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Economic tools for ensuring access to medicines in Latin American countries

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The greatest challenges for pharmaceutical policies in Latin American countries are related to the objective of promoting access for their populations. Around two thirds of the spending on medicine in the region is financed by household incomes, with a strong regressive effect on their financing. For these reasons, the economic regulation tools for controlling spending and prices of medicines take on singular importance.

The present article examines a set of measures implemented by the countries in the region for the economic regulation of medicines centred on ensuring access to them, emphasizing those intended to control the prices of the pharmaceutical products and those oriented to moderating the spending on medicines in the health systems.

Keywords: Public policies, Latin America, access, medicines, medicine prices

1. Introduction

The greatest challenges posed by medicines for public policies in Latin America are not related to their availability, and not even to their quality, but to the population's access to them. This means the possibility of satisfying a demand, which expresses a concrete need for care and can be solved adequately through the "supply" of pharmaceutical products available in a country [28]. In Latin America population's access to medicines depends more on the functioning of the market than in other regions where the social security system and the State take a more active role in providing and financing drugs. Progress in access to medicines could be directly related to improvements in the population's buying power (when people acquire medicines through the market) or to institutional schemes for health protection (when the medicine is provided by the health systems). In Latin America the greatest part of the financing of medicines (around two-thirds) comes from household incomes. This introduces a strong regressive effect, as the lower-income sectors dedicate more than 70% of their health expenses to acquiring medicines [5]. This explains why the regulation of medicine prices can affect access to medicines in a greater proportion than in other regions.

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Within the functions roles states can assume in respect to medicines, the regulatory role includes three aspects: surveillance, technical regulation and economic regulation. This last aspect is only implemented when a government assumes that there is not sufficient harmony between the supply and the demand, in which case the optimal assignation of goods and resources requires norms and incentives to correct the miss functioning of this market.

The countries have not followed a single or homogenous route in the implementation of economic regulation policies for promoting access to medicines. After two decades of deregulation of markets, which has not excluded the pharmaceutical market, a crusade began in Latin America to rationalize the selling prices of the products. Several countries have advanced along this route, among which two major alternative routes have been identified [24]. The first one consists of an imposing intervention in which, although prices appear not to be regulated, in practice the governments set the prices of the products unidirectionally. They often do so without enunciating transparent processes for it, and every time a pharmaceutical company increases the prices of its products it is convened by some authority to explain the increase, and in some cases is forced to reverse that indexation. But the decision is not based on matrixes or procedures with explicit calculations. Venezuela and Argentina – the latter only partially – are representative of this route, while Ecuador is beginning to abandon it, seeking to incorporate more transparent measures for defining its regulatory regimes for medicine prices.

The second route involves a systematic effort to promote competition through prices, increasing the number of suppliers and reducing the asymmetries of information whenever possible. This kind of strategies requires incentives and permanent monitoring of the market, rather than the setting of prices. Various countries in Europe, as well as Canada and Australia have followed this route, and in Latin America there are some incipient steps in this direction.

The present article examines a set of measures implemented by Latin American countries for the economic regulation of the medicine market, both to contain the prices of the products and to limit spending on medicines by the health systems. Both consist on different purposes that do not always go hand-in-hand.

2. Models for regulating medicine prices

Upon reviewing international experiences, one finds that when the goal is to promote access, the most effective strategies of the economic regulation of medicines are those that seek to promote greater competition in prices without compromising technical elements like quality, safety and possibilities of products being substituted [17,18]. However, on some occasions pro-competition solutions are not sufficient to reduce prices because a significant percentage of the products is monopolized (patented) and accounts for an even greater percentage of pharmaceutical spending. Thus, where there are no competitive products it is impossible to achieve increased

Table 1
Options for the economic regulation of medicines

Purpose	Objective of the policy	Possible tools
I. Control of the prices of medicines	Guarantee of competitiveness in the market	Control of anti-competitive practices Promoting of the supply of generic products
	Guarantee of affordable prices	Setting of prices and margins of commercialization. Price negotiation
II. Containment of spending on medicines	Containing public spending on medicines	Promotion of the demand for generic products Changes in the modes of contracting and acquisition. Setting prices for reimbursement. Co-payments
	Ensuring the efficiency of spending	Selective financing

Source: [22].

access through strategies to foster competition. That only is possible through subterfuges that are not very sustainable in time – as, for example, parallel importations or compulsory patent licensing.

Table 1 shows the major options in the design of economic regulation policies for medicines. The measures were separated into two large groups: the first centred on supply and the second on the demand in this market. Each of these groups will be analysed below.

2.1. Control of the prices of medicines

Control of sales prices can involve a broad variety of measures ranging from surveillance to ensure that there are no abuses of asymmetries of power in the setting of prices within the production and commercialization chain, to setting fixed prices for pharmacy sales.

2.1.1. Control of anti-competitive practices

The control of anti-competitive practices comprises the use of a set of economic control actions that normally do not involve the ministry of health or its medicines national regulatory authority, but rather consumer defence and competition defence entities which generally are dependencies of the economic and/or commerce departments. Within Latin America, Chile is the case in which the State has strengthened the most its capacity to detect and punish collusive practices. In April 2008 the National Economic Prosecutor's Office (FNE) summoned the three main pharmaceutical chains to explain why, after a price war among them, the chains agreed to gradual increases in the prices of their products. During the investigation the Attorney's Office detected a price increase in 222 medicines that especially affected

chronic pathologies (with increases of up to 3,000% compared to the public acquisitions through the public supply agency -Cenabast-). The investigation led to a court trial. The maximum fine established by law was requested for each of the chains involved, and the door was left open to later lawsuits in case other infractions or involved actors should appear.

2.2. Promoting the supply of generic products

The countries that advanced in the implementation of pro-competitive regulatory strategies opted for promoting the use of generic medicines, and did so by different means. Adopting generic medicine policies can involve a large set of actions that generally have been oriented to creating a framework of competition through prices in the medicine market [23]. To do so, some countries simplified the procedures for the entry of these products into the market, either through the elimination of restrictions related to expired patents or delays in registration.

In order to advance in the elimination of barriers to competition, national registration systems should be adapted. Sanitary registration constitutes a first barrier to the entry of medicines into the market. It is the basis for authorizing the production, distribution and marketing of medicines, subject to prior authorization by the sectorial regulatory agency, based on the evaluation of effectiveness, safety and product quality. These regulations vary among countries. From a perspective of price and expenditure control, this is a first instance of selection, and therefore a key element in terms of efficiency.

In Latin America this barrier has not been significant in terms of the tariffs that must be paid, as the costs of the registration are lower than in developed countries. However, it does involve opportunity costs, due to the delay in obtaining a product's registration. In some cases it may take longer than two years.

The implementation of fast-track mechanisms is intended to stimulate and facilitate the registration and subsequent circulation of products in the market. An example of this is Brazil, where the times for obtaining a sanitary registration for a generic pharmaceutical product can be reduced by as much as half the time required for the registration of innovative products [8,21].

Because in Latin America medicines marketing chain is financed through the incorporation of margins in each phase of the production-commercialization cycle, there generally is a lack of incentives to promote the commercialization of generic medicines. Some countries have implemented different measures to reverse this. In Nicaragua margins are fixed for commercialization with differential percentages for generics. Thus, the margin for the pharmacy is 30% of the public sale price when the product is classified as a brand, and 32% if it is a generic product (Ministerial Agreement 029/2009). However, these are weak (little persuasive) incentives when compared, for example, to the obligatory nature of substitution as the most economical alternative, as established in Spain [6,15].

Another tool that can contribute to reducing the barriers to the entry of new medicines consists of facilitating imports. This measure can be implemented by presidential decree, and the registration could be approved automatically in minimal time with the applicants' meeting of the minimum set of requisites proposed by the World Health Organization Working Group on Medicines Registration. In Brazil, Decree 3675 of 2000 approved the provisional registration of imported generic medicines that were registered in the United States, Canada or some European countries. In Argentina, the direct importation of generic medicines was enabled in 2002 through the homologation of the registration of the country of origin, although not for its general commercialization but exclusively for the Remediar Programme, for public distribution.

One regulatory tool of greater impact on access consists of controlling the prices at the moment of registration. The European countries and Brazil have advanced in this direction. In Brazil the generic medicines must be 35% cheaper than referential medicines (Law No. 9787 of 1999). However, it should be mentioned that this type of measures does not reduce the barriers to the entry of medicines, but instead seeks direct control of the prices, leaving its promotion of competitiveness open to doubt.

Also, the measures governments take to stimulate the manufacture and sale of generic medicines are considered incentives for the supply of generics; among the most frequently used measures are dispositions for industrial promotion like, for example, reducing or even eliminating the taxes on generic products and the tariffs on the importation of active ingredients or various other ingredients.Brazil has advanced in industrial promotion to improve the supply of generic medicines. The Federal Government, through the National Development Bank (Portuguese acronym BNDES), prepared a Support Programme for the Development of the Pharmaceutical Productive Chain (PROFARMA) aimed at the development of active ingredients and vegetable extracts, pharmochemicals and medicines for human use, as well as other activities related to the pharmaceutical chain. PROFARMA's objectives have been: an increase in the production of medicines and their ingredients; improved medicine quality, meeting the requirements of the national regulatory body (ANVISA); reduced commercial deficit of the productive chain; stimulation of Research and Development activities; creation of conditions for obtaining new molecules; and strengthened economic, financial, commercial and technological positioning for national companies [7].

Another tool has been the restriction of the validity of patents. In the final declaration of the Round of Doha, Qatar, in 2001, the World Trade Organization (WTO) approved the permission for some member countries to relax certain aspects related to the recognition of patents. In its Paragraph 7, it establishes that the less developed countries that have not already done so, have an extension until 2016 to establish the protection of the intellectual property of pharmaceutical products and practices [23]. An additional alternative consists of making use of the so-called "Bolar Clause" which allows the initiation of the necessary studies or product registration before the expiration of its patent. In reality, this measure accelerates the authorization of

possible suppliers to produce and commercialize generic versions of products still protected by a patent. Some countries like the United States, Japan, Australia and Canada have used this tool to strengthen their supply of generic medicines [23].

The measure contemplated in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) that most strongly stimulates the local supply of generics, is the implementation of obligatory licenses. This means that, even without the consent of the patent owner, a government may authorize the production of a determined medicine for various reasons, such as the lack of local production or a national sanitary emergency.

An extreme modality for guaranteeing the availability of generic medicines consists of not acquiring them through the market, but through governmental production. Although this is not a measure to promote competition, but an interventionist response, at any rate it can be a powerful way to facilitate the population's access to medicines.

The policies on governmental production of generic medicines in Mexico, Chile and Brazil have a considerable impact in population's access to medicines. It is also possible to identify four alternative combinations of production and circulation of generic medicines: a) governmental production for exclusive use in public services, for example, when the hospitals manufacture some product for use within the same establishment without requiring registration or commercial authorization; b) governmental production with alternatives for its commercialization; for example products manufactured in official laboratories are sold to patients through popular pharmacies (for example, the Farmaguinhos factory in Rio de Janeiro is the largest public laboratory, playing a strategic role in Brazilian pharmaceutical policy); c) private production for exclusive circulation in public services; the best example of this is the Remediar programme in Argentina, which has been acquiring and distributing generic medicines to more than 6,000 health service centres throughout the entire country since 2001; and also Paraguay's Basic Health Care Programme, which operated between 2005 and 2009. Through an international bidding process, both programmes purchase generic medicines that are boxed in differentiated packages with no commercial name, stating on the label that they are for the exclusive use of the public health services, being their sale or use in private services penalized; and **d)** the incorporation of a generic medicines market through private production and marketing – which is the most frequent alternative.

2.3. Setting of prices and margins of commercialization

Among the measures adopted by the countries for setting the prices of medicines, it is possible to distinguish four major types of instruments:

a) Pharmacological analysis for evaluating the therapeutic advantages of the medicine.
b) Pharmaco-economic evaluation comparing the cost of the treatment with other alternative products

c) Reference price (international and/or internal market)
d) Control of wholesalers and retailers profit margins.

2.3.1. Pharmacological analysis for evaluating the therapeutic advantages of the medicine

Brazil is the most advanced case in this alternative. Procedures for economic regulation of medicines in Brazil include, among other instruments, the adoption of differential pricing schemes favouring innovative products with therapeutic advantages over those that offer no advantages (or, "me too"), as well as generic products (22). Brazil has an organization in charge of this function – the Pharmaceutical Market Regulation Council (CMED), based on Law No. 10.742 of 2003, which establishes the norms governing the pharmaceutical sector, in order to promote mechanisms to stimulate the supply of medicines and the competitiveness of the sector.

Pharmaceutical products are submitted for technical approval to the ANVISA, which after evaluation submits its decision to the CMED, which, in turn, after analysing its clinical effectiveness and using international reference prices establishes the price of the product. Once the CMED makes its pronouncement, the products may be commercialized in the private market. For their incorporation into the public system, they also must pass through another regulatory body, the National Commission for the Incorporation of Technologies (CONITEC), which evaluates sanitary technologies to be incorporated in the Unified Health System (SUS)

2.3.2. Pharmaco-economic evaluation

Another alternative is the use of pharmaco-economic evaluation procedures to contribute to the rationality, efficiency and sustainability of the financing of pharmaceutical spending within the health system. This calls for pharmaco-economic evaluation studies to aid in the selection of the innovative medicines to be incorporated into essential list of medicines that are covered and financed by the government, and eventually into the social security system. In case the evaluation results suggest the incorporation of a medicine into the list, the use of pharmaco-economic instruments may also be used to calculate the price that the health system should pay for these medicines.

However, incorporating pharmaco-economic instruments for regulation requires the creation of evaluation agencies for sanitary technologies, as well as, a certain level of institutional development, technical capacity and political will to adopt and sustain the agency's recommendations. In recent years important progress has been made in this regard in Latin America. In Brazil it was the creation of the National Commission for the Incorporation of Technologies (CONITEC)in the Unified Health System (SUS); in Mexico, the National Centre for Health Technology Excellence(CENETEC); and more recently the Institute for Clinical Effectiveness and Health Policy (IECS) in Colombia, established by Law No. 1.428 of 2011.

2.3.3. International and internal reference prices

Setting a reference price is determining the amount the health system (public or social security) is willing to pay for a medicine. This may be independent of the sale price in the market (giving the user freedom to decide whether he or she wishes to pay an additional amount above the reference value). As mentioned, the pharmacoeconomic evaluation is a mechanism for setting reference prices, but is not the only one. For example, in Europe international comparison has been used extensively as a procedure for setting reference prices.

Reference prices need to be set for homogeneous lists of medicines, (by therapeutic classes and/or by active ingredient). Brazil was the first country in Latin America to incorporate international price comparisons for controlling the monopolistic products, and simultaneously, promote generic competition for the other products. In Colombia the National Drug Pricing Commission, established by Law 100 of 1994, incorporated three regulation systems: under surveillance freedom, regulated freedom and direct control. The differentiation among the systems is an advantage because it would make it possible to stimulate competition where there are diverse suppliers and at the same time avoid abuses in the monopolistic and oligopolistic segments. Nonetheless, Colombia did not incorporate international reference prices until 2011, when Circular NO. 1 incorporated two differentiated procedures for monitoring prices: national reference prices (for the products with three or more suppliers) and international reference prices (for products with fewer than three suppliers).

A relevant methodological definition is how to construct the reference price. This involves two major questions: 1) Which prices to compare? That is, which segment of the medicine production and marketing chain should the measurement be made on [4]? And 2) How to calculate the Reference Price? In other words, what mathematical procedure should be used?

In both cases, Colombia's recent policy is innovative [2]. In first place, the new proposal eliminates the system of regulated freedom, leaving only two systems: direct control and under surveillance freedom. Secondly, the new proposal admits the use of prices taken at different points of the production and marketing chain, instead of considering only the comparison of prices for market sale. This change expands the possibilities of comparison because, at times, the monopolistic products are not sold directly to the public through the commercial channel, but are provided directly by the financing institutions. To make this consideration of alternative prices viable, the proposal incorporates Adjustment Factors (Article 11) that would permit the comparison of prices taken at different points in the chain.

Third, the new Colombian policy replaces the calculation of the Reference Price with the median prices of the same product measured by sales. The international antecedents are divided on this matter. For example, while in some cases like Mexico the weighted average of sales is used, in others the median is used because of lack of information on the quantities of each product that are sold [16]. It has been indicated that a fragility of the price regulation systems in Latin America lies in the fact that the

information used for this regulation tends to depend too much on the same suppliers which are being regulated [3,12].

In conclusion, after 2011 and the passage of Law 1.438, Colombia gathered sufficient political will to begin to modify its health reform, and as was to be expected, drug prices cannot be left out of this revision. A National Pharmaceutical Policy was developed and submitted for discussion and approval by the National Economic and Social Policy Council (CONPES). The reformulation of the National Commission on Prices of Medicines and Medical Devices (CNPMDM) and the regulation of the pricing mechanisms positioned the country at the vanguard of drug regulatory policies [24]. This is a policy that probably will be followed by the rest of the region, since Ecuador is proposing to incorporate similar systems through its Decree 777/2011, and El Salvador has just done so in the regulation its Law on Medicines [19].

A special mention for El Salvador, where the recently created National Directorate of Medicines [20] determines the Maximum Sale Price to the Public for each medicine, based on the principle that it must not be higher than the average price paid in Central America and Panamá, and that will take the International Reference Price as a basis. This is interesting because in order to implement the price setting policy, the National Directorate of Medicines must have a broad database of international prices, and define homogeneous groups of products with the same active ingredients, concentration and pharmaceutical form. On the other hand, in order to implement the setting of prices, making it possible to feed its international price database, the margins of commercialization in the different countries were revealed. This last measure is being considered now in Colombia, through the mentioned proposal to the CNPMDM.

2.3.4. Control of wholesalers and retailers profit margins

This concerns the establishing of a control on the formulation of the public sale price of medicines, establishing profit margins ("ceilings" on the profit margins of pharmacies and drugstores). Some countries in Latin America have advanced in this regard: Brazil was one of them, and did so by establishing differentiated systems and a calculated ceiling on prices based on a price index, a productivity factor and another factor for adjusting relative prices within and among sectors. Ecuador defined a maximum profit margin of 20% for the manufacturer or exporter, a percentage based on the costs and expenditures declared by the companies. In Nicaragua, CIF (Cost, Insurance and Freight) costs are fixed for imported medicines, and comparisons are made for national ones. They also fix the margins for retailers and wholesalers, with differential percentages for generics. In Venezuela, the government establishes the price of medicines though a system of profit margins [22]. Paraguay, in turn, defines differential margins for national and imported products (Decree 20.996 of 1998 National Directorate of Sanitary Surveillance of the Ministry of Public Health and Social Welfare). Colombia established three regulatory systems – overseen freedom, regulated freedom and direct control. A reference price was implemented, and more

recently, in 2011, it was established that, at least once a year, reference prices for all drugs commercialized in the country would be defined (Law 100 of 1994 and Circular No. 002 of 2011 of the National Commission on Prices of Medicines and Medical Devices comprising the Ministry of Commerce, Industry and Tourism, the Ministry of Social Protection and a personal delegate of the President of the Republic).

2.4. Price negotiation

Joint negotiations between the government and the pharmaceutical companies to agree on product prices have been used frequently, both by developed and developing countries. Generally, they have been concentrated on the definition of the final consumer price for a limited set of products for which fixed prices are defined and kept "frozen" for a determined period of time.

Price negotiations seldom have had an impact on affordability. The suppliers can use the asymmetries of information in their favour when negotiating with the government. For example, proposing to freeze "baskets of medicines" that less affect their revenues. When the government establishes a list of high-consumption, medicines whose price it seeks to freeze, the industry counters with a proposal for low-demand pharmaceutical forms or packaging. Another strategy that has been used frequently by suppliers consists of understocking retail pharmacies with the frozen medications, forcing their substitution with commercial alternatives that were not included in the agreement.

For these reasons, price negotiations have not resulted adequate instruments for promoting the population's access to the medicines. However, this continues to be one of the most commonly used tools because it represents, for presidents and ministers, the illusion of obtaining an immediate impact on public opinion.

In those countries where there is sufficient political will and commitment, governments have gone about implementing institutional arrangements that lead to the promotion of generic medicines or the incorporation of more transparent and sustainable price setting procedures, analysis of profitability margins, and technical and pharmaco-economic evaluations.

3. Containment of spending on medicines

The measures implemented by the countries to contain spending on drugs include a group of tools centred on promoting competition in the market and reducing the asymmetries of information. Each of these is explained in the following section.

3.1. Promotion of the demand for generic products

When it has been possible to promote a supply of pharmaceutical products for which there is pricing competition and ensured quality, health systems can benefit,

achieving a reduction in their spending on pharmaceuticals through the promotion of the demand for competitive products. Among the most commonly used tools for promoting the demand for generic drugs, the ones that stand out are those that seek to: a) reduce asymmetries of information; b) stimulate the prescription of generic medicines; c) stimulate patients' demand for generic medicines; and d) encourage dispensing of generic medicines.

3.1.1. Reducing information asymmetry

To reduce the asymmetries of information, the first step is to require that all drug labels, prospectuses and publicity include International Non-proprietary Names – also called the generic denomination – of the medicine. This does not mean that the commercial name must be eliminated, but that both must appear(fantasy name and the real name of product) [23].

The second step is to implement mechanisms for controlling publicity for the medicines. This includes measures ranging from the prohibition of aiming direct propaganda on prescription drugs at the general public, to limiting the distribution of free samples. This kind of measure, in addition to reducing the asymmetries of information (considered one of the most important faults of the pharmaceutical market), also limits induced demand, which generally is neither appropriate nor rational, and unnecessarily increases expenditures. In Brazil, a report by the Parliamentary Investigation Commission on medicines estimated that 20% of the laboratories' spending goes for publicity [14].

The third step in reducing information asymmetries is pharmacy surveillance. Brazil regulated the way advertising may be done, and also financed the examination of a sample of 800 publicity items (around 40% of the 2,000 that were issued). Among its findings, it was detected that 80% of the advertising presented irregularities with respect to the law. The amount collected from fines was equal to the cost of the surveillance.

The most exhaustive way of regulating pharmaceutical publicity is to establish the requirement for authorization of each advertising item by the regulatory authority [13]. In Argentina, a setback was found in this regard in 2004, since the National Agency for Medicines, Foods and Medical Technology (ANMAT) stopped approving publicity with the argument of a lack of budget (Resolution No. 20 of 2005, Ministry of Health of the Nation).

3.1.2. Stimulating the prescription of generic medicines

In addition to the mechanisms for guaranteeing the availability (supply) of generic medicines, it is fundamental to implement measures to stimulate their demand, especially those measures focused on the professionals that prescribe drugs, as they are the ones that decide on their consumption and use. It also is a way of reducing the information asymmetries and fostering the rational use of these drugs.

The most extreme way of promoting prescription by generic name is to make it compulsory by law. This has been done in five countries in Latin America (Argentina,

Ecuador, Panama, Paraguay and Peru). The problem in these countries is that they do not supervise or control compliance with the law at the pharmacy level, or punish those who disobey it [27]. Other countries – as in the case of Brazil – also have advanced in ordering that the entry of these products into the market should be at a lower price (35%) than the already available options.

3.1.3. Stimulation of Demand

In addition to stimulating the prescription of generic medicines, it is necessary for the buyer (either individual or institutional) to decide to acquire these products. When the buyers are institutions, one measure that generates transparency and price alternatives in the evaluation of bids is the incorporation of the International Non-proprietary Names in the call for bidders. This procedure has been widespread in Latin America. Procurement systems can play an important role in the strategies for promoting generic medicines and their adequate use, as long as they guarantee the inclusion and availability of these products in the list of essential medicines.

Another measure that is used is the dissemination of, and sensitizing to, information on the advantages of using generic medicines, through publicity campaigns (focused on patients) and recommendations by governments or health insurance agents (focused on the prescribers). However, in this case the results have not been as decisive as making them compulsory for prescribers and pharmacist [9].

Another powerful tool often used is the establishment of reference prices. This consists in establishing a maximum price per product for governmental or health insurance agents' co-financing or reimbursement. If the patient opts for the more expensive commercial alternatives, she or he must pay the difference out of pocket.

In Argentina in 2002, social security institutions established reference prices. It also was established that health insurance agents would recognize and apply discounts in favour of the insured patient only when the prescriptions issued by outpatient services were presented with the generic name of the medicine (Resolution 163/2002 of the Superintendency of Health Services of Argentina). However, this measure was discontinued a few months after its implementation.

The impact of this kind of measures on the reduction of spending on medicines may be quite strong, but its effectiveness is lower in inflationary contexts, unless the reference prices are constantly recalculated.

3.1.4. Incentives for dispensing and substitution

The main measure for promoting distribution is to encourage the in-pharmacy substitution of the brand stipulated in the prescription for a generic medicine when the active ingredient is identical and the presentation is the equivalent.

Just as in prescribing the main actor is the medical doctor (or nurse, in some countries), in dispensing it is the pharmacist. Therefore, and in order to achieve his/her commitment to the implementation of generic medicine strategies, it is necessary to inform them about the alternatives of generic medicines available in themarket. However, substitution with a lower-priced alternative may not be sufficient, as the

retailer's profits are proportional to the price of the medicine, and this may induce them to make substitutions for more expensive – and not more economical – ones. Therefore, special incentives for retailers must also be promoted for the distribution of generic medicines.

To reinforce the incentives for dispensing, remuneration models, not based on a fixed percentage of the product price, may be established for retailers. For example, paying per pharmaceutical action (a fixed amount per prescription or product dispensed) or a monthly quota per patient – although this sort of incentives has not yet been tried in Latin America.

3.2. Changes in the modes of contracting and acquisition

Another strategy has been the implementation of the centralized purchase or centralized negotiation of prices with the pharmaceutical industry. Centralized purchasing has made it possible to obtain significant savings for various countries. Examples are Chile, through its National Supply Centre (CENABAST); Peru, through the General Directorate of Medicines, Supplies and Drugs (DIGEMID); the Dominican Republic, through its Office for Logistical Support and Programme for the Supply of Essential Medicines; and Argentina, through its Remediar Programme, which acquires 60 high-consumption medicines in a centralized way to supply more than 6,000 Primary Health Care Centres.

In other countries, like Guatemala and Ecuador, decentralized purchasing has been used, but with a framework agreement on distribution prices for previously accredited suppliers. For this, there is a need for a solid technical capacity to verify the information presented by the manufacturing companies. In this way, the State exercises regulation through demand, whereby the most important factors are centralization and taking advantage of scale economies.

In Latin America, the practice of institutions making their purchases exclusively through the International Non-proprietary Names has been generalized. However, the set of measures for promoting competition and consolidating the use of generic medicines is broader than only using International Non-proprietary Names for bids. For example, in cases of medicines for which generic versions are not yet available, two or more branded products can be included to compete. The incorporation of the so-called "me-too" products can be used to expand competition. Another, additional, measure that is increasingly being used in centralized public procurement is to require non-commercial packaging, instead labelled with the names of the ministries and/or providing organizations, but without the product's fantasy name or original brand [23].

3.3. Setting prices for reimbursements

Setting prices for reimbursements is a powerful measure in the health systems where a great majority of the population has social security coverage; instead of

having their own pharmacies that directly provide the medicines, these systems may opt for reimbursing their insured customers for the amount paid in commercial pharmacies.

In that case the regulatory policy does not set the final sale price for the public, instead determining the amount the social security system will reimburse its beneficiaries. This functions as an incentive to the consuming population to opt for generic and/or more economical alternatives, seeking to spend as little as possible. These measures have been used in European countries like Spain, France and Portugal, but have not worked in Latin America, where the social security systems have less coverage, and generally have opted for the direct distribution to their beneficiaries through the system's own pharmacies.

3.4. Co-payments

In Latin America there are very few cases where the public health systems directly provide medicines for out-patient treatment of their populations. Medicines for hospitalized treatments generally are provided without requiring payments by the patients, but out-patient medicines generally are provided in a limited form, subject to availability; these often are discontinued, or are subject to frequent shortages of stock in health services centres.

During the decade of the 1990s, the medicines provided by public health services in Latin America often were not free but subsidized, requiring patients to partially pay for them. From the first decade of the Twenty-First Century, several countries like Ecuador, Paraguay, Argentina, and others declared the health goods and services provided to the population by public services to be cost-free. In other cases, like Panama, patients have to pay for the medicines they receive at the Public Health Services, in the form of a co-payment.

In the case of the social security systems, the most widespread provision modality is distribution to active affiliated members and beneficiaries in their own pharmacies (for example, in all the countries where there is a single health insurance system, and even in Colombia and Uruguay, where there are multiple social security health institutions). In the case of Argentina, dispensation is made through commercial pharmacies that have contracts with the social security systems to provide medicines to the insured population [27]. In the first case the most frequent modality is dispensing at no cost. However, in some cases the social security systems request the insured patient to cover part of the cost. In this case, the insurance entity only covers part of the cost of the medicine and the beneficiary must pay the pharmacy the rest of the price. A change in the percentage that is co-financed by the beneficiaries is a way of reducing the expenditures in medicines for the health system, but is unlikely to improve the population's access to medicines since it means transferring this cost to the patients.

3.5. Selective financing

Turning to selective financing as a tool for containing spending on pharmaceuticals means including only a limited group of medicines in the country's essential list of medicines. In this sense Latin America faces greater challenges for selection, because the number of presentations of registered products is quite high. While the average list of essential medicines in the Latin American countries is 500 items, medicines in the market can be up to four times this number, adding the fact that the number of presentations available in the market may be twenty times higher.

Brazil has more than 20,000 registered presentations, closely followed by Mexico with approximately in 19,000. At the other extreme are Costa Rica and Chile, with only 5,000 presentations. Argentina is in the middle with 10,000; Colombia with 8,300; Bolivia with 8,293 legally registered presentations; the Dominican Republic has 14,182; Honduras 15,000; Nicaragua 12,000; and Peru has 11,241. The median of registered presentations in these countries is 9,632, which is substantially higher than the world median of 2,413 for low-income countries; 5,000 for middle-income countries; and 7,296 for high-income countries.

Not all medicines registered in the country are used and financed by the health systems. All the ministries of health in the region's countries have national lists of essential medicines that account for a little more than 5% of the products with sanitary registrations. The larger countries have permanent commissions to update the list every two or three years. In others, the review of the list is more sporadic.

The social security and private insurance systems tend to operate with the same national lists of essential medicines, although since the decade of the 1990s the social security systems in the region have advanced in outlining care coverage packages that define a positive list of goods and services that are covered for the users. This is the case of Argentina's Obligatory Medical Programme, the Obligatory Health Programme (POS) in Colombia and the Comprehensive Health Care Programme (PIAS) in Uruguay. In all these cases, the social security entities have incorporated a positive list of the medicines covered.

4. Conclusion

Latin American countries have used different tools for solving problems of increased spending and prices of pharmaceutical products looking to assure population's access to medicines. In this article these measures have been separated into two groups: supply-centred policies and demand-centred policies.

For supply-centred policies, two clear alternative routes are identified in the region: a first, imposing intervention route in which the government sets the prices and their indexation unilaterally and following not clear criteria. This contrast with a second route of price regulation that seeks to institutionalize differential regulatory systems by incorporating incentives to suppliers to achieve the accessibility

through competition. This second regulation route includes a set of tools, of which the most important are: the adoption of differential pricing schemes favouring innovative products with therapeutic advantages over those that offer no advantages (or, "me too"); promotion of markets of substitute or generic medicines; use of reference prices for national and international comparisons; the control of profit margins in the market chain, and the setting of reimbursements and co-payment.

The demand-centred economic regulation tools for promoting access to medicines have been less used in the region. Important among them for their potential impact are the strategies to promote the use of generic or International Non-proprietary Names, reducing brand fidelity and avoiding oligopolistic pricing.

In Latin America, the countries that have advanced the most in the economic regulation of medicines have at different moments, used supply and demand centred tools, not only allowing them to achieve better results, but also to sustain the implemented policies over time.

When a pharmaceutical policy simultaneously assumes the objectives of promoting access and increasing competitiveness, the use of monitoring and evaluation tools become necessary, as well as, institutional arrangements to be used are: a)creation of specific agencies with an active regulatory role in the pharmaceutical sector; b)implementation of institutionalized schemes for pricing of pharmaceutical products; c) promotion of industrial production of generic products; d) reduction of barriers to entry of generic medicines into the market (adapting registration systems); e) offering incentives for the prescription of generic medicines, the most radical way has been the compulsory prescription by generic name); f) creating incentives for demand by fixing a maximum reimbursement or co-financing amount by the government or health insurance systems; and finally, g) incentives for dispensing generic medicines, allowing pharmaceutical professionals to substitute the brand-name medicines listed in the prescriptions for a generic medicine.

As previously mentioned, there is no single and effective route that contributes to improving the population's access to medicines. Throughout this article it has been shown that policies implemented by the countries of Latin America are diverse and linked to failures or limitations of the market itself, and the medicine market they attempt to create.

References

[1] J. Bermudez and C. Possas, Análisis crítico de La política de medicamentos em Brasil. Boletín de La Oficina Sanitaria Panamericana. 1995; 1995: 270-7. ("Criticalanalysis of the medicines policy in Brazil").

[2] Colombia. Comisión Nacional de Precios de Medicamentos y Dispositivos Técnicos. "Propuesta de redacción del grupo técnico asesor para ser presentada a la Comisión Nacional de Precios de Medicamentos y Dispositivos Técnicos". 5 de abril de 2013. Available at: http://www.consultorsalud.com/jupgrade/docs/Borrador_metodologia_regimen_control_directo_precios_medicamentos_2013.pdf ("Proposed draft by the technical advisory group for presentation tothe National Commission on Prices of Medicines and Medical Devices").

[3] Comisión Federal de Competencia México y OCDE "Recomendaciones para promover un marco regulatorio más favorable a la competencia en el mercado farmacéutico". Agosto 2009. Documento preparado como parte del programa proceso para el fortalecimiento del marco regulatorio para la competitividad en México" que inicio el ejecutivo federal en enero 2008 en colaboración con la Organización para la Cooperación y el Desarrollo Económico (OCDE). ("Recommendations for promoting a regulatory market that is more favorable to competition in the pharmaceutical market").

[4] A. Creese, Quick Jonathan. Working paper on differential pricing arrangement and feasibility. Contextsettingpaper. Geneva: WHO, 2001.

[5] R. Falbo, "Impacto Redistributivodel Programa Remediar". (Informe Final) Buenos Aires. Comisión Nacional de Programas de Investigación Sanitaria (CONAPRIS). ("Redistributive impact of the Remediar Programme [Final Report]"), 2003.

[6] R. Garcia, España prepara un nuevo paquete de medidas de contención del gasto en medicamentos, 2011. Disponible en: http//www.correofarmaceutico. com/2011/07/04/al –día/profesión/el gobierno-prepara-mas-medidas-de-contención-para- el interterritorial. ("Spain is preparing a new package of measures to contain spending on medicines, 2011").

[7] L. Hasenclever, O mercado de medicamentosgenéricos no Brasil. Prepared for the Franco-Brazilian Symposium on "The New Right to Intellectual Property in the field of health and Human Beings (implications for access to antiretroviral treatment".Brasilia, 23–24 de Junho de 2004. ("The generic medicines Market in Brazil".)

[8] N. Homedes and A. Ugalde, Multisource drug policies in Latin America: Survey of 10 countries, *Bulletinofthe World Health Organization* **83** (2005), 64–70.

[9] P. Kanavos, S. Vandoros, R. Irwin, E. Nicod and M. Casson, Medical Technology Research Group-LSE Health, ET. AL. Differences in cost of and access to pharmaceutical products in the EU. Brussels: European Parliament, 2011, p. 92.

[10] V.L. Luiza, C.O. Castro and N. Marín, Estudio de vigilância de políticas farmacêuticas, Nivel 1 (estructura y procesos) realizado en países de Latinoamérica y El Caribe en 2003. Rio de Janeiro: NAF/ENSP/FIOCRUZ/OPS/WDC; 2006. ("Study of the surveillance of pharmaceutical policies, Level 1 [structure and process] performed in the countries of Latin America and the Caribbean in 2003").

[11] E. Martich, A política de medicamentos genéricos e o mercado farmacêutico na Argentina e no Brasil.Dissertação de mestrado apresentada à Escola Nacional de Saúde Pública (ENSP) FIOCRUZ. Rio de Janeiro. Maio 2013.("Generic Medicines policy and the pharmaceutical Market in Argentina and Brazil. Masters' Dissertation presented to the Escola Nacional de Saúde Pública [ENSP])".

[12] P. Moise and E. Docteur, Pharmaceuticalpricing and reimbursementpolicies in México. OECD-Health Working Papers no 25.2007. http://www.oecd.org/health/health-systems/38097348.pdf.

[13] D. Moura, Saúde não se dá, conquista-se. São Paulo. EditoraHucitec, 1989. ("Health is not given, it is conquered").

[14] A. Nascimento, Ao persistirem os sintomas o médico deverá ser consultado: isto é regulação? São Paulo: Sociedade Brasileira de Vigilância de Medicamentos, 2005. ("Ifthesymptomspersistconsultyourdoctor: isthisregulation").

[15] Pharmaceutical Pricing and Reimbursement Information (PPRI). Portugal Pharma Profile Vienna: European Commission, Health and Consumer Protection. Directorate – General and the Austrian Ministry of Health, Family and Youth, 2008.

[16] J. Puig-Pujoy and G. López Casas novas, La aplicación de precios de referencia a los medicamentos, *Cuadernos de Información Económica* **143** (1999), 77–89. ("The application of reference prices to medicines").

[17] J. Puig-Pujoy, Políticas de fomento de la competencia en precios en el mercado de genéricos: lecciones de la experiencia europea, *Gaceta Sanitaria* **24**(3) (2010), 193–199. ("Policies for fostering competition in prices in the generics market: Lessons from the European experience").

[18] J. Puig-Pujoy, Review of the literature on reference pricing, *HealthPolicy* **54** (2000), 87–123.

[19] República de El Salvador. Presidencia de la República. Decreto del Poder Ejecutivo No 244. ("Executive Decree No. 244").
[20] República de El Salvador. Presidencia de la República. Decreto Legislativo No 1008. 22 de febrero de 2012. (Legislative Decree No. 1008").
[21] F. Tobar and C. Moretti, Regulación económica de medicamentos en América Latina, *Isalud* **4**(17) (2009), 37–44. ("Economic regulation of medicines in Latin America").
[22] F. Tobar, I. Drake and E. Martich, Alternativas para la adopción de políticas centradas en el acceso a medicamentos, *Rev Panam SaludPública* **32**(6) (2012), 457–463. ("Alternatives for the adoption of policies centered on access to medicines").
[23] F. Tobar, Economía de los Medicamentos genéricos en América Latina, *Rev. Panam. SaludPública* **23**(1) (2008), 59–67. (The Economy of Generic Medicines in Latin America").
[24] F. Tobar, Cambios en la regulación de precios de medicamentos en Colombia: Comentarios sobre la Propuesta de Redacción del Grupo Técnico Asesor para ser presentada a la Comisión Nacional de Precios de Medicamentos y Dispositivos Técnicos, *BoletínFármacos* **16**(2) (2013), Mayo. Páginas 68–69. Available at: http://www.saludyfarmacos.org/wp-content/files/may2013.pdf ("Changes in the regulation of medicine prices in Colombia: Comments on the Proposed Draft of the Technical Advisory Group for presentation to the National Commission on Prices of Medicines and Medical Devices").
[25] P. Vacca González, J. Fitzgerald and J. Bermúdez, Definición de medicamento genérico 'un fin o un medio'? Análisis de la regulación en 14 países de la región de las Américas, *Rev. Panamericana de SaludPública* **20**(5) (2006), 314–323. ("Definition of generic medicine, an end or a means? Analysis of regulation in 14 countries in the Americas region").
[26] L. Vera Lucia and J.A.Z. Bermúdez, Acesso a Medicamentos: conceitos e polêmicas. In: Acesso a Medicamentos: DerechoFundamental, Papel Del Estado. (cap. 4, p.45) Rio de Janeiro: NAF/ FIOCRUZ. ("Access to Medicines: conceptsandpolemics"), 2004.
[27] G. Velazquez, F. Tobar and A. Zerdá, Seguros de salud y acceso a los medicamentos en América Latina. OMS-OPS-EdicionesIsalud. Buenos Aires. ("Health insurance and access to medicines in Latin America"), 2001.
[28] M.N.P. Verdú, A. Xurxo, L. Carrea, J. Albarracín, F. Rodriguez, D. Vidal, K.A.A. Avila, A. Perez and R. Japa, El gasto farmacéutico en España 2013. Evolución internacional y situación desde el punto de vista nacional. (2013). EAE Business School. Available at: http://cladea.org/gastofarmaceutico2013.pdf ("Pharmaceutics Spending in Spain, 2013. International evolution and situation from the national viewpoint").