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Towards a theoretical model on medicines as a health need

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ABSTRACT

Medicines are considered one of the main tools of western medicine to resolve health problems. Currently, medicines represent an important share of the countries' healthcare budget. In the Latin America region, access to essential medicines is still a challenge, although countries have established some measures in the last years in order to guarantee equitable access to medicines. A theoretical model is proposed for analysing the social, political, and economic factors that modulate the role of medicines as a health need and their influence on the accessibility and access to medicines. The model was built based on a narrative review about health needs, and followed the conceptual modelling methodology for theory-building. The theoretical model considers elements (stakeholders, policies) that modulate the perception towards medicines as a health need from two perspectives – health and market – at three levels: international, national and local levels. The perception towards medicines as a health need is described according to Bradshaw's categories: felt need, normative need, comparative need and expressed need. When those different categories applied to medicines coincide, the patients get access to the medicines they perceive as a need, but when the categories do not coincide, barriers to access to medicines are created. Our theoretical model, which holds a broader view about the access to medicines, emphasises how power structures, interests, interdependencies, values and principles of the stakeholders could influence the perception towards medicines as a health need and the access to medicines in Latin American countries.

1. Introduction

Medicines are considered one of the main tools of western medicine to resolve health problems. Currently, medicines represent an important share of the countries' healthcare budgets and it is expected that the prices of new technologies, increasingly regarded as essential medicines, become higher and the expenditures on medicines will therefore increase (Wagner et al., 2014). Although South American countries have established some

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measures in the last decade in order to guarantee equitable access to medicines, access to essential medicines is still a challenge (Giedion et al., 2014). Furthermore, although pharmaceutical spending has considerably increased in recent years, it has not been translated into better health outcomes for the population (Sanchez-Serrano, 2014). Hence, innovative approaches are needed to find solutions to the barriers set up to access to medicines and to improve medicines use.

According to Soares (2013), it is necessary to differentiate access from accessibility in order to improve the analysis of the barriers to access to medicines. For this author, access is an individual behaviour in health that consists of using goods and services aiming to achieve a goal defined by the need of a person or a community. The services comprise the healthcare services provided by qualified professionals, while the goods comprise the products used as inputs in the clinical practice, such as medicines. On the other hand, accessibility is a feature of the health system related to its capacity to supply needed goods and services (Soares, 2013).

Medicines are considered a health need and their valuation can vary depending on the actors involved (users, prescribers, managers, etc.) and differences materialize in the incorporation of certain technologies over others. However, this approach is poorly discussed in the literature, and its relationship with accessibility and access to medicines is little explored in theoretical or empirical research. In view of this scenario, this paper proposes a theoretical model for analysing the social, political and economic factors that modulate the role of medicines as a health need and their influence upon accessibility and access to medicines.

2. Methodology

The model was built as a part of the research project "Public policies and access to high-cost medicines: the situation of Brazil in relation to other Latin American countries" formed by researchers from Argentina, Brazil, Chile and Colombia. The theoretical model was built in three steps. First, a narrative review was carried out to select the theoretical framework on health needs. The databases Scopus, Pubmed and Google Scholar were searched using as keywords "human need" and "health need".

Secondly, based on the theory-building general procedure proposed by Wacker (1998), the following steps were taken: the variables (what and who are to be included in the model) were defined, the domain (when and where the model is to be applied) was limited, and the relationships among the variables were built according to the conceptual modelling methodology (Wacker, 1998). The theory-building process was supported by the information obtained from three literature reviews: Bigdeli et al. (2013), Emmerick et al. (2013), and Vargas-Peláez et al. (2014); and from the health system analysis framework proposed by Paina and Peters (2012). This information was supplemented with other bibliographic sources.

Paina and Peters (2012) proposed analyzing health systems as Complex Adaptive Systems (CAS), considering 5 aspects: (1) path dependence, (2) emergent behaviour, (3) scale-free networks, (4) feedback loops and (5) phase transitions. Those aspects allow taking into account the influence that external factors have on the health system performance, for instance, the historical background and the relationship established among the stakeholders of the system in answering to or making changes in the operation thereof.

Finally, the model was discussed and validated during two seminars. The seminars brought together researchers to discuss and validate the influence of the factors proposed, taking into account the local realities of the health systems. The debate was audio-recorded and transcribed verbatim. The transcribed data were summarized and used for refining the model.

3. Results

3.1. Medicines as health needs

Different approaches are found in the literature towards a definition for health needs, and many theoretical essays and empirical studies have sought to characterize this construct. However, given its complexity, the results are highly variable and even today there is not a uniformity in the conceptualization of need, either in ontological or epistemological terms, neither in the most appropriate indicators for the measurement of health needs (Acheson, 1978; Butter, 1967; Donabedian, 1974; Jeffers et al., 1971). For the present theoretical model, the definitions of 'needs' considered were those proposed by Bradshaw (1972), Willard (1982) and Max-Neef et al. (1998).

Max-Neef et al. (1998) argued that it is necessary to differentiate actual needs from satisfiers of these needs. Fundamental human needs are finite, few and classifiable; they are the same in all cultures and in all historical periods; what changes, both over time and through cultures, is the way or the means by which these needs are satisfied. Then, each economic, social and political system adopts different ways for satisfying the same fundamental human needs.

Satisfiers are not the available economic goods. "While a satisfier is in an ultimate sense the way in which a need is expressed, goods are in a strict sense the means by which individuals will empower the satisfiers to meet their needs". So, in other words, health systems are satisfiers of the need for protection (Max-Neef et al., 1998), and medicines are goods that allow increasing or decreasing the health systems' efficiency.

In the same sense, Willard (1982) argued that human needs are not facts (properties, states, processes, relations) about people, but values. This author also defined needs as means to achieve valuable ends; and considered that "needs are goal-oriented and goals are things people value" (Willard, 1982). For this reason, disagreements about what people need are disagreements in attitude toward, and emotional attachment to, things variously considered to be valuable.

Bradshaw, (1972) "Taxonomy of social need" is useful for understanding the different value assessments about medicines. Bradshaw classified social needs, also including health needs, as *normative* (corresponding to a professional standard definition of need), *felt* (corresponding to the individual desire), *expressed* (also called demand, corresponding to the felt need turned into action) and *comparative* (corresponding to a deficit of a population when compared to other similar characteristics).

In terms of access to medicines, the *normative need* corresponds to the *experts'* decision-making on the definition of the medicines to be covered by the health system. The *felt need* is the need perceived by the user after getting a medical prescription or by the effect of pharmaceutical marketing. The *expressed* need is when the patient goes to the pharmacy to get the product; and the *comparative need* corresponds, in practice, to the health system's capacity of responding equitably to the people's needs (Soares, 2013).

Each category of need is influenced by social, political and economic elements, and the different perceptions created about medicines as a health need (according to Bradshaw's categories) do not always coincide, and as a result of this "conflict" the patients sometimes do not get access to the medicines they perceive as a need. Bradshaw's taxonomy is useful to explain why a person gets or does not get access to medicines, using the definition of health needs. Three possible combinations are displayed in Fig. 1.

Situation 1 represents the ideal scenario: the medicine is prescribed, is covered by the health system, and is supplied when demanded by the patient. *Situation 2* represents two possible scenarios: (a) The patient does not receive a covered medicine because

the health system is not able to ensure accessibility of the medicines covered; or (b) despite the medicine being covered, the patient or the prescriber requests a specific brand not available in the health system. Finally, *Situation 3* also represents two scenarios: (a) The health system does not offer a therapeutic option or an alternative that is adequate for the patient's specific situation (e.g. in case of low-prevalence diseases or when the patient does not respond to the therapies offered by the health system); or (b) The patient is prescribed a medicine that could be substituted for a medicine covered by the health system (e.g. me-too medicines).

The social, political and economic elements and their influence on the perception of medicines as a health need are explored in the theoretical model presented below.

3.2. Theoretical model

The theoretical model (Fig. 2) comprises factors (stakeholders, policies) that modulate the perception of medicines as a health need at three levels: international, national and local levels (individuals, households and communities) (Bigdeli et al., 2013) from two perspectives: health and market. From the health perspective, medicines are considered social goods whose purpose is the prevention and solution of health problems; from the market perspective, the pharmaceutical industry is knowledge-intensive and generates great added value, becoming a strategic sector for the economy. From this perspective, medicines are products that aim to generate profit (Tobar and Sanchez, 2005).

At the international level, potentially modulating factors include the recognition of the Right to Health in Human Rights treaties, the World Health Organization (WHO)'s definition of essential medicines, the Innovation Model, the intellectual property protection treaty (TRIPS) and the multinational pharmaceutical industry.

The national level includes as potentially modulating factors the constitutional definition of right to health, the health system model and its components (*software* and *hardware*, according to Sheikh et al. (2011)) and the national pharmaceutical industry. This level also comprehends the national policies related to intellectual property protection, science and technology development and medicines price control. All these elements could be influenced by pharmaceutical policies.

The local level comprises individuals, households and communities and includes as potentially modulating factors the role of people as citizens demanding their right to access to medicines and as healthcare consumers (Olmen et al., 2012). The relationship among the variables and their influence on the categories of need are described below.

3.2.1. Medicines as a felt need

From the market perspective, the perception of medicines as a health felt need is related with how the industrial capitalism has organized the goods' production and consumption, making the goods an end (Max-Neef et al., 1998). The industrial capitalism has also created a close relationship between science and market (Santos, 2008), which can be evidenced in the pharmaceutical industry, that is an economic strategic sector because of its huge profit margin (almost 20% in 2013, surpassing the banking and the oil industries) (Anderson, 2014), and whose sales depend on its ability to innovate (Sanchez-Serrano, 2014).

The relationship between science and market also materializes in the intellectual property protection model established by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). According to the TRIPS agreement, the product, including medicines, that meets the requisites of novelty, inventive step and utility can get patent protection (World Trade Organization - WTO, 1995). This protection guarantees a monopoly for at least 20 years to the manufacturer, who can set the prices, usually high, to the medicines in order to recoup investments in R&D activities and stimulate innovation (Sanchez-Serrano, 2014).

The aforementioned framework shows that medicines are products closely related to scientific progress. This relationship creates the perception that new things are better than old ones. It also implies health professionals can be more concerned about techniques and procedures than about the patient's health, instilling "a moral flavour as follows: If medical science and technology can do it, then people need it" (Willard, 1982).

At the same time, as a result of the hegemonic scientific development based on the positivist paradigm and the consequent predominance of a reductionist view of health focused on the biological and individual causes of disease, the market turns the individuals into healthcare consumers, making them dependent on the medical-industrial complex to resolve their health problems (Illich, 1975).

This phenomenon, known as *medicalization of life* (Illich, 1975), is promoted by the pharmaceutical industry by means of its marketing practices, which has influence over the perception of medicines as a health need at the international, national and local levels. Pharmaceutical marketing strategies include the redefinition or reconfiguration of health problems as having a pharmaceutical solution (disease mongering); the use of medicines for non-medical (enhancement) purposes; and the creation of new social identities and mobilisation of patient or consumer groups around medicines (Moynihan and Henry, 2006; Williams et al., 2011). Pharmaceutical marketing has become more aggressive over time targeting physicians and, with increasing frequency, the public, even in countries where direct-to-consumer advertising is forbidden (Liang and Mackey, 2011; Vacca et al., 2011).

Marketing strategies also focus on prescriber and user loyalty to specific branded medicines. These kinds of strategies are used by both national and multinational pharmaceutical industries. In some cases, these strategies are used for questioning the quality of generic medicines by creating the perception that generic medicines are cheaper than original ones because they allegedly have poor quality (Holguin, 2014).

From the health perspective, there are factors at the international and national levels that can influence the perception of medicines as a health need, through a legal/formal recognition as such. At the international level, there are two factors: (1) recognition of access to essential medicines according to the WHO's definition as a part of the right to health; (2) the states obligation of giving sufficient recognition to the right to health in their national political and legal systems (Committee on Economic, Social and Cultural Rights - CESCR, 2000). At the national level, the factors are the recognition of the right to health in the national constitution explicitly or indirectly by the signing of international treaties, the design of the health systems and the definition of the list of medicines that will be supplied (Soares, 2013).

It is worth noting that it is not mandatory that health systems recognize all the medicines available in the marked as being a health need. This statement will be discussed in the following section.

3.2.2. Medicines as a normative need

At the international level and from the health perspective, the definition of a medicine as a normative need is closely related to the WHO's definition of "essential medicines". Most international treaties recognize the access to only essential medicines as a part of the right to health (CESCR, 2000), not all medicines. In 1977, the WHO published for the first time the definition of essential medicines. The concept has changed over time, incorporating prioritization criteria and availability conditions. The current definition

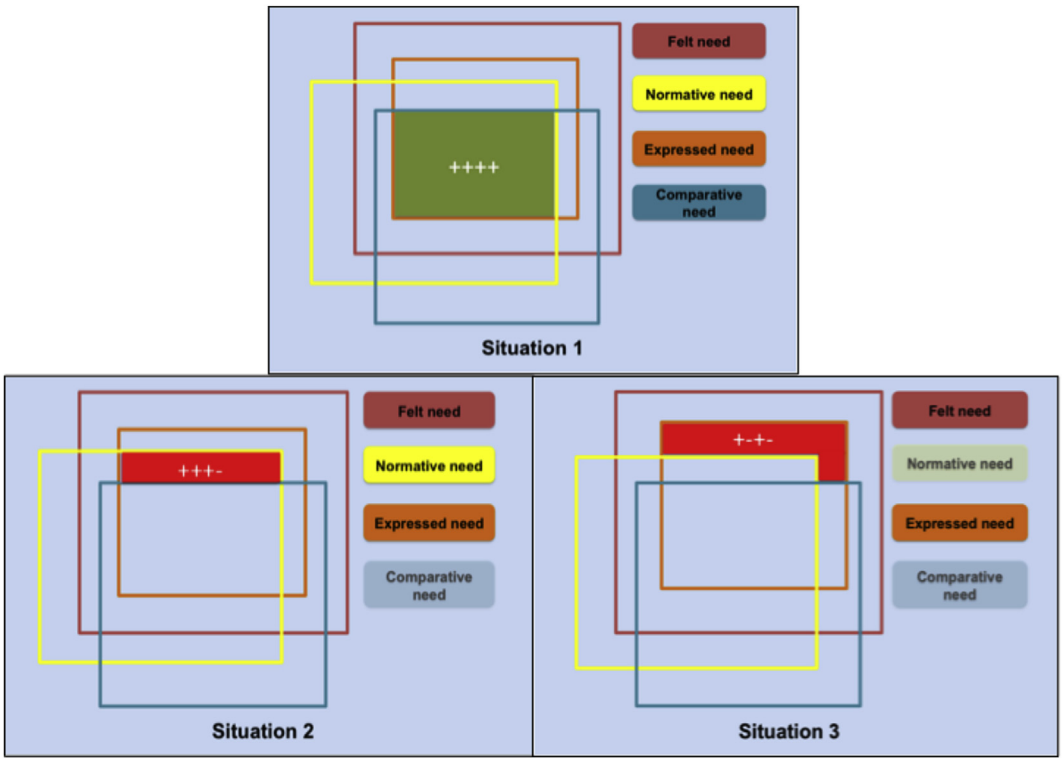

Fig. 1. Analysis of the access to medicines according to the characterization of a medicine as a 'need'. Source: Adapted by the authors from Bradshaw (1972). *Situation (1)* represents a user who wishes to get a medicine after receiving a prescription (positive felt need), the medicine is covered by the health system (positive normative need), and when he or she goes to the pharmacy to collect the product (positive expressed need), it is available and accessible for him or her (positive comparative need). In *Situation (2)* the need has been felt, expressed and recognized by *experts*, but the comparative need is not met because the medicine is not provided. In *Situation (3)*, the patient is prescribed a medicine, which is not covered by the health system, although the need is felt and expressed by the patient, the medicine is not accessible.

states that essential medicines are those that satisfy the priority health care needs of the population, which must be selected considering criteria of prevalence of the disease, evidence of efficacy and safety and comparative cost-effectiveness (WHO, 2015a).

These criteria have been established because, although the patent protection system aims to stimulate innovation (WHO, 2006), this model does not necessarily translate into significant therapeutic advances. In recent decades, the pharmaceutical industry has devoted more efforts to developing *me-too* medicines (both chemically synthesized and biotechnological medicines) instead of real innovations (Hopkins et al., 2007; Sanchez-Serrano, 2014). Furthermore, *me-too* medicines are usually high priced; even considering that their development is easier and involves less financial risk than the development of truly innovative medicines. Abuses in setting exorbitant prices for medicines that offer little benefit to patients have risen (Sanchez-Serrano, 2014), and pharmaceutical industries often justify high prices as a result of high investments in R&D activities. This argument has been questioned because evidence indicates that the expenses for marketing activities are higher than those for R&D activities (Morgan et al., 2011).

However, nowadays several new therapeutic options or alternatives meet the criteria to be classified as essential, but their affordability is compromised because they are priced, in some cases, at over ten times the gross domestic product (GDP) per capita of Low and Middle Income Countries (LMIC) (Gorokhovich et al., 2013). Examples are sofosbuvir and daclatasvir for hepatitis C treatment and trastuzumab for breast cancer treatment, recently included in the WHO essential medicines model list (WHO, 2015b).

On the other hand, the emergence of high-priced medicines for the treatment of rare diseases, which cannot be considered as essential medicines according to the WHO's definition, fuels the discussion on how to guarantee the right to health for people diagnosed with such diseases without compromising the health system's sustainability (Stolk et al., 2006).

At the national level, in order to harmonize the market and the health contexts, governments define national pharmaceutical polices. These policies express and prioritize medium to long-term goals for the pharmaceutical sector, and identify the main strategies for attaining them. They provide a framework within which the activities of the pharmaceutical sector can be coordinated. They cover both the public and the private sectors, and involve all the main actors in the pharmaceutical field (WHO, 2001).

Pharmaceutical policies are transversal, considering both market aspects (local production of medicines, production of generic medicines etc.) and regulatory aspects (regulations related to marketing authorization, quality assessment etc.). Many also include the promotion of International Non-proprietary Name (INN) prescribing, strategies for selecting the medicines covered by the health system, price regulation policies and orientation of science and technology policies to meet the health needs of the population (Tobar and Sanchez, 2005).

In Latin American countries, the definition of the health system's medicine list usually follows the WHO criteria to select essential medicines, although the health technology assessment process is not institutionalized in all these countries (Banta, 2009). The process of defining the medicine list is particularly interesting for the pharmaceutical industry, since the incorporation of a new medicine will guarantee its funding, according to the Universal Health Coverage (UHC) commitments (WHO, 2010).

The pharmaceutical industry uses its large lobby capacity to influence decision making concerning both health and trade policies, even in developed countries (Sanchez-Serrano, 2014). Lobby

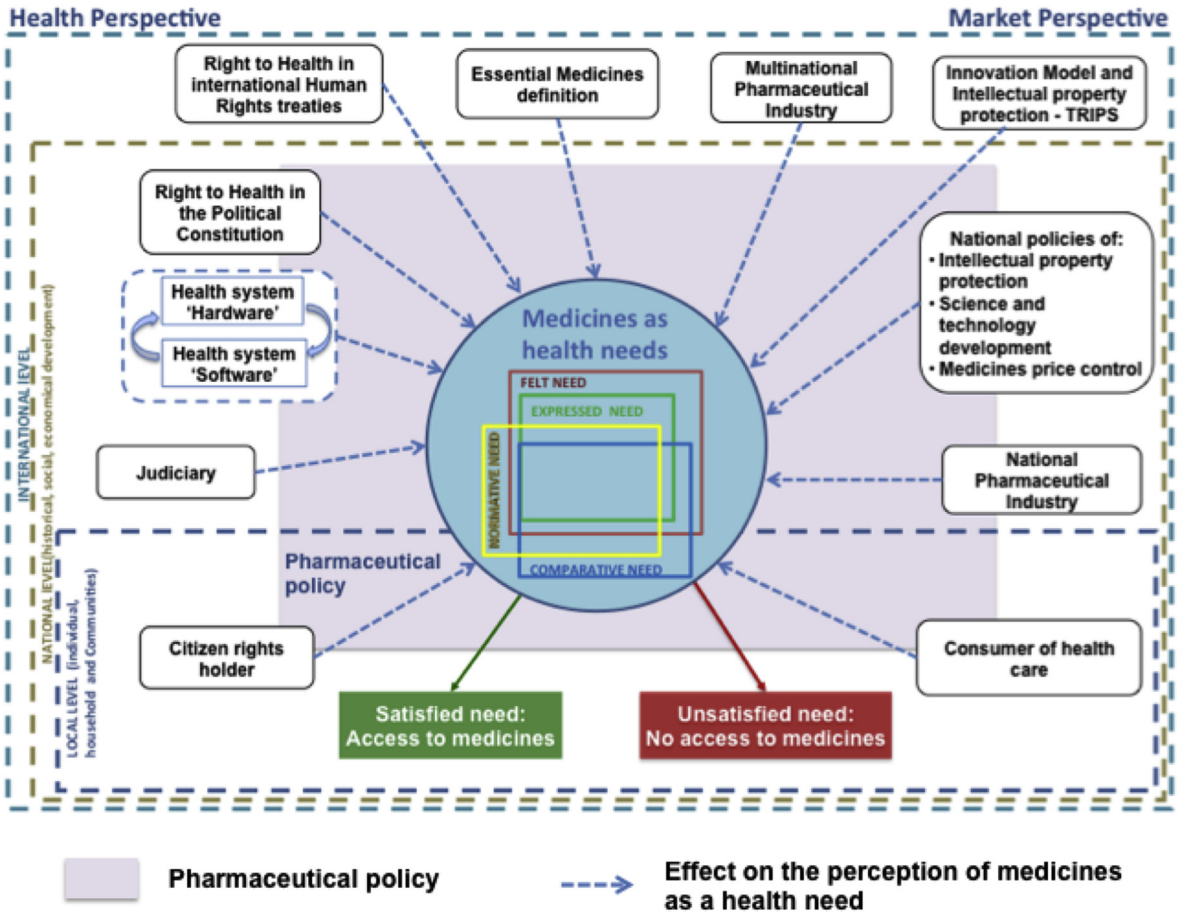

Fig. 2. Theoretical model. Source: authors. The theoretical model comprises stakeholders, policies and practices that modulate the perception of medicines as a health need from two perspectives - health and market - at three levels: international, national and local levels. The different perceptions created of medicines as a health need (according to Brashaw's categories) do not always coincide, and as a result of this "conflict" the patients do not get access to the medicines they perceive as a need. The health system scheme was adapted from Sheikh et al. (2011). The health system hardware considers human resources, finance, medicines and technologies, organizational structure, service infrastructure and information systems. The health system software includes ideas and interests, relationships and power, values and norms of the different stakeholders. Pharmaceutical policy is represented as a square behind the stakeholders and policies considered at the national level, since pharmaceutical policies could adopt different forms according to the context: (a) a unique document considering all the aspects defining them; or (b) a policy that guides the development of the other policies.

strategies include the modification and/or harmonization of regulatory frameworks across countries (i.e. International Conference on Harmonization – ICH) in order to facilitate the licensing of new products and open new markets in emerging economies. Moreover, as a result of the pharmaceutical lobby, the review time for new patentable medicines has been significantly reduced, and alternatives of fast-track approval requiring less data about efficacy and safety have been created for medicines indicated for "serious" or "life-threatening" conditions (Williams et al., 2011). This influence is important since in order for a medicine to be recognized as a normative health need it first has to be licensed.

Another strategy established by the health systems to define the medicines list is the promotion of International Non-proprietary Name (INN) prescribing. However, this strategy depends on the availability of generic products in the market. At this point, the national science and technology policies became relevant because they can stimulate/inhibit the creation/expansion of the national pharmaceutical industry and the production of generic medicines (Tobar and Sanchez, 2005).

The orientation of science and technology policies depends on the national development and on the economic model (neoliberal or protectionist), the nationwide implementation of the TRIPS agreement; and the local technical capacities. These policies may include measures both to promote investments by foreign companies in the country and to stimulate national initiatives such as the creation of public pharmaceutical industries or encouraging the creation of private pharmaceutical companies of national capital to ensure local production of generic medicines (Tobar, 2008). The states can also create and maintain public research institutes or allocate resources for funding research to generate technological knowledge and capacity to produce medicines, and the required materials (active pharmaceutical ingredients and excipients) aiming to reduce the country's dependence on external imports (Pinheiro et al., 2014).

Pharmaceutical companies have great interest in policy making related to national science and technology policies, specially the implementation of the TRIPS agreement (Tobar and Sanchez, 2005). Some of the pharmaceutical industry pretensions include the relaxation of the patentability criteria to achieve protection for both *me-too* medicines and second medicines uses; the extension of the monopoly period, the limitation of the applicability of the TRIPS flexibilities and the demand for application of the TRIPS-Plus requirements to delay the entry of generic medicines (i.e. data exclusivity) (Correa, 2006; Goldman and Love, 2015; Rossi, 2006). Other strategies to delay the entry of generic medicines include the lobby for the harmonization of the regulations related to

bioequivalence and bioavailability of chemically synthesized medicines, and biosimilarity of biotechnological medicines (Seuba, 2010), and payment to generic companies to suspend the release of generics (Federal Trade Commission, 2013).

Price regulation policies are also another approach considered by the health systems to define the medicines list. Some authors argue that pharmaceutical companies set the prices of new medicines in the early stages of their development process. Just as with luxury goods, the more devastating the disease is and more unique and effective the medicine is, the greater price it has, regardless of the development cost (Sanchez-Serrano, 2014). Moreover, in the pharmaceutical market, monopolistic competition is common in the case of branded multisource medicines (Rovira Forns, 2015). This is the reason why medicines price regulation is relevant, not only in the case of medicines under monopoly or oligopoly but also in the cases of monopolistic competition (Rovira Forns, 2015). There are different strategies such as the international reference pricing or direct price regulation to contain medicine prices. Nevertheless, the effectiveness of price regulation heavily depends on strong legal systems and supportive purchasing and administrative agencies to underpin their healthcare systems, but these are fragile in Latin American countries. The strategies required encompass pharmaceutical sector regulation, competition and anti-corruption law to create a level playing field in order to ensure a healthy competitive generic market given the clear advantages of pricing through competition over direct price regulation (Nguyen et al., 2014).

Additionally, in Latin American countries judicialization of access to medicines has turned the Judiciary system into another stakeholder that directly influences the recognition of medicines as a normative need. This happens when a patient resorts to the Judiciary to request from the health system a medicine that has not been included in the medicines list or a specific brand of a covered medicine (Vargas-Peláez et al., 2014).

3.2.3. Medicines as a comparative need

The *comparative need* corresponds to the health system capacity of responding equitably to the people's needs (Soares, 2013). At the international level, the comparative need is related to the international treaties of human rights, as they provide that the State must guarantee equitable access to health service, and the adoption of a universal health coverage (UHC) as a priority of the post-Millennium Development Goals (United Nations' General Assembly, 2012). UHC means that all people must receive the health services (including medicines) they need without suffering financial hardship when paying for them (WHO, 2010).

At the national level, the definition of the health system model depends, besides the international level factors, on the social justice values, equity and efficiency interpretations (Vargas et al., 2002), the historical background and development model adopted (Mejía-Ortega and Franco-Giraldo, 2007). Based on those factors, each State defines in its political Constitution the type of citizenship that will be recognized (Fleury and Molina, 2002), and the State's role in the fulfilment of the social rights, including the Right to Health (Perehudoff et al., 2010). Moreover, national constitutions define whether social rights would or not be claimed through the courts, and whether these claims would be through specific judicial ways (Hogerzeil et al., 2006; Yamin and Gloppen, 2011).

In states where a liberal culture predominates, social policies tend to be residualist: the state action, in the form of social assistance, aims mostly at the social needs of those who are unable to seek solutions in the market resulting in an *inverted citizenship*. In states where a conservative culture predominates, social policies on social protection are based on rights and duties related to the occupational status, in the form of social insurance, corresponding to a *regulated citizenship*. Finally, in the social democratization of capitalism, a state intervention aims to correct distributive social inequities and has as a scope all the individuals, resulting in a *universal citizenship* (Fleury and Molina, 2002).

Each country establishes its health system model based on the assumptions set out in the Political Constitution as well as on the values of each society (Fleury and Molina, 2002). Health systems are social constructions with certain power structures, interests and interdependencies, and the relations are permeated by the values and principles of the stakeholders (institutions and individuals) involved. The stakeholders comprise the government, healthcare professionals, trade unions, political parties and the medical-industrial complex, including the pharmaceutical and medical device industry, healthcare providers, and insurance companies (Labra, 1999; Paina and Peters, 2012).

In the designing of their health system, each country defines the population coverage (universal or segmented), the sources and resources that will be used for funding (taxes, social contributions, public or private insurance, direct payment), the management of services and level of integration between financing agents and providers (number of donors, the presence of the Ministry of Health or a National Insurance), the ownership of health services (public, private-for-profit, philanthropic), the forms of remuneration and regulation of health professionals, especially doctors (act, salary, capitation, degree of regulation), and the services and medicines that will be provided to users, as well as the regulation that defines the operation and control of the actors of the health system (Conill, 2006; Lobato and Giovanella, 2008).

In order to recognize the complexity of the health systems, Sheikh et al. (2011) classified the components of the health system as '*hardware*' and '*software*'. The *'health system hardware'* includes finance, medical products, information systems, levels and types of human resources, forms of service delivery, and governance understood as organizational structures and legislation, while the *'health system software'* comprises ideas, interests, values, affinities and power relationships between the health system stakeholders. The definition of the health system hardware does not guarantee access to health services for the population, since the health systems performance also depends on the health system software once not all the stakeholders have as main goal to improve the health of the population (Sheikh et al., 2011).

In the same sense, the availability of a list of essential medicines which must always be available in adequate amounts, in appropriate dosage forms, with assured quality and at prices the individual and the community can afford (WHO, 2015a) does not ensure that such medicines will be accessible. Actually, many barriers that hinder the accessibility of medicines are related to factors that compromise the responsiveness of the health system to the legitimate expectations of the population for care that respects the dignity of persons and promotes their satisfaction (Frenk, 2010). Examples of those barriers are weak governance, fragmentation of the healthcare networks, and health sector pluralism (Bigdeli et al., 2013).

In some Latin American countries, the Judiciary has become an alternative way of gaining access to medicines; however, the level of intervention of the courts in issues related to access to medicines depends on each country's characteristics. The organization of the judiciary system (hierarchy of the tribunals, level of decentralization) determines the level of accessibility. On the other hand, factors like the law system (civil or common law), the perception about the health system performance, and the perception of the physician's authority as professionals capacitated to decide about the best treatment for a specific patient could influence the judges' willingness to accept and grant lawsuits for access to medicines (Gauri and Brinks, 2007; Yamin and Gloppen, 2011).

3.2.4. Medicines as an expressed need

An expressed need is a felt need turned into action. Acting is a possible expression of behaviour. Thus, the demand for health articulates behaviour and action of the user to obtain services or health goods that are felt necessary.

In the relationship between users and the health system, users can be considered as citizens demanding their right of access to health services and medicines, and as consumers of health care (Frenk, 2010). In both cases, the health services accessibility (e.g. organization, geographical distribution and financial issues), and the enabling factors (e.g. socio-economic status, perception about the system and the right to health) influence the possibility of getting access to medicines (Soares, 2013).

People allocate scarce resources (financial investments, time) in different goods and services to use them to achieve a desired outcome. Individual wishes depend on the cultural, educational and social level of the population. In turn, the demand for health services corresponds to the relationship of these variables with the financial ability to purchase goods and services. Geographic aspects, demographic characteristics, socioeconomic factors, knowledge about health, disease incidence, and the attitude of the population can influence the demand for health care and modulate the wishes of care consumption (Asadi-Lari et al., 2003; Feldstein, 2012).

Despite the fact that the demand for health services and medicines is usually individual, in most difficult situations people tend to organize and form support networks that facilitate overcoming barriers of accessibility. However, some studies show that the power of patient activism and collective mobilisation have been 'captured' by the pharmaceutical industry by means of marketing strategies 'to inform or to educate patients' that highlight the "expert patient" discourse (Abraham, 2010; Williams et al., 2011). Thus, patient groups have become important stakeholders in the health systems, particularly in the case of high-priced medicines, in two ways: (1) their advocacy during the process of incorporation of new medicines in the coverage of health systems (Perehudoff and Alves, 2010), and (2) for the support and promotion of accessibility of medicines through the courts (da-Silva & Terrazas, 2008).

4. Discussion and conclusions

Medicines have become health needs in modern society because they are goods considered valuable (Willard, 1982). This value results from the combination of the social expectation that scientific development will resolve the health problems (Williams et al., 2011) and the economic and political interests of different health system stakeholders that rise around medicines as products.

In recent years, the discussion about the health systems performance has been colonized by pharmaceuticals (goods) despite the fact that the health system (the satisfier) may be more efficient and have broader impacts on the population's health by the implementation of other strategies (i.e. promotion and prevention activities). Moreover, the discussions about the satisfaction of health needs related to access to medicines are limited, once they do not take into account the conceptual discussion about health needs, and are frequently focused on both the recognition of medicines as normative needs and the customer satisfaction.

In this sense, our theoretical model considers a broader view of access to medicines, overcoming the positivist view that predominates in the health system research (Paina and Peters, 2012). The central proposition of the model is that needs influence the accessibility of medicines and that this relationship is permeated by values. Once the model emphasises how power structures, interests, interdependencies, values and principles of the stakeholders from both health and market perspectives it will be useful to find solutions to access to medicines barriers in Latin American countries.

The model is sufficiently comprehensive to allow comparisons with different countries in terms of access to medicines. However, the diversity in the health systems development as well as their political and economic contexts increases the complexity of the model, while reduces their explanatory power.

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