, development of information systems, development of MSC indicators (coverage, quantity, quality, continuity, etc.); development of evaluation systems, establishment of coordination mechanisms, the preparation of tools to evaluate quality and performance in health facilities, among many others.

With the successful implementation of this project, the Ministry of Health will have a comprehensive standardized MSC methodology for water and food that includes sanitary and nutritional aspects, resulting in a favorable change in the epidemiological profile of the acute diarrhea diseases (ADD) and the malnutrition associated with them. This will make an important contribution and lead to better health and nutrition at the national and regional levels. In the area of health facilities, it will have accreditation systems that ensure the equity and quality of local health services.

Under the category of public health policy instruments, a project to analyze the burden of disease is also being developed. Its anticipated results include an estimate of disease burden measures, the development of an application to automate estimates of disease burden, and the organization of a system to report the results in order to prepare policies and action plans.

Other subprojects underway include a study of the Ministry of Health's regulatory and legal framework, the design of an information system, and a plan for its implementation, and the development of a supply-and-demand model for human resources in health, among others.

5.1.5. Future Challenges

In its health policy, Costa Rica places a high priority on the steering role and the strengthening of the Ministry of Health as the regulatory entity. Numerous goals have been reached since the project began in 1994, and the Ministry of Health is a restructured entity whose organizational and structural operation is directed toward performing steering functions. These strategic functions have been defined and redesigned to better adapt to the changes that are evolving in the sector as a result of the reform.

At this time the steering role is perceived as a participatory process in which the organizations of civil and political society help to identify health problems as well as design and implement solutions. Similarly, human resources are not only better informed and aware of the steering role, but also trained in specific and relevant areas. All of this is an achievement attributed to major efforts in consensus-building and communication.

Health service consumers and people in general have a growing interest in evaluating and improving the quality of health services, a concern to which the Ministry of Health responds by directing its efforts toward the continued improvement of quality.[25]

The list of achievements is long; nevertheless, there is much to be done. One of the main challenges is insufficient technical capacity to implement processes in which the Ministry of Health must exercise technical leadership and influence inside and outside the health sector. For example, the fact that the Ministry does not have an adequate monitoring system to analyze the sources, uses, and allocation of health expenditures, both public and

[25] Ministry of Health of Costa Rica, *Política Nacional de Salud 2002-2006* (San José, Costa Rica, 2002).

private, weakens its capacity to determine and support the health spending priorities of the CCSS and other institutional and private actors.[26]

In the area of human resources, supply-and-demand forecasting models for health professionals are still unavailable. They would enable the Ministry of Health to establish a dialogue with training entities and the CCSS, in order to avoid situations such as the recent surplus of health professionals in the country.[27] Neither does it have policy instruments that enable it to estimate the economic and social impact of the current health and disease profile, to focus spending on excluded and vulnerable populations or to supervise the equitable delivery of services.[28]

With the impetus provided by the second round of financing and a sustained political commitment, it is possible to state that, in the medium term, Costa Rica has a Ministry of Health with the institutional capacity to effectively and successfully lead the health sector.

5.2 Health Reform in Chile: Prioritization of the Steering Role and the Role of Citizen Participation

The process of health reform in Chile, which begun in May 2000, led to a profound transformation of the health system, both public and private. Its objective was to provide people with greater and better access to treatment, reduce waiting times, expand the network of facilities and eliminate economic barriers that prevented people from accessing complex medical treatments.

The objective of this section is to highlight, within the broad reform process that has taken place in the country during the last five years, two examples of extraordinary efforts that have strengthened the conduct/lead dimension of the health authority's steering role.[29]

The first and most fundamental effort was the high priority given to the "steering role" concept as such, and how this concept was translated into a series of proposals that have become the basis of the Chilean health sector today.

Secondly, they show how citizen participation played an important role in the reform process by validating both the reform project itself and the steering role concept. In other words, when the health authority promoted the active participation of civil society in identifying problems and planning and implementing actions in health (in this case, a reform proposal), it put in practice the conduct/lead dimensions of the steering role.

It is important to clarify that this section, in limiting the Chilean reform experience to these two elements, does not mean to place less importance on other equally important changes that have taken place. These two were selected simply for being more representative of the conduct/lead dimension of the health authority's steering function.

---

[26] Ministry of Health of Costa Rica, "Public Bidding for the Contracting of Consultants," *Loan Agreement 1451 IC-CR between the Republic of Costa Rica and the Inter-American Development Bank*. Health Sector Development Program.

[27] Idem.

[28] Inter-American Development Bank, "Health Services Improvement Program ," *Proposal for Loan Number(s)of project: 711/OC-CR;712/OC-CR;CR0120* (Washington, DC. November 1992).

[29] Leadership is understood to mean the capacity to guide the sector's institutions and mobilize them and other social groups to support the national health policy.

5.2.1. Background

At the end of the 1990s, the health authority was affected by a series of problems that weakened its role:[30]

- Dispersal, bureaucracy, and ineffectiveness: because of overlapping functions and the lack of clearly defined responsibilities, the Ministry of Health and the Health Services did not coordinate their activities. The Ministry of Health, on the one hand, was involved in managing public health care providers. On the other hand, the Health Services, which were decentralized entities, carried out functions that belonged to the health authority. This dual role of manager and health authority presented challenges since the Services were both evaluators and executors of their own functions. The overlapping functions did not facilitate an effective coordination of the steering role functions.

- Unequal normative capacity: a situation of imbalance where standards were either excessive or nonexistent for health care areas, the environment, or the workplace, leading to irregular oversight and limited health impact.

- Insufficient oversight of the quality of services: the legal framework under which the health authority operated was an obstacle to efficient regulation of the private system. Furthermore, oversight of health care providers was the responsibility of Health Services, which did not have updated standards to regulate health facility operations. It was important to achieve homogeneous standards for public and private health care providers.

- Insufficient regulation of private health administrators: in a health insurance market characterized by competition, information imbalances between consumers and health insurances, and defensive behavior regarding the selection of insurance risk made government intervention necessary. Thus, actions to regulate the quality of the package of services, to prevent segmentation of the population and to avoid diverting resources to unproductive practices from a health and economic point of view, would be backed by an adequate legal framework.

- Lack of understanding of the role of the health authority by the citizenry: there was limited awareness within the sector and on the part of the general population of the concept of the health authority's steering role. Nor were people certain of where to address their needs or claims, much less how to demand their rights.

In short, there were shortcomings in existing legislation that did not allow integrated public and private subsystems. This resulted in faulty management of resources and restricted equitable access to health. Furthermore, the prevailing definition of the health authority limited its scope of action to the public sub-sector, thus limiting its responsibility for developing the entire health system and the health of the population. For these reasons, legal changes were required.

Armed with this diagnosis, the technical reform team was given the task of drafting legislation that would make clear the Ministry of Health's traditional responsibilities, adding capabilities and relevant functions to invigorate the institution and thus strengthen its steering functions. Several documents forming the basis of the doctrinal consensus on the steering functions of the health authority were taken as input and reformulated into the

[30] Government of Chile. Bulletin No. 2980-11. "Informe de las Comisiones de Hacienda y de Salud sobre el Proyecto de Ley que modifica el Decreto Ley No. 2763 de 1979, con la finalidad de establecer una nueva concepción de la Autoridad Sanitaria de las distintas modalidades de gestión y fortalecer la participación ciudadana."

content of the law using internationally adopted terminology. This is how the health authority's draft legislation was born.

5.2.2. Health System Reform and the Health Authority Law

The reform, of great complexity from both an economic and organizational perspective, was divided into five major subject areas, each treated in a respective piece of legislation. The first bill approved by the national Congress was the health authority law, the purpose of which was to establish a new concept of the health authority. (*See Table 4 for details on the five bills.)*

Table 4. The Five Bills Comprising Health System Reform in Chile

1. Health Authority
The health authority bill restructures the Ministry of Health, the regional ministerial secretariats (Seremis, in Spanish), and the health services; it creates self-managed hospitals with clear standards for their accreditation, and creates financial incentives for staff members in accordance to health and management goals.

2. Universal Access with Explicit Guarantees (AUGE, in Spanish)
AUGE provides clear guarantees to the population when an individual faces a specific health problem: when and how a patient will be treated, how much it will cost, coordinating all network facilities and explaining everything clearly to the patient in order to ensure the guarantees. Furthermore, access is guaranteed for life-threatening emergencies, the public health program (vaccines, tuberculosis, supplementary feeding plan), and the family health plan in all clinics and small hospitals.

3. Provisional Health Institutions (ISAPRES, in Spanish)
The objective of ISAPRES is to prevent that a patient is adversely affected because of a health problem (uncontrolled plan increases because of a specific diagnosis, for example: diabetes or other common and natural circumstances as pregnancy or old age). It establishes the mandatory nature of the explicit guarantees system for all its consumers (AUGE), and guarantees the protection of members in the face of an ISAPRE bankruptcy.

4. Financing
The higher cost of the system of guarantees will be financed by a higher tax contribution, an increase of one point in the value added tax (I.V.A.).

5. Rights and duties of health personnel
This project establishes laws on the treatment and relationships between health care providers and consumers.

Source: Llanchipal Health Service, 2005, available at http://www.llanchipal.cl/Reforma.

The principal thrust of the health authority bill was to strengthen the steering role. It defines the non-delegable responsibility of the State to guide health sector development and ensure its effective performance in fulfilling the population's health needs. The health authority is the State's permanent institution in charge of implementing these objectives by exercising its authority throughout the country and over each actor in the system, to ensure a comprehensive steering role. Thus, the law defines the duties and responsibilities necessary to regulate and oversee health care activities and protect consumers.

The law establishes the functions and competencies of the sector's public agencies, separating those involved in the delivery of services from those involved in regulation and enforcement; it establishes a new model of care in local and national networks; it promotes hospital self-management and establishes performance incentives for the sector's workers, including civil service careers, assignments, and promotions until retirement.

Furthermore, the bill set forth a new structure for the public health sector, with three fundamental purposes:

i) strengthen the institution and powers of the health authority by clearly separating them from the functions related to the management of health services, specifying that the regulatory and enforcement roles belong to the health authority;
ii) establish standards to improve health service management, adapting it to the AUGE system requirements; and
iii) establish instances for citizen participation at the ministerial regional secretariats and at the health service bureaus.

Its principal duties include formulating policies that allow people to develop healthy lifestyles and better health conditions, guaranteeing access to health promotion and treatment of disease that is dignified, timely, humane and of high quality, at a level that the country is capable of providing. Furthermore, the health authority must be clearly identified by the population as the entity responsible for guaranteeing rights to health.

Within the Ministry of Health's new framework of vision-mission-functions,[31] the first of its functions is "to exercise the steering role of the health sector," which includes, among other actions, the following:

- elaborate, monitor, and evaluate plans and general programs on health;
- define the national health objectives;
- coordinate sectors to achieve the health objectives;
- coordinate and cooperate at the international level in health;
- steer and guide all government activities related to delivering health actions, in accordance with set policies.

These include, among others, the following actions: define standards and instruments for evaluating the quality of care, strengthening the performance of essential public health functions, defining a health plan and establishing its guarantees.

The health authority must have reliable instruments to exercise its steering role functions of regulation and enforcement of the public and private health system, as well as the authority to ensure compliance with current regulations.

[31] Portal of the Ministry of Health of Chile,: http:/www.minsal.cl.

Table 5: Health Authority Law 19,937
Published in the *Diario Official* (Official Journal) February 24, 2004

"*Amends Decree Law 2763 of 1979, with a view toward establishing a new role for the health authority, different managerial modalities and strengthening citizen participation.*"

The law ensures the following:

- A steering role for the Health Authority and regulation over the entire health sector, both public and private
- An intersectoral approach to the Health Authority's steering role
- A comprehensive management policy for the health sector
- Strategic technical leadership over all stakeholders of the system
- A system of coherent and balanced norms, obligations, and rules for the operation of all agents involved
- A system of monitoring compliance with current regulations and mechanisms that allow their enforcement throughout the country
- Capacity to guarantee health protection and promotion for the population
- Ensure access to health services, particularly for the most vulnerable populations
- Guarantee health care rights for users
- Guarantee financial protection for the family
- Provide health care coverage to the entire population
- Oversee compliance with the AUGE system

Source: http://www.bcn.cl.

5.2.2.1 The Health Authority at the Regional Level

The design of the draft legislation was based on the premise that a decentralized institution was needed to exercise the steering role. Therefore, it was important to have an entity close to the population where citizens' claims, problems and requirements regarding public and private health care providers could be addressed.

The regional health authority proposed by the initiative envisioned separating the management functions characteristic of the Health Services networks from those of the authority. The management functions would continue to reside with the Director of Services and the authority functions would be performed by the Ministerial Regional Secretary.

In addition, this separation thus meant that the reformed Health Services would have no health authority functions, that is, neither the steering role nor the regulatory function. It would concentrate on providing medical care and coordinating the health care networks. The regional health authority would still have the power to intervene in financial and health management if unsatisfactory circumstances arose.

Furthermore, this separation meant that the newly empowered Ministerial Regional Secretary, in addition to supporting the Superintendent, would carry out all the functions of epidemiological surveillance, environmental health control, monitoring the quality of public and private providers, receipt of comments and complaints, and settlement of disputes.

In order to ensure community criteria and response capacity, this authority would be territorially and functionally deconcentrated, with a presence in all regions of the country

and would use regulations and standards of national scope, defined by the central authority.[32]

5.2.3. The Strategy

The Chilean experience has demonstrated that it is feasible to put together such a complex and in-depth project as health sector reform and to implement it in less than five years. In order for the project to achieve success, the personal commitment of the President of the Republic was essential from the start. The reform had the unconditional support of the Presidency throughout the entire process, a factor that undoubtedly had an important influence on the outcome.

Secondly, another factor facilitating the project was the creation of a committee for technical-policy decision-making made up of the Ministers of Treasury, Labor, the General Secretariat of the Presidency, and Health. The committee functioned as the government's formal decision-making mechanism for the reform process. When an agreement could not be reached, the president was called on to make a decision.

The technical teams consisted of technical personnel from the four ministries—Health, Treasury, Labor, and the General Secretariat of the Republic—who worked in tandem. The work began in 2000 with the diagnostic phase, and by February 2002, a concrete reform proposal had been mapped out. In May 2002, the first bill (AUGE) was sent to the legislature.

The order in which the bills were presented to Parliament was also strategic. Although the first bill submitted to the legislative process was AUGE, the first one actually ready was the health authority law, because it was the base that established the regulations for the health authority and the management of the health care networks. However, because it contained institutional amendments that were functionally and structurally complex, this was not a bill that appealed to the general population. Thus, it was the second to be sent to the legislature but the first to become law, in order to restructure the sector and lay the groundwork for the other requirements proposed by the reform.

Originally the idea was to draft a single bill. But it would not have worked. Splitting the different bills avoided complex cross negotiations in the Chamber of Deputies. For example, when the role of the National Health Authority was discussed, the deputies could not enter into a discussion of AUGE. This turned out to be a critical strategy, not only to protect the integrity of the bills, but also to show progress as the reform was advancing.

The Ministry of Health coordinated closely with Treasury. They emphasized that the reform was based on solid public health needs and not on financial criteria, although these were important. Furthermore, it was emphasized that health reform was being implemented for political reasons, given the pressure from the general public due to dissatisfaction and uncertainty. The argument was strong, and had sufficient merit to bring about a profound change in the health area.

Together with the government team, they presented the view that the reform was not for the medical establishment, but for the people. Their political strategy was to seek an

[32] Government of Chile. "Informe de la Comisión de Salud," put into a bill, in stage two of the legislative process, which amends Law No. 2.763, of 1979, for the purpose of establishing a new concept of the health authority, to set up new managerial methods and strengthen citizen participation. Bulletin No. 2980-11. August 2003.

alliance with the population. In the beginning, the general public had little understanding of the reform, but it was clear that rights to which the public aspired were being created and that the population would become an actor that could demand good health care, instead of passively waiting for promises to be fulfilled.

The strategy with the unions was to keep a continuous dialogue, but never to compromise on any point that meant jeopardizing the key elements of the proposal. The negotiations took advantage of the political capital created when the President directly confronted the medical union and the citizenry supported the confrontation.

Negotiations in the Senate were important, since it is there that sweeping national agreements are passed. The political cost of opposing the reform was extremely high for a lawmaker—so much so that the Senate unanimously passed the four bills.

The effect that has been created is a citizenry that today supports the reform process. From the beginning there was a clear dialogue with the population. Three media campaigns were undertaken—with 3 slogans—that ran at the same time as the reform. The first was: "Reform that Moves Forward," followed by "Chile Wants the Reform," and once the bills materialized: "Chile is Better!"

The first campaign was actually more advertising than content oriented and an opportunity to educate the population about the reform was wasted. Nevertheless, subsequent campaigns took advantage of the President's and the Ministry of Health's space in the communications media, which helped lead to an intense dialogue with the population.

The Ministry of Health communicates:

One million people have received care through AUGE since this initiative went into effect last July 1. All Chileans, regardless of the ability to pay, gender, or age, will have access to better health and high-quality, more efficient, and timely care.

Source: Address by the Minister of Health, Pedro García, November 8, 2005

The following subsection provides more details on the strategy that was implemented to promote citizen participation in the reform process.

5.2.4. Citizen Participation in the Reform Process

From the beginning, the health reform process in Chile was designed to include citizen participation as one of its pillars of development. Although historically in Chile there have been a number of experiences with public participation, no capacity or significant experience exists in the use of citizen participation to influence public policies. With regard to health specifically, the tradition of participation was aimed more at information and performance of previously defined activities. It was a double challenge: no successful experiences were available to anticipate results and consequences, and they had to contend with conflicting points of view about the risks of a citizen participation strategy of this type.

The health system management dimension included encouraging the active participation of civil society in identifying problems, planning, and implementing actions in health. This involves the development of mechanisms that allow people to exercise social control over

the different functions of the system, to ensure that these are implemented with equity, efficiency, and effectiveness and respond properly to the needs of the population.

The strategic guidelines for citizen participation needed to be translated into mechanisms and specific actions. A citizen participation work program was therefore created, which tried to open up multiple opportunities for participation according to criteria that differentiated and grouped citizens in relation to their association with the health system. Recognizing the relevant actors and interest groups was also part of the process.[33]

There were two stages for the participation process:

Stage 1:
The first stage focused on incorporating people's concerns into the design of the reform. This was done through techniques of group discussion and a public opinion surveys on the population's perception of the health system, which would serve as the project's fundamental methodological basis. Three elements were included:

i) A survey on health care and protection as perceived by the population;
ii) A survey on the state of health as perceived by the population (personal health); and
iii) A survey on health workers' (all classes and in the public and private sectors) perception of the services they provide and the organization in which they work.

Many health officials participated, including service directors, Ministerial regional health secretaries, regional superintendants, and provincial governors. The population showed great interest in participating in events of this type, and a quick and widespread response was obtained.

Table 6: Citizen Participation in the Reform Process

First round—January 2001
- "Citizen participation workshops:" 48 community meetings in which 3000 representatives from public organizations discussed the sector's problems, elaborated a diagnosis and prepared proposals to improve health.
- Subjects addressed: health objectives, people's health rights, solidarity in health, participation, and promotion.

Second round—March to May 2001
- Once the process had been systematized in the 48 communities, 250 additional community meetings were held that covered 288 communities and included the participation of 25,000 people.

Third round—September to November 2001
- 199 local meetings to discuss the draft legislation on patients' rights and duties and the 2001 intervention plan.

Source: Celedón C. and R. Orellana. 2003

Stage 2:
This stage laid the foundation for the health system reform, in a broad participatory process of civic seminars and workshops with groups of social stakeholders and trade unions on the key reform issues, in light of the conclusions of the opinion surveys. These

[33] Carmen Celedón and Renato Orellana, "Gobernancia y participación ciudadana en la reforma de salud en Chile," *Presented at the Third Subregional Inter-American Forum of Leadership in Health*. January 2003.

workshops — called working groups on health system reform — produced technical proposals from the various groups represented, which were presented to the Ministry of Health.

Four groups were formed: i) a working group with academics, trade unions and consumers of public health services, ii) a group that included ISAPRES, providers, unions, and private health care consumers, iii) a group of social leaders and representatives from nongovernment organizations and institutions, and iv) a group involved in municipal care.

With consensus from all the stakeholders, the reform bill on health workers' rights and responsibilities was presented.

5.2.4.1 The Results

Civic participation was more effective in those areas where unanimous agreement had been reached in the draft legislation. In particular, the work on citizens' health rights was enriched by community discussion. With respect to national health objectives, a participatory process to exchange information with a large number of experts was held, which produced health guidelines for the next decade.

With respect to health unions, negotiations were held, which helped diminish the sense of threat that the reform project might cause. The negotiations led to satisfactory agreements for the parties in line with the spirit of reform. The relation with the medical professionals in their corporate dimension was more difficult, as their interests tended to be perceived by the citizenship as purely economic — a factor that weakened their position and ultimately made the approval of the draft legislation possible.

In general, it could be said that civic support for the reform process has been established. Not only was the citizenry included in defining the project, but also the message was clear: every health problem is not going to be resolved, just the population's major problems.

5.2.5. Future Challenges

The health system reform process in Chile has been a successful example in establishing legal, institutional, and operative changes to be able to orient its sector toward achieving the key guiding principles of the reform — to increase the sector's effectiveness, equity and solidarity, and improve the efficiency of sectoral management.

Chile's next step is to continue along the road to governance and continuity with the commitments made during the last six years, given that the reform process is not over. For other countries in the region, the Chilean experience offers a valuable example of extraordinary efforts made to strengthen the national health authority's steering role, specifically in the areas of management and regulation.

5.3 Drug Regulation: the Case of Antiretroviral Treatment in Brazil

Brazil is the first developing country to implement a national program for distribution of antiretroviral drugs. The program, launched in the early 1990s with the distribution of AZT, was expanded and consolidated in 1996 through Law 9113, which guarantees universal access to free treatment for all people living with HIV/AIDS.

Brazil's national health authority has shown exemplary leadership in the area of drug regulation, specifically in the case of antiretroviral drugs, within the framework of the policy of universal access for people living with HIV/AIDS. So much so that international interest has been keen to reproduce in other countries the "formula" that has made this program so successful.

It is important to note that the Brazilian experience of providing antiretroviral drugs has been widely documented from several different perspectives. Here, a general view will be provided from the perspective of the NHA regulatory activity. It will be shown how the NHA — in full exercise of its steering role — applied the drug regulation to support the national policy on HIV/AIDS.

The first part of this section presents a general view on drug regulation and its basic elements — its objectives, areas of responsibility, and the key elements in achieving effective regulation. Once the conceptual framework of this NHA activity is established, the second part will look at how Brazil has specifically focused on the subject of drug regulation in the specific case of antiretroviral drugs, including the issues of legislation, logistics of purchase, production, distribution, financing, quality control and guaranteed access. The last section describes economic regulation mechanisms for antiretroviral drugs in Brazil's pharmaceutical market, with the objective of facilitating access to this treatment.

5.3.1. Basic Elements of Drug Regulation

Drug regulation is one of the specific components of the national health authority's regulatory function. Analysis of the pharmaceutical regulation in a country must evaluate not only the normative technical content, but also the institutional framework and legal backing to make the regulation effective, as well as the NHA's institutional capacity to enforce the regulations and the coordination mechanisms and transparency.

The main objective of drug regulation is to promote and protect public health by ensuring that:[34]

- medicines have the required quality, safety and efficacy;
- health professionals and patients have the necessary information to enable them to use medicines rationally;
- medicines are appropriately manufactured, stored, distributed, and dispensed;
- illegal manufacturing and trade are detected and adequately sanctioned;
- promotion and advertising is fair, balanced and aimed at rational drug use; and
- access to medicine is not hindered by unwarranted regulatory procedures.

To achieve effective drug regulation, there must be a regulatory entity — previously defined by the national government and the Health Authority — that has a clear mission, a solid legal base, realistic objectives, appropriate organizational structure, duly qualified staff, sustainable financing, access to technical literature, equipment, and information, and, finally, the capacity to exert effective market control. This regulatory entity will be responsible for developing and implementing most drug legislation and regulation, as well as ensuring that the information on each product in the market is accurate.

[34] World Health Organization (WHO), *Norms and Standards: Quality, safety and efficacy of medicines*. www.who.int/medicines/areas/quality_safety/regulation_legislation_2005.

Experiences in developed countries have shown that a country's regulatory capacity is implemented in phases and takes time. Several factors that determine what type of regulatory functions can be enforced include the degree of development of the drug sector and the availability of skilled staff, infrastructure, and financial resources. As part of the development process, the regulatory entity must identify and implement priority functions: that is, it must first define exactly what needs to be regulated, what activities it wants those being regulated to do, and how to ensure their compliance. Identifying the beneficiaries and stakeholders of the regulation process is essential.

In many countries, especially those with public health systems, drug regulation is based not only on the need for *efficiency* — to control quality, avoid market distortions such as the presence of externalities or imbalance of information — but also for *equity* — to ensure satisfactory territorial coverage or universal access to the drugs — to successfully meet the ultimate goal of regulation: to maximize social well-being, obtaining efficient operation of the market and at the same time meeting previously established objectives. In these cases, the central government, in addition to being the regulator, tends to be the principal financier of drug procurement, which introduces another element in regulation objectives: *guaranteed access.*[35]

Drug legislation forms the legal foundation that sustains drug regulation. To be effective, it must be broad, applicable, and flexible enough to adapt to new health situations. At the same time, legislation must be in line with national policies, reflect the degree of regulation that the government considers desirable and feasible to perform, and take into account the situation of the country's drug sector.

In general, drug legislation:[36]

- specifies the areas and activities to be regulated;
- establishes the roles, responsibilities, rights, and duties of all stakeholders participating in drug regulation, for both the regulators and the regulated;
- creates the administrative structures necessary for implementing drug regulation, and defines their functional relationships;
- establishes the qualifications and standards required for people who handle drugs;
- creates the mechanisms to ensure that the responsible parties are duly licensed and inspected, as well as the standards and specifications established for people, establishments, and practices;
- defines norms, standards, and specifications necessary for ensuring the safety, efficacy, and quality of pharmaceutical products;
- establishes the terms and conditions under which licenses to import, manufacture, distribute, sell, provide, and promote drugs may be suspended, revoked, or canceled; and
- specifies the administrative measures and legal sanctions to be applied when the provisions of the drug legislation are violated.

[35] FarmaIndustria, *Carta del Presidente: El sector farmacéutico fuertemente regulado* ("Letter from the President: The Heavily Regulated Pharmaceutical Sector") (Spain. Autumn, 2005).

[36] WHO, *Effective Drug Regulation: what can countries do?,* Theme paper for Discussion (Geneva: WHO, 1999).

5.3.2. Antiretroviral Drug Regulation in Brazil

Brazil is the first developing country to implement a national program for the distribution of antiretroviral drugs. In 1996, Law 9313 was passed, which establishes the right to complete medical care for people living with HIV; they thus have access to free comprehensive care, which includes antiretroviral drugs.

Article One of the law explicitly affirms the state's duty to provide all HIV-positive individuals and AIDS patients, free of charge, with all the drugs required for their treatment, duly standardized and, when necessary, reviewed by the Ministry of Health for purposes of purchase by the Unified Health System administrators. Article Two establishes that the expenditures resulting from the law must be financed with Social Security funds at all levels of government (national, state, the Federal District and municipality) in accordance with specific regulations.

Two decades ago, experts predicted that at the beginning of the 21st century there would be 1.2 million cases of people with HIV/AIDS in Brazil. However, thanks to strong leadership and political commitment, along with successful civic mobilization on the part of the public health community and social activists, the country has coordinated an effective national response to confront the issue of HIV/AIDS. The result is a drop in the projected levels of infection — with a prevalence rate today that is low in comparison with global levels — 0.65% of the population, or approximately 600,000 HIV-positive individuals. Of these, 170,000 need and receive antiretroviral drug treatment.

5.3.2.1. General Policy on Medicines

The program to provide antiretroviral drugs is protected by Brazil's general policy on drugs (dated 30-10-1998), which aims at "ensuring that the population has access to safe, efficient, quality drugs, at the lowest possible cost."

Brazil bases its drug regulatory policy on the following pillars, which also form the key elements of the country's antiretroviral drug regulation:

1 Formulation of a list of essential drugs (RENAME): essential drugs whose use has been tested and effectiveness guaranteed, to provide treatment for the majority of the country's health problems, in the appropriate dosages. The list must be continually updated and disseminated by all areas in the health sector.

2 Promotion of the use of generic drugs: it is mandatory that the drug's generic name be used in the prescription.

3 Change in orientation of the pharmaceutical systems: in terms of dispensing, distribution, promotion, procurement, storage, quality control, and availability of products, according to health needs.

4 Rational drug use, including educating consumers on the risks of self-medication, interruption of treatment, and the need for a medical prescription for certain drugs.

5 Encouragement of scientific and technological development and promotion of drug manufacturing: proposes developing the production of drug-related products and national production of the RENAME drugs.

6 Ensure the safety, efficacy, and quality of drugs: coordinated by the National Health Surveillance Agency (ANVISA).

7 Encouragement of the development and training of human resources.

8 Price control.

In general terms, the national health authority oversees two types of drug regulation: technical and economic. Technical regulation introduces health standards to ensure drug quality and safety, using mechanisms such as health records, inspection, and surveillance.

Economic regulation introduces policies to reduce the drug industry's influence on the drug market and to increase consumer access to drug products. The instruments used include price control, market monitoring, and development of access policies, as well as policies to promote the use of generic drugs. Although economic access to drugs has always been an important issue on the public agenda, it became more important in response to the AIDS epidemic, and price control took on a predominant role in economic regulation.

5.3.2.2. Drug Legislation

The pharmaceutical law protecting antiretroviral drugs consists of a set of laws, regulations, standards, guidelines, and instructions that determine the pharmaceutical practice in Brazil. It is the legal support on which the HIV/AIDS Program is based in order to provide antiretroviral treatment to all individuals who need it. Specifically, it's worth mentioning Law 9313 as well as the Law on Generic Drugs — Law 9.787/99[37] — which regulates all drugs and both national and international patent rights.

This national patent law allows labs to make drugs that were in the market before 1997 (already free from intellectual property rights) and establishes that drugs that have since entered the market are under patent protection. However, two articles in the law make it possible that in the event of national emergency or price abuse the government can decree mandatory licensing and thus make it possible for national labs to make generic drugs that cost nearly 50% less.[38]

5.3.2.3. Guidelines for Use and Antiretroviral Treatment Protocol

The procurement and indications for use of antiretroviral drugs must comply with technical and scientific recommendations based on nationally and internationally recognized studies. The Advisory Committees on Antiretroviral Treatment are the agencies responsible for discussing and determining the most appropriate forms of treatment.

Three technical commissions currently advise the Brazilian STD/AIDS program and prepare the recommendations on antiretroviral drug use called "treatment consensus." One committee defines the treatment to be used by adults and adolescents, a second is for children, and a third for pregnant women in order to reduce vertical transmission. The consensus documents are dynamic and are frequently updated, in accordance with medical-scientific advances on AIDS.[39]

[37] In June 2005 the citizenship commission on the Constitution and justice of the Chamber of Deputies (CCJ) unanimously approved draft legislation 22/03, which alters Article 18 of the patent law (9.279.96), freeing the patents on drugs that combat AIDS. The measure also covers the production of antiretroviral drugs. With the modification of the article, national labs can manufacture the medicines. The vote on the bill was conclusive and moves to the Brazilian Senate. If approved, it will be sanctioned by the President of the Republic. See: http://www.essentialdrugs.org/emed/archive/200506/msg00026.php.

[38] For more details, see the last section of the present document.

[39] Ministry of Health of Brazil, "The Experience of the Brazilian Aids Programme", 2002, www.aids.gov.br.

5.3.2.4. Establishing Quality Standards

The National Health Surveillance Agency (ANVISA) is responsible for the drug registry and for establishing quality standards. It evaluates the patentability of drugs along with the National Institute of Intellectual Property (INPI) and standardizes legislation on clinical trials of drugs and health products. It also incorporates the international guidelines on good clinical practices and gathers scientific research results and evidence on treatment advantages and safety of products of public interest and scope.

ANVISA's goal is to eliminate or minimize the risks of drugs eligible for the registry, obtaining medicines with scientifically verifiable safety margins, treatment efficacy, and quality.

5.3.2.5. Administration of Drug Purchase and Distribution

Without a doubt, an essential element for success in the antiretroviral distribution program is the administrative logistics of purchasing and distributing the drugs. The large-scale purchases, distribution throughout the entire health services network, and control of inventories to ensure uninterrupted availability of the various antiretroviral drugs are complex activities requiring physical, financial, and human resources.

In order to rationalize the costs and facilitate control of these processes, investments have been made to modernize the logistics of the drug distribution program, which include i) implementing a National Registry of Patients living with HIV/AIDS, and ii) full computerization of the drug distribution process through the SICLOM system (computerized system for the logistic control of drugs). SICLOM is centralized in Brasilia but operates in coordination with state administrative authorities. All dispensing locations for the antiretroviral drugs are computerized, and each patient has a magnetic card containing personal information. Thus, an up-to-date record of inventories, distribution, consumption, and patients' adherence to their treatment is maintained.

5.3.2.6. Training Health Professionals in Antiretroviral Drug Use

Another key element in drug regulation is ensuring that health professionals have the information necessary to ensure rational drug use. In the case of HIV/AIDS, the antiretroviral drug treatment has become increasingly sophisticated and complex with the introduction of new medicines in the market and new drug combinations. It is thus essential to constantly update the physicians who prescribe these drugs, in addition to continually monitor the results.

The challenge of training health professionals in Brazil has been addressed in several ways. One way has been to connect the National AIDS/STDs Program with universities throughout the country, which has resulted in refresher courses and training for professionals who care for patients infected with HIV/AIDS. This project, known as "UNIVERSI-AIDS," [40] began in 1997, and that same year trained more than 2000 health professionals on HIV/AIDS-related topics. The trainings follow the priority criteria established by the state and municipal HIV/AIDS programs.

[40] J.L. De Mattos Dias et al, *Terapia anti-retroviral y salud pública: un balance de la experiencia brasileña*, General Coordination of STD/AIDS, Ministry of Health in Brazil, UNAIDS, 2000.

Additionally, monitoring the results of drug use must be done in tandem with distribution. This means that infected patients must be monitored, results of the prescribed drugs tracked, and information made available to the health professionals who see these patients. To implement this monitoring, Brazil has developed a system for information and control of lab tests (SISCEL), which operates in 50 reference labs of the CD4 and viral load network. Implementation of this database makes it possible to access test results safely and quickly by Internet within the connected networks.

5.3.2.7. Financing the Antiretroviral Treatment

As Law 9313 explicitly states, the cost of providing antiretroviral drug treatment to all HIV/AIDS-infected people who need it must be borne by social security at all levels of government (federal, state, the Federal District, and municipality), in accordance with specific regulations.[41]

The Ministry of Health is responsible for financing a portion of the ongoing operations, including training human resources and supplying drugs. On the other hand, the states and municipalities are responsible for administrative expenses, for example, personnel, infrastructure, medical facilities, maintenance, and other direct operating expenses.

The budget of the Central Agency for Medicines (CEME) of the Ministry of Health reflects the federal government's commitment to fighting AIDS. The portion of the budget allocated for the purchase of HIV/AIDS medicines rose from 0.5% before Law 9319 to 9% in 1996, and by 1998 had reached 27.3%.

Of the 600,000 people living in Brazil with HIV, more than 170,000 need and receive antiretroviral drug treatment free of charge through the public health sector. The annual cost per capita of the treatment is approximately US$1,300 — one-tenth of the cost for the same treatment in developed countries, and 78% less than what it cost in Brazil in 1997.[42,43]

Although drug prices have dropped significantly, especially for second line drugs — leading to a reduction in the annual per capita treatment cost — the growing number of patients and the introduction in the market of newly patented drugs are factors that have led the Ministry of Health to make projections that the annual per capita treatment cost will increase this year to US$2,500.

Currently, almost 80% of the annual budget for antiretroviral drugs of the National AIDS Program is used to import patented drugs. Approximately 70% is spent on purchasing four patented drugs: Lopinavir/Ritonavir, Tenofovir, Efavirenz, and Nelfinavir.[44] The remaining 20% of the budget is used for the national production of generic drugs to develop eight of the 16 drugs used in triple therapy.

5.3.2.8. Citizen Participation

It has been shown that countries with strong consumer associations, public interest groups, or other socially active groups have a greater degree of consumer protection. This affects

[41] Idem.

[42] Pascual Ortells, "Brazil: A Model Response to AIDS," *Americas Program Special Report* (Silver City, NM: Interhemispheric Resource Center, April 2003).

[43] Ministry of Health of Brazil, National STD/AIDS Program, *The Sustainability of Universal Access to Antiretroviral Medicines in Brazil* (Brasilia, August 9, 2005).

[44] Rio de Janeiro, May 5, 2005: Declaration of Civil Society regarding Brazilian Negotiations for Voluntary License for AIDS drugs. *Available at*: http://www.cptech.org/ip/health/c/brazil/civsoc-brazil05052005.doc.

drug regulation in two ways: first, social groups act as "vigilant guardians" of the process, and second, they serve as spokespeople, allowing citizens to express their concerns about or dissatisfactions with drug regulation. The process of updating drug regulation has often been influenced by pressures from civic interest groups, resulting in higher-quality regulation.

One of the Brazilian HIV/AIDS program's main preventive strategies has been to foster civil society participation, with the involvement of more than 600 nongovernmental organizations (NGOs). The national health authority has promoted society's participation in the fight against AIDS through partnerships among the public sector, the private sector, and NGOs. Civil society — organized in NGOs — has been a key dimension of the Brazilian program, participating in policy formulation and evaluation, with a presence on steering committees of the National HIV/AIDS Program, as well as in other governmental forums. NGOs also collaborate in the delivery of services, especially to high-risk groups. When financial constraints threatened to interrupt procurement of international antiretroviral drugs in 1999, NGOs organized street demonstrations to pressure governmental authorities.[45]

5.3.3. Price Control as an Economic Regulation Tool

For many countries with budgetary constraints, drug prices can have a direct effect on the number of patients able to receive treatment. Even for Brazil, the high prices of antiretroviral drugs still present a threat to the sustainability of the program and for universal access to these drugs.

The national health authority has resorted to various price control strategies in order to facilitate access to antiretroviral drug treatment,[46] including:

- *Price differentiation* is the mechanism preferred by the multinational pharmaceutical industry to respond to the tensions between access and innovation (research and development). Price differentiation makes it possible for antiretroviral drugs to be sold at reduced prices in developing countries in order to facilitate access, maintaining high prices in markets such as the United States in order to support research and development.[47] Brazil has negotiated intensively with all the drug companies in the country, achieving major discounts in the prices of brand-name antiretroviral drugs.
- *Generic competition* has also helped lower prices. Drug prices have proven to decline with competition from generic products. The Brazilian experience with antiretroviral drug regulation led to an 82% drop in prices.
- *Voluntary licensing*: Companies that manufacture generic drugs can negotiate voluntary licenses with patent owners for local antiretroviral drug production and pay fees for the rights. For example, since March of 2005, the Ministry of Health has been negotiating to obtain voluntary licenses from Abbott, Gilead, and Merck for Lopinavir/Ritonavir, Tenofovir, and Efavirenz, respectively. If these companies do not voluntarily comply with the Ministry's request to transfer technology for production of these drugs to the public laboratories, a *mandatory license* can be issued. In either case, fees must be paid to the patent owners.

[45] Valéria Oliveira-Cruz et al, "Viewpoint:: The Brazilian HIV/AIDS "success story: can others do it?," *Tropical Medicine and International Health.* 9, No. 2, February 2004.

[46] Theo Smart, "Getting antiretrovirals to where they are needed: drug procurement and quality," *HIV&AIDS Treatment in Practice* 45, April 6, 2005.

[47] WHO, "Report of the Workshop on Differential Pricing and Financing of Essential Drugs," *A WHO/WTO Secretariat Workshop* (2001).

- *Mandatory licensing*: refers to the permit issued by the government to produce a patented product or use a patented procedure without the consent of the patent's owner. It is one of the flexibilities allowed by the WTO agreement on intellectual property with respect to patent protection. Normally, the person or company requesting a license must have previously attempted to negotiate, in reasonable business terms, a *voluntary license* with the patent owner. Only if this is not possible, can a mandatory license be issued.[48] In the case of several antiretroviral drugs, the Brazilian government has been able to issue mandatory licenses, alleging that the patent owners have abused its rights by setting high prices that are outside the reach of buyers. Thus, the national drug labs have been able to manufacture generic versions of several drugs that are still under patent.
- *Local production* of antiretroviral drugs can mean important savings in price. Brazil manufactures locally many of the drugs used in triple antiretroviral treatment. The most significant drop in prices has been in nationally manufactured drugs, both by government labs and private companies. From 1996 to 2000, the cost of drugs manufactured in Brazil decreased an average of 72.5%, while the cost of imported brand-name drugs fell only by 9.6%.[49]

5.3.3.1 National Production of Antiretroviral Drugs

The drug market in Brazil tops $7.5 billion dollars per year. The price of generic drugs in the country is on average 40% lower than the price of brand-name drugs, although in some cases it is 75%. Presently, 86% of the brand-name drugs marketed in Brazil has generic versions.

Starting in 1998, the Ministry of Health began to invest in infrastructure and in strengthening national public drug laboratories in order to manufacture antiretroviral drugs nationwide. The first lab to manufacture such drugs was the Far-Manguinhos Institute, the Ministry of Health's official lab, where investments were made to adapt and improve the facility's infrastructure, and to ensure quality control, in compliance with WHO and ANVISA standards. Just one year later, the country was already producing 47% of the antiretroviral drugs (92% in government labs and 7% by private companies), and purchasing the remaining 53% from multinational drug companies.

Since 2002, strategic public-private alliances have been forged among official labs, Brazilian private enterprises, and international manufacturers of generic drugs. Through these partnerships, and with financing from the Brazilian National Development Bank (BNDES), it has been possible to establish at the national level the capacity to manufacture active ingredients (raw material) and antiretroviral drugs.

Today, Brazil manufactures generic versions of eight of the 15 drugs used in antiretroviral treatment. In terms of purchases from multinational companies of the seven patented drugs that Brazil needs, despite successful price negotiations in recent years, the country continues to pay extremely high prices. The experience with voluntary licensing procedures has not yielded the desired results — it has not translated into reductions in the purchase prices that the Ministry of Health has to pay nor has the transfer of technology to national companies taken place.

---

[48] AVERT, AIDS Education Research & Trust. UK. 2005. Available at: http://www.avert.org/generic.htm.

[49] Mario Glanc, "Los medicamentos genéricos: Una herramienta posible para mejorar el acceso de la población al tratamiento efectivo de las enfermedades", Presented at the*: 3er Foro Interamericano Subregional de Liderazgo en Salud* (Buenos Aires, 2002).

In view of this, the NHA has declared that in order to ensure the medium- and long-term sustainability of the HIV/AIDS program, the following steps are necessary:[50]

i. Issue mandatory licenses for those antiretroviral drugs that are the greatest burden on the Ministry of Health's procurement budget;

ii. As soon as possible undertake the local production of these antiretroviral drugs, through public/private strategic alliances between the official drug labs and Brazilian chemical-pharmaceutical companies, in order to successfully reduce prices;

iii. Strengthen the national technological capacity to develop and produce the active ingredients and antiretroviral drugs in order to make production of these drugs viable at the national level and reduce the medium- and long-term dependency on international technology; and

iv. Establish a close relationship between the country's public sector and private drug manufacturers with support from the PROFARMA program of the Brazilian National Development Bank (BNDES).

5.3.4. Future Challenges

The Brazilian government's commitment to guarantee its population free access to antiretroviral drugs has been established in the Constitution since 1988 and has been duly regulated by law. Although the program for universal access to antiretroviral drugs does not meet 100% of the demand, the policy has indisputably had proven results. Since 1996, mortality from HIV/AIDS has declined by 50%, and hospitalization due to HIV/AIDS has dropped by 80%.

Without a doubt, the successful results of the HIV/AIDS program are a product not only of the policy of providing antiretroviral drugs, but also of the combination of factors that Brazil managed to coordinate to combat the HIV/AIDS epidemic. These factors include an early response from the public sector, robust and committed participation from civil society, a multisectoral mobilization of efforts and resources, a balanced combination of prevention and treatment, and consideration of human rights in all strategies.[51]

The day-to-day continuity of the program in supplying drugs, as it is formulated, depends on the capacity to sustain its volume of expenditures. This sustainability is closely tied to its capacity to overcome and surpass the restrictions imposed by the organizational realities of public administration (procurement mechanisms, level of human resources, distribution systems, among others) in the program's execution.

In the legal-administrative framework, a large number of variables influence program execution. One of the major risks to be avoided is an uneven drug supply, which diminishes treatment effectiveness and causes repercussions in terms of increased mortality and costs of hospital and ambulatory care. The large cities currently provide antiretroviral treatments without major problems, although access to new drugs sometimes presents difficulties, especially in certain regions of the country.

[50] Ministry of Health in Brazil, National STD/AIDS Program. "La sostenibilidad del acceso universal a medicamentos antiretrovirales en Brasil" (Brasilia, August 2005).
[51] Levi G. and Vitoria M, "Fighting against AIDS: the Brazilian Experience," *AIDS* 16, 2002.

Another challenge is to ensure availability of raw material for national production. For example, in February of 2005 there was a shortage of raw material due to a two-month delay in a shipment from India (the raw material is used by Brazilian laboratories to manufacture the drug AZT, or Zidovudine).[52]

Investments in the modernization of the program's drug distribution logistics must also be continuous. Strategies must be developed to overcome the difficulties in operating the SICLOM and SISCEL systems, due to the sprawl of the network of interconnected services and geographical distances separating them. Human resources must be continually trained and motivated; a certain degree of resistance still exists on the part of the drug distribution units to adopt computerized records and distribution control systems.

Health professionals who prescribe the medication and monitor the results must receive ongoing training, in view of the growing sophistication of the treatment. Also, it is essential to review and update the treatment consensus and quality standards to ensure rational use of the drugs and their quality, safety, and treatment efficacy.

In terms of economic regulation, Brazil will continue its strategy to develop the local industry to produce its own antiretroviral drugs, which has allowed the country to cut prices drastically and to set a precedent for the entire world. The national health authority is committed to the goal that all patients with HIV/AIDS should have access to the treatment, and it has declared that it will not hesitate in licensing the patents of some drugs if the universal program is threatened by lack of resources.[53]

6. Lessons Learned

This section presents the lessons learned from the evaluation of case studies and other efforts made by health authorities in the Region to strengthen conduct/lead and regulation. However, as will be seen, the lesson learned sometimes arises from what has *not* been done — but should have been — to strengthen the steering role.

- ***Political support is essential to effectively perform the conduct/lead dimension of the steering role***

The experience in **The Bahamas** has shown that political support for the health authority from the highest level of government is essential to achieve processes of change. In 2002, with a view toward seeking a sustainable solution to the financial crisis in the health sector, the Prime Minister appointed "The Blue Ribbon Commission" to study the feasibility of implementing a national health insurance program. Two years later, after extensive analysis, the Commission proposed a broad restructuring of the health system, with the creation of a National Health Insurance Plan that would ensure free universal coverage through a public system financed by taxes.[54] Despite criticism from several actors, the process has continued forward with sustained political support. The health authority appointed a steering committee that is currently in charge of all aspects involved in implementing the national health insurance plan.

[52] News Agency on Alternative Information (ANIA, in Spanish): "Red Gapa protesta sobre la falta de cóctel contra el SIDA". 27 February 2005.
[53] Closing remarks by the Brazilian Health Minister, Saraiva Felipe, at the III International Conference on HIV Pathogenesis and Treatment 2005. Available at: http://www.impactaperu.org/pages/news.htm.
[54] Report of the Blue Ribbon Commission on National Health Insurance, January 2004.

In **Argentina**, a good example of health authority leadership was the elaboration of the Federal Health Plan 2004-2007.[55] In 2002, the country went through an unprecedented political, institutional, and socioeconomic crisis, suffering a vast drop in real income and a sharp increase in unemployment and poverty. After the crisis, the health authority took advantage of the opportunity for consensus-building that already existed — albeit fragile — to carry out a planning exercise with all the jurisdictional and national regulatory authorities (the provincial and national ministers of health), who effectively hold authority over regulation and the steering of the health system.

This exercise produced the medium- and long-term Federal Health Plan (PFS in Spanish), which includes the care model, the management model, and the financing model. This plan is not a law, but a political document that establishes health guidelines. It is open-ended and will be tailored to the priorities to be established in the future. In the post-crisis political and social scenario, where different actors such as laboratories, private providers, public providers, among others were competing for resources, the PFS offers guidance, showing in which direction the sector should go. It is important to note that the plan was successfully consolidated despite changes in almost all the provincial ministers and even a change in the president of the Republic. The health and political authorities were able to finalize the project despite the political instability of the moment.

In **Chile**, the health system reform process, which began in 2000, led to a profound transformation in the public and private health system; a key element was the commitment to and political support for the project. The president unconditionally supported the project throughout the entire process, a factor that indisputably had an important weight in the results obtained. In the face of the challenge of a weakened health authority, the country gave a high priority to the "steering role" and was able to consolidate the NHA's leadership role in the health sector with the changes implemented, which included a health authority law.

- ***Accurate, timely, and reliable information is indispensable for setting health priorities and objectives***

In the processes of analyzing the health situation, the quality of the information used determines the quality of the results. Thus, to the extent that the epidemiological, clinical, social, and economic data used as input are accurate, reliable, and timely, the analysis generated will more closely approximate reality. Likewise, the processes of mapping out priorities based on sound and precise analysis will be higher quality and more reliable. Quality information is also an input for developing policies that aim at obtaining concrete objectives and measurable and quantifiable results.

In **Costa Rica**, developing the capacity to accurately analyze the health situation has been a priority for the health authority, particularly since the Ministry of Health consolidated its steering role. A focus on equity has been stressed in data collection, especially in the geographical and population regions with greater levels of inequality. At the same time, strategies have been developed to strengthen the planning, surveillance, and evaluation systems. The objective is to collect reliable data that helps establish priorities, define health interventions, make the necessary adjustments, and guide the decision-making process so that it is rational, effective, and equitable.

[55] Source: Lic. Claudia Madies, Sub-Secretariat of Policies, Regulation, and Oversight. Ministry of Health. Argentina. September 2005.

In the Huetar-Norte region of the country, a pilot project was undertaken that has yielded successful results. The objective was to establish a regional health agenda for the area, based on priority public health problems and in line with the national health agenda, with the expectation to redirect and mobilize resources from public and private institutions and nongovernmental organizations for the identified priorities. Information gathering was organized in such a way that it was possible to generate the following products: (i) a measurement of essential public health functions (EPHF); (ii) a functional analysis of the health services network; (iii) a health situation analysis (ASIS); and (iv) formulation of a consensus health agenda.[56]

Chile, in its health system reform plan AUGE, presents an interesting example of how quality scientific information is necessary in order to set priorities. The AUGE plan identified 56 health priorities, through which the entire population is guaranteed access to a set of safe and effective interventions. The process of determining what these interventions would be involved the development of treatment protocols based on the best scientific evidence, in several stages: (i) identification of the benefits linked to the health problem (screening, diagnosis, treatment, etc.), (ii) effectiveness of interventions (technology, evidence, scale, safety, etc.); (iii) adverse effects; (v) cost effectiveness; and (vi) qualifications of the interventions (accreditation, certification).[57] Finally, the evaluated interventions were categorized based on the weight of the evidence. This process ensured the selection of the safest and most effective interventions to include in the AUGE project.

One tool that several countries are using to help improve the quality of information gathered is electronic health records (EHRs). These records, which go beyond traditional medical records, include epidemiological, administrative, and management data, which, on the one hand, places a high priority on quality, and, on the other hand, improves the quality and efficiency of health care. While the high costs of such technology are still beyond the reach of many countries, other medium-income countries have begun to explore their use. **The Bahamas**, for example, have tested a system of electronic health records, reporting successful results.[58]

- ***The formulation of health policies and strategies must be accompanied by evaluations of these policies and strategies***

Evaluation of health policies and strategies allows the identification of which interventions have been the most successful in terms of the established objectives, allowing the assessment of results, the quantification of achievements, and the detection of imbalances and weaknesses. It also allows the identification of the determining factors that have an impact on the results. It is the stage in the policy-making cycle that provides feedback for the health authority -- essential information on implementation of health policies and strategies. As a result, it is a key exercise that the health authority must undertake in order to successfully exercise the steering role.

Colombia has recently made a significant effort in the evaluation of health policies by assessing the impact of Law 100, which was implemented in 1993 by the general social security system. Ten years after the law went into effect, the health authority has undertaken an evaluation of the system's complex operations to make recommendations

[56] The Ministry of Health of Costa Rica and PAHO, *Apoyo a la Región Huetar Norte a formular la Agenda Sanitaria Regional Concertada*, 2004.
[57] E. Chapman, "La MBE en la toma de decisiones dentro de los sistemas de salud: de la teoría a la práctica," Presented at the: *Foro Internacional de Medicina Basada en la Evidencia*. 26 de Abril de 2004.
[58] Susannah Mayhew, "Acting for reproductive health in reform contexts: Challenges and research priorities". London School of Hygiene.

on the challenges for its improvement, especially on the issues of coverage and financial sustainability. Given the difficulty of gathering information — the Ministry often does not participate in actual market and contractual relationships in the sector — many actors participated in the evaluation. The evaluations indicate some progress and also critical problems that must be resolved in order to consolidate the benefits, and recommendations were made for adjustments to the health reform approved by Law 100.[59]

Costa Rica, with its 2002 health sector analysis, offers an example of a health authority proactive in the practice of evaluation. Specialists were convened from the Ministry of Health, the Costa Rican Social Security Fund, the Ministry of Public Education, the Costa Rican Institute of Water Supply and Sewerage Systems, the National Insurance Institute, the Institute of Alcoholism and Drug-Dependency, and the National Child Welfare Agency, as well as other entities connected with the health sector, in a joint task force to analyze the sector. The analysis included the study of various strategic areas such as organizational structure; international cooperation; the economic, political, and social context; epidemiology and demography; the steering role and essential public health functions; social protection in health; expenditures and financing of health care; and supply and demand for health services. In all these areas, the high priority policies and strategies[60] were evaluated, in order to identify the results, achievements, and areas that require strengthening.

The evaluation of health policies is still one of the weakest areas in the exercise of the steering role by health authorities in the region. Ongoing evaluation practices provide strategic information to improve the quality of efforts made by the sector. Evaluations measure improvements in the status of health and generate health system performance indicators that can be linked to specific policies and strategies. This is an area of great importance that should be strengthened in all countries of the Region.

- ***The sectoral stakeholders' awareness of the importance of the steering role facilitates the consolidation of the health authority as the regulatory entity***

To consolidate the steering role, the health authority must *first* understand the concept of "the steering role." *Second*, it must be aware of the importance of the steering role and make sure that the institution, the sector, and the general population share the same view; and *third*, strategies must be developed to strengthen the performance of the steering role.

A good example of raising awareness among social actors about the importance of the steering role can be seen in the health sector reform process in **Chile**. The reform project first defined the steering role of the health authority, and draft legislation was prepared to back it up. At the same time, a political strategy was developed to seek an alliance with the general public, who at the beginning did not fully understand the reform, but realized that rights that they aspired to have were being created. Three media campaigns with three slogans were carried out, each attuned to a specific stage of the reform process. The first, "A Reform that Moves Forward," was followed by "Chile wants the Reform," and once the projects were underway, the third was "Chile is Better!" The first campaign was actually more geared toward advertising the reform itself than educating the public about its content, and an opportunity to truly inform the population was lost. However, the next two campaigns took advantage of the prominence of the President and the Ministry of Health in

[59] Study by the Faculty of Economics of the Rosario University. "Viabilidad del sistema de salud: Qué dicen los estudios." Corona Foundation. 2005; and interview with Jaime Ramirez, Consultant, health reform support program. Colombia.
[60] Ministry of Health of Costa Rica, executive summary of the analysis of the health sector *2002*, www.netsalud.sa.cr/reass2002.htm.

the media, and an intense communication effort was undertaken to reach the population. There was always a clear discourse addressed to the general public; and the effect today is positive civic support for the reform process.[61]

In **Costa Rica**, for example, experience has shown that internal communication is vital for changes. The process of making social actors in the country aware of the importance of the steering role was carried out *first* within the institution and subsequently with the general population. The transformation process in the Ministry of Health involved transferring nearly 1600 staff members from the Ministry to the Social Security Institute, a move that undoubtedly created anxiety and instability for the institutional personnel. To placate the concerns and alleviate the impact of the process, an internal communication strategy was instituted to disseminate information and facilitate the process of change. Then, an extensive social communication campaign was carried out using all media to inform the population about the steering role of the Ministry of Health and the changes in the sector. Both exercises managed to raise awareness of the institutional actors and the general public and to empower them, thus helping the health authority consolidate its steering role.

- ***The mobilization of relevant actors and civil society participation in the promotion of health are often key elements of success***

Promoting active civil society participation in identifying problems, planning, and implementing health actions is a key component of the conduct/lead dimension of the steering role in health. The extent to which the health authority informs, educates, and empowers civil society on health issues will determine its degree of active participation. Equally, a civil society that actively participates in the sector is a partner in promoting health and reducing risk. Seen from another perspective, mobilization of interested actors can have an effect on the actions of the health authority by raising the NHA's awareness about specific subjects that perhaps were not viewed as priorities.

An important lesson that can be learned from the experience with HIV/AIDS in **Brazil** is that with civil society participation, changes can be achieved in health policies. Groups of people living with HIV/AIDS organized to demand care for their situation. They managed to promote a solidarity movement that led to concrete results, specifically, the approval of Law 9313/1996, which guarantees free distribution of antiretroviral treatment for all people with HIV/AIDS, fulfilling one of the principles of the unified health system (UHS), which is universal access to health.

In the Brazilian context, the role of the civil society in the fight against AIDS has been solid and constructive, playing an important part in defending the rights of people living with HIV/AIDS, accelerating government processes and supporting the efforts of public agencies by implementing projects. From 1994 to 2002, more than $40 million was invested in 2,300 projects implemented by civil society organizations, including communities of people living with HIV/AIDS and NGOs working with them.[62]

In **Chile**, civic participation played an important role in the health sector reform process in recent years. The health authority promoted the active participation of civil society in identifying problems, planning and implementing health actions, and generating

[61] Interview with Andrés Romero, Legal Advisor, Ministry of Health in Chile. September 2005.

[62] Paulo R. Teixeira et al, "The Brazilian Experience in providing Universal Access to Antiretroviral Therapy," *Economics of AIDS and Access to HIV/AIDS care in developing countries*. Issues and Challenges. 2003.

collaborative mechanisms to establish a transparent and continuous dialogue, thus achieving civic support for the reform process.

Other significant examples of social participation in the area of health promotion and protection can be found in several countries, such as **Costa Rica** and **Nicaragua** for control of dengue, and **Bolivia** for control of Chagas' disease. Many experiences are at the grassroots level and the challenge is turning them into mass movements that can have real impact. Nevertheless, it is important to learn from these experiences that vertical non-participatory efforts are not sustainable. The creation of health promotion and prevention models based on community participation that are linked to education and mass communication must be encouraged.

- ***For international cooperation in health to have impact, respond to the identified needs, and be sustainable, the health authority of the country must be involved in its negotiation, coordination, and evaluation***

Coordinating international cooperation in health is a challenge for all countries receiving international financing. In fact, in poorer countries, an inverse relationship often exists between the volume of financing the country receives and the capacity that its health authority has to coordinate and supervise the international cooperation.

Coordinating international cooperation is not an easy task. It implies managing relationships with multiple donors with varying interests and policies that tend to direct efforts toward previously defined priorities. It involves preparing, supervising, and technically evaluating cooperation projects as a national counterparty, in addition to negotiating new financing and projects in the sector. Successful coordination calls for trained human resources, financing, infrastructure, and logistic support.

Nicaragua presents a praiseworthy example on the coordination of international cooperation in health. Since 2002, the Nicaraguan government has promoted a joint work initiative with other countries and cooperating agencies to advance toward the alignment and harmonization of international cooperation. The Secretariat of Economic Relations and Cooperation (SREC), a department of the Ministry of Foreign Affairs (MINREX) was created to coordinate, manage and negotiate reimbursable and non-reimbursable international cooperation agreements for the country's economic and social development programs and projects. Its function is to act as a facilitating entity among the state institutions that are recipients of international cooperation and the cooperating community, made up of approximately 19 bilateral cooperating organizations, 21 multilateral organizations, and nearly 150 nongovernmental organizations.

International cooperation is usually channeled into Nicaragua in the form of donations and concessional loans, or else through technical cooperation. These resources can be tied to the implementation of specific projects (committed resources), or consist of liquid funds usually used to service the payment of external debt. For Nicaragua, this cooperation represents an economic, financial and technical assistance source for the country's priority development programs and projects.[63]

In this collaborative framework, the Ministry of Health developed a code of conduct in 2005 that defines the good practices of relationships between the Ministry and "partners for development" (SPD, in Spanish). These good practices establish guidelines for the

[63] Portal de la Secretaría de Relaciones Económicas y Cooperación, Nicaragua, http://srec.cancilleria.gob.ni/ .

coordination, harmonization, and alignment of the cooperation so that it responds to the priorities of the country and the government's international commitments mapped out in the policies and plans of the Ministry of Health and the government, optimizing the resources' effectiveness.[64] The code of conduct creates the conditions to consolidate the Ministry of Health's leadership and steering role in the steering and management of the sector.

- ***The legal framework supporting the health authority in the performance of its functions must be consistent with the leadership that — as the steering entity — it exercises in the sector***

In other words, the regulatory framework must be effective — its elements must be applicable — and consistent with the policies and actions of the health authority. The regulations and laws must be up-to-date, must not be contradictory, and must be of unequivocal interpretation.

The health system reform experience in **Costa Rica** is an important example. The transformation that the Ministry of Health underwent in the 1990s was extreme: the Ministry went from being a health service provider to a regulatory entity, which had to have the "political, technical, administrative, and legal capacity to direct, lead, regulate, and control the different aspects related to the delivery of health care services."[65] This shift implied, in the legal area specifically, the broad task of revising the legal framework and formulating proposals for expanding, modifying, and creating legal instruments for the practice of the steering role.

Another interesting example is the issue of drugs in **Argentina**, with the formulation of a new policy and creation of a complementary legal framework that protects it. In 2002, the health authority established as a high priority ensuring access to drugs, which is reflected in the national drug policy. The policy identifies the key elements to promote access: regulation of the drug market and direct provision of drugs for the population group that does not have the means to purchase them in pharmacies. Subsequently, a new regulatory framework was established with fixed and clear rules for supporting the policy, which included: (i) the law of utilization of drugs by their generic name, (ii) measures to regulate drug advertisements, (iii) a federal agreement on drug regulation, through the National Administration of Drugs, Food and Medical Technology (ANMAT, in Spanish), which involves common actions of oversight and control, and (iv) the gradual incorporation of criteria on cost effectiveness of drugs in the registry, among other things.

- ***For regulation to be effective, the regulatory role must be accompanied by enforcement efforts***

The health authority is responsible for ensuring that the laws, norms, and public health regulations designed to protect the population are adopted, disseminated, evaluated, and followed.

The enforcement function encompasses all that is related to the aspect of ensuring compliance with the law, and includes such diverse areas as vector control, protection of

[64] Code of conduce that establishes the relations between the Nicaraguan government, through the Ministry of Health, and the partners for development.. Managua, Nicaragua. January 2005.
[65] Definition of the steering role of the Ministry of Health. Annual Report 1999. The Ministry of Health of Costa Rica.

drinking water, food safety, minimum standards of care in the delivery of services, accreditation of health institutions and human resources, the drug marketing chain (production, distribution, importation, sale and use), use of medical equipment, and health inspections of public establishments, among other things.

Many countries in the region are deficient in this regard, in general due to a disorganized regulatory framework and poor institutional capacity to monitor and control. In many cases the regulatory framework of the health sector consists of an intricate set of laws that generate legal confusion. There are gaps, contradictions, overlapping responsibilities, and little clarity in many of the laws and regulations, which in turn create unnecessary bureaucratic obstacles, promote corruption, and weaken the health authority's capacity to control and sanction. Moreover, the lack of technical capacity of many countries to exercise control — due to insufficient human, physical, and financial resources — and in some cases even the lack of political will to hand over real powers to the health authority.

To take corrective actions, governments in the region must evaluate the performance of their regulatory and control systems and identify weaknesses and their causes, which tend to be multi-faceted. Experiences in developed countries have shown that the regulatory capacity is developed in phases, based on factors such as the degree of evolution of the private sector, the availability of trained human resources, infrastructure and financial resources, and the size and sophistication of the regulatory agency. These factors also influence the type of oversight function that is performed.

The health authority of the government of **Buenos Aires (Argentina)**, with financing from an IADB loan, is currently carrying out an institutional-strengthening project to develop the capacities of the General Bureau of Regulation and Oversight (DGRF, in Spanish) of the Ministry of Health. The program's goals are to provide the DGRF with instruments to fulfill its primary responsibilities, defined as "the regulation, qualification, categorization, and oversight of health care facilities; the evaluation of the quality of care in all the sub-sectors in the greater metropolitan area of Buenos Aires; and regulation and control of health-related professions."[66]

In regulation, attempts are made to develop an organizational structure, set a normative foundation, and implement a new regulatory framework. The oversight model has two components: oversight of professionals and of facilities. In the first, the objectives are to develop a program to enroll professionals, with particular emphasis on a retraining subprogram for nurses. In the second, the objectives are to strengthen the program for certification, accreditation, and oversight of health facilities. Components include organizing and streamlining the regulatory framework for health facilities and preparing guidelines on certification procedures, allowing those responsible for health facilities to be fully familiar with the essential requirements.[67]

In **The Dominican Republic**, for example, an issue that has become evident through evaluation exercises is that there are "many laws, but little enforcement." In other words, while the legal framework appears to be sufficiently complete and aligned with the policies established by the health authority, the oversight function is weak, basically due to lack of

[66] Available at http://www.buenosaires.gov.ar/areas/salud/regulacion/index.php.
[67] Program for institutional strengthening. General Direction of Regulation and Oversight. Health Secretariat. Buenos Aires government. 2006.

institutional capacity to perform it. This diagnosis has helped the health authority to become aware of the situation and identify concrete strategies to resolve it.[68]

- ***Skilled human resources are a prerequisite for success in performing the steering role***

Human resources are an indispensable factor in the execution of the steering role. A health authority that has aspires to give high priority to the steering role but does not have qualified human resources cannot adequately perform it. One of the major challenges that health authorities in the Region face is to accurately develop policies and long-term plans to adapt human resources to the changes in health systems.

Strengthening human resources in the health sector — especially personnel in positions of leadership, administration, and management of regulatory health entities —tends to be a component that is invariably included in internationally financed sectoral reform projects. The intent is to improve the "human factor" in the reforms through training components to increase the motivation and technical skills of the workers who implement the changes.[69]

Under the process of sectoral reform, the Ministry of Health in **Costa Rica** modified its institutional framework in 1998, reframed its work processes, and began to perform four strategic steering functions: policy leadership and management, health surveillance, technological research and development, and regulation of the development of health. To this end, it was essential to make adjustments in personnel and train staff members to perform new tasks. There were many training processes, from short-term training to the education of experts at the graduate level (including epidemiologists and health economists, among others).

The Minister of Health in **Uruguay** recently stated[70] that no reform can happen without the involvement and active participation of health workers, since global experience clearly shows that human resources are strategic in any health reform process. In Uruguay the goal was to bring about a comprehensive worker statute for the integrated national health system with the force of law, i.e., a framework to establish not only the rules of the game, but also to plan and structure issues related to the health workers, with the challenge of improving the quality of training.

In **Argentina**, the Ministry of Health has identified the main problems with respect to human resources in the health sector, which are: (i) the neglect of the essential function of developing human resources, (ii) the relative and disorganized coordination between sectors and institutions, (iii) the lack of consensus in adapting supply to the profile of demand and the model of care, (iv) the lack of managerial information, and (v) the extreme fragmentation of norms and regulatory regimes.[71] In the framework of the federal health plan, the Ministry of Health has implemented a policy on human resources for health — based on the problems identified — to respond to the following question: "How can we integrate the health-sector workforce in the efforts to achieve the national health objectives?" For each of these above-mentioned points, the Ministry has presented health policy proposals for human resources, and proposed concrete strengthening actions.

[68] PAHO/WHO- Secretary of state for public health and social assistance (SESPAS), "National workshop on training and evaluation of the steering role function" Dominican Republic, March 2006)

[69] PAHO/WHO, *Los Observatorios de Recursos Humanos en Salud*, 2001.

[70] Speech by the Interim Minister of Health Miguel Fernández Galeano, on World Health Day 2006.

[71] Claudia Madies, Sub-Secretariat of Policies, Regulation, and Oversight. Ministry of Health and the Environment. "Política de Recursos Humanos en Salud: Desafíos prioritarios." ("Policy on Human Rights in Health: Priority Challenges.") Presented in Toronto. September 2005.

Brazil, in turn, has created a new secretariat in the Ministry of Health in 2003 to manage human resources and education in health. Its functions include setting policies and strategies to address the crucial problems that exist in this area. Management of human resources in health aims at promoting information on the workforce to empower states and municipalities to resolve problems in human resources at every level, regulation of health professions, as well as to create and monitor professional certification systems at the national level, among other things. The responsibilities of the health education management area include promoting integration with the educational system, supporting the coordination of public schools with the Ministry of Health, promoting continuing education in health, supporting technical schools for health workers, and promoting the establishment of health education information systems.[72]

7. Conclusions

The present document is the result of a study done under the Health Sector Reform/Health System Strengthening component of the agreement between PAHO/WHO and USAID. The study's objective was to identify essential criteria needed for the performance and strengthening of the national health authorities' steering role, namely *conduct/lead* and *regulation/enforcement.*

The study focused on identifying lessons learned — on the one hand compiling good practices in the strengthening of the health authorities' steering role and on the other hand allowing the collection of evidence in the key areas that must be strengthened in order to perform the steering role more effectively. In other words, based on the analysis of the situation of the health authorities' steering role in the countries of the Region, a set of "lessons learned" could be identified arising from positive experiences, or the absence of them.

The study found that several countries have made significant efforts to strengthen the steering role. Although some countries have a more developed steering role than others, it is impossible to identify a single country that has a prescription for success. Each country, within its reality and its possibilities, will have to perform an analytical exercise in order to assess the performance of its steering role.

The main *lessons learned* are:

1. Political support is essential to achieve effective conduct/lead.

2. Accurate, timely, and reliable information is indispensable to set health priorities and objectives.

3. Policy-making and health strategies must be complemented by subsequent evaluation.

4. Raising awareness of relevant actors about the importance of the steering role facilitates consolidation of the health authority as the regulatory entity.

[72] José Agenor Alvares da Silva, Executive Secretary, Ministry of Health, Brazil. "The Role of Policies and Planning: Health Objectives and Human Resources Policies: The Case of Brazil." Presented in Toronto, September 2005.

5. The mobilization of interested actors and the participation of civil society in the promotion of health are often key elements to success.

6. For international cooperation in health to have impact in a country, meet the identified needs, and be sustainable, the health authority must be involved in negotiating, coordinating, and evaluating such cooperation.

7. The legal framework supporting the health authority in the performance of its functions must be consistent with the leadership that — as the steering entity — it exercises in the sector.

8. For regulation to be effective, the regulatory role must be accompanied by enforcement.

9. Qualified personnel are needed to carry out the functions of the steering role.

The health authorities of the Region must identify problems, formulate criteria and continue to develop institutional strengthening strategies for the effective exercise of the steering role. The health authority must first diagnose how it is performing its steering functions; the subsequent step is to design and implement strategies to strengthen priority areas to strengthen their leadership role, without hindering its capacity to forge strategic alliances with relevant actors (the private sector, NGOs, universities, communities, social sectors, etc.). The health authorities must also invest in human resources — a key element in putting the steering role into action. They must also strengthen their capacity for negotiating with sources of financing and ensure the financial sustainability necessary to carry out their functions.

In summary, the great challenge is to present the steering role as a high level government function, and guide the strengthening efforts toward developing the responsibilities related to planning, financing, allocating, developing resources, knowledge management, and public administration.

References

Acuña Ulate, E. e Fuentes Bolaños, C. Salud y desarrollo. *Rev. cienc. adm. financ. segur. soc*, 2003, vol.11, no.1, p.97-107. ISSN 1409-1259.

Banco Interamericano de Desarrollo. Costa Rica: Desarrollo del Sector Salud, CR-0144. Resumen Ejecutivo. Washington, DC. 2003.

---. Costa Rica: Desarrollo del Sector Salud, CR-0144. Documento de Préstamo. Washington, DC. 2003.

---. Marco Lógico. Costa Rica: Desarrollo del Sector Salud, CR-0144. Resumen Ejecutivo. Washington, DC. 2003.

---. Programa de mejoramiento de servicios de salud. Propuesta de Prestamo Número(s) de proyecto: 711/OC-CR;712/OC-CR;CR0120. Washington, DC. Noviembre 1992.

Banco Mundial. Costa Rica: El Gasto social y la pobreza. Washington, DC. 2004.

Celedón, C, y R. Orellana. *"*Gobernancia y participación ciudadana en la reforma de salud en Chile*"*. Presentado en el Tercer Foro Interamericano Subregional de Liderazgo en Salud. Enero 2003.

Clark, M. Health Sector Reform in Costa Rica: Reinforcing a Public Health System. Prepared for the Woodrow Wilson Center Worshops on the Politics of Education and Health ReforMinisterio de Salud. Washington, DC 2002.

Entrevista personal al Sr. Andrés Romero, Asesor Legal del Ministerio de Salud. Mexico, D.F. Septiembre de 2005.

Erazo Latorre, A. "La reforma de la salud: Una obligación social". Fundación Chile 21. Septiembre de 2004.

Essential Drugs: A WHO/WTO Secretariat Workshop (2001).

Holtgrave DR, Curran JW. What works, and what remains to be done, in HIV prevention in the United States. Annual Rev Public Health (in press).

Homedes, N & A. Ugalde. Multisource drug policies in Latin America: survey of 10 countries" Bulletin of the World Health Organization. Geneva. January 2005.

Glanc, M. "Los medicamentos genéricos: Una herramienta posible para mejorar el acceso de la población al tratamiento efectivo de las enfermedades". Presentado en el 3er Foro Interamericano Subregional de Liderazgo en Salud. Buenos Aires, 2002.

Gobierno de Chile."Informe de las Comisiones de Hacienda y de Salud sobre el Proyecto de Ley que modifica el Decreto Ley No. 2763 de 1979, con la finalidad de establecer una nueva concepción de la Autoridad Sanitaria de las distintas modalidades de gestión y fortalecer la participación ciudadana." Boletín No 2980-11. Septiembre de 2002.

Gobierno de Chile. "Informe de la Comisión de Salud", recaído en el proyecto de ley, en segundo trámite constitucional, que modifica el decreto ley Nº 2.763, de 1979, con la finalidad de establecer una nueva concepción de la autoridad sanitaria, instaurar distintas modalidades de gestión y fortalecer la participación ciudadana. Boletín No. 2980-11. Agosto de 2003.
Gobierno de Costa Rica. Análisis Sectorial de Salud. Ministerio de Costa Rica. San José, 2002.

Government of Brazil. National AIDS Drug Policy. June 2001

Lucchini, S, Cisse, B. et al. Decrease in Prices of Antiretroviral Drugs for Developing Countries: from Political "Philanthropy" to Regulated Markets?" Economics of AIDS and Access to HIV/AIDS Care. June 2003.

Matsoso, P, Auton, M et al. "How does the Regulatory Framework affect Incentives for Research and Development?".

Mattos Dias, J.L de, et al. "Terapia Anti-Retroviral y Salud Pública: Un balance de la experiencia brasileña". Coordinación General de ETS/SIDA del Ministerio de Salud de Brasil y ONUSIDA. 2000.

Ministerio de Salud de Costa Rica. Licitación por registro. Diseño y ejecución de un Programa de Calidad y Bioseguridad para servicios de salud de mediana y baja complejidad. Contrato de Préstamo 1451 OC-CR entre la República de Costa Rica y el Banco Interamericano de Desarrollo. Programa de Desarrollo del Sector Salud.

---. Informe Anual 1999. San José, Costa Rica.

---. Informe Anual 2000. San José, Costa Rica.

---. Licitaciones Públicas para la Contratación de Consultorías. Contrato de Préstamo 1451 IC-CR entre la República de Costa Rica y el Banco Interamericano de Desarrollo. Programa de Desarrollo del Sector Salud.

---. Memoria Anual 2004. San José, Costa Rica.

---. Política Nacional de Salud 2002-2006. San José, Costa Rica 2002.

Ministry of Health of Brazil. "The Experience of the Brazilian Aids Programme", available at www.aids.gov.br (2002?).

---. National STD/AIDS Program. "The Sustainability of Universal Access to Antiretroviral Medicines in Brasil". Brasilia, August 9, 2005.

---. National STD/AIDS Program. "The Sustainability of Universal Access to Antiretroviral Medicines in Brazil". Brasilia, Brasil. August 2005.

Oliveira-Cruz,V., J. Kowalski and B. McPake. Viewpoint: The Brazilian HIV/AIDS "success story" – can others do it? Tropical Medicine and International Health, Volume 9 No. 2. February 2004

Organización Mundial de la Salud. Norms and Standards: Quality, safety and efficacy of medicines. www.who.int/medicines/areas/quality_safety/regulation_legislation 2005.

Organización Panamericana de la Salud/Organización Mundial de la Salud. "Lineamientos Metodológicos: Análisis Sectorial en Salud: Una Herramienta para la formulación de políticas". Serie LACRSS - Edición Especial # 9, Tercera Versión, Washington, DC., 2004.

---. Perfiles de Sistemas de Salud: Costa Rica. OPS/OMS. Washington, DC 2002.

--- "Marco legal de la Autoridad Sanitaria de Chile para la dimensiones de conducción y regulación". Borrador. OPS/OMS, Washington, DC. Septiembre de 2005.

---. "Información para la equidad en Chile". Santiago de Chile. Marzo de 2001.

---. "Instrumento de evaluación del desempeño de la función rectora de la Autoridad Sanitaria Nacional". Washington, DC. Febrero 2005

Ortells, P. Brazil: A Model Response to AIDS. Americas Program, Interhemispheric Resource Center (IRC). April 2003.

Outtterson, Kevin. Pharmaceutical Arbitrage: balancing access and innovation in international prescription drug markets. Yale J. Health Policy, Law and Ethics. December 2004.

Peppers, S. "El sistema de salud de Chile: Propuestas para una reforma en salud". Revista Médica de Santiago. Volumen 4. Número 18. Septiembre de 2001.

Portal de Web de la Biblioteca del Congreso Nacional de Chile: http://www.bcn.cl/portada.html.

Portal de Web del Gobierno de Chile: http://www.gobierno.cl/plan_auge/index.asp.

Portal de Web del Ministerio de Salud de Chile: http/www.minsal.cl.

Queiroz, S. Brazilian/American Dispute over Patents at the WHO. Technology Paper Briefs. Volume 1 Issue 3. 2002

Quesada, C. "Claves de una estrategia eficaz: Brasil emerge como un modelo en la lucha contra el SIDA". BIDAmérica, Revista del Banco Interamericano de Desarrollo. 2001

Ruiz-Esquide, Dr. M. "La reforma de salud según un médico legislador". Revista Vida Médica, publicación oficial del Colegio Médico de Chile, volumen 55, Nº 2, 2003.

Salas Abarca P. El papel rector del Ministerio de Salud. Una visión desde el nivel local de la CCSS. Revista de Ciencias Administrativas y Financieras de la Seguridad Social. Vol. 10, No. 2, San José, Costa Rica. Julio 2002.

Smart, T. "Getting antiretrovirals to where they are needed: drug procurement and quality". HIV&AIDS Treatment in Practice #45, April 6, 2005.

Teixeira, P.; Vitória, M.A. y Barcarolo, J. “The Brazilian Experience in providing universal access to antiretroviral therapy”. Economics of AIDS and Access to HIV/AIDS Care. March 2003.

World Bank. Costa Rica: Health Sector Reform Project—Social Security System. PHNFlash Issue 15. Population, Health and Nutrition (PHN) Department. World Bank. 1994.

World Bank. Implementation Completion Report on a Loan in the amount of US$22 million to the Republic of Costa Rica for a Health Sector Reform Project. Washington, DC. May 2003.

World Bank. Project Appraisal Document on a Proposed Loan in the amount of US$17 million to the Republic of Costa Rica for a Health Sector Strengthening and Modernization Project. Washington, DC. May 2001.

WHO Policy Perspectives on Medicines. How to develop and implement a national drug policy. World Health Organization. Geneva. January 2003.

World Health Organization. Essential drugs and other medicines. “Effective Drug Regulation: what can countries do?” Theme paper for Discussion. Geneva. March 1999.
---. Pro-Poor Health Policy Team. “3 by 5”, Priority in Treatment and the Poor. Geneva. January 2004.

---. Report of the Workshop on Differential Pricing and Financing of Essential Drugs: A WHO/WTO Secretariat Workshop (2001).

Annex I

Operational Criteria for Conduct/Lead and Regulation

CONDUCT/LEAD

- **Health Situation Analysis**
  - Collection and availability of information
  - Data quality control
  - Institutional capacity for conducting health situation analysis
- **Definition of health priorities and objectives**
  - Conducting topic-focused diagnoses
  - Institutional capacity to set health priorities and objectives
- **Determining health policies, plans, programs, and strategies**
  - Preparing and developing health policies, plans, programs, and strategies
  - Disseminating health policies, plans, programs, and strategies
  - Monitoring and evaluating health policies, plans, programs, and strategies
- **Steering, ensuring consensus-building, and mobilizing actors and resources**
  - Consensus-building and leadership
  - Mobilizing resources
- **Health promotion, participation, and social control**
  - Designing and promoting public health policies
  - Promoting the active participation of civil society in identifying problems, planning, and implementing actions in health
  - Promoting intersectoral coordination
- **Harmonization of international technical cooperation in health**
  - Negotiating with donors and other international cooperation sources
  - Coordinating international cooperation in health
  - Monitoring and evaluating the counterparts in international cooperation projects
- **Political and technical participation in international, regional, and subregional organizations**
  - Political and technical coordination with international, regional, and subregional organizations
  - Implementation of subregional, regional, and global agreements
- **Evaluating health system performance**
  - Measuring achievement of goals
  - Measuring the resources used and estimating the efficiency of the health system
  - Performance evaluation and feedback

REGULATION

- **Institutional framework and legal support for exercising the steering role**
  - Implementing and refining the legal framework
  - Effectiveness of the legal framework
  - Institutional capacity to perform the regulatory function
- **Enforcement and control**
  - Capacity of the national health authority to enforce regulations
  - Coordination and transparency
- **Regulation and control of medical inputs (drugs, medical equipment and devices) and health technology**
  - Regulation of the pharmaceutical sector
  - Regulation and control of medical equipment
  - Regulation and assessment of health technology
- **Regulation and control of goods and services in health**
  - Regulation and sanitary control of consumer goods
  - Sanitary licenses of public establishments
- **Regulation and control of the environment**
- **Regulation and certification of human resources in health**
  - Characterization of the health-sector workforce in the country
  - Setting standards and criteria for the accreditation and certification of health professionals
  - Setting standards and criteria for the accreditation and certification of training institutions for health professionals