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Status Update of the Reimbursement Review Environment in the Public Sector across Four Latin American Countries

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ABSTRACT

In Latin America, social security and public sectors represent the largest financiers and providers of health care. Many countries in the region have compulsory packages of basic health care benefits. As part of an effort to improve quality of care and access, several health technology assessment agencies, both governmental and academia, among a number of Latin American countries have been formally established in the past few years. Several Latin American countries have recently developed and published methodological guidelines in economic evaluation, indicating that there is a growing interest in evaluating health-related products, drugs, and technologies used by the population. Presentations on the health care system and the role of health technology assessment, pharmacoeconomics, and risk sharing policies, from the public sector perspective, in the Latin American countries Argentina, Brazil, Colombia, and Mexico were made at the 3rd Latin American ISPOR Conference held in Mexico City in 2011 and are discussed in this article. In conclusion, there is a clear need for Latin American countries to evaluate the value of new technologies that are being incorporated into their health care system. In addition, health technology assessment guidelines are important for their local needs in terms of regulation along with common country unions. In the future, the Latin American region needs to increase drug access along with implementing cost-containment measures to improve quality and health outcomes.

Keywords: health technology assessment, Latin America.

Introduction

The health care system in Latin America is highly fragmented and has subsystems that target specific strata of the population grouped by social class, income, occupation, type of employment, ethnic origin, or urban or rural residence, producing a phenomenon of population segregation that has led to higher segmentation, fragmentation, and low efficiency [1].

To address the fragmentation of the health care systems in the region, the Organizacion Panamericana del Salud (Pan-American Health Organization) created a new health technology assessment (HTA) network in the Americas (Red de Evaluación de Tecnologías Sanitarias), which triggered the HTA development in Latin America [1,2]. As part of this initiative, countries representing Mercosur (Brazil, Argentina, Paraguay, and Uruguay) and Grupo Andino (Bolivia, Chile, Colombia, Ecuador, Peru, and Venezuela) commenced focusing their efforts on the implementation of HTA. Currently, Mercosur has guidelines for HTA methods, new technologies, and economic evaluation. The Grupo Andino is also working toward developing methodological HTA guidelines [1,2].

There are several HTA agencies, both governmental and academia, among a number of Latin American countries, which were formally established in the last couple of years. Countries such as Cuba, Brazil, and Mexico have recently developed and published methodological guidelines in economic evaluation, indicating that there is a growing interest in evaluating health-related products, drugs, and technologies used by the population [3,4].

In 2009, during the 2nd ISPOR Latin America Conference held in Rio de Janeiro, Brazil, the first symposia was held to discuss questions on HTAs, decision-making reimbursement, and pharmacoeconomics to support each country's needs at that time, with a focus on four Latin American countries (Argentina, Brazil, Colombia, and Mexico) [5]. To provide an update on the information presented in 2009, at the 3rd Latin America Conference held in 2011 in Mexico City, Mexico, a second symposia served to discuss the health care reimbursement environment and

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risk-sharing agreements for the same four Latin American countries (Argentina, Brazil, Colombia, and Mexico).

In Latin America, social security and public sectors represent the largest financiers and providers of health care. Many countries in Latin America have compulsory packages of basic health care benefits. What follows are country-specific updates of the public sector environment in Argentina, Brazil, Colombia, and Mexico concerned with the reimbursement environment and HTA based on the presentations and discussions at the 2011 3rd Latin American ISPOR Conference held in Mexico City [6].

Mexico

The Mexican health care system is divided into public (social security and Ministry of Health) and private (employers and self-pay), with only 64.6% of its population having health insurance [7]. The Mexican general law of health assigns to the Ministry of Health the responsibility to elaborate Mexican official norms of the sector and gather sanitary statistics. Under the Ministry of Health, Mexico has a general health council, which is the body of the Mexican state and is the health authority across the country. The Mexican council is assigned the responsibility to elaborate, review, and maintain permanent updates of the data of formulary drugs and studies and serves to resolve requests for updating the formulary drugs of the providers of health, scientific organizations, and suppliers [7].

According to the general law of health, before each new technology is introduced to the national market for its consumption, it must first obtain a sanitary registry. This request is made to the "Comisión Federal para la Protección contra Riesgos Sanitarios" [8], a commission that evaluates safety and efficacy of the product at issue.

Since 2000, once a product is in the national market it needs to be included in the formulary called "Basic Formulary Medications" and medicine catalogue made available through the Public System of Social Security. The private system of national health has the freedom to use drugs that are not included among the Basic Formulary Medications.

In 2007, to better evaluate health products and technologies available to the Mexican population, a program of action specific to HTA was established. HTA reports and recommendations are provided by university research centers and medical societies to the general health council and the minister of health to inform the Ministry of Health, payers, and providers. Since 2003, pharmacoeconomic studies are regarded as being mandatory as part of the HTA submission. To ensure the quality of the economic evaluations generated for the Council of General Salubrity, the academy and the pharmaceutical industry published in 2008 the "Guide for the conduction of studies of economic evaluation for the update of the Basic Formulary Medications of consumptions of the health sector in Mexico" [9].

As of 2003, in Mexico, there has been a growth in the development of economic evaluations with the intended purpose to fulfill the requirements for inclusion to the Basic Formulary Medications. These economic evaluations are, for the most part, presented to providers who have requested an update of the Basic Formulary Medications. Apart from those created by the government, some of the economic evaluations are also performed by academic groups and private consultants.

To perform HTAs in Mexico, the Center of National Health Technology (Centro Nacional de Excelencia Tecnológica en Salud) was instituted, which is a Ministry of Health agency. Its main purpose is to produce objective, reliable, and timely information related to health technologies. It is organized into three main programs: 1) medical equipment planning, to provide information on medical equipment as well as to supply the National Health Care System with information on the incorporation of medical devices; 2) the HTA, generating evidence to aid decision making from the Ministry of Health and the general health council; and 3) e-Health, to generate health information to the national health care system and communication of technologies [10].

Brazil

The Brazilian Constitution (1988) states that the country is responsible for providing heath care access to every Brazilian citizen [11]. For this reason, the Brazilian health care system is composed of a public mandatory, tax-based unified system (Sistema Único de Saúde) as well as an optional, premium-based private health care system, frequently provided through employers representing 75% of the private care system. The Brazilian health care system is organized into three categories: 1) the Ministry of Health (major policies), representing the entire country; 2) state secretaries of health, representing on a state level; and 3) municipal secretaries of health, on the city level (general practice, primary care services) [12].

The Ministry of Health is responsible for the development of a formulary, listing the drugs to be available to the entire Brazilian population at no cost to the patient in what is called RENAME (essential drug list). RENAME contains drugs that are approved by Agência Nacional de Vigilância sanitária (ANVISA), have proven effectiveness, and are indicated for diseases that affect a large population. In the past decade, another list was created to cover exceptional drugs or high-cost drugs that, after evaluation by the Ministry of Health, are considered effective and needed, and must be available at no cost for the entire Brazilian population [13].

There are two regulatory agencies, the National Agency for Private Health Care (ANS) and the National Health Surveillance Agency (ANVISA) [14,15]. ANS is an agency that oversees the relationship between patients and insurance companies to ensure transparency [15]. ANVISA is responsible for licensing, registering, and pricing of drugs, devices, equipments, and medical products in the country. It is illegal for patients in Brazil to consume drugs or utilize procedures that are not regulated and approved by ANVISA [16]. Until 2003, ANVISA would make decisions based exclusively on safety and effectiveness; however, in 2003, a governmental council that aims to economically regulate the market of drugs in Brazil (Chamber of Medicine) was created to evaluate the price of new health products as well as establish a cap to the annual price increase for drugs [17].

In December 2006, the Ministry of Health approved a national policy to evaluate and manage health care technologies requiring a description of technology, identification of submitter, number of ANVISA registry, proposed price approved by ANVISA, technical report presenting the scientific evidence of safety, efficacy/effectiveness comparing the proposed technology with the available and current technology, economic evaluation (cost-effectiveness and cost-utility evaluation) when there is a trade-off involving effectiveness, costs, and a budget impact analysis; however, it is market driven.

In 2011, the Brazilian Congress approved a new bill establishing the following [16]:

1. The establishment of the National Council for the Incorporation of Medicines and Products for Health (Comissão Nacional de Incorporação de Tecnologias [CONITEC]) in substitution of the Commission for Incorporation of Technologies. CONITEC includes representatives of Ministry of Health secretaries, ANVISA, ANS, National Council of Health Secretaries, National Council of Municipal Health Secretaries, and Federal Council of Medicine.
2. Decisions for listing products should be completed within 180 + 90 days after the submission of the dossier.