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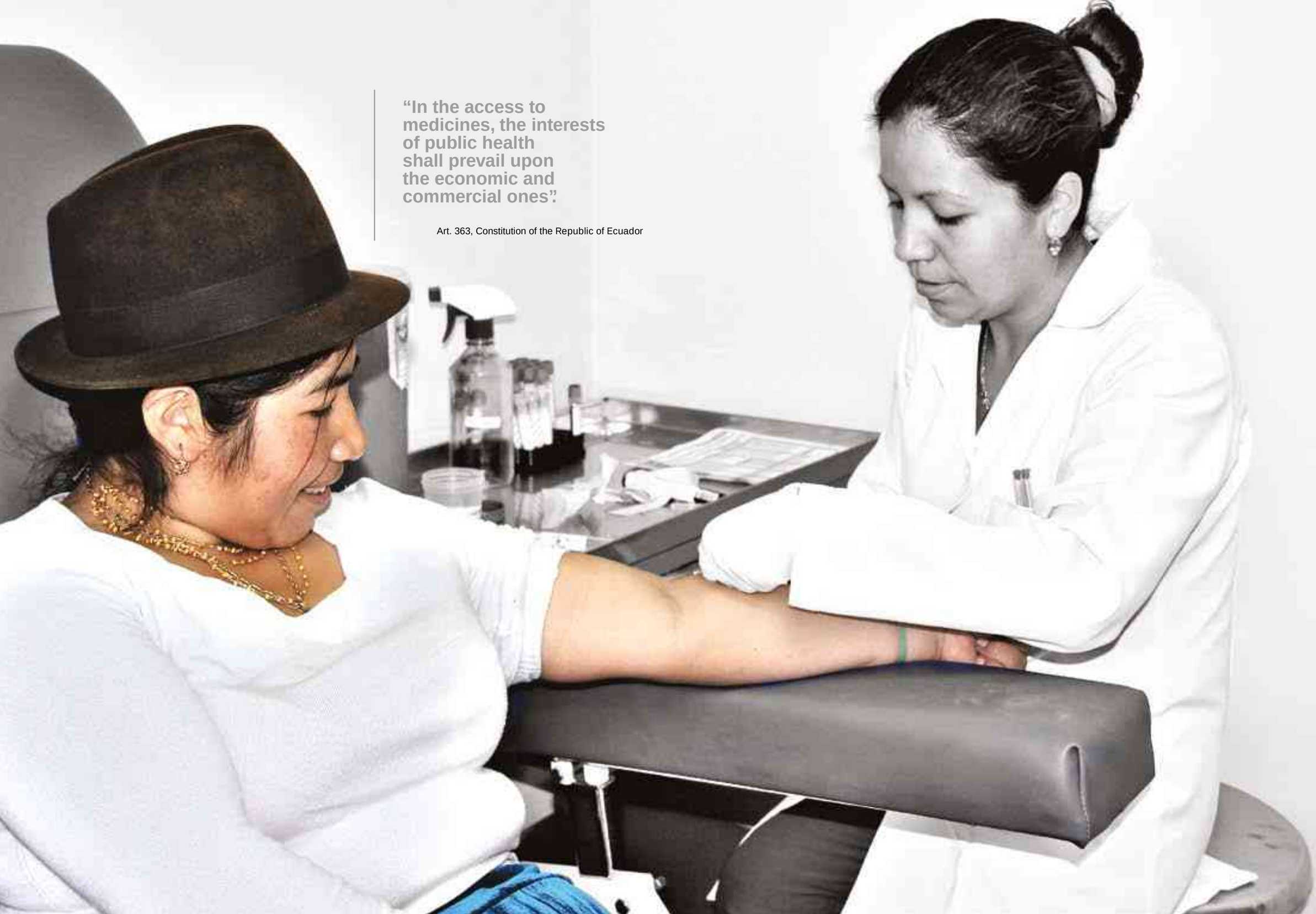
CORPORATE REVERSE
DRUGS BIDDING

PUBLIC ACCESS TO QUALITY MEDICINES:

PUBLIC PROCUREMENT AS A MECHANISM TO GUARANTY THE RIGHT TO HEALTH

“In the access to medicines, the interests of public health shall prevail upon the economic and commercial ones”.

Art. 363, Constitution of the Republic of Ecuador



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Quito, Ecuador

Content

PRESENTATION

The Citizen's Revolution started a process of reconstruction of the Nation, a process that guaranties a dignified life that truly responds to the common welfare and to the will of the majority of the population. This meant going from its dismantling and, therefore, its de-institutionalization, to the design of a Nation in which the value of the human being has operative precedence over capital throughout its entire dimension.

Almost nine years after the achieved transformations, the Ecuadorian government is immersed in a new enterprise that comprises the public purchases in the health sector in order to improve the effectiveness of the processes of acquisition and prompt distribution of quality medicines to the Public Health Centres across the country. The 2015 Corporate Reverse Drugs Bidding (SICM – for its Spanish acronym) is a cross-institutional effort put in place by the Integral Public Health Network (RPIS – for its Spanish acronym), which is formed by the Public Health Ministry (MSP – for its Spanish acronym), Ecuadorian Social Security Institute (IESS – for its Spanish acronym), Armed Forces Social Security Institute (ISSFA – for its Spanish acronym) and National Police Social Security Institute (ISSPOL – for its Spanish acronym), as well as the National Public Procurement Service (SERCOP – for its Spanish acronym).

While guarantying the fundamental right stated in the Constitution of the Republic of Ecuador, and expanding the access to medicines, the Ecuadorian Government, through the RPIS and SERCOP, has the political will to increase the economic savings margin in the acquisition of more than 400 different types of drugs, as well as, to give priority to the local pharmaceutical industry by applying preferential margins.

The challenge is to combine the diverse interests of the sectors involved, answer their needs, and remain loyal to the principal that health and its care are not merchandise but a fundamental human right. At the same time, it is imperative to observe what is stated in the Magna Carta.

> *"To guaranty the availability and access to quality, safe and effective drugs, to regulate their commercialization, and to promote the national production and use of generic drugs that respond to the population's epidemiological needs. Regarding the access to drugs, the public health interests will prevail over economic and commercial interests". Art. 363, number 7, Constitution of the Republic of Ecuador 2008.*

The Ecuadorian experience regarding the 2015 Corporate Reverse Drugs Bidding (SICM) opens the debate to allow Government Officials, such as the Health Minister, Carina Vance, and authors, such as Jaime Breilh and Maria Cecilia Acuña, to display in Chapter I their vision about the right to health and drug access, and Juan Carlos Maldonado presents the elements necessary to consider a drug to be of quality, safe and effective, qualifications that are often questioned by the pharmaceutical giants, who have certainly found in this questionings the source to increase their profitability.

It is a fact that the pharmaceutical industry creates knowledge – that is patented – through heavy investment and years of research. However, it is necessary to question the limits of intellectual property when a piece of knowledge that is considered a public asset is privatized, to the detriment of the majority of the population. To this regard, in Chapter II, Carlos Correa asks: What happens with the patents, competition and public health?; also, Andres Arauz and Diego Mogollon make an analysis of intellectual property in Ecuador and the processes to move towards the democratization of knowledge and the fair and egalitarian socialization of its benefits.

Later on, academics such as Marc Rodwin, Aidan Holli and Pedro Paez analyze in Chapter III the pharmaceutical market practices, and the mechanisms that can be instated by the Government to regulate them.

Furthermore, in Chapter IV, Pablo de la Torre and María Belén Mena, review the current state of the local pharmaceutical industry, its development, and the availability of essential drugs in the market.

Finally, in Chapter V, the Chair of the National Public Procurement Service, Santiago Vasquez, presents the details of the Corporate Reverse Drugs Bidding (SICM 2015) as a process to guaranty the right to health, through the strategic, corporate, efficient and transparent public procurement. This initiative, which has been implemented twice in Ecuador, has been executed with technical directives and standards never before applied in a process like this one, to this regard, Camila Restrepo and Karla Ulloa explain the decisions made to ensure its integrity in every stage of the process.

It is worth taking advantage of this opportunity and the Ecuadorian expertise presented in this document, to unravel the economic dispute to dominate and rule over the political and over politics, and how this fight is visible from an objective point of view, in regards to the social, and, in the day by day, in the minute by minute of the population that must live knowing that its rights are guaranteed by the Government.

CHAPTER I:

Right to Health and Access to Medicines

Drugs and the right to health

Carina Vance*

The Constitution of Ecuador encompasses the rights to health and medicines from a more global and systemic perspective, when compared with the previous constitutions. It is aligned with the Universal Declaration of Human Rights (1948), the International Agreement of Economic, Social and Cultural Rights (1966), and the Declaration of Alma Ata (1978).

Hence, since 2008, Ecuador has taken on an important challenge determined by a guarantying Constitution, which highlights the most fundamental of all rights, the right to life. Health has then become a responsibility of the State and a constitutional mandate for all Ecuadorians.

To achieve the execution of the right to health, the Constitution also states that the Government will guarantee access to quality, safe and effective drugs; also, it indicates that "regarding access to drugs, the interests of public health will prevail over economic and commercial interests."[1]

Therefore, this constitutional framework recognizes the importance of drugs as a fundamental element for health care as they are involved in prevention, healing, rehabilitation and palliative care. Nevertheless, from an economic point of view, there are some factors that can transform this social asset into simple merchandise that is regulated only by markets forces and not by the health needs of the population.

Access to medecines is an essential issue to secure health as a "public asset to which everyone is entitled"; the lack of availability and access could have a negative impact in the health of the population and in the way to exercise justice in the distribution of resources within society.[2]

Even though drugs are important to the health of the population, their availability is limited due to many factors: their price, the availability of resources for their procuring, the market structure, national production capacity, among others.

Supply and demand of drugs

The Ecuadorian pharmaceutical market has experienced a noticeable sales growth in the past years, from 680.94 million dollars in 2007 to 1,142 millon dollars in 2012, equivalent to 56% of growth.

Likewise, Ecuador has the highest number of drug stores per capita among the countries of the South this indicator that does not represent greater access for the population, but has repercussions on the rational use of medicines. Despite the growth of the national pharmaceutical market and the high number of drug stores (approximately 6 thousand), the market supply of essential medicines is limited.

* Minister of Public Health of Ecuador in office from August 2012 to November 13th, 2015, Bachelor in History and Political Sciences at Williams College Massachusetts; Master in Public Health, University of California, Berkeley.

Distribution of drug stores per capita

Country	Number of Drug Stores	Population (Millions)	Number of people per drug store
Ecuador	5 915	13,6	2 303
Colombia	19 068	45,6	2 395
Uruguay	1 250	3,3	2 689
Argentina	12 979	40,2	3 103
Brasil	58 232	193,7	3 327
Paraguay	1 861	6,3	3 412
Bolivia	2 867	9,8	3 440
México	31 398	109,6	3 491
Perú	8 287	29,1	3 519
Centroamérica	8 686	39,5	4 548
República Dominicana	1 980	10,0	5 096
Venezuela	5 246	28,5	5 449
Chile	1 798	16,9	9 438

Source: *Acceso a medicamentos y situación del mercado farmacéutico en el Ecuador. Ortiz, 2014.*[4]

The pharmaceutical industry sells drugs based on demand, and not in accordance with the health needs of the population. The drugs of highest commercialization in 2011 and 2012 can be seen in the next table; it is clear that there is no coherent relation between the supply and the health needs of the population.

An analysis performed in August 2015 by the National Direction of Drugs and Medical Devices identified that 91 drugs included in the current Basic Drugs National Chart are not accessible to the population. A closer look into each therapeutic group found that some were more severely affected. For example, Morphine, Loperamide, Active Carbon, Streptokinase, Melphalan, Phenobarbital, among others, comprise the group of difficult access drugs, that, despite being essential to the Ecuadorian population, have no guaranteed supply in the market by the national providers.[5]

Drug market in Ecuador 2011-2012

	Marketed products with medical prescription		Marketed products without a prescription	
	2011	2012	2011	2012
1	Lipor	Seretide	Ensure	Arcoxia
2	Plavix	Humira	Apronax	Kufer Q
3	Seretide	Crestor	Pharmaton	Complejo B
4	Crestor	Nexium	Pediasure	Fluimucil
5	Nexium	Enbrel	Mesygina	Mesulid
6	Seroquel	Remicade	Neurobion	Omezzol
7	Humira	Abilify	Mesulid	Neurobion
8	Enbrel	Lantux	Arcoxia	Doloneurobion
9	Remicade	Mabthera	Aspirina	Abrilar
10	Abilify	Cymbalta	Unasyn	Mesigina

Source: *Access to medicines and market situation in Ecuador. Ortiz, 2014.*

1. *Constitution of the Republic of Ecuador (2008), published in the Official Registry No. 449 of October 10th, 2008 Ugalde A,*

2. *Homedes N. (2007) América Latina: La acumulación de capital, la salud y el papel de las instituciones internacionales. Salud colectiva. Vol. 3 n.1 Available at http://www.scielo.org.ar/scielo.php?script=sci_arttext&pid=S1851-82652007000100003&lng=es&nrm=iso>. ISSN 1851-8265. Recovered on July 6th, 2015.*

3. *Ortiz-Prado E, Galarza C, Cornejo Leon F, Ponce J. (2014) Acceso a medicamentos y situación del mercado farmacéutico en el Ecuador. Rev. Panam. Salud Pública. 36(1):57-62.*

4. *Public Health Ministry, Drugs and Medical Devices National Direction.(2014) Reporte interno de análisis de medicamentos de difícil acceso. 2014*

5. *Fojo T, Mallankody S, Lo A. (2012). Unintended consequences of expensive cancer therapeutics – the pursuit of marginal indication and a me-too mentality that stifles innovation and creativity. The John Conley Lecture JAMA Otolaryngology – Head & Neck.*

On the other hand, exorbitant prices of certain drugs can also limit their access to the population. Most of the more expensive new drugs – although sometimes less effective – are available in the market, but their price makes them difficult to access.[6]

Drugs represent a high proportion of the health spending in every country in the world. It is estimated that in the Latin American and Caribbean region drug spending represents between 18% and 70% of the health spending of every household.[7]

Despite the rationalization process, the expenditure and consumption of drugs show an upward trend; Because of this the Public Health Ministry has invested more than 1,100 million dollars in drugs to treat the health needs of the population since 2008 to 2014, and this budget has been increasing throughout the years to keep up with the expansion of services. The great investment in health has been, without any doubt, one the historic changes that have allowed the achievement of tangible improvements in the coverage and integral attention of the population, however, high costs and a sustained enhancement in spending can risk the sustainability of the National Health System that aims to guarantee universal coverage.

Efficient drug access

In this context, being responsible and coherent with the public policy aligned with human rights and their needs, which shall prevail over capital, the National Health Administration has conducted a series of actions that aim to achieve efficient access to drugs. Therefore, it has defined a list of essential drugs, in accordance with the World Health Organization (WHO). The essential drugs are those that satisfy the primary health needs of the population. They have been selected taking into consideration their relevance to public health, the evidence of their effectiveness and safety, and their compared effectiveness in relation to their cost. The essential drugs must always be available in the health systems, in sufficient quantities, in the appropriate pharmaceutical forms, with quality assurances and adequate information, and with an affordable price to the patient and the community.[8]

The Basic Drugs National Chart – CNMB (for its Spanish acronym) contains the mentioned list of essential drugs. The CNMB is periodically published and meets the epidemiological profile of the country; the drugs described therein were analyzed with the best available scientific evidence, taking as a reference the WHO model and with criteria of effectiveness, safety and convenience.

The ninth revision of the CNMB contains 399 active principles, 727 pharmaceutical forms and concentrations, and approximately 1,000 commercial presentations that answer the real public health needs of the country. The CNMB constitutes a tool to address the essential drug production in Ecuador.[9]

To make these essential products available at all times in order to satisfy the needs of the population, it is necessary to conduct provisioning processes that are able to secure quality, safe and effective drugs, with the best market prices, achieving efficient expenditures, and optimizing the available resources. In order to do so, it is necessary to exhaust all the national and international options, within the legal framework, to guarantee drugs access.

The Corporate Reverse Drugs Bidding is an efficient mechanism to achieve the previously mentioned goals. This purchasing mechanism consolidates the drug demands of all of

6. *ONU (2008). Objetivos de Desarrollo del Milenio, La progresión hacia el Derecho a la Salud en América Latina y el Caribe. Publicaciones Naciones Unidas. Capítulo V. pp. 85-102.*

7. *IINEC-SENPLADES. (2012). Encuesta Nacional de Ingresos y Gastos de los Hogares Urbanos y Rurales. Estadísticas Socio Demográficas. Taken from http://anda.inec.gob.ec/anda/index.php/catalog/291/datafile/F108/V3490*

8. *Ministerio de Salud Pública, Consejo Nacional de Salud, Comisión Nacional de Medicamentos e Insumos. (2014). Cuadro Nacional de Medicamentos Básicos, Registro Terapéutico Nacional (Presentación), CONASA*

9. *Public Health Ministry, Health National Council, Drugs and Supplies National Commission, (2014), Cuadro Nacional de Medicamentos Básicos, Registro Terapéutico Nacional (Presentación), CONASA.*

the institutions that are part of the Integral Health Public Network (RPIS). This aims to guarantee the best prices through the logic economies of scale, with the certainty of distribution for the awarded providers, for at least 2 years; and, it plans to guarantee an extensive participation of national and international providers in order to allow better price competition, maintaining always the same standards required for quality, safety and efficacy. Moreover, the consolidation of the national needs becomes a bonding mechanism leading towards an integrated National Health System, which tears down the old paradigm of a fragmented and inefficient system.

Bulk purchases and the presence of many competitors offering the best market prices, nationally and internationally, could generate savings for the Ecuadorian Government of more that 100 million dollars according to the projections made by SERCOP, and will allow the available resources to be sufficient to cover the growing needs of the population. This will facilitate access and availability of quality, safe and efficient drugs in a transparent, agile, timely and effective manner, promoting rational consumption, exercising the right to health with a broader reach and optimizing the use of available public resources.

Tognioni mentioned in 2010: “Drugs have no right to exist, but only as an instrument of service, the dream of a right to health that would be prioritized in relation to the market interests”.[10] Only by guaranteeing the access to drugs through concrete actions, as the ones stated in the Corporate Reverse Drugs Bidding, we can walk forward towards the dream of the right to health, and we can justify the existence of technology and science in service of humanity and not in service of the markets.

10. *Tognioni, G (2010) Buscando remedio, AIS-Nicaragua.*

Towards an emancipatory construction of the right to health*

Jaime Breilh**

Health: the need to restate it and to renew the justiciability spectrum

Most of the time when people, including many specialists, think about health and its problems, terms related to a nursing care notion immediately springs to mind, such as: sickness, ill, health services. Sometimes terms usually associated with prevention are also included, such as vaccine, nutrition, sanitary infrastructure, etc.

The reason why these notions, part of the logic of conventional thinking of the old public health, stand out is because of the hegemony of the so called bio-medic model, of the positivist paradigm that supports it, and of the functionalist conception of its practice. Also, since the bio-medic approach is hegemonic, that logic frequently finds its way from time to time into other fields, such as Justice, that eventually require to reflect about health.

To work for health from a renewed perspective, it is not enough to focus the terminals and specific health problems as a result expressed in forms of disease and death, but should focus on those processes that generate or cause health conditions. In legal terms, this is important because it implies to broaden and deepen the coverage of the right towards key elements in issues studied by specialists, such as the positive and negative obligations required, goods to be safeguarded, and, ultimately, the field of justiciability. [1]

The first step to understand health and its rights from a holistic perspective is to break the hegemony of these biomedical notions and liberal logic of conventional practice that we mentioned. The health of human beings, their protection, recovery and progress, is not basically a problem of sick people who need to be treated. If the full scope and responsibility of health as a field of collective action is assumed, it is primarily a matter of having good knowledge of what creates and develops a healthy life and the processes that support or affect it.

We need to consolidate and become aware of the urgency of a comprehensive vision of health as part of life on Earth, and the conditions that affect it. The holistic principle of comprehensiveness, as we have explained in previous works,[2] articulates both the ancestral thoughts of our people and the critical vision of life sciences and health. Unlike the positivist perspective that fragments and associates only just externally the parts, it is required to recognize the profound concatenation of the processes of various orders, which define life and health, encompassing both the social organization and the world of the life that sustains it. Therefore, we say there is a relationship between health, the environment and society. And, of course, legally, we draw the obvious conclusion that the right to health includes more than just the right to the goods that facilitate an adequate curative care, it also covers the fact that the validity of the right to a healthy life is linked to the validity of other rights of good living. Our struggle, together with multiple organizations in the constituent stage, as part of the Network for the Right to Health, ensures that the new Constitution consigns this relationship.

From the above, it appears that health problems are not just confined to the disease and the prevention as individual phenomena. They are not, first because the facts that lead people to become ill not only affect one person or a few people, but potentially affect a whole community and, second, because those events do not occur, or multiply, or are distributed in a family or individual space, but are produced and spread throughout the entire community and, moreover, in the entire society.

In epidemiological terminology, this means that health issues cover two dimensions:

- *Individual health:* health phenomena that are observed, explained, and treated in people and their families.

- *Collective health:* phenomena that are produced, seen, and faced in a social or collective dimension.

We say then that individual health and the collective health constitute different dimensions, but are profoundly interrelated. This is an extremely important issue when reflecting about the right to health in order to cover both the individual and collective dimensions of such right.

Social determination of health as knowledge of the right spectrum

Preparing the health component of the 2009 Human Rights Report from a critical perspective that goes beyond the linearity and reductionism of positivist thought of health, poses the challenge of a construction of critical, interdisciplinary and intercultural character, to combine a renewed vision of both the right, as well as health itself.

In these pages we refer to the relationship between the two necessary elements of this construction in their academic part: the collective health sciences and the sciences of law. In any historical period, and even more in a time when the extreme economic acceleration, social and legal inequality, both the science dealing with the knowledge of the processes that affect lives and health, and the one that deals with the characterization of the respective right, advance subject to demands and tensions that permeate the epistemological and, legal-political debate.

Of all the scientific disciplines that converge to study health as an object of praxis and law, critical epidemiology is a strong starting point for an innovative analysis of law, since, being the integral "diagnosis" branch of collective health (name of the new public health), allows us not only to know the health status of a population, but the processes that determine it, and, therefore, derive the obligations that must be consolidated to give effect to the right to a healthy life.

The increasing proximity of epidemiology with law has been painfully witnessed

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1 Victor, Abramovich y Christian Courtis. "Apuntes sobre la exigibilidad judicial de los derechos sociales, en Christian Courtis y Ramiro Ávila. Edit. La protección judicial de los derechos sociales. Quito. Ministerio de Justicia y Derechos Humanos. 2009. p 3-29

2. Jaime Breith. Epidemiología crítica: ciencia emancipadora e interculturalidad. Buenos Aires. Lugar, 2004. 2a. ed.

* The complete version of the article was originally published by Universidad Andina Simón Bolivar, 2010 in: Programa Andino de Derechos Humanos, compilador, ¿Estado constitucional de derechos? Informe sobre derchos humanos Ecuador 2009. Reproducted here with the author's permission.

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by many affected communities, but also by institutions and scientific centers that push for an independent science of power. Environmental epidemiological conflict scenarios are multiplying and that trend is reflected in the scientific literature references, which boasts a growing convergence of epidemiology with law issues.

The in-depth explanation of this coincidence goes beyond the limits of these reflections, but the evidence of the last few decades shows that legal conflict scenarios around health, largely caused by large-scale economic expansion, put pressure on epidemiology to interpret "causality", which in this case weighs more as legal problem than as a health one.

However, current research into possible violations against the law has taken important steps. Both public health - and its interpretative branch, epidemiology - as the specialized health law, have generated deep conceptual, methodological and practical innovations that require rethinking the right to health. We, the health specialists, move forward in the knowledge of the complexity of health,[3] and legal specialists advance according to whether or not "rights are justiciable, and establishing protective measures that are designed to assert any recognized rights.[4]

An inconsistent point of view of the International Right to Health?

As we have said, health is a complex socio-eco-biological process, and even though which is generally recognized as health is only that "distal" or "terminal" side of a complex process of determination, its development happens beyond the individual order and the appearance of physical and mental consequences, and must open to a comprehensive view of health. Unfortunately, it seems that from the horizon of visibility of Latin American collective health and critical epidemiology, that comprehensive understanding of the complexity of health, has not quite managed to enter in key Acts we know of specific International Law.

For example, a valuable collection of legal articles recently published in the country, includes an essay that discusses article 12 of the International Covenant on Economic, Social and Cultural Rights, and especially the General Comment 14 (GC14) of the Committee on Economic, Social and Cultural Rights of the United Nations (UN), citing paragraph 11 thereof where the idea of the right to health beyond medical care in case of illness is collected, to cover "a wide range of socio-economic factors that promote conditions in which people can lead to a healthy life, and that makes that right extensive to the underlying determinants of health, such as food and nutrition, housing, access to clean potable water and adequate sanitation, safe and healthy working conditions and a healthy environment ".[5]

In a recent article signed by one of the figures of the Commission on Social Determinants of WHO, 6 together with important reflections on the philosophical and ethical implications of epidemiology focused on "the social determinants of health" and the moral imperatives of investigation, several of whose ideas we recognize as highly relevant, an argumentative body centered on the "causal relations" is developed, and, despite proclaiming the needs of a new paradigm, implies the reissue of the linear principles of empiric causality, but now assumed in the layers or levels of multilevel analysis (using the metaphor of the structure of Chinese boxes). As if the intention was to extend and complicate the old notion of the causal chain, to cover what is defined as "causes of the causes". In short, the

3. *There is extensive scientific literature that has been produced by the Latin American collective health that has been described in many works of science analysis.*

4. *Ramiro Ávila. "Los retos en la exigibilidad de los derechos del buen vivir en el derecho ecuatoriano", en C. Courtis Avila, edit., op. cit., p. 545.*

5. *Miguel Carbonell, "Derecho a la Salud en el derecho internacional de los derechos humanos", en C. Courtis y R. Ávila, edit., op, cit., p. 174.*

argument is that what the authors define as micro-epidemiology focuses only on the associations between morbid or death effects with the three levels of individual determinants (individual biological factors, individual behavior, and individual exposure to hazardous elements), so there is a need of a macro-epidemiology that covers social phenomena as "causes of the causes", that is, as distal factors that make up the "social environment" that greatly impacts health outcomes.

In other words, what our criticism raises is that instead of developing a conceptual and methodological body for understanding the social determination and building the socio-historical relationships and structural processes that are involved in determining health, these structural processes are dissolved in the form of factors, or in the so called "social determinants of health" (new letterhead but the same essence), only better organized in levels, and recognizing, unlike other theorists of empirical epidemiology such as MacMahon, that what is distal does have interpretative value. That is, we return to the logic of isolated risk factors for health, to the old positivist, linear and fragmented notion of reality that we precisely seek to overcome.

Critical epidemiology, from the late 70s of last century, does not build the notion of "social determinants of health", but works in the historical-dialectic process of social determination of health, 7 as a complex and multidimensional process of generation and reproduction of health and life conditions, whose development is generated in the middle of a great movement between society and nature, subject to the productive and social relations of a system of accumulation, power, and culture. A metabolism between society and nature, between the biological and social that is moved by dialectical opposition, in historically determined social spaces, among the healthy-protective trends and the unhealthy-destructive trends of those processes, some of which correspond to the general order, others to the particular order, and others to the singular order of social reproduction, as will be seen later. Therefore, health is a process subject to the social determination, based on what has been mentioned previously, but also because the physical and psychic phenomena operating in the phenotype of individuals, as well as in their genome, keep a deep relationship with the phenomena of social and socio-natural order. 8

In this line of thought, critical epidemiology establishes three dimensions of the determination of health, each of which, by the way, is an area that claims obligations and justiciability:

- General dimension: encompasses structural-economic, political and cultural processes that shape the logics and rationalities that, expressing a civilizing model, organize life within a society. Here the determinants are the economic accumulation system, the great cultural and epistemic patterns, and the system of power relations and political organization. These general processes also determine the social composition of a society, with its classes setting, its communities and ethno-national groupings, and its gender relations, all of which operate to define relationships and degrees of inequity, and the resulting inequalities in the face of the law.

- Particular dimension: corresponding to the characteristic ways of life, characteristic of socioeconomic groups (social classes crossed by gender relations and ethnicity) and involving five dimensions where good living conditions or unhealthy living conditions can be replicated (see Figure 1).

6. *Sridhar Venkatapuram and Michel Marmot. Epidemiology and Social Justice in Light of Social Determinants of Health Research, vol. 23, S.l, Bioethics, 2009, p. 79-89.*

7. *Jaime Breith, Epidemiología: economía política de la salud, Quito, Universidad Central del Ecuador, 1979*

8. *To study the contributions of Latin American social medicine in this area, information systems such as Howard Waitzkin and the library of the University of New Mexico can be consulted, who have worked that rich production and have highlighted as classical of that line the productions of Laurell (Mexico); Almeida Filho (Brazil); Samaja (Argentina); and Breilh (Ecuador).*

Figure 1

Dimensions of the way of living

(Collective conditions and structured spaces according to the placement of each group in the matrix of social power of society)

a) Working conditions (social classes): position in the productive structure (hierarchical and supportive relations); labour patterns (types of requirements and exposure to unhealthy elements); degree of dignity, protection, solidarity and work qualification.
b) Quality and enjoyment of consumer goods: type of quota according to the social distribution; constructions of need; access system (private or joint); consumption patterns (healthy or unhealthy).
c) Actual capacity and autonomy of the group to create and replicate cultural values and an authentic collective identity (social class "for itself").
d) Group capacity of supportive self-organization and empowerment; enjoyment of protective and helpful collective supports in benefit of the group.
e) Quality and sustainability of the ecological relations of the group; relation with nature; enjoyment of healthy ecosystems.

- *Singular dimension*it encompasses the individual lifestyle and the physical and physiological processes of people, where the final impacts of the determination are expressed.

At this point, it is necessary to clarify an issue that we deem important for legal reflection. Due to the confusion created by empirical sociology, we often misinterpret the notion of "way of life" with that of "lifestyle". The first corresponds to the structured processes of the group way of living, characteristic of the different classes of a society, while personal and family lifestyles, which obey to the free will of people, have a relative autonomy but operate within the historical possibilities of a collective mode of life.

That is, the interpretive construction of critical epidemiology emphasizes the decisive power of the collective and comprises the individual phenomena as elements subject to collective determination, although maintaining a relative autonomy. [9]

Additionally, critical epidemiology gives decisive interpretative importance to the intercultural construction of health. Thus, as we have noted in other work,[10] it considers important the conjunction of subjects and cultures in health constructions. And, for this reason, its interpretations are twinned with those coming from indigenous wisdom, forged as part of a logic of community living, and a worldview that places the lives and livelihood of the community at the center, giving prominence to the notion of living in community (kawsay) and attaching it to the notion of the good, protective, beautiful, pleasant or appealing (sumak):

The important coincidence between the autarkic and protective indigenous Sumak-Kawsay sense matches properly with the emancipating and preventive sense of the critical epidemiology way of life. The two views share the necessary priority of the

9. *A broader explanation of the social determination is presented in diverse works of Latin American social medicine.*

10. *Jaime Breilh y Ylonka Tilleria. Acelereación global y despojos del Ecuador: El retroceso del derecho a la salud en la era neoliberal, Quito, Universidad Andina Simón Bolívar / Abya-Yala, 2009.*

common good, of community life and of the harmonious relationship with nature, above the logic and private interests that limit and deteriorate them.[11]

The new Constitution of Ecuador places well living at the heart of the rights, but there is a huge distance to travel until that constitutional theoretical statement can be projected on an economic, legal and cultural order that actually puts it into effect.

There is no doubt that, in order to walk in that direction, an interdisciplinary vision becomes imperative, and it is essential for legal specialists to accompany those of us who are health specialists in the analysis of the elements of that way of life in order to set obligations, with its positive and negative behaviors that must be regulated and guaranteed to fulfill all four levels of obligations:[12] to respect, protect, ensure and promote the right to life and health, avoiding unhealthy ways of living and exposures.

Low enforceability alibis and barriers to health justiciability

Even though the writer of this paper is not a specialist in the science of law, the research experience in defense of threatened life and health, in areas such as agro-industry or urban health in Ecuador and other countries, has clearly shown that not only the construction of the right to health is limited and weak, but that the resources of justiciability and enforceability are equally fragile.

There is no doubt that the country and the mobilization of its political organizations, unions and social movements took an important step by promoting the new Constitution, but it is nonetheless true that the favorable potential inscribed in the Constitution of Montecristi is facing obstacles and shortages that are threatening the real justiciability of many rights, such as the right to health. Let us consider these contradictions.

It has been correctly recognized that the Ecuadorian Constitution requires the Judicial Function to protect all rights, even those related to good living, and not exclusively the property rights, and that it has all the elements to consider that social rights are fully justifiable.[13] However, from our experience, even after the enactment of the new Constitution, there are still major distortions and obstacles that the right for life and health is facing.

The health of thousands of Ecuadorians will depend on how we resolve, for example, the clash of interests and rights between those who push the expansion of scale mining in the face of the urgency to stop the pollution by mercury, cyanide and other highly hazardous metals, and to protect the life and health of miners, of neighboring communities, and even of food crops of the lower portions of basins irrigated by contaminated rivers. It will depend, also, on how they resolve the conflict of interests between agribusiness, and their systems of dangerous and polluting work, and the sustainability of ecological systems affected not only by pollution, but also by the extraordinary or non-sustainable consumption of vital resources (water, wood, and biomass). This is also true regarding the way of handling the growing threat of electro-pollution waves such as radio frequency (mobile phones) in urban areas or the multiplication of the production and marketing of products containing carcinogens and functional disruptors, such as genetically modified foods, artificial sweeteners, colorings, nano-components of cosmetics, etc. It is the ethical and legal challenge of how to proceed in the face of an economy of planned extravagance

11. *Jaime Breilh, "Sumak Kawsay ¿en version light?, in El Telégrajo journal, Guayaquil, July 7, 2008, p.11.*

12. *GGreert Van Hoof, "The Legal Nature of Economic, Social and Cultural Rights: A Rebutal of some Traditional Views", in Nijhoff Marinus et al., 1984, quoted by V. Abramovich and C. Courtis, op., cit., p. 3-29.*

13. *R. Avila, op., dt., p. 3-29.*

and waste that impels us to a generationally irresponsible consumerism, and to the massive accumulation of non-biodegradable elements that project a sinister future, where a good living approach will never be feasible and will end up becoming a rhetorical piece that thickens the archeology of good intentions.

In that way, we could list countless processes, technologies and substances of remarkable expansion in Ecuador, which contain elements that cause damage to and injure our right to a healthy life, for which science has already provided a valuable arsenal of evidence, but that are not subject to the protective mantle of public policies, nor justice, due to non-enforceability or lack of knowledge, technical resources, and especially social awareness to ensure the justiciability for any damage.

The interdisciplinary work of health, environment and law specialists has to address, and without ambiguity, the weakness of the justiciability of the right to health, to form a legal platform that provides greater opportunities for efficiency and sustainability to the actions of the specific field of health. A priority line of action in this regard is the impetus and support of the principle of precaution.

Around the world, health and environment sciences, and even legal sciences, have highlighted the principle of precaution as a fundamental instrument of justiciability. Such precept established that if there is a reasonable suspicion of the destructive process, and a scientifically established uncertainty, then there is an obligation to take action to prevent it; the burden of proof should lie not on the affected community, but rather on those whose activities caused the suspicion of damage; and, once the available alternatives have been evaluated to find the least harmful one, there must be assurance of a transparent, informed and democratic process of decision, that includes those affected.

A commission of scientists from the European Union, after systematizing and analyzing the ten years record of this type of conflicts in the European Community, established that the most important tool, if not the only one, ultimately, to ensure justiciability, is the application of the principle of precaution.[14]

The precautionary principle is mentioned in four articles of the new Constitution. In Article 32 on the right to health; Article 73 of the rights of nature; Article 313 referred to the strategic systems, services and public companies; and Article 397, which focuses on the environmental damage and risks and disaster prevention; but, unfortunately, it is only mentioned marginally and ambiguously.

The second shortcoming of justiciability is the one that corresponds to the subjective dimension that limits collective power and its awareness of the right to health, and it is the hegemony of that reductionist, biomedical vision we denounced in a previous section, and correspondingly, the lack of awareness of the dimensions of the right to life and health.

The need to transform the ethical bases of the right to health

From the epidemiological perspective we have mentioned, the status of health of a community, and the people who conform it, is generated in the middle of the contradictory movement that functions between the healthy, protective processes, supports and defenses that society allows a social class or community to enjoy, and

14. *Angela Guimaraes et al., edit., Interfaces Between Science and Society, Sheffield, Greenleaf Publishing. 2006.*

the unhealthy, destructive processes, the vulnerabilities and uncertainties, to which the way of living of that group is forces it.[15]

The movement between the processes noted in the way of living of a class or community, that might be healthy or unhealthy, occurs in both the general dimension, as well as in the particular and individual dimensions, and development in each of these dimensions of reality is given in a dialectical and interdependent relationship with the other two. The general processes operate as an integrated whole that encompasses and subsumes the particular and singular processes, imposing its logic, its hierarchical trend and reproduction. The particular and singular processes, despite being hierarchically subjected to the general determination, can influence its movement, as it holds a relative autonomy. In other words, the subsumption is not mechanical and unilateral from the totality towards the parties, but social energy can be accumulated in the particular and singular dimensions to transform the general logic.

That is, the general determination regarding the particular one, and the particular determination regarding the singular one are not absolute, but are subject to the generation of changing trends that can be embodied in the particular and singular dimensions. In other words, although the general logic of capital accumulation , the matrix of power and political relations, and the cultural epistemic conditions of a society determine the way of life of social classes, and the latter determines the individual lifestyles and personal health conditions of individuals, that structural tendency of society to reproduce its economic, political and cultural conditions, is faced with the contrary motion, dialectics of generation and social energies that operate classes and individuals. Therefore, this is a movement in two opposite directions, which altogether ends up determining health, both collective and personal. That complex and contradictory movement, characteristic of a community, is what we have called the epidemiological profile.

The epidemiological profile includes therefore two great movements projected in the three dimensions analyzed: a profile of healthy protector processes and a profile of unhealthy-destructive processes. If we want to defend life and health, and promote them, then we must act to promote healthy-protective processes (we call this health promotion) and counter unhealthy-destructive processes (we call this deep prevention - to differentiate it from the individual etiological conventional prevention -).[16]

What is the importance of what was said regarding health interventions and law? The fact is that if health is determined in three dimensions of reality, and if there are relations of mutual determination of the general, particular and singular processes, then it would be a mistake to act and practice with elements of law focused on only one of the three dimensions. What we should look for is that our efforts have an impact on all three dimensions.

Health programs must combine preventive actions focused on both counteracting the unhealthy processes, and promoting protective-healthy processes. The actions are more effective and sustainable as long as they cover most of the three dimensions of reality. We must act respecting, protecting and ensuring the right to health services for the people, but these actions are not sustainable if they are not accompanied by actions that act on collective, particular and general processes. The individual health actions can be more immediate, and are required as an emerging reaction

15. *J. Breilh, Epidemiología: economía politica., op., cit.*

16. *Ibid.*

to individual health disorders that demand immediate answers, but, while these restore individual health, they do not solve the issue of modifying the determining factors that caused the problem.

Similarly, law must strengthen the comprehensive justiciability of the right to health through the establishment and guarantee of obligations covering the three dimensions. Both positive ones, which promote and enforce healthy processes, as well as negative obligations, which protect and guard us from unhealthy/destructive processes. Thus, for example, when trying to solve the health problems of workers in the agricultural industry and nearby communities, it would be negative to think only on how we would address the health problems already present in that town and seek medical assistance, but instead we would have to enforce a regulation that covers the obligations to protect their way of life, that eliminate hazardous work patterns, and that are consistent with the logic of production within limits of respect to human health and ecosystems.

Two ethical arguments, with profound influence on justiciability of health, emerge from there. First, to act with deep preventive sense, preventing the disorders provoked by a disease, and sparing human suffering and destruction of nature, is an ethical imperative rather than a technical option. Second, to meet this ethical imperative, it is necessary to expand the conventional notion of bioethics to the integral notion of ethics, whose health dimensions are expressed in the following figure.

Figure 2

Domains of the ethics of health and construction of judiciability

- **General domain (sustainable logic)**
  Sustainable capacity of a social reproduction in equity.
  Human rights (economic, social and cultural rights).
  Rights of nature.

- **Particular domain (principle of good living)**
  Dignified, secure and rewarding work.
  Dignified, healthy, just and solidary consumption.
  Capacity building regarding identity and values.
  Enjoyment of solidarity organization, supports and defenses.
  Healthy and sustainable environments.

- **Singular domain (protection and repair) Harmonious labor itinerary.**
  Full access to dignified intercultural consumption.
  Conscience of the individual, emancipatory knowledge.
  Emotional support, from the family and the immediate community.
  Healthy and sustainable domestic ecosystem.

The breakdown of the domains of action allows us to guide the identification and improvement process of the obligations of the right to health, which would have to move

between the promotion, protection and security of the healthy activities and assets, the obligation of protection or defense against unhealthy patterns of life, and harmful processes and exposures.

We say that a society or community is sustainable when it meets several requirements:

- First of all, it has a production system that allows it to offer water and enough food of good nutritional quality and free of harmful components (infectious contamination, or due to chemical poisons or GMOs); in other words, provides food security. However, food security is very fragile and dependent if the community does not meet other requirements.

- It has to be sovereign, in other words, its members must have the capacity to be the owners of the requirements needed to make their own decisions regarding agriculture and must have access to food and water to the extent and quality decided by the collective. To make this possible, they should have sufficient land and water, own their own seeds, and have a guaranteed technical and financial support. All these rights are established by our Constitution, but they are often empty words. Ultimately, a sustainable community is able to produce, protect and safeguard the lives of both humans and nature. That is what we have called vital capacity, referring to the comprehensive productivity needed in its socio-natural space, to support the reproduction and improvement of life and economic, cultural and political conditions that guarantee a good living for the present and future generations alike.

We say that a society or community is supportive when people cooperate with each other and no one hoards or monopolizes the land, water, credit, resources, knowledge, ideas that are required to build a just society where good living is possible for everyone, with healthy ways of living. And the good living is not only having enough money in your pocket. Money is required to live, and it must be sufficient, but with only money in everyone's pockets, you cannot organize healthy ways of living.

And finally, a healthy society or community is one where people live a healthy life, and healthy life has some prerequisites:

- To work in a place where you feel good; that is protected from possible hazards; where you are treated with dignity and under ethno-cultural and gender rights; a place for improvement and learning; to have time for a good quality rest and also for healthy recreation, with sports and physical activities suitable for age and gender.

- To eat healthy and safe products, not contaminated by microbes, chemicals or pesticides, or transgenic, or, in the case of cultural products (newspaper, films, radio, television, etc.), that recreate and support values of equality, gender and ethnic multiculturalism, and that do not have any content that reproduces inequality or unhealthy values and ideas.

- A special part of social rights is the right to use public health services, of good quality, with full coverage, that do not require payment to access them, or that are part of the right to a universal public insurance (hospitals, clinics, medicines, diagnostics equipment, clinical research systems, etc.).

- Have a strong organization and collective, democratic control over the social organization and community services so they can be used as tools for prevention, guarantee of protection and health promotion, and to ensure public-social management mechanisms, accountability, control, and social oversight.

- To have the ability, knowledge, awareness and ideas to build and recreate a genuine culture, free, authentic, liberating and joyful.

- To live and develop all the activities of social reproduction in healthy environments, where not only the physical elements (light, temperature, humidity, noise, vibration, etc.) are harmless, but where there are also spaces for the continuation of a healthy life.

The horizon of our countries show diverging paths for the right to health, at times there seems to be a stranded path even in progressive governments. It is expected that the social mobilization will maintain a progressive direction in management, and that it will push the process of legal reform to move towards full justiciability of the right to health. If the organized population does not support a process of enhancement of rights, this could cause a serious political setback and return to a camouflaged neoliberalism.

There is still a long way to go in our country regarding the health and law areas of our universities in order to support the social mobilization for the right to health, and to prevent the country from downgrading within this fundamental field of good living.

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Access to medicines as an expression of the right to health

Maria Cecilia Acuña*

Background

The Constitution of WHO states that the enjoyment of the highest attainable standard of health is one of the fundamental rights for every human being without distinction of race, religion, political belief, or economic or social condition[1]. The right to health includes access to prompt, acceptable, affordable, and good quality health care.

The right to health is enshrined in international and regional human rights treaties and in the Constitutions of most countries in the world. This implies that governments must create the conditions that enable all people to live as healthy as possible. These conditions include, among others, the existence of a clean and protected environment where individuals, families and communities live, study, work and play; ensuring safe water and uncontaminated and nutritious food; health services that are appropriate and close to the people; and timely availability of safe, effective and good quality medicines.

Despite the significant progress made in the health situation in the past years, both in the Region of the Americas and other regions of the world, there are still great inequalities that reproduce the social gradient: the worse the socioeconomic situation is, the worse the health status is [2]. Three decades after the studies drew from the research Marmot and Wilkinson began in the '80s regarding the social determinants of health[3], substantial accumulated evidence shows that people who live in poorer socioeconomic conditions have fewer resources to make changes in their lifestyle, they get sick more often, and have less access to quality health services, including medicines[4]. All this determines systematic inequalities between their health and that of other more advantaged social groups, but these inequalities are avoidable.

The avoidable inequalities in health status among various population groups are called health inequities, and it is a matter of social justice to correct it. Access and use of health services are crucial factors to preserve health and to achieve health equality. The health system is in itself a social determinant of health; it influences the effects of other determinants, and is influenced by them[5]. In this context, timely access to safe, effective and quality medicines is a key component of the access to health services.

One might assume that access to the medicines needed by the public depends on

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1. *United Nations. Constitution of the World Health Organization; New York, United States: 1946 [accessed on February 2, 2015]. Available at: http://www.who.int/governance/eb/who_constitution_sp.pdf*

2. *Panamerican Health Organization (PHO). Salud en las Américas. Panorama regional y perfiles de País. Washington, D.C.: OPS; 2012.*

3. *Michael Marmot y Richard Wilkinson. Determinantes Sociales de la Salud. Oxford; Oxford Universtity Press; 1999.*

4. *Comisión sobre Determinantes Sociales de la Salud (CDSS), Organización Mundial de la Salud (OMS).Subsanar las desigualdades en una generación: Alcanzar la equidad sanitaria actuando sobre los determinantes sociales de la salud. Ginebra: OMS; 2009*

5. *Homedes N, Ugalde A (2002). ¿Qué ha fallado en las reformas de salud de América Latina? Trabajo presentado al VII Congreso Internacional del Centro Latinoamericano de Administración para el Desarrollo [CLAD] sobre la Reforma del Estado y de la Administración Pública, realizado en Lisboa, Portugal, del 8 al 11 de octubre de 2002.*

the availability of such products on the market and is not related to access to health services. This was the premise that guided many of the policies implemented in the framework of the reforms of health systems carried out in the countries of the region during the 1980s and 1990s, which were aimed to increase the role of the market and the private sector in healthcare. However, recent studies show that lack of access to medicines significantly depends on the access to health services, and that the health system is a key element to improving access to medicines[6].

The conceptual framework of access to medicines

To grant access to medicines, two conditions are required[7]:

1. The user must have the means (physical, economic, of information) that allows him/her to contact the provider of the drug required (demand).

2. The provider must be able to supply the required medicines(supply). For this to happen, it is necessary that three separate and sequential processes have previously occurred (production, procurement and distribution), which are the ones that make it possible for the medicine to be physically available at the point of service, where it will meet the user through the final process (dispensing)[i]. Although different operators or agents carry out these four processes, they are interdependent and are links of the same chain, the supply chain for drugs (or supply).

Therefore, access to drugs can be visualized as a complex and sequential set of various interdependent processes. In this framework, we could say that access to medicines is composed of the following dimensions[8,9] :

a) Physical availability, defined by the relationship between the type and quantity of products that are needed and the type and quantity supplied thereof.

b) Affordability, defined by the ratio between the price of the products and the user's ability to pay for them. This dimension refers to the sale price of medicines in the private sector.

c) Geographical accessibility, defined by the relationship between the location of the products and the location of the user that requires them.

d) Acceptability, referring to the characteristics of the drug related to the expectations and needs of users, and to the technical and legal standards (regulatory framework) of the country.

The dimension of availability corresponds to the "supply of medicines", which includes the production, distribution and dispensing of the drug, while the "demand for drugs" is represented by the dimensions of affordability, geographical accessibility and acceptability.

Figure 1 illustrates the theoretical model of access to medicines developed by MSH and WHO9, with their respective dimensions and components, and allows visualizing quality as an essential component that passes through the four dimensions.

6. *Acuña C, Marín N, Mendoza A, Emmerick ICM, Luiza VL, Azeredo TB. Determinantes sociales de la exclusión a los servicios de salud y a medicamentos en tres países de América Central. Rev. Panam. Salud Pública. 2014; 35(2):128–35.*

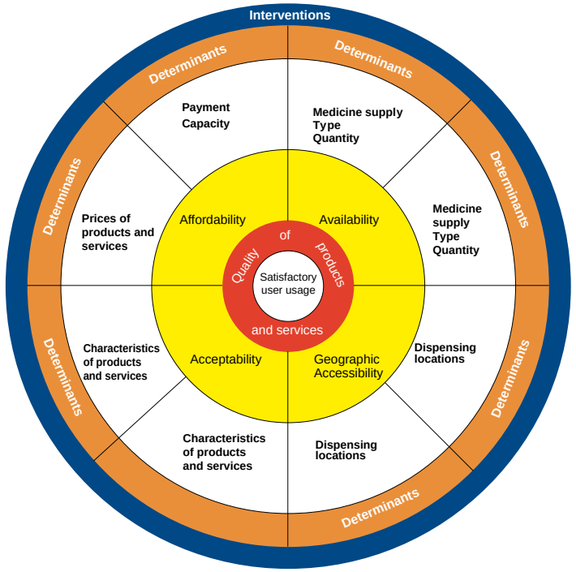
7. *Organización Panamericana de la Salud (OPS). Estudio del impacto de la exclusión de los servicios de salud sobre el acceso a medicamentos en Guatemala. Informe Final. Washington, D.C.: OPS; 2010.*

8. *Luiza VL, Bermudez JZ. Acesso a medicamentos: conceitos e polêmicas. In: Bermudez JZ, Oliveira MA, Esher A (eds.). Acesso a medicamentos: derecho fundamental, papel do Estado. Rio de Janeiro: ENSP/OPS/ OMS 2004:45–67.*

9. *WHO/MSH: World Health Organization/Management Sciences for Health. Defining and measuring access to essential drugs, vaccines, and health commodities. Report of the WHO-MSH Consultative Meeting, Ferney-Voltaire, France: WHO/MSH; 2001.*

i. *The production process is the development and manufacture of a medicine; procurement is the process of purchase; distribution is the process of transferring the drug from the producer to the supplier; and dispensing is the process by which the drug is physically made available to the user along with information for proper use.*

Figure 1. Dimensions of access to medicines



Source: Adapted f rom MSH/WHO, 2001

For each of these dimensions there are a series of conditioning factors and a complex network of actors that interact in various ways. Some of these factors (as the price of drugs on the affordability dimension or location of the dispensing points in the geographic accessibility dimension) are more visible and can be modulated directly by public policy; however, others, such as the characteristics, expectations and behaviors of users, are less visible and more difficult to address.

The determinants of access to medicines

The 45th Directing Council of PAHO/WHO urged Member Nations to allocate priority to the problem of lack of access to medicines by addressing the determinant factors, with emphasis on poor and marginalized populations (PAHO/WHO, 2004). In this context, it is crucial to expand the existing knowledge about the behavior of individuals in relation to the sourcing and procurement of the medicines they need.

Acuña et al 6 examined the social determinants that affect drug search and procurement behaviour in three countries in Central America, Guatemala, Honduras and Nicaragua, and found that the major determinant of the lack of access to medicines is the lack of access to health services, which indicates that an important part of the search for drugs was mediated by the prescription.

Other identified determinants of access to medicines were the lack of health insurance coverage, informal employment, household economic condition, and housing characteristics.

This highlights the importance of addressing access to drugs from an inter-agency viewpoint and with inter-sectoral logic.

Moreover, each one of the mentioned drug access dimensions face barriers determined by the characteristics of the health system and their interaction with user characteristics. The main barriers to medicines access are[10]:

a) The economic barrier, determined by the price of drugs, their coverage by an insurance scheme and the capacity of the individual or the family to pay, which directly affects the affordability of medicines.
b) The geographical barrier, determined by the distribution of the points of health services and provision of medicines, and their relationship with user location, which defines accessibility to the drug.
c) Barriers identified by the organization of the provision of health services and the cultural and personal characteristics of users, which also define the acceptability of the drug by the user.
d) Barriers identified by the drug delivery system, which affects the physical availability of these in relation to the demand.

As shown in Figure 2, the ability of the system to provide medicines and of the users to obtain them depends on whether the demand for drugs will be partially or completely served (satisfied), or if it will become an unsatisfied demand.

Drugs procurement at the point of service and its relationship with the prescription

Unlike health care services, which are consumed at the time when the service is provided, the use of drugs involves two interrelated steps:

a) A dispensing service which should provide enough information to ensure the rational use of medicines; and,
b) The physical delivery of such drugs.

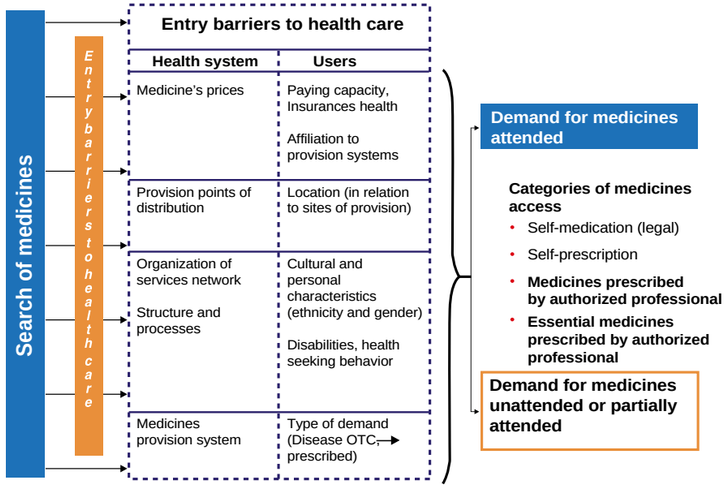
In general, users should obtain drugs by submitting a prescription (“recipe”) made by a licensed professional (prescriber).

In some cases, however, medications can be obtained without the intervention of such professional. The laws in most countries define a list of over-the-counter medicines, in other words, those that can be sold without a prescription (in English Over the Counter or OTC). Only for drugs included in this list there is legal backing for users to acquire them without the mediation of a prescriber.

The act of demanding drugs classified as sold without prescription (OTC), and obtaining them directly from a supplier, is known as self-medication.

10. Organización Mundial de la Salud (2002b). Promoción del uso racional de medicamentos: componentes centrales. Perspectivas políticas de la OMS sobre medicamentos. No. 5; OMS; septiembre de 2002.

Figure 2. Model of access to medicines and its relationship with access barriers



Source: *Pan American Health Organization (PAHO). Study of the impact of exclusion of health services on access to medicines in Guatemala. Final Report. Washington, D.C.: PAHO; 2010.*

However, in many countries, users can obtain drugs classified as a prescription medication without presenting this document. This behavior is called self-prescription, and is one of the most serious manifestations of irrational use of medicines, as it poses serious risks to the health of the population.

The importance of the rational use of medicines and the concepts it involves

Chart 1. Categories of access to medicines

Category	Definition
Self-medication	The act of demanding drugs classified as over the counter, and obtaining them directly from a vendor, that is, without a prescription or mediation of a licensed health professional.
Self-prescription	The act of demanding prescription drugs and obtaining them directly from a vendor, that is, without a prescription and without the mediation of an authorized health professional.
Medicines prescribed by an authorized professional	The act of demanding and obtaining medicines through the prescription of a licensed health professional.
Essential medicines prescribed by an authorized professional	The act of demanding and obtaining essential medicines through the prescription of a licensed health professional.

Source: *Pan American Health Organization (PAHO). Study of the impact of exclusion of health services on access to medicines in Guatemala. Final Report. Washington, D.C.: PAHO; 2010.*

The drug is a product that presents some peculiarities in relation to other health commodities, since it can be used by autonomous decision of the individual, on the recommendation of who provides it, or if indicated by the health care provider.

As a result, the provision of drugs constitutes a provision that, in addition to providing products, must guarantee a set of procedures in order to promote their rational use.

At the Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985, it was established that they are rationally used when "patients receive proper medication to their clinical needs, in the necessary doses according to their individual requirements, over an appropriate period of time, and at the lowest possible cost to them and to the community."

The selection of essential drugs[ii] and the strategies to promote the use of generic drugs are part of the efforts to improve access to drugs and control its price.

The concept of essential drugs is one of the basic principles of a national drug policy because it helps to define priorities for all the components of the pharmaceutical sector in any country, regardless of their level of development; it is also considered one of the twelve key components for promoting the rational use of medicines[10].

Since the non-rational drug use may lie in the prescription, supply and/or sale of drugs, it is not only important to measure the degree of access to them, but also to establish whether this access is qualified, that is, if priority is given to essential medicines, usually contained in a list that incorporates principles of rationality and quality, and financial sustainability of the health system.

The challenge of financing access to needed medicines

Drug expenditure constitutes a major proportion of total health spending. In the region of the Americas, this expenditure was estimated to be about 35% of the households' health expenditure in 2004, proportionally higher among the poor and corresponding mainly to out-of-pocket expenses.

In the Region, out-of-pocket spending is the most common way to finance the purchase of drugs, which determines an important barrier that blocks access to these goods. To finance the purchase of medicines, many families incur in catastrophic expenditures,[iii] which means reducing the consumption of other commodities such as food, clothing and children's education.

In this context, the State must ensure that all people, particularly the most vulnerable groups, have access to essential medicines in a timely manner whenever needed.

This has huge implications in the field of financial sustainability. To fulfil this responsibility, the Governments have developed various strategies. The most relevant ones are shown in the following table:

10 - 11. *De la Puente C., Tobar F. Políticas y estrategias de adquisición de medicamentos esenciales: un análisis sistematizado de modelos y experiencias claves en América Latina. EUROSOCIAL – ISALUD; 2007.*

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ii. *Essential medicines are those that satisfy the priority health needs of the population. They are selected based on their relevance to public health, evidence of their efficacy and safety, and comparative efficiency in relation to the cost. Must be available in health systems at all times, in adequate amounts, in appropriate dosage forms and appropriate concentrations, with a guarantee of quality and adequate information, and at a price the individual and the community can afford (WHO, 2002a).*

iii. *Catastrophic health expenditures are expenditures to which households are forced in order to meet their health needs, and which adversely affect the satisfaction of other basic needs such as housing, food or education. According to WHO (2000), a household incurs in a catastrophic expenditure when it allocates more than 30% of its payment capacity to finance health care for any of its members.*

Table 2. Strategies for sustainable financing of drugs in Latin America

Strategy	Countries that implement it
Public production of medicines	Argentina, Brazil, Costa Rica, Paraguay, Uruguay
Public procurement of medicines	Argentina, Brazil, Chile, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Panama, Paraguay, Uruguay
Medicines' distribution through official pharmacies	Argentina, Brazil
Reduction of access barriers: • International public bids • Reduction of the medicine taxes • Exoneration of customs fees	Argentina, Brazil, Costa Rica, Chile, Ecuador, Honduras, Panama, Uruguay
Demand aggregation: • Aggregated procurement in the entire public sector • Aggregated procurement through regional funds (Strategic Fund, Rotatory Fund)	Every country in the Region
Selective financing through essential medicines listings	Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, Panama, Paraguay, Uruguay
Creation of markets of interchangeable generic medicines	Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Peru
Medicines price fixing	Brazil, Colombia (only for monopolistic products) Ecuador, Paraguay

Source: Compiled data from PAHO/WHO and based on the analysis of De la Puente C., theoretical and practical framework for the regulation of drug prices. Presentation conducted at the social protection in health, access to medicine policies and equity workshop organized by PAHO/WHO in Mexico in April 2008.

Access to medicines as part of the agenda of Universal Health Coverage

In August 2014, all Member Nations of PAHO/WHO that met at the 53rd Directing Council adopted the Resolution CD53/5 "Strategy for Universal Access to Health and Universal Health Coverage".

The strategy articulates the conditions that will enable countries to guide and evaluate their policies and measure progress towards universal access to health and universal health coverage. Four simultaneous and interdependent strategic priorities were set out in the strategy:

a) Expand equitable access to comprehensive quality health services, focusing on individuals and communities;

b) Strengthening stewardship and governance;

c) Increase and improve financing, with equality and efficiency, and move towards the elimination of direct payments, which becomes a barrier to access at the time of service delivery; and,

d) Strengthening sectoral coordination to address the social determinants of health to ensure sustainability of universal coverage.

The first axis includes a component that is oriented to define the processes that improve the availability and rational use of medicines (including vaccines), as well as other health technologies, systematically and progressively, in addition to the development of the regulatory and assessment capacity to ensure drugs are safe, effective and of high quality.

AXIS 1: Enhance equitable access to comprehensive quality health services, centred on people and the community.

- Define a universal set of guaranteed, enforceable, and progressively scaled benefits.
- Transform the organization and management of health services.
- Immediately increase investment in primary care.
- Expand the labor market in the first level of care.
- Ensure the availability and rational use of essential drugs and other health technologies.
- Implement empowerment programs, including advocacy, prevention and education activities.

The adoption of the resolution "Strategy for universal access to health and Universal Health Coverage" establishes a unique framework to go forward with the access to universal and equitable medicines required by the population of the region of the Americas as part of the right to health.

Ensuring that this happens depends on the joint and coordinated efforts of all those who work in favor of peoples of the Americas' health.

Quality, safety and efficacy of medicines

Juan Carlos Maldonado R.*

What are the best drugs for a population? The reasoning and arguments could lead to different responses according to the stakeholders. For drug manufacturing laboratories, responsible for the processes of research and development, those would surely be the newest drugs intended for diseases or chronic conditions that affect large populations. However, for several years it has been clear that the development of new drugs is mainly due to market interests rather than health needs,[1] which is evident in the absence of drugs that are particularly useful against diseases that specifically affect developing countries, such as several tropical diseases.[2] Additionally, there tends to be a clear interest of the industry to encourage the market penetration of a new drug and achieve high sales, in such a way, to recover the cost that represented its research and clinical development (which has been estimated to reach US $ 224 million) before the expiry of its patent, as sales may drop up to 50% when generics of that drug come in the market.[3] When the economic benefit for a manufacturing laboratory is little or none, its interest decreases and it can stop its production, leading to shortages thereof in the pharmaceutical market of a country or region.[4]

For users or ordinary people, perhaps the best drugs are also the newest ones, even though the cost is higher. Drugs are social assets and people give them not only an economic value, but also a value related to wellness. However, commercial pressure on consumers usually causes them to idealize the benefits and minimize the risks of a drug, in addition to creating the false idea that lower cost products are often not of good quality.[5] For prescribers, possibly the best drugs would be those that achieve a good therapeutic outcome. Professionals are often not interested in the cost of the product or simply ignore it,[6] and the quality of the drug is often not understood as something related to manufacturing, but they incorrectly use as a quality indicator the name (branded or generic) it is commercialized with.[7]

Moreover, from the perspective of public health, the best medicines are those that satisfy the main health needs of a population, which is why they are called essential within the provision of health services. The essential drugs concept was introduced in 1975 by the World Health Assembly; later, in 1977, the World Health Organization made the first Model List of Essential Medicines and in 1978 the Declaration of Alma-Ata determined the "provision of essential drugs" as one of the eight basic elements of primary health care. In conformity with the Committee of Experts of the World Health Organization for the Selection and Use of Essential Drugs, these drugs are selected according to the prevalence of diseases and the evidence of their favorable profile of effectiveness, safety and cost-effectiveness compared to other pharmacological alternatives.[8]

Despite the enormous amount of existing drugs in the world market, not all of them have, simultaneously, the mentioned qualities to be considered essential. Efficiency is the degree of benefit that a therapeutic intervention offers (in this case the drug) applied under ideal use conditions, which occurs exclusively in the framework of the investigation, specifically in controlled clinical trials, correctly designed and well executed.[9] In order to make a decision regarding the clinical efficacy, the information

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1. *Maldonado JC. Medicamentos: ¿bienes para la salud o para el consumo? En: Instituto Catalán de Cooperación Iberoamericana, ed. Tendencias actuales en investigación social. Barcelona: I.C.C.I.; 2001: 122 – 32.*

2. *Maldonado JC. La falta de vacuna contra el virus del Ébola: otro caso de las enfermedades abandonadas por la lógica de mercado. Rev Med Vozandes 2014; 25: 5 – 6.*

3. *Grabowski H. The effect of pharmacoeconomics on company research and development decisions. Pharmacoeconomics 1997; 5: 389 – 97.*

4. *Gatesman ML, Smith TJ. The shortage of essential chemotherapy drugs in the United States. N Engl J Med 2011; 365: 1653 – 55.*

5. *Haaijer-Ruskamp FM, Hemminki E. The social aspects of drug use. En: Dukes MNG, ed. Drug utilization studies. Methods and uses. Copenhague: World Health Organization, Regional Office for Europe; 1993: 97-124.*

6. *Walkaz D, Swindells S, Bhardwai A. Primary care physicians and the cost of drugs: a study of prescribing practices based on recognition and information sources. J Clin Pharmacol 1995; 34: 1159 – 63.*

7. *Serrano VG. Eficacia, efectividad y falla terapéutica de los medicamentos. Rev Fac Cien Med (Quito) 2006; 31: 5 – 9.*

8. *Quick JD, Hogerzeil HV, Velásquez G, Rägo L. Twenty-five years of essential medicines. Bulletin of the World Health Organization 2002; 80: 913 – 14.*

9. *Marley J. Efficacy, effectiveness, efficiency. Aust Prescr 2000; 23: 114 – 15.*

is useful when it compares a drug against another (and not only against placebo) in the same therapeutic indication, and even more if it was developed evaluating relevant outcomes during a follow-up time suitable for the pathology. If a correct therapeutic process and a good use of the drug at the time of prescription take place during the clinical practice, there will be a greater chance that the effectiveness (defined as the degree of benefit of an intervention under normal conditions of use) is close to the clinic efficiency.[7,9]

The safety of a drug refers to a favorable risk-benefit balance. In this regard, an adverse drug reaction is defined as the presence of any deleterious or undesirable effect that appears after the administration of a drug at doses normally used in a human being for the prophylaxis, diagnosis or treatment of a disease. Its synonyms are the terms "undesired effect" and "adverse effect".[10] According to international studies, adverse drug reactions are the cause of approximately 10% of hospital admissions and have an incidence of between 10% and 20% in patients pharmacologically managed.[11] That is the reason why they are considered a public health problem, due to their sanitary and economic impact.

All drugs carry the risk of adverse reactions, which may debut as new health problems, worsen the course of the disease or increase morbidity and mortality. As there are differences in the safety profile for alternatives of the same pharmacologic class with similar efficiency (for example, different gastro toxicity of different nonsteroidal anti-inflammatory drugs), it is important to prefer the drug with lower associated risk of adverse reactions. New drugs are those for which less information is available regarding their long term safety profile due to the specific characteristics of the stages of research and development: the limited predictability of animal models, the total number of patients that are investigated is often insufficient to detect serious low frequency adverse reactions, the investigated populations tend to be highly selected and are closely monitored, unlike the high level of heterogeneity of the population that will afterwards consume the commercialized drug, there is no way to investigate all the clinical scenarios in which the drug could eventually be used during the usual clinical practice, and some adverse effects occur only after the prolonged use of the drug or have long latency effects.[7] This tends to determine that, only after the commercialization of the drug, previously unknown adverse reactions start being identified, for this reason, pharmacy-awareness activities are useful tools in the public health of a country.

The third quality refers to efficiency, understood as the effects or results achieved by an intervention in relation to the effort expended in its implementation, in terms of human, financial, material and time resources. In the case of medicines, this means taking into account the results obtained with their administration and the cost associated with their use. Those drugs with a favorable cost-effectiveness in pharmaco-economic aspects are preferred.[12] Keep in mind that "essential drugs" does not necessarily mean something "cheap", but efficient to public health. Logically, many drugs with proven efficacy and safety in the long term, classified as essential, have already seen their patents expire and, with the presence of a generic market, tend to become appropriate to optimize health expenditures.

The pharmaceutical quality of a drug is also crucial and has to do with its manufacturing process. It is the responsibility of health authorities to monitor that good manufacturing practices are fully respected and that there are no problems in quality control. Otherwise, because of a bad pharmaceutical drug condition, low concentration of the active ingredient, changes in the physicochemical properties of the molecule, deterioration

10. *Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. Lancet 2000; 356: 1255–59.*

11. *Pirmohamed M, Breckenridge AM, Kitteringham NR, Park BK. Adverse drug reactions. BMJ 1998; 316: 1295–98.*

12. *Sacristán JA. Farmacoeconomía: el cálculo de la eficiencia. Med Clin (Barc) 1994; 103: 143 – 49.*

during transportation, distribution or storage, the bio-availability and pharmacological effects may be adversely affected. The requirement of bio-equivalence studies is unfortunately widely used as a pretext to discredit generics, but this would not always be indispensable, especially when the drugs present a wide therapeutic index (the difference between the lowest effective dose and the maximum tolerated dose) and their clinical effects can be assessed objectively and quickly, without compromising the patient's health status.[7- 13]

Within a health system, it is important that the medicines considered as essential are always available in the market, that they exist in adequate quantities for their distribution, have a good manufacturing quality, and are commercialized in the pharmaceutical forms and concentrations that are appropriate for their dosage and dispensing, in addition to having a price that allows secure access, both by an individual as well as by the community.[8]

In Ecuador, during the 1970s, the Government's interest regarding the population's access to essential medicines at reasonable prices and good quality became notorious. The joint work between the Health Ministry, the Pan American Health Organization and the Hipólito Unanue Treaty led to the creation, in 1975, of the so-called Basic Chart of Drugs and Medicines, an initial list that served as a working tool to arrange, with the national pharmaceutical industry, the provision of products, but, for various reasons, the initiative and availability of drugs declined substantially in 1979. Later, when the country was considering the implementation of a National Health System, the Basic Drugs National Chart was finally issued by Executive Decree No. 1337 of 1985, which simultaneously eliminated some earlier provisions related to it.[14] Since 2014, the Ninth Revision of the Basic Drugs National Chart is in force for its application primarily in operational units under the Public Health Ministry.[15] The list is drawn up under the basic principles of efficacy, safety and cost-effectiveness, which guide the selection of essential medicines and drugs that are considered appropriate for the major health needs of the country, both for frequent health problems and for specific diseases.[16]

Despite the above, in Ecuador, socio-economic inequalities still affect the population's access to health services and medicines.[17] In addition, a number of problems persist in the country concerning the pharmaceutical market, the government procurement of drugs and price regulation. 18 The available data on drug use in Ecuador allows us to understand that during the period between 1988 and 1997, the total units sold increased by 45.9% (from 66 to 97,000,000 per year), while the evolution of sales (in monetary terms) had an impressive growth of 145%, reaching US $ 332 million per year.[1] The increase in sales, rather than in units sold, means that people continued to consume virtually the same quantity, but each time paying more; and it is an indicator of the increase in prices and the introduction of new drugs at higher costs. The picture has not changed substantially in recent years, between 2007 and 2012 the Ecuadorian pharmaceutical market showed an increase of 56.6% in sales, from US $ 680 million to a total of US $ 1,142 billion per year, especially due to brand-name drugs trade.[17] The increased public spending would also represent an important part of this phenomenon as the purchases made by the Public Health Ministry for its operating units amounted almost US $ 300 million.[18]

In order to improve the access of the Latin American population to essential drugs, it has been recommended to strengthen the generics market and create a system of competitive prices for their procurement.[19] However, in 2011, the Corporate Reverse Drugs Bidding took place in the country as a strategy for transparent public procurement,

13. *Williams RL, Chen M-L, Hauck WW. Equivalence approaches. Clin Pharmacol Ther 2002; 72: 229-37.*

14. *Maldonado JC. Informe técnico - Situación del Cuadro Nacional de Medicamentos. Instituto de Ciencia y Tecnología, Proyecto FASBASE, PNUD. Quito: Instituto de Ciencia y Tecnología; Diciembre de 1999.*

15. *Comisión Nacional de Medicamentos e Insumos. Consejo Nacional de Salud. Cuadro Nacional de Medicamentos Básicos y Registro Terapéutico. IX Revisión 2014. Quito: Ministerio de Salud Pública; 2014.*

16. *Maldonado JC. Enfermedad de Parkinson y medicamentos básicos del Ecuador. Rev Fac Cien Med (Quito) 2013; 38: 3 – 5.*

17. *López-Cevallos DF, Chi C. Health care utilization in Ecuador: a multilevel analysis of socio-economic determinants and inequality issues. Health Policy Plan 2010; 25: 209 – 18.*

18. *Ortíz-Prado E, Galarza C, Cornejo León F, Ponce J. Acceso a medicamentos y situación del mercado farmacéutico en Ecuador. Rev Panam Salud Pública 2014; 36: 57 – 62.*

19. *Tobar F. Economía de los medicamentos genéricos en América Latina. Rev Panam Salud Pública 2008; 23: 59 – 67.*

about 30% of the Government requirements had no tenders, which then forced a direct acquisition of the products.[18] This is an example of how the economic interests of the pharmaceutical industry are the main determinants of the supply of drugs, and how they can affect the health needs in the absence of a comprehensive, clear and solid medication policy.

The generics market is not strong in the country either. By 2014, in the National Health Regulation, Control and Surveillance Agency, of 13,451 registered drugs, only 30.4% were generic, and, in recent years, its use has been significantly lower in relation to brand name drugs, although the price increase was 0.86% and 12.5%, respectively. This resulted in a clear difference regarding the increase in sales; in 2011, the increase was only 6.5% for generic drugs compared to a 93.4% for branded drugs.[18]

The above suggests that several multidisciplinary efforts to improve the pharmaceutical market and optimize health expenditure on drugs are still required. Among them, there should be those designed to ensure the availability of drugs deemed basic (essential) for the country, as their use is certainly an effective public health strategy, as well as achieving their acquisition at acceptable prices. Other elements that should be part of the agenda include the adoption of regulatory measures for the market, control of pharmaceutical promotion, frequent monitoring of the distribution systems and products dispensation, assessment of patterns of drug use, improvement of pharmaco-vigilance activities, promotion of the proper use of medications, training regarding rational prescription of drugs, and public education, all in the context of a well-organized drug policy, in order to be able to cover the various links that exist regarding the social behavior of medicines. [20]

20. *Maldonado JC. Los estudios de utilización de medicamentos. Rev Fac Cien Med (Quito) 2003; 28: 64 – 65*

CHAPTER II:

Intellectual Property and
Generic Drugs

Patents, public health and competition

Carlos M. Correa*

1. Introduction

There is a wide agreement regarding the role that patents and intellectual property rights (IPRs) can play in the development of research and development (R+D) applied to the health field in more developed countries. Patents are considered particularly important in those countries, since R+D implies high costs and risks, and at the same time can lead to inventions of potential usefulness for all countries.

IPRs can generate, however, significant costs, especially in developing countries. In the health sector, where the timely access to treatment or to pharmaceutical products can have life or death consequences, the conditions that determine the access to drugs and, among them, their price, are critical issues, especially for those population segments with low income. Even by recognizing that IPRs are not the only pertinent factor, it seems clear that the way in which they are established and applied can have a significant impact on the access to drugs. Therefore, every IPRs regime must establish a balance between the creation of innovation incentives and the consumers´ interest regarding the availability and accessibility of the protected goods.

Currently, it is of common knowledge that the patents protection regime, globalized by the Agreement on TRIPS, can have serious repercussions on the health sector. The Agreement specifies detailed obligations related to the protection of inventions, among them:

- To recognize patents for inventions in all the technology fields, with limited exceptions.
- No discrimination in relation to the availability or enjoyment of the patent rights;
- To grant patent rights for a period not less than twenty years from the date of the request;
- To limit the scope of the exceptions to the patent rights and grant compulsory licenses only under determined circumstances; and,
- To enforce the patent rights in an effective way.

The increasing concern about the way in which this or the other international trade agreements can limit the access to drugs led, as it has already been said, in the adoption of the Ministerial Declaration of Doha about the Agreement on TRIPS and Public Health.

The pharmaceutical sector is a user of fundamental importance inside the patent system. While every year only a small number – and decreasing – of new chemical entities obtain their approval, thousands of applications are submitted to protect variations of existing products, manufacturing procedures or, if allowed, second indications of known pharmaceutical products.

Given the background effects that patents can have upon competition and, consequently, on drugs prices, criteria that are applied to examine and grant pharmaceutical patents are of extreme importance for the public health policies and are not only a topic of interest for the industrial policy. The responsible for designing policies in the public health area, and also the offices in charge of examining patents' applications, shall take into account that the decisions related to the granting of a patent (that is generally presumed valid unless proved otherwise) can affect, in a direct way, the health and lives of the inhabitants of the country in which the patent is granted.

As already seen in Module I, to obtain a patent an inventor must prove that his invention is new, that it shows "inventive activity" (i.e. it is not obvious) and is susceptible to industrial application.

The Agreement on TRIPS, by regulating the patent system, established in Article 27.1 that "patents may be obtained for every invention… provided that they are new, present an inventive activity and are susceptible to industrial application", but it did not define the term invention, nor did it prescribe how patentability criteria must be defined, leaving within the sphere of freedom of opinion of the Nations the determination of the degree of rigor with which they would apply these criteria in compliance with their national policies.

The traditional meaning of "invention" is linked to the result of an intellectual activity that consists of a new knowledge of technical nature. To invent is to "create by thinking, originate (a new method, instruments, etc.)".[1] It also suggests a distinction between creations and mere discoveries and, in a more general way, between inventions and other matter that is not the result of an inventive process.

The concept of invention that is applied in different countries differs significantly. Nevertheless, the Agreement on TRIPS seems not to interfere in such diversity. The text of Article 27.1 indicates that the members have freedom to interpret, in good faith, the concept of invention in their juridical systems, observing the application of the interpretation regulation established by the Vienna Convention on the Law of Treaties. The members can demand the existence of an invention as a previous condition for patentability.

Beyond the established definition of invention, the fundamental issue is that the patent must give an unobvious technical contribution to the state of the technique, by means of which a technical problem can be solved with technical methods.

Subject to the same interpretation regulation mentioned before, the Agreement on TRIPS also allows the countries who are members of the WTO to adopt their own definitions of patentability standards.

The general terms used in Article 27.1 have allowed the member countries to maintain different criteria to evaluate patentability. The definition of such criteria represents a key aspect in patents policy, and brings consequences to other areas,

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1. "Concise Oxford Dictionary" Dictionary definition, 1989, Page 527.

such as industrial policy and public health. A great number of granted patents based on low patentability standards can produce unnecessary limitations in competition, without any benefits in terms of greater innovation to treat the needs of society.

2. Relevant aspects of pharmaceutical patents[2]

Pharmaceutical products and procedures represent a significant part of patents that are requested and granted around the world, especially in developing countries.

The adoption of the Agreement on TRIPS represented a clear victory for big pharmaceutical companies, as it imposed the obligation to provide patent protection in every technology field, including pharmaceutical products in all the countries which are members of the WTO. However, the Agreement did not set specific regulations that rule the totality of the aspects related to patents concession, as, for example, the form and scope of the claims, which remain in the decision sphere of each country.

A patent claim delimits the technical advance that is contained in it. The claim formulation constitutes the legal base to determine the subject matter of the protection. Consequently, it is necessary to take into account the features of the different claims that are typical within the area of pharmaceutical inventions, in order to evaluate and adopt the necessary measures provided in each national legislation to protect public health in those cases where patents applications cover a matter that does not deserve the reward that they grant.

While the development of new molecules of pharmaceutical application can comprise different levels of inventive steps, the pharmaceutical techniques used for drugs preparation in different presentations and dosages are generally known and are part of the body of knowledge that a "skilled in the art person" possesses. Therefore, there is a limited spectrum of developments that could be considered genuinely inventive in this field.

Formulations and compositions

The same active principle can be presented in different forms, for example, as a tablet, a capsule or a water solution for its parenteral administration, which, in turn, can be formulated by using different pharmaceutically acceptable excipients.

A large number of patents claim presentations of new or already-existing drugs and they frequently include dose or concentration specifications, either as a main claim or as subordinated to claims of the active principles or their uses. The "compositions claims" cover active principles and excipients or pharmaceutically acceptable vehicles, such as fillings, binders, disintegrators and lubricants.

As a general rule, the formulation techniques and the compounds spectrum that can be used to develop pharmaceutical products viable in different forms are well-known elements for a skilled person in the technique. Therefore, it is possible that inventions that are claimed in this field lack the inventive step.

New formulations and compositions, as well as the processes for their preparation, should be considered obvious taking into consideration the previous technique, particularly, when a unique active principle is claimed together with known or

2. This section is partially based in Carlos Correa´s, (2006) Guidelines for the Pharmaceutical Patents Test, a Perspective from Public Health. WHO/CTSD/UNCTAD, available at http://www.iprsonline.org/resources/docs/Correa_Guidelines%20spanish%20FINAL.pdf

not specified vehicles or excipients. As an exception, this type of claims could be patentable if a really unexpected or surprisingly effect is obtained; for example, when they can solve, in a unobvious way, a problem which is truly difficult or a long-standing need, such as a significant decrease of collateral effects, or when the solution that has been found originates a huge advantage in comparison to the technique's state.

Combinations

Sometimes claims are directed to a combination of two or more previously known active principles. Generally, the patents applications that contain these combinations are presented when the patents of the compounds they comprise have expired or are about to expire, which indirectly extends the period granted in the original patent.

In some cases, the combinations claims can be equivalent, in practical terms, for claims on medical treatments (whose patentability is excluded in most of the countries) when they only provide one method to administrate a combination of existent drugs.

The combinations of known active principles shall be considered non inventive. However, most of the patent offices grant this type of patent with the provision that there shall not be a mere juxtaposition of effects, but there should instead mediate a surprising element in the combination behavior. Consequently, if a new synergic unobvious effect[3] is considered as the basis for patentability, this shall be appropriately demonstrated through biological tests and released in a proper way in the patent's specifications.

Dosage/dose

Some patent applications claim inventions that consist in the dosage form of an existent product. Even though they are formulated as product claims, they have the same effect as the claims about medical treatment methods, this is because the matter is not a product or a process, but the form in which a product is therapeutically used.

Some countries admit patents on dosages under certain circumstances, for example, when there is a new medical use and the dosage is substantially different from the known use. However, the used concept is valid only when the granting of patents on second uses is allowed.

Dosage changes are rarely of inventive nature and it can be considered that they do not comply with the industrial applicability standard since the invention would only have effects on the organism, but no technical effects.

The claims of new doses for the same indication or for a different one are not inventions, particularly (though not exclusively) in those countries where medical treatment is not patentable.

Salts, ethers and esters

Frequently, pharmaceutical patents protect new salts of known active principles. Typically, salts are formed to enhance the drug stability or solubility. It is commonly

3. Synergy: is the result of the joint action of two or more causes characterized for having a superior effect. In the pharmaceutical field it refers to the action of two or more compounds that when administered together produce an effect greater than expected considering the sum of the actions of the compounds separately.

known, in the pharmaceutical field, that salts produce a different solubility and, consequently, a different bioavailability. If the active ingredient is an acid or a base, any chemistry student will know how to elaborate a salt and will be able to foretell its possible physical-chemical properties. The salts patents are one of the main ways of "evergreening"[4] pharmaceutical patents.

There may be exceptional cases in which the properties of the new salts present unexpected advantages in comparison to the previous technique. Such advantages must be well-founded with information about the outcomes of suitable trials incorporated in the patents' specifications.

The salts formation procedures are also obvious for people who are skilled in the field. Likewise, ethers and esters of known alcohols, while they basically differ from salts, generally suffer the same obviousness objection.

New salts, ethers and other forms of existing pharmaceutical products can generally be obtained with common knowledge and are not patentable. This may not be the case if the existence of unexpected differences is proved (for example, an important increase in the therapeutic efficiency and not only concerning bioavailability) regarding the previous technique by means of trials appropriately developed and described in the specifications.

Polymorphs

Some therapeutically active principles present polymorphic forms, namely, they can exist in different physical forms and can have different properties with therapeutic outcomes of greater or lesser importance. Polymorphism is a natural property: polymorphs are not "created" or "invented", they are normally discovered as part of the routine experimentation in drugs formulation. They are the result of the conditions under which a compound is obtained. Any compound that presents polymorphism tends naturally to its more stable form, even without any kind of human intervention.

Independent patent applications on polymorphs have become more and more frequent and controverted, since their patents can be used to obstruct or delay the entrance of generic competition. It can be considered that polymorphs are within the previous technique, -and are therefore not patentable- if they are inevitably obtained following the original patent process on the active principle. Besides, when polymorphs are discovered, the possibility of discovering different crystals is obvious.

Therefore, taking into account that the polymorphism is an inherent property of the matter in its solid state, polymorphs are not created, but they are discovered. The patents offices must be aware of the possible unjustified extension of the protection period that emerges from successive patenting of the active principle and its polymorphs, including of the hydrates/solvates, which are "pseudo-polymorphs".

"Markush" claims

The denominated "Markush claims" refer to a chemical structure with multiple chemical entities, functionally equivalent, admitted in one or more parts of the compound. These claims can include a vast number (even millions) of possible

4. Evergreening" is a patenting strategy which consists of acquiring patents of minor modifications, sometimes trivial, of existing pharmaceutical products or processes in order to extend, in an indirect way, the patent protection period over previously patented compounds.

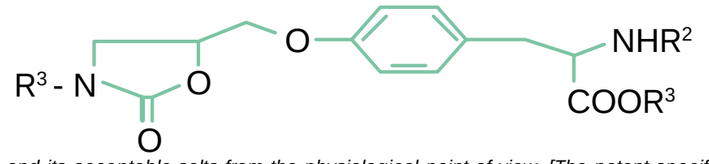
compounds. They can be used to obtain a wide patent coverage that includes a large number of compounds whose properties have not been proved, but have been supposed in a theoretical way based on the equivalence with other compounds included in the claim. Consequently, their acceptance generates rights over an extremely wide set of compounds, without a trial or any prior experimentation.

In addition to the usual issues related to the patentability requirements, the analysis of these claims originates approaches regarding disclosure and enforceability since, generally, the patent's applicant has only obtained, in an effective way, few of the possible elements of the group.

Examples of "Markush" claims

AR 005224 B1- Oxazolidinone derivatives, procedure for its preparation and use, as well as pharmaceutical preparation that contains them and procedure to obtain pharmaceutical preparations.

1. Oxazolidinone derivatives, characterized by the formula



and its acceptable salts from the physiological point of view. [The patent specifies the substituents for the radicals R1, R2 and R3].

AR016428B1-Compounds of 1, 3, 8 – triaza – spirol [4,5] decan - 4 - ona, a process for its preparation, drugs which comprise such compounds and the use of these compounds for the manufacturing of a drug.

Derivatives of 1,3,8-triaza-spirol[4,5]decan-4-ona, which comprise compounds of the general formula (i) in which: r1 is hydrogen, lower alkyl, halogen, lower alkoxy, trifluoromethyl, lower-alkyl-phenyl, or cycloalkyl c5-7; r2 is hydrogen, lower alkyl, phenyl or lower-alkyl-phenyl; r3 is hydrogen, lower alkyl, benzyl…

The claims that cover a large number of compounds should not be allowed. At most, limited coverage claims could be granted if it is proven, as minimum, that the same disclosed outcome can be obtained if any element in the same family is substituted. The patent coverage would be limited to that which can effectively be executed by means of the disclosure of the specification.

Selection patents

A "selection patent" is the one under which only one element or a small segment inside a known larger group is "selected" and claimed in an independent way, based on a particular feature that has not been mentioned in the larger group.

If a large number of elements are patented, the holder of the patent can use the selection patent to extend the protection term for the selected sub-group beyond the expiration of the original patent.[5] Even though the selection patents are accepted in some jurisdictions when the selected elements have an unexpected advantage, such patents have been rejected when the supposed advantage was a property shared by all or almost all the elements of the extensive group.

As a general rule, selection patents should not be granted if the selected components have already been revealed and therefore, lack novelty. If they were considered unexpected patentable advantages of existing products under the current law, the patentability of a selection could be considered when an invention step is present.

Analog procedures

The manufacturing procedures that are not by themselves novel or inventive, but that are used for the preparation of new or inventive compounds that are not patented (frequently called "analog procedures") are considered patentable in some jurisdictions under a legal fiction. The doctrine of analog procedures enlarges the appropriation possibility of the knowledge that is in the public domain.[6]

Non-novel or obvious pharmaceutical procedures shall be considered not patentable as such, even if the starting or intermediate materials, or the final product, are novel or inventive.

Enantiomers

The molecules that possess an asymmetry center or chiral center (denominated chiral molecules) can exist in two different forms that keep a relationship of non-superimposable mirror images between them and are called enantiomers (or optic isomers). In organic chemistry, enantiomers occur spontaneously, for example, in compounds that comprise a coal atom with four different substitutes.

This property has been exploited in the field of patents, claiming, in the first place, the "racemic" mix of both enantiomers and, then, the rights over the active enantiomer, through which the originally obtained protection is perpetuated.

However, it is routine to prove if one enantiomer, or the other, is, in isolation, more active than the racemic mix of both since, in general, it is accepted that an optic isomer is much more active than the other; therefore, it is foreseeable that at least one of the isomers has a much higher activity in comparison with the racemate. When the molecular structure of a compound with enantiomers is revealed, the novelty of them is also lost since the formula necessarily reveals the existence of enantiomers.

Consequently, isolated enantiomers should not be considered patentable when the racemic mix is already known. However, the processes to obtain of enantiomers could be patentable if they are novel and carry an inventive activity.

Active metabolites and prodrugs

When a pharmaceutical compound is administrated to a human being, part of it can be excreted without changes, while the remaining suffers complex unforeseen chemical modifications due to the action of the enzymatic processes in the organism. The

5. *However, a third party can apply for a selection patent and not necessarily the holder of the original patent. This can originate patents dependence problems and eventually give rise to the application of mandatory licenses. See Article 31(1) of the Agreement on the ADPIC*

6. *A different situation occurs when a compound shall be produced by means of the large number of consecutive steps (chemical reactions). It can be inventive to produce this compound through another much more efficient way (which involves less steps), even if these individual chemical reactions were known as such for other compounds.*

product of these metabolic modifications is denominated metabolites, and it cannot be considered they are "created" or "invented".

On the contrary, inactive compounds (called "prodrugs"), when metabolized in the body, can produce a therapeutically active principle. In some cases, patent claims cover a drug and its prodrugs. When the active principle is not patented, a patent concerning the prodrug by itself can enlarge the holder's control over the market of the active principle that is being metabolized. A prodrug can be considered as a "disguised" original drug.

In general terms, the active metabolites of medicines should not be considered patentable as separated elements of the active principle from which they derive.

Regarding the patents over prodrugs, if they were granted, they should exclude from the claim the active principle as such if this was previously disclosed or if it is not patentable. Like any other claimed matter in a patent, a prodrug must be accompanied, in a sufficient way, by the information provided in the specifications. Additionally, it should be required that the prodrug be inactive or less active than the compound to be released, that the creation of the active compound assures an efficient level of the drug and that it minimizes the drug's direct metabolism, as well as the drug's gradual inactivity.

Treatment methods

As it was observed in module II, the Agreement on TRIPS expressly authorizes the patentability exclusion of diagnostic, therapeutic and surgical methods for the treatment of people and animals. Most countries do not grant patents over such methods due to ethical reasons or to the difficulty of controlling its observance in the practice; besides the methods that are applied to the human body are not susceptible of industrial application.

Use claims, with inclusion of second indications

The patenting of a product's medical use, which includes first and second indication of a known medicinal product, has become a common practice in the pharmaceutical field.

The new uses of a drug are classified in:

a) First pharmaceutical use (also denominated first medical indication): situation in which a new therapeutic use for a product that did not have any previously known therapeutic use is discovered. In such circumstances, the product will be used in the pharmaceutical field for the first time.

b) Second pharmaceutical use (second medical indication). In this case, it is discovered that a product for which one or more therapeutic uses are known, has an additional therapeutic use, even if it's not related to the previously known use or uses.

Even if some countries have accepted, for example, patents over a therapeutic indication of a known substance, this has been based on a fiction about novelty.

The Agreement on TRIPS only obliges to grant patents on products and procedures, the members have no obligation to grant use claims, including those of second indications.

Besides the lack of novelty, there are other possible objections to the patentability of second indications:

- Lack of industrial applicability, since what is qualified as new is the effect that is identified in the organism, and not the product as such or its manufacturing method;

- A patent that covers the second medical indication of a known product is equivalent to a patent on a therapeutic treatment method.

3. Impact of patents on generic drugs competition

Since patents grant exclusive rights on the production, sales and use of the patented matter, they can be used to limit the competition and fix higher prices than the ones that would exist if there were competitive products.

Thus, in the field of pharmaceutical patents, a product's protection can conduct to monopoly conditions and generate an extraordinary revenue. The magnitude of the restrictive effect depends on the market structure and, particularly, on the availability and access conditions to substitute products. In the United States, for example, the doctrine and jurisprudence have characterized the patent as a legal monopoly; though, in the frame of the antitrust right,[7] the sole existence of a patent does not imply the existence of a condemnable monopoly. Patents can conduct to a situation of monopolistic power in a whole market, especially when they protect pioneer or basic inventions, as long as there is no possible competition of substitute goods.

Patent laws can contain elements that, while recognizing the rights of the owner, mitigate the possible effects of the exclusive rights in the relevant market and even more, emphasize a pro-competition application of the protection regime. The way in which the patentability criteria are defined and applied become a fundamental and determinant element of the set of knowledge that is extracted from the public domain. This issue is, as it was observed before, very important in the case of pharmaceutical products.

Frequently, the registration of a large number of patents on pharmaceutical compositions, therapeutic uses, polymorphs, procedures and/or forms of administration related to an active ingredient, allows the proprietary company to raise a high barrier against competition. If these patents (sometimes called "secondary") are used aggressively by means of "strategic" litigations to discourage the competition, they can improperly expand the market power granted by the original patent. Such abuses may reach particular severity in developing countries where, in general, there is little or null tradition regarding the control of anti-competitive practices through a competition defense regulation.

The strong inter-companies competition that exists in the pharmaceutical sector has given rise to much opposition to pharmaceutical patents on the part of the affected competitors. However, smaller companies that are generic manufacturers in development countries frequently lack the resources needed to start such costly actions. Besides, the fusions wave has reduced the number of main actors and has accentuated the sector's oligopolistic structure. This trend makes it even more important to administrate the patents' system with the purpose of protecting competitors and the public, especially against the restrictions derived from patents that are granted under too flexible patentability criteria.

7. It refers to the right of defense of the competition or against anti-competitive or anti-monopolistic conducts.

Some authorities responsible for the competition defense have addressed the problems derived from patents concession with low patentability standards and the use of patents to delay or exclude legitimate competition.

Due to several reasons, the capacity of innovative large companies to develop new molecules of therapeutic action has dramatically decreased in the last years. Consequently, when the patents of the more profitable older products expire, there are no new products to replace them. To counteract this trend, one of the strategies of the companies is to request patents related to old products that cover developments that generally lack an inventive merit: a new "formulation" or a different salt of the same active principle, a particular crystalline form (polymorph), changes in the dose, etc. Thus, the entrance of generic products to the market, after the patents that protected them have expired, is deliberately delayed due to actions based on new patents that are related to the same product.

This situation is a consequence of two interrelated phenomena. On one hand, large companies use different patenting strategies to block generic manufacturers (see chart).

Patenting strategies

Blanketing: to create a "jungle" of "minefield" with patents over each manufacturing procedure stage.

Flooding: to get several patents concerning the same product.
Fencing: their objective is to block the research lines regarding the protected products.

Surrounding: to surround a central patent with minor patents.

Patent networks: to establish patents portfolios to increase protection and negotiation power with other companies.

Naturally, only those companies that have large budgets to process patents and engage in costly legal litigations can use these strategies.

On the other hand, since the 1980's decade, many patent offices have relaxed the "patentability" criteria they apply. They consider that the patent's applicant is a "client" that must be served so he/she can obtain a patent as fast and less costly as possible.

A direct consequence of the proliferation of pharmaceutical patents is the increase in the number of litigations addressed to enforce these patents with the aim of preventing the market entry of generic competitors. The problem is that, while the litigation lasts, the patent is presumed valid and the market exclusion acts are legitimated by a title that only later will be annulled. Namely, protected by this presumption, the patent holder can avoid the payment of the damages and interest that would ordinarily correspond when the industrial or commercial activity is blocked by a third party. As a result, this individual has no rush in getting the definitive sentence that can end his/her market monopoly.

For this reason, the behavior of the judges is of vital importance, especially regarding the precautionary measures they might adopt, sometimes unprecedented, that is, without the intervention of the defending party in order to avoid the alleged violation of a patent, and the role of the competition authorities.

Conclusions

Public health protection is one of the most urgent problems in developing countries. The way of facing this situation is by means of an integrated approach to the national policies related to health, the pharmaceutical industry and patents. None of these policies can be drawn or applied individually.

Conceived to promote innovation through a temporary reward to those who contribute, the patents system is nowadays used in some cases like a commercial tool to exclude legitimate competition. It could be argued that the possibility of requesting and obtaining the cancellation of an incorrectly granted patent, is enough reassurance for society that patents will not be used in an improper way. However, for small and medium companies, the threat of costly and prolonged litigations is generally enough to abandon the market. The health ministries and other organizations involved in the purchase of medicines use "original" products when they face patents tangles that may block the generic products' purchase at a lower price. This, naturally, reduces the number of patients who can have access to treatment.

A pharmaceutical patent abuse does not only affect commercial interests, but also people's life and health. It is necessary, therefore, that the governments carry out a coherent action against abusive behaviors such as: a)definition of rigorous patentability standards that prevent patents concession on trivial "inventions", and the availability of effective opposing procedures to patent applications; b)establishment of fast and effective legal or administrative procedures for the invalidation of patents that compromise public health; c)the development of guidelines for the intervention of the competition authorities; d)training and instruction for public organisms, including health ministries, to observe or oppose to patents applications or to require the cancellation of granted patents that restrict competition inappropriately in the pharmaceutical market.

Finally, it is appropriate to remember that, as the Federal Trade Commission of the United States did, the patent offices that apply lax patentability criteria forget that their main mission is to protect the people from improper appropriations of knowledge that are, and should remain, in the public domain.[8]

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8. *Federal Trade Commission (2003). To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003), available at www.ftcgov/os/2003/10/ innovationrpt.pdf, p. 14.*

Intellectual property and the right to health

Andrés Arauz* and Diego Mogollón**

Our current reality, marked by an accelerated globalization, has modified in a considerable way the traditional trends of information flow at the local, national, regional and global scale. As society members are better informed with more supple and flexible communication appliances, which respond to the exchange demands in real time regardless of the physical distances, the debates that could formerly remain isolated, have now the potential to virally spread, thereby the problematics that afflict diverse and different societies are now properly global. It is the social dimension of these transformations that we cannot lose sight of, not even for a moment.

The truth is that the use of technologies is in constant improvement, the unprecedented speed of information and the overwhelming compression of time-space are demanding the creation of common answers and proposals to shared challenges. Even though these historical processes did not start in this century, as they have a strong background dating from at least five centuries ago, when the planet started to link through commercial bonds with its epicenter in Europe, it is true that the technologies available to our generation have disrupted the temporal and geographic dimensions to which humanity was used to. The globalization notion is highly relevant. The convergence of a mutual and simultaneous coexistence between the local and global is a symptom of the complexity of our time. In this way, there is a combination of the need of having answers that respond to the particularities of specific human groups who are territorially located, and, at the same time, it is indispensable to project the eventual solutions towards the worldwide context.

There are worldwide organizations, around the architecture of the United Nations Organization (UNO), that, since the middle of the XX century, have been in charge of gradually developing an institutional framework to ensure the compliance of ratified mechanisms by means of conventions and agreements. The multilateral spaces for international negotiation are the concretion scenarios of these mechanisms. In a time when the worldwide concert of nations has just set a new package of universal objectives, currently denominated Sustainable Development Goals (SDGs), in replacement of the Millennium Goals s (MDGs), it is not surprising that deep questions arise about the efficacy of these means to guarantee the well-being –and the good living, we anticipate to suggest- of the people. Ultimately, they are the fundamental principles that inspired the Universal Declaration of Human Rights, approved by the General Assembly of the UN on December 10, 1948, namely, freedom, justice and peace, which continue to operate as a compass that points out the stony path towards a horizon, frequently elusive, of real social justice.

The materialization of these principles, however, finds some obstacles on the way. Every day the international commissions that are part of the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) meet together; the latter is heir to the organs created in the XIX century, like the 1886 Paris Convention. Through it, the newly independent countries were committed to follow the game rules in the matter of industrial protection and inventions of the metropolitan countries. A set of bilateral and multilateral trade agreements and other instruments followed, like the one that became known as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Ecuador, along with the rest of Hispanic American countries that had achieved their independence in the first decades of the XIX century, was part of many of these commitments. It is no mystery that the peripheral and dependency conditions of our countries, added to the supremacy of national elites oriented towards the North, allowed the predominance of particular interests in detriment of those of the immense majority of the population.

The XX century meant the irruption of the popular power. In Ecuador, the "July Revolution" and the process that led to the Constitution of 1929, was the great first expression of it. Such Constitution created, for the first time, a mechanism that was really framed within the appearance of the welfare states. The appearance of the Insurance Fund and the Pension Fund, and institutions like the National Development Bank, became key background for the development that, only after a long time, the Nation would reach. In health matters, the constant social fights also forced the change from a mechanism based exclusively on beneficence, towards one that slowly developed health as a right. On that path, unfortunately, during the last decades of the XX century, there was a drastic dismantling of the States thanks to a conservative agenda that was reflected in the Washington Consensus. The structures of the public health systems were object of shameful privatizations. The State not only lost its institutionalism, but also its regulation and control capacities. The most fundamental rights, such as health, became goods.

The first years of the XXI century were the beginning of a radical change towards a second and definitive irruption of the popular power in politics. Democracy radicalization in a unique participative process, an example is the Constituent of Montecristi in 2007, which led to the approval through a referendum of a new constitutional charter during the following year, which changed the scenario. Different social groups that participated actively in Montecristi, most of them representing historically marginalized social sectors, placed great trust on the belief that a change in the power structures was possible. Seven years after the entry in force of this Constitution, today firm steps towards that direction can be seen. Regarding what concerns us here, for example, we have milestones, like the Declaratory of Public Interest of the Drugs Access for Human Use given by the Constitutional President Rafael Correa in 2009, through which it was declared of public interest the access to drugs used for the treatment of diseases that affect the Ecuadorian population and that are a priority for public health; therefore, the possibility to grant mandatory licenses on patents regarding the medicines for human use that are necessary for treatments was left open. This decision is in the frame of the flexibilities of the Trade-Related Aspects of Intellectual Property Right and the Andean decisions.

The context for transcendental decisions like this one is much wider, and must be understood as such. The three National Development Plans that the Citizen Revolution has had, have smoothed the way for a new comprehension of knowledge. Free and open knowledge is a demolishing challenge to the ossified structures that we inherited from the past. These public policy decisions have been accompanied by a greedy agenda of normative development with the purpose of providing these changes with intertemporal sustainability. A good deal of that normative development constitutes also the non-

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protection of trial data, a mechanism encouraged in the new free trade agreements, but that at the same time is an obstacle to the competition by generic developers. Likewise, Ecuador refused to ratify a bilateral agreement concerning intellectual property that the United States sought to be signed between both countries in the 1990s. In 1997 and 1998, the United States, through its ambassador Leslie Alexander, even pressured and threatened Ecuador by announcing that Washington would impose commercial sanctions due to the non-compliance of the supposed agreement.

The fundamental axis is an ongoing process: the approval of an Organic Code of Social Economy of Knowledge, Creativity and Innovation, known as 'Código Ingenios' (Itellects Code), currently in legislative process inside the National Assembly. Besides this legislation, which intends to protect the common interests over the private ones, a set of supporting initiatives can be also mentioned, such as the project of public purchase of drugs through reverse bidding processes. This is a mechanism promoted by Ecuador in order to lower the costs and reach an effective distribution, which also has perspectives of regional expansion for the effective management of scale economies at a macro level.

The orientation change is clear: the rights of many prevail over the economic interests of a few. Our Constitution establishes that the content of the rights must be progressively developed through regulations, laws and public policies. During these years, there has been overwhelming evidence of the progressive measures that have been taken with each one of these three constitutional guarantees for the exercise of rights. These are correct decisions that point in the same direction and that start to be recognized not only in the national context, but also in the international setting.

The recognition of a set of human conglomerates as priority attention groups in the Constitution has boosted a series of cutting edge measures for the full guarantee of everybody's rights. One of these priority attention groups are people with HIV, for whom the Government guarantees the provision of health services that assure them a dignified life, free of discrimination and with free access to the required drugs. There is important national jurisprudence about the assurance of the rights of these people, especially regarding access to health. The dotation of antiretroviral drugs through the public system is understood as an obligation, which, if not complied with, beyond the administrative, civil and penal responsibilities that it might carry for the responsible officials, is understood in a human dimension which emphasizes the need for a constant and predictable flow of medicines in an uninterrupted way in order to assure that people can continue with their lives. We are talking, thus, of the materialization of the constitutional Nation of rights and justice, of a State that recognizes itself as a duty-bearer before its citizens, who are recognized as rights bearers.

The Nation has qualitatively improved its response capacity, which does not mean that there are no inconveniences to be solved, and it is these agile answers to local problems which are acquiring political transcendence beyond the national frontiers. For example, a recent fact of great notoriety was the sudden and unilateral raise in the cost of a very potent drug to combat infections like toxoplamosis in newborn children or in people with cancer or HIV. The price increase of Daraprim in the American market was of an astronomic 5,000%, with a change in the cost of a 30 tablets box from US$13,50 to US$750. Such measure took place after the change in the domain of the drugs' commercialization rights and revealed the survival of twisted

schemes that put profit before collective interest within a permissive and casually regulated market. This raises a renewed interest about difficult, but unavoidable, questions such as: how to understand financial speculation in the pharmaceutical industry?; which is the fair price for drugs?; how to guarantee universal access to health, but without compromising the research, development and innovation of new drugs?; and, fundamentally, what is the role of the Government before the markets that commit and condition in the most arbitrary way the morbidity and mortality of other human beings?

The executive director of the pharmaceutical company responsible for the increase in the drug cost, Martin Shkreli, said that it was a measure that was taken because, as he said: "it was about time to generate profit with this drug as the former sales companies had been practically given it away." Besides, he said that the previous sales value did not consider indirect costs like marketing and distribution. This is something that brings up other questions such as: how long does a medicine need protection, via a drug patent, to even assimilate this type of collateral costs? It is important to mention that the subject drug started its commercialization in 1953.

It is evident that drugs production carries costs and that it is necessary to motivate the participation of the private sector in the innovation process, however, one cannot lose sight of sensitive and priority topics like the fundamental principles of the Universal Declaration of Human Rights that we mentioned at the beginning. It is a fallacy to think that each other are mutually excluding. Ecuador is determined to find a way towards an economic model that democratizes the production, transmission and appropriation of knowledge as a public interest good, thus, guaranteeing the accumulation and redistribution of wealth in a fair and sustainable way and in harmony with nature. In this sense, the aspiration is to reach a collaborative and solidary knowledge production through high-fluidity social innovation networks with transmission bands that take advantage of current available technologies.

Over this basis, and as we already mentioned, there is a huge bet on a radical doctrinarian update of the regulations that deals with the intellectual property field. In this sense, generic drugs production and the participation of the Government in the market, retake basic principles for the maintenance of a social and solidary economic system. Going back to the mentioned case about the sudden and unilateral increase of Daraprim, on the one hand, it is encouraging that the timely action, headed by a political leader that is looking for the democratic nomination for the presidency of the United States, mostly through a massive mobilization in social networks, stopped the increase and even shook the stock price of the pharmaceutical firms' shares, but, on the other hand, it is still disturbing to depend on one person to stop an unfairness of such proportions.

In this sense, we must think of structural and sustainable solutions. The Ecuadorian government currently encourages the conformation of four emblematic universities, after the approval of the new Organic Law of Higher Education (LOES, -Spanish acronym) in 2010. The Amazonic Regional University – IKIAM – is one of the four emblematic universities. It is located in one of the most megadiverse places in the world, in the Amazon Rainforest, and is it privileged for having the Colonso-Chalupas reserve as its laboratory; this university was created as the ideal space for the study of the genetic patrimony and for the production of bio-knowledge. This is the greatest legacy for the future generations. We are certain, from the knowledge and human talent sector, this is the case.

In this short space, we succeeded to merely sketch a set of concerns regarding the problematic relationship between the intellectual property regimes and the full guarantee of rights. On the other hand, just as our National Plan for Good Living provides, we wish to move from a dependent economy of finite resources to one based on infinite resources, namely, sustained on knowledge and innovation. To remain consistent with it, we have taken specific measures to mobilize in this direction. A new normative frame, a set of public policies and advanced jurisprudential developments are true evidence that it is possible to transit towards the democratization of knowledge and fair and equal socialization of its benefits.

In Ecuador, the right to health is a constitutional mandate, and it is a responsibility of the Government to guarantee the access to decent services, as well as to high quality, safe and effective medicines.

Photographic archive: Public Health Ministry of Ecuador

Chapter III:

Pharmaceutical market practices and regulation mechanisms

Reforming Pharmaceutical Industry - Physician Financial Relationships: Lessons from the United States, France, and Japan*

Marc A. Rodwin**

Post-industrial societies confront common problems in pharmaceutical industry-physician relations. In order to promote sales, drug firms create financial relationships that influence physicians' prescriptions and sometimes even reward physicians for prescribing drugs. Three main types exist: (1) kickbacks, (2) gifts, and (3) financial support for professional activities. The prevalence of these practices has evolved over time in response to changes in professional codes, law, and markets. There are certainly differences among these types of ties, but all of them can compromise physicians' independent judgment and rational prescribing.

Drug firms have paid kickbacks for prescribing drugs, purchasing drugs, switching brands prescribed, adding a drug to a hospital formulary, enrolling patients in post-marketing clinical trials, and writing practice guidelines that encourage the use of certain drugs. They also shower gifts on opinion leaders, including physicians who advise the Food and Drug Administration (FDA) on drug safety, draft practice guidelines, and set drug formularies for hospitals and health plans. Gifts include: cash; gift certificates; invitations to resorts; entertainment such as theatre, golf, or sporting events; computers; cases of wine; artwork; consumer goods; meals; medical and office supplies; assistance on literature reviews and research; and help with personal errands. Pharmaceutical firms also fund physician activities. They subsidize professional meetings, providers of continuing medical education (CME), and professional associations. They sometimes reimburse physician expenses related to attending professional meetings and CME, payments which are sometimes treated as gifts rather than funding.

This article compares the means that the United States, France and Japan use to oversee pharmaceutical industry-physician financial relationships; it also proposes reforms.[1] These countries rely on professional and/or industry ethical codes, anti-kickback laws, and fair trade practice laws. They restrict kickbacks the most strictly, allow wide latitude on gifts, and generally permit drug firms to fund professional activities and associations. Consequently, to avoid legal liability, drug firms often replace kickbacks with gifts and grants.

Kickbacks

All three countries prohibit paying kickbacks to publicly employed physicians, just as they do for other public officials. This policy applies to more physicians the larger the size of its public medical sector. Japan employs nearly 42 percent of physicians in public hospitals, while France employs 28 percent, and the United States only 9.5 percent.

1 *This work was developed as part of a broader study of conflicts of interest in medicine. See M. A. Rodwin, Conflicts of Inter¬est and the Future of Medicine: The United States, France and Japan (New York: Oxford University Press, 2011).*

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National policies differ on kickbacks to private prac¬titioners. Only France bans kickbacks for all private sector physicians.[2] Since 1972, American federal law prohibits kickbacks to private practitioners for work related to Medicare or Medicaid patients. It does not prohibit kickbacks for medical care paid for by private insurance and employer self-funded benefit plans that cover more than half of Americans.[3] Several American states prohibit kickbacks to some or all physicians or for certain activities. Japan lacks an anti-kickback statute for private practitioners. However, its fair trade law prohibits firms from paying premiums and rebates, which include kickbacks, certain gifts, and financial support.

Beginning in the 1990s, the United States enforced the Medicare/Medicaid Anti-Kickback Act more strictly than previously. Prosecutors charged defendants with violating the federal False Claims Act in addition to the Anti-Kickback Act. This tripled the fines imposed and allowed prosecutors to retain a portion of those fines to fund further enforcement. In addition, the federal Qui Tam statute encouraged individuals inside firms to report evidence of fraud to prosecutors by awarding them 25 percent of any settlement.[4] Furthermore, new federal sentencing guide lines encouraged firms to establish compliance programs that are certified by the Department of Health and Human Services, Office of Inspector General (OIG), the agency that enforces the Anti-Kickback Act. It directs judges to treat firms with OIG-approved compliance programs more leniently if an employee violates the Medicare/Medicaid Anti-Kickback Act without corporate authority.

Gifts and Financial Support

France

Founded in 1941, France's Order of Physicians was reconstituted after World War II as a physician-elected organization and granted significant authority over medical practice.[5] The Order of Physicians drafts a code of deontology (Medical Deontology) which, if approved by the Council of State, the government then promulgates as an administrative decree.[6] The Order of Physicians licenses physicians and can suspend or revoke licenses of physicians who violate Medical Deontology. Government ministries also oversee medical practice.

Medical Deontology regulates relations among physicians and relations between physicians and laymen.[7] The Code of Medical Deontology states that physicians must be independent from and unconstrained by third parties to ensure that they are loyal to their patients.[8] Physicians may not receive kickbacks, commissions, payment for prescriptions, nor may they dispense medical products for profit. Private practitioners must submit proposed contracts to the Order of Physicians, which advises them whether it complies with Medical Deontology.

Responding to scandals in which drug and medical device firms paid physicians disguised kickbacks and funded international travel unrelated to professional work, in 1993, Parliament passed a law limiting certain gifts and established a framework to oversee industry funding.[9] Since then, potential donor firms and physician and medical organization recipients must report the amount of money requested and its use to the Order of Physicians, which then issues its opinion as to whether the proposed grant is legal. The same rules apply to all physicians. In contrast, United States and Japan have stricter rules on gifts and funding for publicly employed physicians than for physicians in private practice.

Parliament appointed the Order of Physicians to oversee industry funding, yet

2. *French Public Health Code [C. Sant. Pub.] art. L1110-3 (Fr.) (2010).*

3. *42 U.S.C. § 1320a-7a (2010).*

4. *Health Insurance Portability and Accountably Act of 1996, Pub. L. No. 104-1915, 110 Stat. 1936; 5 U.S.C.A. §§ 601et seq. Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 25. False Claims Act ch. 67, 12 Stat. 698 (1863) (current version at 31 U.S.C. §§ 3729-3733 (2010)); 47 U.S.C.A § §337 et seq. (West 2010); 42 U.S.C.A. § 1320 a-7b(a) (West 2010); 18 U.S.C.A. § 286 (West 2010); 31 U.S.C A. § 3730(b) (West 2010). Federal Qui Tam Statute; 31 U.S.C.A., § 3730 (West 2010).*

5. *P. Guillaume, "La Préhistoire de l'Ordre des Médecins," [The prehistory of the Order of Physicians] in P. Guillaume, L'Exercice Médical Dans La Société: Hier, Aujourd'hui, Demain The Exercise of Medical Practice: Yesterday, Today and Tomor¬row] (Paris: Masson, 1995): at 273-284,*

6. *J. P. Alméras and H. Péquignot, La Déontologie Médicale [Medical Deontology] (Paris: Litec, 1996); Conseil National de l'Ordre, Commentaires du Code de Déontologie Médicale [Commentaries on the Code of Medical Deontology] (Paris: Ordre National des Médecins, 1996).*

7. *J. Moret-Bailly, Les Déontologies [Deontology] (Aix-en- Provence: Presses Universitaires d'Aix-Marseille, 2001).*

8. *See Alméras and Péquignot supra note 6.*

9. *French Public Health Code [C. Sant. Pub] art. L-4113–6 (Fr.) (2010).*

to implement the law, the Order of Physicians formed a joint commission with pharmaceutical and medical device industry trade associations. The commission interpreted the law as banning kickbacks and certain gifts, but permitting industry funding for professional activities. Today, the Order of Physicians allows commercial interests to pay individual physicians all reasonable expenses they incur to attend professional meetings and CME. It excludes payment for expenses beyond the duration of the event or for a physician's companion. Since 2007, unless the Order of Physicians issues a negative opinion within one month, proposed funding for educational activities is automatically approved.[10] Today, drug firms routinely reimburse physicians for registration fees and transportation, hotel, and meal expenses for professional meetings and CME. They offer lavish hospitality at conferences.[11] They fund general medical journals, research, and CME providers.

Continuing medical education

Since the mid-1990s, the French Ministry of Health has promoted CME. Nevertheless, physicians face no penalty if they do not participate in CME. Until recently, drug and medical device firms funded and developed virtually all CME for private practitioners, and it was largely promotional, even though sponsored by local medical societies.

In 2001, the National Health Insurance Fund for Salaried Workers began to fund CME for private prac-titioners as part of fee accords with physician trade unions. In theory, the money pays CME speakers with a small administrative fee to the physician unions. In practice, the funds subsidize physician unions because they rely on physician volunteers as instructors and compensate physicians who attend for lost practice income.[12]

In 2004, Parliament created the National Councils for Continuing Medical Education (CNFMC) to accredit CME.[13] It does not restrict drug firm funding, nor does it require that drug firms report pay-ments to CME providers, nor that CME providers report income from drug firms. It does not restrict individuals with conflicts of interest from serving as faculty, nor require peer review of their presentation. Presenters are supposed to reveal conflicts of interest but rarely make written disclosure, and no one checks whether they disclose conflicts in lectures.

In 2006, the Inspector General for Social Affairs (IGAS) estimated that commercial interests spent between €300 million and €600 million ($376.86 to $753.73 million) on accredited CME – much more than all other combined sources. Industry observers believe that commercial firms spend just as much for so-called educational events that are not accred¬ited. The government then spent about €112 million ($139.48 million) on CME and evaluation of medical practices and the National Health Insurance Fund for Salaried Workers spent €70 million on CME.[14]

IGAS criticized the CNFMC for rejecting two proposals that would have helped prevent biased CME. One would prevent CME providers from receiving over 40 percent of their revenue from drug firms. The second would require several firms to support each program to ensure it did not favor one firm's products. The Inspector General charged that an "omnipresence of conflicts of interest" clouds CME, that neither public authorities nor experts control curriculum or course content, and that CME promotes sales and supports unions.[15] It proposed taxing drug and other commercial medical firms to fund government-sponsored CME.

10. *Décret n. 2007.454 du 25 mars 2007 relatif aux conventions et aux liens unissant les membres de certaines professions de santé aux entreprises et modifiant le code de la santé publique (dispositions réglementaires) [Decree of March 25, 2007 regarding fee agreements and ties between certain health care professions and private firms and modifying the Code of Public Health (regulations)].*

11. *Prise de position et premiers commentaires concernant l'article 47 DMOS du 27 Janvier 1993. [Common position and first commentaries concerning article 47 of Diverse Measures for Social Order of January 27, 1993] Nouvel Article L. 365–1 du Code de la Santé Publique [New Article L. 365-1 of the Public Health Code] Conseil National de l'Ordre des médecins, Con¬seil National de l'Ordre des pharmaciens, Syndicat National de l'industrie pharmaceutique, 21–04–1993, 21 March 1993.*

12. *J. Pascal, F. Riou, and J. Chaperon, "Difficultés de Mise en Place et Enjeux Institutionnels de la Formation Continue Des Médecins Libéraux," [Difficulties of Institutional Implementa¬tion of Continuing Medical Education for Self-Employed Phy¬sicians] Santé Publique 12, no. 2 (2001): 177-189. Y. Matillon, D. LeBoeuf, and H. Maisonneuve, "Defining and Assessing the Competence of Health Care Professionals in France," Journal of Continuing Education in the Health Professions 25, no. 4 (2005): 290-296. H. Maisonneuve, "Medical Education and the Physician Workforce of France," Journal of Continuing Education in the Health Professions 25, no. 4 (2005): 290- 296; C. d'Autume and D. Postel-Vinay, Mission Relative a L'organisation Juridique, Administrative et Financière de la Formation Continue des Professions Médicales et Paramédicales [Report on the Organization of Legal Aspects, Admin¬istration and Financing of Continuing education for Medi¬cal and Paramedical Professions] Paris: Inspection Générale Des Affaires Sociales, 2006. Rapport no. 2006–02, available at <http://www.ladocumentationfrancaise.fr/rapports-publics/064000180/index.shtml> (last visited September 14, 2011).*

13. *La loi 13 aout 2004 relative à la reform de 1'Assurance Mala¬die, Art. L. 4133–1-L.4133.2 du Code de la Santé Pub¬lique. [Law of August 13, 2004 regarding the reform of medi¬cal insurance]*

14. *See d'Autume and Postel-Vinay supra note 12.*

The Ministry of Health did not support the proposal; some physician unions did, believing that they would receive funds to organize CME.

The United States

The federal government lacks a policy that regulates gifts and industry funding for all physicians and medical associations. It relies on voluntary medical organization and industry trade association guidelines and codes of conduct, bolstered by the Medicare/ Medicaid Anti-Kickback Act and state anti-kickback laws.

Professional and industry guidelines

Founded in 1849 as a private voluntary organization, the American Medical Association (AMA) adopted an ethical code and revised it periodically. The AMA and affiliated state and local medical societies lacked membership and clout until the early 20th century. Then its membership, income, and influence grew rapidly. Until the mid-1960s, the AMA shaped medical practice and health policy. During that period, physicians without AMA membership had difficulty obtaining hospital privileges, physician referrals, and malpractice insurance. The AMA ethical code prohibited physicians from receiving kickbacks, commission, or gifts. The AMA also used its code to oppose physician employment, prepaid group practice, national health insurance, and market competition.[16]

The AMA had perennial difficulty enforcing ethical restrictions on kickbacks and entrepreneurial prac-tices. Then, in the 1950s, the AMA dropped many eth¬ical prohibitions and allowed physicians to dispense medicine, own pharmacies and drug companies, and accept gifts.[17] The AMA ceased its oversight of drug marketing, increased drug advertising in its journals, and opposed new drug regulation.[18] Subsequently, the AMA and pharmaceutical trade associations resisted government oversight and developed professional and industry self-regulation in tandem. In 1979, a federal court of appeals required that the AMA cease using its ethical code to restrict competition because that violated antitrust laws.[19] The AMA lost its power over medical practice, but continued to influence health policy through lobbying.

Senator Edward Kennedy (D-MA) chaired hearings in 1974 that documented the wide spread practice of drug firms awarding points to physicians for prescribing their drugs. Those points were redeemable for gifts, such as: phonographs, tape recorders, color televisions, watches, freezers, lawnmowers, lug-gage, microwave ovens, bicycles, and golf clubs.[20] The value of gifts increased as the price and volume of pre¬scriptions rose. Kennedy told the AMA and Pharmaceutical Manufacturers Association (PMA) that Congress might prohibit these practices. They pleaded for another chance at self-regulation.[21]

By 1986, Congressional pressure led the AMA to adopt conflict of interest guidelines. The AMA then opposed governmental regulation arguing that its guidelines were sufficient.[22] Thus, the AMA guidelines serve contradictory aims: they discourage certain practices while deterring legal prohibitions, which makes it possible for physicians to violate the guidelines without penalties.

Pharmaceutical firm gifts did not subside, so in 1989, Senator Kennedy announced new hearings. The AMA then drafted an ethical opinion and guidelines on gifts,

15. *See, d' Autume and Postel-Vinay, supra note 12.*

16. *J. G. Burrows, Organized Medicine in the Progressive Era: The Move Toward Monopoly (Baltimore, MD: Johns Hopkins Uni¬versity Press, 1977); J. L. Schwartz, "Early History of Prepaid Medical Care Plans," Bulletin of the History of Medicine 39, no. 5 (1965): 450-475.*

17. *G. A. Wooodhouse, past chairman of the AMA Judicial Coun¬cil, in testimony before the U.S. House Committee on Energy and Commerce, Subcommittee on Health, Physician Dispens¬ing of Drugs: Hearings on H.R. 2093 (22 April 1987): at 15, 105-124; M. A. Rodwin, "The Organized American Medical Profession's Response to Financial Conflicts of Interest: 1890- 1992," Millbank Quarterly 70, no. 4 (1992): 703-741.*

18. *M. A. Rodwin, "Drug Advertising, Continuing Medical Edu¬cation, and Physician Prescribing: A Historical Review and Reform Proposal," Journal of Law, Medicine & Ethics 38, no. 4 (2010): 807-815.*

19. *C. F. Ameringer, The Health Care Revolution: From Medi¬cal Monopoly to Market Competition (Berkeley: University of California Press, 2008); In re American Medical Ass'n, 94 F.T.C., 701, (1979). For the FTC order, see [1979–1983 Transfer Binder] Trade Reg. Rep. (CCH) 21,955, 418–19.*

20. *U.S. Senate, Subcommittee on Health and Committee on Labor and Public Welfare, Examination of the Pharmaceutical Industry: Hearings on Section 3441 and Section 966, Part 3, March 8, 1974, 12, 13, 1974, Testimony of Gerald D. Laubach, President of Pfizer, at 793-866; excerpts from gift catalogues, at 1014-1037.*

21. *Id., at 1348, 1353-1354, 1361.*

22. *AMA, Report of the Council on Ethical and Judicial Affairs, A (I-86): Conflicts of Interest, 1986.*

and solicited the PMA's comments.[23] The PMA endorsed the guidelines, the AMA published them, and the PMA adopted a similar code.[24] The guidelines discouraged kickbacks and the most offensive gifts, but permitted pharma to fund professional activities. In Senate hearings, AMA and PMA representatives admitted they could not enforce their guidelines, but argued for selfregulation.[25]

The AMA's 1990 guidelines and subsequent revisions prohibited doctors from accepting "substantial gifts with strings attached," namely kickbacks.[26] It allowed gifts worth up to $100 per item that had educational value or primarily benefited patients. Under that rubric, the AMA allowed gifts that subsidized practice, including textbooks, gram stain test kits, and stethoscopes. The guidelines did not limit the total value of multiple gifts from a drug firm. Drug firms could pay the expenses of medical interns, residents, and fellows to attend conferences when medical schools chose the recipients and conferences. They could pay for physician meals, sponsor receptions, and, of course, employ physicians to speak on behalf of their products, serve on boards, or work as consultants.

The AMA and PMA gift guidelines differ from France's gift/funding regulation in that they do not authorize drug firms to pay for physician expenses in attending professional meetings. However, reports by the AMA and other organizations found low compliance with the AMA/PMA Guidelines.[27] In fact, throughout the 1990s, drug firms invited physicians to conferences at resorts, paid physicians to attend promotional dinners, and offered tickets to sporting events and theaters.

Regulating industry gifts and funding with the anti-kickback act

Around 2000, the OIG announced it might prosecute certain gifts under the Medicare/Medicaid Anti-Kickback Act and that it would develop Anti-Kickback Act Compliance Guidelines. In response, the AMA and the Pharmaceutical Research and Manufacturers Association (PhRMA, formerly known as PMA) mounted a million-dollar campaign to publicize their guidelines.[28] Each issued slightly revised guidelines in 2002. Then the OIG proposed Compliance Guidelines which, "at a minimum," required drug firms to follow the PhRMA code.[29] The PhRMA replied that the OIG should grant "the benefit of the doubt" to firms that followed its code.[30] Nineteen drug firms urged the OIG not to make PhRMA guidelines a "minimum standard" since that would discourage future industry standards.[31] They said that the government should not prosecute firms under the Anti-Kickback Act if they followed PhRMA guidelines. They wanted the AMA/ PhRMA guidelines to preclude further restrictions.[32]

Organized medicine and PhRMA prevailed. The OIG 2003 guidelines stated that following the PhRMA code "demonstrates good faith efforts" thereby making it a proxy for compliance. However, the OIG said it would also consider whether the remuneration would "diminish, or appear to diminish, the objectivity of professional judgment."[33] That left open the possibility for additional restrictions.

In 2002, Vermont required pharmaceutical firms to report physician gifts worth over $25.[34] By 2007, five states required reporting gifts.[35] In 2009, Senator Chuck Grassley (R-IA) introduced a bill to prohibit physicians participating in Medicare or Medicaid from accepting gifts worth more than $25 by pharmaceutical or biological product companies.[36] Starting in 2013, the Accountable Care Act will require manufacturers of drugs, biologics, medical devices, and medical supplies

23. *Telephone interview by author with David Orentlicher, former counsel, AMA Council on Ethical and Judicial Affairs, Decem¬ber 12, 2006.*

24. *AMA Council on Ethical and Judicial Affairs (CEJA), "Opinion 8.061, Gifts to Physicians from Industry, 1990; Gifts to Physi¬cians," JAMA 265, no. 4 (1991): 501.*

25. *U.S. Senate, Committee on Labor and Human Resources, Hearings on Advertising, Marketing and Promotional Prac¬tices of the Pharmaceutical Industry, 101st Cong., 2nd Session, December 11 and 12, 1990, at 174-175.*

26. *See AMA CEJA, supra note 24.*

27. *R. P. Kusserow, Promotion of Prescription Drugs through Pay¬ment and Gifts: Physicians' Perspectives (Washington, D.C.: OIG-DHHS, 1992); A. O. Goldstein, "Gifts to Physicians from Industry," JAMA 266, no. 1 (1991): 61; L. Page, "Are Goody Grab Bag Days Over? Dermatologists Eye New Ethics," American Medical News 35, no. 5 (1992): 30-31.*

28. *S. Okie, "AMA Blasted for Letting Drug Firms Pay for Ethics Campaign," Washington Post, August 30, 2001, at A3.*

29. *U.S. Department of Health and Human Services, Office of Inspector General (OIG). "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers," Federal Register 67, no. 192 (2002): 62057-62067.*

30. *PhRMA's comments on the draft, submitted by Sidley Austin Brown and Wood LLP, Comment No. 119, obtained under the Freedom of Information Act.*

31. *Comments from 19 pharmaceutical companies on the draft, submitted by Arnold & Porter and PriceWaterhouseCoopers LLP, obtained under the Freedom of Information Act.*

32. *S. Chimonas and D. J. Rothman, "New Federal Guidelines for Physician-Pharmaceutical Industry Relations: The Politics of Policy Formation," Health Affairs 24, no. 4 (2005): 949-960.*

33. *Office of Inspector General (OIG), United States Department of Health and Human Services, "Compliance Program Guid¬ance for Pharmaceutical Manufacturers," Federal Register 68, no. 86 (2003): 23731-23743, at 23737-23738.*

to disclose gifts worth more than $10 to physicians or teaching hospitals.[37] They will report the information to the Secretary of Health and Human Services, who will make the information public.

Organized doctors and PhRMA also opposed restrictions on funding CME, research and other activities in proposed Anti-Kickback Act Compliance Guidelines. Twenty-five major professional medical organizations opposed all restrictions.[38] Several specialty societies asked the OIG to allow all drug firm grants to medical societies.[39]

The OIG final compliance guidelines adopted the organized-medicine-industry position. It held that "support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse." However, following the Food and Drug Administration's earlier attempt to regulate drug promotion for off-label uses through CME, it said commercial funders risk prosecution if they control CME. It said that drug firms should use separate departments for marketing and grant making.[40] Until then, drug firm marketing departments often disbursed CME funds and some CME providers marketed drugs. Now, separate entities organize CME and marketing. However, one company may own both a CME provider and a drug marketing firm.

Continuing medical education

The Accreditation Council for Continuing Medical Education (ACCME) has accredited CME providers since 1980.[41] It allows commercial interests to fund providers and uses standards for commercial support to prevent bias. Its 1992 standards said that CME providers and speakers must disclose conflicts of interest. After the OIG issued Compliance Guidelines, the ACCME revised its standards to hold that providers and speakers cannot participate in CME unless they resolve their conflicts of interest, preferably by having program materials peer reviewed. It said providers could resolve conflict by other means but that disclosure was insufficient.[42]

The 2004 ACCME standards also held, "A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services" (emphasis added).[43] That does not prohibit offering advice, nor does it prevent CME providers soliciting and voluntarily following funder suggestions.

In 2007, the Senate Committee on Finance investigated industry-funded CME. It concluded that ACCME standards were inadequate because the "provider can technically maintain 'control' of content... while continuing to accommodate suggestions from the companies that control their funding," thereby "afford[ing] drug companies the ability to target their grant funding at programs likely to support sales of their products."[44]

The ACCME responded that it "recognizes that CME can receive financial support from industry without receiving any advice or guidance, either nuanced or direct, on the content of the activity or on who should deliver that content."[45] Later, in its web page answers to frequently asked questions, the ACCME interpreted its standards to preclude providers from soliciting suggestions or advice from

34. *M. Petersen, "Vermont to Require Drug Makers to Disclose Payments to Doctors," New York Times, June 13, 2002, at 1.*

35. *A table of state legislation is available at <http://www.ncsl.org/ IssuesResearch/*

36. *Physician Payment Sunshine Act S.2029, introduced by Sena¬tor Charles Grassley (R-IA).*

37. *Patient Protection and Affordable Care Act, Section 1128 G (a) Physician Payment Sunshine Act Transparency Reports.*

38. *Office of Inspector General, "Draft OIG Compliance Program Guidance, supra note 29, at 62057-62067; see Chimonas and Rothman, supra note 32. AMA comments on the draft, sub¬mitted by Michael Maves, executive vice president, obtained via the Freedom of Information Act.*

39. *American Association of Electro-diagnostic Medicine, Com¬ment No. 55; American College of Rheumatology; American College of Chest Physicians, Comment No. 87; the Endocrine Society, comment No. 106; American College of Chest Physicians, Comment No. 87; and the Endocrine Society, comment No. 106. All comments were obtained by the author from the Office of Inspector General through the Freedom of Information Act.*

40. *U.S. Department of Health and Human Services, Office of Inspector General, "Compliance Program Guidance," Federal Register 68, no. 86 (May 5, 2003): 23731-23743, at 23738.*

41. *For a discussion of CME funding see, Rodwin supra note 18.*

42. *ACCME, Updated Standards for Commercial Support: With Back-Ground Rationale and Answers to Questions about Com¬pliance (Chicago: ACCME, 2004), available at <http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725- 80a1504e520c_uploaddocument.pdf> (last*

commercial supporters or showing them a program draft.[46] Even if this policy can be enforced, commercial interests limit the CME topics offered because they supply more than half the funds, so providers choose topics they support.

Japan

Pharmaceutical firms have had close financial ties to physicians in Japan, in part, because prior to the adoption of Western medicine in the 1860s, physi¬cians dispensed drugs and they continued this prac-tice after Westernization. Until the 1990s, physicians earned most of their income from drug sales.[47] As in France and the United States; pharmaceutical firms in Japan make gifts to physicians and fund meetings, professional associations, and research.

Until 2004, when the government began a certi¬fication program, CME providers lacked oversight. Since then, the Ministry of Health, Labor and Welfare encourages physicians to participate in certified CME by allowing them to advertise their educational certifi¬cates. There is still very little industry or other funding for CME.

In 1951, the Japan Medical Association (JMA) adopted its first ethical code, which stated six principles in 150 words. It revised these as Principles of Medical Ethics in 2002.[48] Neither version mentions conflicts of interest, gifts, or financial relations with drug firms and other commercial interests. The JMA does not issue ethical opinions, and its code plays no role in policy discussions. Physicians do not turn to the code when faced with practice problems; indeed, most are unaware it exists. The JMA has not developed guidelines on industry gifts and funding, as the AMA has, and neither the JMA nor any other physician organization oversees industry funding as the Order of Physicians does in France.

To promote fair market competition, Japanese fair trade law regulates pharmaceutical firm-physician financial ties. The Premiums and Representations Act of 1962 restricts drug firms from making certain pay¬ments or supplying inkind benefits to induce sales to publicly and privately employed physicians.[49] In 1984, the Japan Fair Trade Commission (JFTC) issued Guidelines on Pharmaceutical Manufacturers and Gift Giving that restricted certain gifts and payments to all physicians. Those guidelines are revised periodically.[50] The JFTC delegates oversight to an industry self-regulatory organization, the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry (FTCEPDMI), which promotes compliance through an industry code of conduct.[51] The Japan Pharmaceutical Manufacturers' Association (JPMA) revises its code of conduct to conform to JFTC and FTCPDMI rules.[52]

In 1993, new JPMA rules restricted drug firm assistance to physicians unrelated to their products to ¥100,000 ($700) per year per institution. However, it did not limit assistance related to their products, which the JFTC deemed legitimate promotion. Drug firms could also pay physicians to participate in post-marketing trials, conduct research, write articles, or lecture.

The JPMA also expanded an existing alternative to individual drug firm grants. Each drug firm contrib-utes to a drug-industry-sponsored foundation budget a share that is the same percentage as its share of the drug market. Firms donate funds to one foundation operated by the Pharmaceutical Manufacturers' Association of Tokyo (PMAT) and one by the Pharmaceutical Manu¬facturers' Association of Osaka (PMAO), which make grants to regional physician organizations. The JFTC holds collective industry funding does not violate the Premiums and Representation Act because no company directly pays an individual physician or association.

In 2001, the PMAT and PMOA reported contribu¬tions over ¥2.17 billion ($17.88 million) to 94 national or regional medical associations for conferences, meetings, and other activities through their affiliated foundations and ¥1.508 billion ($12.82 Million) to 150 medical associations in 2007. PMAT officials say that it would be unfair to ask all firms to contribute to local medical associations because their business may not be related to or in the location of those associations.[53] Local medical societies typically request and receive support directly from companies that do business in their area. The JFTC has tolerated this practice.

Common Elements and Differences

Long-standing laws to prevent government corruption have resulted in stronger sanctions for kickbacks to physicians that are publicly employed than those in private practice. Over time, nations extended restrictions on kickbacks at least in part to physicians in private practice. France extended prohibition on kickbacks to all private physicians in 1953.[54] Since 1962, Japan's fair competition law restricted kickbacks to private practitioners, but these are less strict sanctions than for kickbacks paid to publicly employed physicians.[55] In 1972, American federal law extended prohibitions on kickbacks to private practitioners for services to Medicare and Medical patients.

Yet while governments increased restrictions on kickbacks, pharma developed alternative financial ties that engender institutional corruption which is much more subtle. It used gifts and grants to influ-ence medical research, journals, CME, and physician prescribing. Organized medicine and public authorities have not responded very effectively to this institutional corruption.

The United States and Japan today restrict drug firm gifts more strictly for publicly employed physi-cians than for doctors in private practice. In France the same rules apply to all doctors. However, France allows individual drug firms to directly fund physician expenses for travel, lodging, food, and registration fees for conferences and CME, while the United States and Japan prohibit such funding.

In the United States, organized medicine developed ethical codes in consultation with the pharma-ceutical trade associations, which developed similar codes of conduct for their member firms. The AMA and PhRMA codes, which are voluntary, say that drug firms should not pay for expenses that physicians incur to attend professional conferences and CME, but they allow drug firms to fund CME providers, medical societies, and many professional activities. The AMA and PhRMA have lobbied against restrictions on pharma funding. The federal government adopted this standard in its Medicare and Medicaid Anti-Kickback Act compliance guidelines.

In France, when Parliament appointed the Order of Physicians to oversee industry funding of medical activities, the Order of Physicians formed a joint commission with drug and medical device industry trade associations. The Commission decided to allow commercial interests to pay physicians expenses to attend professional meeting and CME, and to fund organizations that develop CME.

In Japan, organized medicine did not address industry funding of physicians and neither did the pharmaceutical trade association. However, to promote fair market

visited September 3, 2011); R. Steinbrook, "Commercial Support and Continuing Medical Education," New England Journal of Medicine 352, no. 6 (2005): 534-535.

43. *ACCME Standard for Commercial Support, 3.2. <http://www. accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725- 80a1504e520c_uploaddocument.pdf> (last visited, September 3, 2011)*

44. *Letter from Max Baucus, Chair, Senate Finance Commit¬tee, to Murray Kopelow, ACCME, April 27, 2007, Committee on Finance, United States Senate, 2007, Use of Educational Grants by Pharmaceutical Manufacturer, Prt. 110–21, 110th Cong., 1st Session (April), available at <http://www.arbo.org/ cope/SCF%20report%20june%20 2005.pdf> (last visited Sep¬tember 6, 2011).*

45. *Letter from Murray Kopelow, Chief Executive of ACCME to Max Bucus and Charles Grassley, Senate Committee on Finance, August 3, 2007, available at <http:// www. accme.org/dir_docs/doc_upload/ff745720-2080-496a-bece- 2c50b09d4c7c_uploaddocument.pdf > (last visited Septem¬ber 6, 2011) (emphasis added); see also, ACCME, "Policy Updates," August 24, 2007, available at <http://accme.org/ index.cfm/fa/news.detail/news_id/3605f21a-302a-40d1- ab4d-3ceb88087b1a.cfm> (last visited September 6, 2011).*

46. *ACCME, "Standards for Commercial Support," available at <http://www.accme.org/index.cfm/fa/faq.detail/category_id/667b72cf-6277-4317-99f9-1e476b621e76.cfm> (last visited September 6, 2011).*

47. *S. Sugita, "A Historical Study of Iyaku-Bungyo (The Separa¬tion of the Dispensary from Medical Practice) in Japan," in Y. Kawakita, S. Sakai, and Y. Otsuka, eds., History of the Doctor- Patient Relationship: Proceedings of the 14th International Symposium on The Comparative History of Medicine – East and West (Tokyo: Ishiyaku EuroAmerica, 1989): 147-164; K. Rupp, Gift-Giving in Japan: Cash, Connections, Cosmologies (Stanford, CA: Stanford University Press, 2003).*

48. *Japan Medical Association (JMA), Physician's Ethics Code (Tokyo: JMA, 1951); JMA, Principles of Medical Ethics (Tokyo: JMA 2002). English summary of 25-page text is available at <http://www.med.or.jp/english/about_JMA/principles.html> (last visited September 6, 2011); "The JMA Guidelines for Phy¬sician's Professional Ethics 2008," Japan Medical Association Journal 52, no. 2 (2009): 75-91.*

49. *Act Against Unjustifiable Premiums and Misleading Repre¬sentations, Act no. 134 of May 15, 1962, as amended October 1, 2007. Fair Trade Commission, Pub. Notice no. 31 of 1991; Fair Trade Commission, Pub. Notice no. 54 of August 11, 1997.*

50. *Fair Trade Commission, Fair Competition Code Concerning Restriction on Premium Offers in Ethical Pharmaceutical Drugs Marketing Industry, issued March 10, 1984, revised, October 1, 2007.*

51. *Fair Trade Council of the Ethical Pharmaceutical Drugs Mar¬keting Industry, Fair Competition Code Concerning Restric¬tions on Premium Offers in Ethical Pharmaceutical Drugs Marketing Industry, 1984, as revised in 1997 and 2007; Fair Trade Council of the Ethical Pharmaceutical Drugs Market¬ing Industry, Enforcement Rules of the Fair Competition Code Concerning Restrictions on Premiums Officers in The Ethical Pharmaceutical Drugs Marketing Industry, 1984 as revised in 1997 and 2005.*

52. *In 1993, the JPMA developed three sets of guidelines: (1) Promotional code of pharmaceuticals (March 1993, a revi¬sion of the 1976 Federation of Pharmaceutical Manufacturer Associations of Japan's Code of Practices for the Promotion of Ethical Drugs; (2) Guidelines on Gift-Giving to Health Care Providers Permissible Under JFTC Rules; and (3) Guidelines on Remuneration for Case Reporting Allowable under JFTC Rules (1993), revised as Promotion Code for Prescription Drugs (May 23, 2008), available at <http://www.jpma.or.jp/english/isuues/pdf/2007code_e.pdf> (last visited September 6, 2011). The JMPA modified its code of conduct again in 2008.*

53. *PMAT, Organization*

competition the state restricted individual drug firms from making payments to individual physicians or medical organizations.

Reforming Policy

Each country employs strategies that the other two could adopt to improve their oversight of pharma-physician relations.

The United States and Japan illustrate the value of strict standards for publicly employed physicians by prohibiting them from accepting industry gifts and funds. France, which allows publicly employed physicians to receive commercial support, should enact a similar prohibition. France and Japan illustrate the advantage of legislation that applies to all physicians. In the United States, federal law only prohibits kickbacks for services related to care of Medicare and Medicaid patients. Only a few states prohibit kickbacks in medicine. Congress should prohibit kickbacks to all physicians.

The United States developed a powerful tool to detect and deter kickbacks in federal programs. The Qui Tam statute compensates individuals who report corporate misconduct to prosecutors. It also allows lawyers to act as private attorneys general to prosecute fraud if the federal prosecutors do not. Legislation should extend these policies to all kickbacks in medicine so they also apply to private insurers and medical care financed through employer self-funded benefit plans. France and Japan would benefit by using a similar anti-kickback strategy.

Japanese fair trade regulation shows a way to control commercial gifts and support. It prohibits drug firms from individually funding physicians and medical organizations. In its place, pharmaceutical firms pool contributions and make grants through foundations to professional associations. This breaks the link between individual donor firms and recipients. Yet while these measures reduce the influence of individual firms, the pharmaceutical industry can still fund whatever activities it chooses.

The Need for Independent Funding

Still, all three countries continue to rely on discretionary pharmaceutical firm grants to fund important professional activities, thereby entrenching a major source of conflicts of interest. Why does this practice persist? Mainly because organized medicine and the pharmaceutical industry oppose restrictions. Most physicians and drug firms object to what I will call abnormal corruption: explicit kickback payments made to physicians to prescribe or purchase drugs. But they accept what I call normal corruption: influence through gifts and financial support.[56]

Physicians and drug firms dislike kickbacks because they undermine their public image. Even firms that pay kickbacks object when physicians extort payments by threatening to choose a competitor's product. However, both believe that industry support benefits them and is socially acceptable. Drug firms know that their spending on grants and gifts yields ample returns on their investment and creates relationships that facilitate marketing and boosts sales. Physicians and medical organizations need resources and know that drug firms can supply ample funds.

Government officials tolerate industry funding because they want neither to battle pharma and orga-nized medicine (which would be necessary in order to stop the practice) nor to have the state publicly finance these professional activities. They hope to limit the negative effects of industry funding. How-ever, banning kickbacks while allowing industry funding, does not end physician dependence on pharma. This dependence still compromises medical practice; it merely shifts the mechanisms used to influence physicians. It solidifies a form of institutional corruption that resists reform.

All three countries need to create an alternative to pharmaceutical industry funding for professional medical activities. Public policy should tax pharmaceutical firms and other commercial interests, health insurers, and physicians to support CME, professional conferences, and other crucial professional activities. A government agency should distribute these funds either directly, or through a government-sponsored independent entity. Legislation should prohibit all industry gifts and financial support—including funds donated indirectly through an intermediary—to physicians, physician organizations, and organizations that develop CME and professional medical activities.

Critics will argue that a tax will be too burdensome. But in fact, the public already pays for pharmaceutical firm gifts and grants. Firms that fund these activi¬ties typically treat these expenses as a cost of business and pass the cost on to consumers through the price of their products, which are paid by government health programs, private insurers, and the public. Other drug firm gifts and grants are tax deductible, which amounts to a public subsidy for marketing. True, pharmaceutical firms might absorb part of their contributions and lower their profits. They have ample resources to do so because since the 1950s, the pharmaceutical industry has consistently earned higher profits than the average for Fortune 500 companies.[57]

Once nations tax pharmaceutical firms to raise funds for professional activities, drug firms could absorb part of these expenses and reduce their profit, but most likely they will pass on these costs just as they do today. However, when consumers and public authorities pay these expenses directly, they eliminate a major source of dangerous conflicts of interest that compromise medical practice. In contrast, rules that require drug firms to disclose their payments, or that attempt to limit their control over grant recipients, do not solve the problem. We need to move beyond regulatory tinkering.

Acknowledgements

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55. *Act against Unjustifiable Premiums and Misleading Represen¬tations, Act no. 134 of 15 May 1962, as amended by Act No. 44 of 30 May 1977.*

56. *This distinction is inspired by Charles Bosk's and Eliot Fre¬idson's distinction between normal and abnormal errors: nor¬mal errors are technical errors that any physician can make; abnormal errors have a moral component that call the physi¬cian's character and judgment into question. C. Bosk, Forgive and Remember: Managing Medical Failure (Chicago: Univer¬sity of Chicago Press, 1979); E. Freidson, Doctoring Together: A Study of Professional Social Control (Chicago: University of Chicago Press, 1984).*

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Anticompetitive practices in the pharmaceutical sector: a view from the competition and citizen participation

Pedro Páez Pérez*

The support process carried out by the Market Power Control Superintendence (SCPM, for its Spanish acronym) for the National Public Procurement Service (SERCOP) in the design of the 2015 Corporate Reverse Drugs Bidding is framed in the Manual of Good Commercial Practices for Public Purchases, which was jointly developed and issued by SERCOP a few months ago, has to be understood from the new framework of the citizenship role. Sometimes this is the hardest part to understand because the country has been known for centuries to always find solutions in the Public apparatus. And this does not mean that the Government has to reassign at all any of its functions, but part of this constitutional process we are experiencing is that it is not only a time of change, but also a change of era were we, the citizens, have a daily capacity to influence real life, the course of the economy of our people, and the way our country must perform. If we do not understand this, we are wasting our time.

We are opening doors for different sectors of society to hold in their hands, here and now, the ability to change our country and this involves growing as human beings. This is not what yesterday's Ecuadorian citizens could do, this is already part of what we are building: to grow in dignity, to grow in consciousness, to grow in responsibilities.

The Market Power Control Superintendence has developed 12 workshops devoted to the subject of health and 7 workshops devoted to the subject of public purchases; now, the two sides concur to give concrete results expressed, for example, in the case of public purchases with the Manual of Good Commercial Practices for Public Purchases.

The competence analysis inside the public purchases sector is complex because, in the first instance, not all economic operators participate in biddings. We must take into account the high levels of concentration in the various segments of the pharmaceutical industry due to possible distortions that may arise in the competition of the sector, especially upon possible agreements that may be generated in different public purchases processes. From the analysis conducted by the Market Power Control Superintendence to various public purchases processes in the pharmaceutical industry, it was found that there is a moderately high concentration regarding the total awarded value, where the 5 main suppliers reach moderate concentration indexes.

There are five major economic groups that operate in the Ecuadorian territory. These groups are vertically integrated along the entire production chain, i.e., there is an exclusive link between producers (laboratories), distributors and marketers (pharmacies and medicine cabinets). Other economic groups additionally present a horizontal integration that, at the level of drugs vendors (pharmacies), have drugstores with different establishment names and that respond to the target group (users) to which it is directed; some of these pharmacies belong to the group while others are called "franchised" or "affiliates". From an interview conducted to the key actors, there is evidence of a possible exclusivity in the commercialization and purchase of drugs, restrictive and anti-competitive practices especially between these five economic groups against independent pharmacies.

The markets and public services to drugs access are involved in a similar reality of market distortions and require a joint treatment in the context of a strategic proposal for promoting competence, and removing abuses, unfair practices and business harassment. The strong hand of authority will not fail to apply sanctions to operators who persist in these distortions, but the strategy cornerstone is the strict compliance with the law, and this is only possible from a new power correlation between citizens and large companies.

This first experience of the Market Power Control Superintendence in the preparation of the drugs public purchase meta-process is linked to new organization forms of civil society: we have at national level 2,300 Users Committees, with all the formalities of the law, monitoring prices and quality of food, drugs and agricultural supplies and other elements that have a direct or indirect impact on health issues. These organizations have great impact potential because this is not an issue that is centered only on medicalization, this is only one of the aspects, there has been a massive effort in recent years, the country's infrastructure has changed, and public services have changed. People´s access to satisfy and fulfillment of their basic needs has been transformed beyond poverty and inequality reduction rates. We now have organized citizens who are frustrating intended destabilization agendas in the country, which increase prices unreasonably and sometimes with the purpose to cause artificial shortages, even with drugs. Therefore, the question is, how long will the Ecuadorian society be held hostage by those powerful interests?

This is what is precisely changing. This framework is a citizen conquest. Users Committees play a fundamental role in that dimension. But then a new type of organization appears: the National Network of Health Observatories that we have just assembled in Schools of Medicine, of Pharmacy, of Nursing and of Social Work. We have one in Economics, one in Clinical Psychology, one in Biology, one in the Dispensaries of the Farmers Social Insurance, in professional associations, etc. We currently have 30 Health Citizens Observatories.This is a process in which we generate a new kind of dialogue, not only with the "ordinary citizen", but also with experts who will be discussing priority issues to rigorously support the citizens' mobilization to oversight and participate in each ward and precinct.

The Market Power Control Superintendence has also carried out a series of inspections at pharmacies and drugstores due to the number of market distortions. For example, what is now classified as a violation of the Organic Law for the Regulation and Market Power Control, all the denigrating campaign against generic drugs is part of the business because, afterwards, they end up selling us the same generic drugs but thirty times more expensive, just by means of a marketing trick.

The academy, through the Observatories for example, can now make direct contributions in people's favor. For example, students from The Central University of Ecuador made an investigation fully knowing what they had to look for: they went to pharmacies in Quito and found very revealing things about the markets' behavior, like the fact that there were no anti-parasitic drugs in poor neighborhoods, where parasites is one of the prevalent diseases.

These are distortions that are generated by the fact that few individuals control

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access of people to a chance to improve their health. This, in a way, means trafficking with human suffering. The disappearance of certain regular-use drugs for further appearance of new brands with a higher price is a dominant logic and is one of the market characteristics that root underdevelopment.

The difference between development capitalism and underdevelopment capitalism has to do, for example, with core behaviors like the predominant strategy of Ecuadorian managers that triggers quickly price raises. In the United States and Europe, in contrast, the prevailing strategy is to increase sales volume. So, if prices are increased predominantly, the result is more inflation, less production, less employment, and less purchasing power.

It is necessary to transform this situation and at the same time set out the conditions for a new type of State. The President has said it very clearly; we must transform the bourgeois State into a State that represents the whole nation.

On the other hand, we must end this vision of putting the State against the market with the purpose of allowing, in the confusion, certain people to always "channel water to their mills". State and market have always been serving the same masters, here and elsewhere in the world. Only recently the State is being transformed. Modestly, progress is being made from the Market Power Control Superintendence in another area: in a discrete but incessantly manner, branch by branch of the economy, we are also transforming the markets.

Markets are lousy masters, but can be good servants if you place people first and not the greed for capital. We must take the best from both, the public side and market side. It is precisely around this that the Manual of Good Commercial Practices for Public Procurement is designed and, in this framework, the Corporate Reverse Drugs Bidding will regulate the drugs supply in the Integral Public Health Network in the coming years has also been issued. However, all this cannot have concretions if it is not based on citizen participation. Citizen participation is not a hot-air festival or high-sounding voices claiming that "to the extent that my pocket is not satisfied, my expression freedom is impeded." Because there are also such abuses... On the contrary, it is about deploying a dialogue that contains discrepancies, plurality, respect, rigorousness and arguments.

Furthermore, in a transparency framework: all actions carried out by the Market Power Control Superintendence are published on the corporate website. And, especially what is now being presented for the first time in the country's history, "citizen organization" as an element to combat corruption, to promote transparency, to encourage domestic production, to allow that the few dollars remaining in an unfavorable international circumstance might be more effective in the performance of public policies and private participation. This is the priority of this new era. I believe that is the new role of citizens and there should not be self-disqualification: students, young people, new generations are an essential voice in this exercise. We are confident that youth, the most sensitive antenna of society, can make a difference this time.

Youth, thanks to this sensitivity, shall give its contribution with full responsibility, showing its commitment to the country in such a specific issue as drugs procurement for the coming years, this is a very delicate exercise; especially when, at worldwide level we are increasingly being subjected to the colossal and crushing weight of

multinationals. I speak, for example, about the recently signed agreement based on secret negotiations of the Trans-Pacific Public Private Partnership, which violated people's rights, included fundamental drugs. This is one of the so-called "Singapore issues" in the failed Doha Round of the World Trade Organization.

It is no longer the topic of free trade: these are issues that have been neglected because even between the factions of transnational companies there is no agreement on how to divide the loot; for example, concerning the patents issue, the misuse of intellectual property issues to artificially generate monopolies and hijack the health situation of people, which allows them to profit from human suffering.

It is important to execute actions coming from the people against the greed of big business in order to generate concrete answers. One of them is the task of the National Network of Citizens in Health Observatories.

With the support of SERCOP, there have been a series of regional meetings that are activating the operation of these observatories and supporting the Citizen Watch Councils, as well as the functioning of User Committees to have an integral participation in monitoring the territory, the village, the precinct, to observe how drugs sales are developing in both the private and the public sector.

We can add to this, the paradigms and schemes break with what we are achieving with other specific actions in different markets. The PhDs who are returning from abroad, for example, with veterinary diplomas and discussing with the Indigenous Ecuadorian Federation and the Eloy Alfaro Farmer Coordinator about genetic engineering issues to improve the breeding of farm animals and improve their living and production conditions on a daily basis, and with a new form of market organization. Supermarkets have just delivered the information regarding the first semester of 2015 compared to the first semester of 2014, where it is evident that they bought an additional amount of nearly 300 million dollars to small and medium producers. Resources that in other times would had left the country, weakening even more the problem of the balance of payments and the Ecuadorian productive apparatus, are now overturned in the territory, in the community, to eradicate poverty, to create jobs, showing that people are capable, contradicting a number of businessmen who said it was an utopia or evidencing the irresponsibility of some high Government officials who echoed those powers by saying that small and medium producers cannot produce with the required health, labor, environmental, tax and safety standards. The evidence is there.

And not only that, the subjugated mentality to certain inferiority complexes that have grown in the Ecuadorian people, which have led us to believe that our production is not good, is also being transformed. Supermarkets show that the consumer mindset is changing: people ask about the date of issue –it has been possible to eradicate the sale of expired products-, about the information contained in the product package. This is already part of a conscious effect of people; they are caring about and taking responsibility for what they buy, thus opening the doors for a more systematic culture of buying healthier in all markets.

We should never forget that the health problem is holistic because it has to do with the way of living of the people; the construction of the Good Living, the construction of the Sumak Kawsay, is in the first place building a healthy society, filed with values and possibilities. Many possibilities open up for the popular and solidary economy, for example, they will also be able of placing its products in the Coca Cola – Arca Ecuador refrigerators; citizens

can now demand that 20% of that space features products that are healthy, organic, from the popular and solidary economy, and not only from transnational brands.

This is a new country; these 300 million represent new opportunities without a single dollar coming from state spending. New attitudes from the State, from the market and from the public are converging.

The same spirit is beginning to materialize in public procurement. It is a new way of organizing things. In the case of the Market Power Control Superintendence, the process was started in Cuenca, in the midst of the previous presidential campaign in January 2013, in an international event co-financed by the mayor and the prefect, who were on opposite sides in the electoral spectrum, and yet had a political courage that is now indispensable. That is the environment with which the oversight workshops of the Corporate Reverse Drugs Bidding have been organized in the provincial capitals, gathering various innovations and contributions from the different sectors of the city, especially the Citizens Observatories.

It is important to keep generating actions in this regard to incorporate different society segments. Precisely, a "Health and Markets" International Congress was carried out in Esmeraldas several months ago in preparation for the new forces correlation in the markets linked to health; besides professionals, scholars and experts, the small neighborhood drugstores were represented there. Among the achievements that were evidenced regarding citizen criteria and new scientific concerns in the field, new trends in corporate social responsibility were also concreted. Two of the large pharmacy chains signed an ethics agreement under which they commit to correct their distorting and anti-competitive behavior, which has led in the recent years to the disappearance of 44% of small neighborhood drugstores.

In the more specific area of health strategy, on the other hand, the Market Power Control Superintendence has determined at national level the geographic concentration of the pharmaceutical establishments and their competitive practices in order to learn and evaluate the geographical distribution of the economic operators (pharmacies and medicine cabinets), to identify the isochronous where geographical concentration of pharmacies occurs, and identify the geographic boundaries where the rivalry of competitors has beneficial effects for consumers.

The logic of the various markets is changing. But none of this can be done without the participation of society and the academia. We can understand how the task of the Market Power Control Superintendence is bearing fruit after nearly 1,200 National Events, 55 International Workshops, 7 International Congresses, and 69 Productive Assemblies to put the products of small and medium producers in the market. The new forces correlation is projected to be even more encouraging by pushing forward this new strategic alliance with the academia, of the whole innovation, science and technology system, which will directly respond to the basic needs of producers and consumers.

The strategic vision of the Market Power Control Superintendence to improve the forces correlation in the health markets was designed with the preparation of the "Manual of Good Commercial Practices for pharmaceutical establishments", which is still awaiting for the statement of the Regulatory Board.

Its effect is complemented, as a framework for the Corporate Reverse Drugs Bidding, with the "Manual of Good Commercial Practices for Public Procurement" that we developed

with SERCOP, which aims to prevent the realization of anti-competitive practices in public procurement procedures that are performed by contracting entities of the National Public Procurement System.

These instruments jointly aim to promote transparency and prevent distorting competition. Also, through these instruments, it is intended to drive and strengthen fair trade, promote quality and fair price for the benefit of users and / or consumers; to foster the access to quality generic drugs at low cost; to control economic concentrations, as well as its activities and practices; to monitor the contractual relations of pharmaceutical establishments; to avoid agreements and restrictive practices between pharmaceutical establishments to prevent abusive and unfair practices in this market; to control brokering activities in order to achieve undistorted competition that reduces the asymmetries in the sector; and, to harmonize the competitive and efficient business practices between the different pharmaceutical establishments.

We hope that both, the general and the specific conditions that we are creating, will open up real possibilities for the Government, market and citizens to find new and higher forms of articulation that allow a constant improvement of what we do, and will enable us to build the country we all want.

Access to medicines and drug price control policies in Ecuador

Aidan Hollis*

Introduction

Medicines create a special challenge for governments everywhere. To an increasing extent, pharmaceuticals are an essential component in fulfilling the right to health: they extend and improve lives and are now necessary to achieve "the highest attainable standard of health."[1] At the same time, many pharmaceuticals are sold by firms that benefit from monopolies created by governments under the terms of the WTO Trade-related Intellectual Property Rights Agreement. When government has an obligation to provide health care, including essential medicines, and when it also has an obligation to grant a patent, the government faces a quandary, since the monopolist is in a position to take advantage of the government's commitment to enabling the highest standard of health. In these circumstances, governments are obliged to control the prices at which pharmaceutical products are sold.

The question of how to control prices, however, is deeply complex. On one side, it is important for countries to create an environment that supports innovation into new and useful medicines. And access to existing medicines is even more important, since patients who do not survive this year will not benefit from future innovations. Balancing these imperatives is challenging for all countries, including for middle-income countries such as Ecuador.

In the balancing of values between innovation and access, it seems reasonable that high-income countries should bear most of the cost of supporting innovation: if research and development costs were shared proportionally by income that is the outcome that would arise. It is also true that high-income countries typically obtain access to the newest pharmaceutical products earliest; there are usually significant delays before manufacturers apply for regulatory approval in middle- and low-income countries. This increases the responsibility of high-income countries to support innovation from which they primarily benefit.

Industrial policy is another important consideration for governments: they wish to have a strong local pharmaceutical manufacturing capacity because this creates good jobs and security of supply. In many countries, including Ecuador, pharmaceutical policies are in part designed to support a local industry. Generally, if such a policy is not designed with a view to reducing support over time, it will create an industry that is dependent on high prices and that cannot compete on international markets.

The problem of price control of drugs is exacerbated by the presence of insurance. Generally high-income people have better insurance, as well as greater ability to afford pharmaceuticals. This not only creates inequality of access: it also changes the incentives of sellers, who may maximize profits by setting high prices and targeting high-income patients with insurance.[2] This, of course, reduces access by uninsured poor people. In these circumstances, it is essential that price control policies reflect the ability to pay of ordinary patients and their families, including those who do not have insurance.

One interesting proposal to help to reconcile conflicting priorities of government, including particularly to assist in supporting the development of products for currently neglected diseases, is the Health Impact Fund.[3] This proposed institution would separate the payment of rewards for innovation from the price paid for the product, so that access would not be limited by mark-ups on price, and so that firms would have strong incentives to develop medicines with the greatest benefits for poor people. However, while this proposal presents an approach for improving access and innovation, it cannot address all the different circumstances present in pharmaceutical markets. Other strategies will also be required.

Pharmaceutical price control policies are complex and generally will depend on the extent of market power exercised by the seller. We consider four types of drugs, which can be characterized by whether they are monopolistic or competitive; and whether they are patented or not patented. A different strategy is required for each type of drug.

Type 1 drugs – Monopolistic patented drugs

Monopolistic patented drugs create the largest problems for pricing, since the manufacturer can attempt to withhold the drug from the market if payers do not offer a price that is high enough. Countries have adopted a variety of types of price controls to address this problem, with two common strategies.

a. International price referencing

The most common strategy, which has the merit of being administratively simple, is to set a maximum price based on the price of the same drug in other countries.[4] Brazil, for example, under its Resolution 2 established in 2004, created a price reference mechanism to Australia, Canada, France, Greece, Italy, New Zealand, Portugal, Spain, United States and the medicine's country of origin. Under Resolution 2, the price in Brazil is supposed to be no higher than the lowest price in this basket of reference countries. This strategy has been relatively successful, and the Brazilian agency Agência Nacional de Vigilância Sanitária has calculated that prices would have been 35% higher in the absence of this regulation.[5] One particularly attractive feature of this approach is the regulator only needs to know prices in other countries.

There are, however, three significant flaws in international price referencing. First, companies are responsive to price referencing in that they are able to respond by simply setting the same price in all countries. Thus, pharmaceutical marketing strategists are recommending firms to address this problem: "For those who have responsibility for multiple countries, it is critical to have some level of price uniformity across them, even if this will hurt competitiveness in smaller countries with low price levels. What you cannot allow is to have this small country with very low price become reference for a bigger country and hurt overall business."[6] It is clear that this in general reduce the opportunity for lower-income countries that serve as a reference for other countries to obtain price reductions. Equally worrying, we could have a situation where price regulators think that they have succeeded simply because every country faces the same high prices!

Second, international price referencing is flawed because companies are also responding by making secret deals with confidential rebates.[7] The way that these

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rebates work is that the insurer agrees to pay a certain public price for the drug, and the manufacturer pays back a fraction of this price. In some cases, these rebates may be over 50% of the public price. Thus, a country that references the public price is using a fake price. While there may have been some benefit from price referencing initially, it is collapsing as a useful mechanism as companies respond to the incentives it creates.

Third, to the extent that many countries are using price referencing, it is hard to see how it solves the primary problem: how are prices set in other countries?

b. Health technology assessment pricing

The second general approach to new drugs that have no effective competition is to calculate a maximum reimbursement price based on the therapeutic value of the product. This approach is certainly challenging: it requires the price regulator to make some estimate of the incremental therapeutic benefit of the product, and to determine a threshold willingness to pay for health benefits. Fortunately, many countries -- including Colombia, Brazil, Uruguay and other Latin American countries -- are now engaging in health technology assessment.[8] The use of health technology assessment to assist in pricing policy is becoming more common in middle-income countries.(9) Ecuador could certainly develop its own health technology assessment capacity. However, this will take time, is costly to maintain, and any process developed needs to be responsive to the unique institutional situation of the country.[9] One important challenge is how to set the threshold willingness to pay. For example, it is generally understood that the UK's National Health Service is willing to pay in the range of $30,000 - $50,000 per QALY. Ecuador might adopt a much lower threshold, perhaps in the range of $5,000 per QALY to reflect its lower income.

An important challenge to implementing this kind of system is that other countries, including Colombia, also use Ecuador in their international price reference scheme. Since Colombia is larger and has a higher per capita income than Ecuador, it is extremely challenging for Ecuador to obtain prices that are low; companies will not want to sacrifice profits in Colombia by agreeing to a low price in Ecuador. In this case, Ecuador has limited options for ensuring the availability of the drug domestically; clearly, invoking compulsory licensing is possible but also politically difficult.[10]

Type 2 drugs – Competitive patented drugs

Many important patented drugs have therapeutic competitors. For example, statins such as pravastatin, atorvastatin, rosuvastatin and simvastatin perform similar functions, although the evidence on how similar they are is typically not fully developed.[11] While their respective manufacturers emphasize differences, these may be relatively small. Many other important drugs are in a similar situation: the new PCSK9 inhibitors; the new hepatitis C antiviral medicines; certain antiretroviral medicines; certain oncology medicines. These drugs are, to some extent, therapeutic substitutes for each other. In these circumstances, using competition effectively can generate large discounts on the prices offered. Two strategies are commonly applied to drive prices down.

a. Preferred formularies

First, insurers sometimes create "preferred formularies": they offer contracts that ensure the lowest bidder gets all or almost all the sales into a market. For example, Express Scripts, in the US, arranged to put AbbVie's Viekira Pak on its preferred formulary, excluding Gilead's Sovaldi, since AbbVie offered a lower price.[12]

The preferred formulary strategy helps with insurer expenditures for several reasons. First, it encourages patients to switch to low-cost drugs. Second, for those patients who do not switch, the patient pays a larger share of costs. And third, and possibly most important, it creates pressure on manufacturers to lower their prices so their products are the preferred, high-volume ones. However, preferred formularies also create challenges.

First, in order to make preferred formularies effective, it is important that the insurer communicates actively with prescribers, so that they are familiar with which drugs are preferred. If doctors prescribe non-preferred drugs, patients may be stuck paying very high prices or they may be forced to make a return visit to the doctor for a new prescription. Educating physicians about the formulary, and keeping them up to date with changes, may be costly.

Second, preferred formularies may create an additional burden on physician use when the preferred drugs change.[13] Unfortunately, in order to create the most pricing pressure on manufacturers, the insurer must be prepared to switch patients when a lower price is offered. For example, if one of the drugs in the class becomes generically available, it may become the preferred drug, requiring patients to obtain new prescriptions. This process of switching patients from one product to another, even if it does not create any medical problems owing to the change in medicine, does create a need for patients to be seen by physicians to change the prescribed drug and in some cases to monitor the effect of the new medicine.

Third, many insurers charge high copayments to those patients who do not choose the preferred product. This can also create a heavy burden on those patients who are unable to switch.

Fourth, when drugs are imperfect substitutes, there may be some patients who benefit more from the non-preferred drug. If they are pushed onto the preferred drug, sub-optimal health outcomes will result.

Despite these challenges, some version of preferred formularies is an essential tool for using competition to control prices. In particular, if a price regulatory authority seeks to control costs without also providing insurance, the "preferred" strategy can be used to give marketing authorization only to one drug in a class – the one that offers the lowest price. This may be seen as draconian because it effectively prevents access to substitute medicines. However, it is a technique for imposing stringent competition on manufacturers to maximize access to at least one drug in a therapeutic class. When the cost of drugs creates important barriers to access, it may be more important to drive down prices than to ensure that every single patient has the therapeutic option that best suits him or her.

b. Therapeutic reference pricing

An alternative strategy is to use a system of "therapeutic reference pricing" in which the insurer pays only the price of the lowest priced drug in a reference class. British Columbia, in Canada, has used this strategy in several drug classes; it has also been

8. *INAHTA Members List [Internet]. [cited 2015 Oct 13]. Available from: http://www.inahta.org/our-members/members/*

9. *Dankó D. Health technology assessment in middle-income countries: recommendations for a balanced assessment system [Internet]. Journal of Market Access & Health Policy. 2014 [cited 2015 Oct 13]. Available from: http://www.jmahp.net/index.php/jmahp/article/view/23181/32824*

10. *Public Citizen. Leaked cables show U.S. tried, failed to organize against Ecuador compulsory licensing [Internet]. 2011 [cited 2015 Oct 13]. Available from: http://www.citizen.org/leaked-cables-show-US-tried-failed-to-organize-against-ecuador-compulsory-licensing*

11. *Furberg CD, Herrington DM, Psaty BM. Are drugs within a class interchangeable? Lancet [Internet]. 1999 Oct [cited 2015 Oct 13];354(9185):1202–4. Available from: http://www.sciencedirect.com/science/article/pii/S0140673699031906*

12. *Brennan T, Shrank W. New expensive treatments for hepatitis C infection. JAMA [Internet]. American Medical Association; 2014 Aug 13 [cited 2015 Oct 13];312(6):593–4. Available from: http://jama.jamanetwork.com/article.aspx?articleid=1890401*

13. *Morgan S, Hanley G, Greyson D. Comparison of tiered formularies and reference pricing policies: a systematic review. Open Med [Internet]. 2009;3(3):e131–9. Available from: http://www.pubmedcentral.nih.gov/articlerender.*

used in Germany, Norway and Spain.[14] Reference pricing is particularly effective once one of the drugs in a class has become generically available. It leaves high priced drugs available, but only if patients are willing to pay the cost difference. For markets in which all the drugs are new, such as the PCSK9 inhibitors, it is unlikely to be effective and instead simply creates a mechanism for coordinating prices.

Therapeutic reference pricing does not help patients who are not covered by insurance and cannot be used as a general form of price control.

Type 3 drugs – Competitive non-patented drugs

Generic drugs should be priced in a way that reflects competitive provision. This means, from an economic perspective, that prices should be near the variable cost of production. In practice, however, many obstacles can impede the effectiveness of competition. First, in some generic drug markets, there are relatively few firms; this usually leads to less aggressive competition. In some cases, when there are few firms, they can collude, either implicitly or explicitly, to keep prices high. Second, sometimes retailers and wholesalers have substantial market power, so that even if manufacturers offer low prices, retailers set high prices.

Addressing the first problem requires that the payers maximize the number of viable competitors in the market. Regulations that favor domestic producers, for example, may effectively inhibit competition. Ecuador has had a policy under which if a domestic producer submits a bid to supply the market, it will win the competition, even if foreign producers bid lower.[15] This, of course, results in prices that are not as low as they could be. It also is likely to reduce the willingness of foreign manufacturers to submit bids at all, since submitting a bid entails some costs, and there is no point in submitting if a domestic manufacturer is competing. Such a policy favors domestic manufacturing over health.

One reasonable way of addressing this would be to allow for a price preference for domestic manufacturers: for example, domestic manufacturers might be successful if they bid no more than 10% above the lowest foreign bid.[16] This strategy is commonly used by developing countries in order to provide some stimulus to local manufacturing, while preserving some discipline on pricing. However, even this kind of preference should be phased out over time: for example, the preference for domestic manufacturer bids could be reduced by 1% a year until in ten years they had to compete on a level playing field. This would put pressure on domestic manufacturers to become more competitive, but would also allow them time to reduce their costs, so that ultimately they could compete in international markets.

As with preferred formularies, one way to obtain low prices is to offer a tender for the entire country's needs. This would be implemented through limiting regulatory approval to only generic manufacturer of a given molecule. A tender process of this sort would drive manufacturers to offer their very best price to capture the entire market. However, some caveats are important. First, with a single seller who is supplying the product with very thin margins, the seller has only weak incentives to offer excellent service to distributors and pharmacies.[17] Second, there are some risks of shortages when there is only manufacturer, particularly if the manufacturer is operating with a very slim margin. It is possible to require suppliers to offer to cover the costs of addressing shortages, but doing so increases the costs of the tender.

14. *Lee JL-Y, Fischer M a, Shrank WH, Polinski JM, Choudhry NK. A systematic review of reference pricing: implications for US prescription drug spending. Am J Manag Care [Internet]. 2012;18(11):e429–37. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23198752*

15. *Grazyte I, Callejas J. Multimarket Contact and Collusion in the Ecuadorian Pharmaceutical Sector. MSc Thesis, Barcelona Grad Sch Econ. 2013;,.*

16. *Müller A. Special and differential treatment and other special measures for developing countries under the Agreement on Government Procurement: the current text. Arrowsmith and Anderson (2011) [Internet]. 2011 [cited 2015 Oct 13]; Available from: https://scholar.google.ca/*

17. *Hollis A, Grootendorst P. Tendering Generic Drugs: What are the risks? [Internet]. 2012. Available from: http://www.canadiangenerics.ca/en/advocacy/docs/10.24.12 Tendering Generic Drugs - What Are the Risks_FINAL.pdf*

Type 4 drugs – Non-competitive non-patented drugs

Sole-source non-patented drugs are typically a small component of pharmaceutical expenditures, but there are benefits from paying careful attention to these drugs. Some drugs for which all the relevant patents have expired are only produced by one or two manufacturers globally, and often only one manufacturer has received marketing approval in a country. This has led in recent years to two common problems. First, shortages have become much more frequent, since with only one manufacturer there is no reserve capacity in case of production problems. Second, in some situations the manufacturer decides to take advantage of limited or non-existent competition to increase prices. There have been numerous examples of this kind of behaviour in recent years.[18,19] This strategy has become common in Canada and the United States in recent years, spearheaded by Valeant Pharmaceuticals. One appropriate response to this is for the regulatory authority to be prepared to provide rapid approval for a competitive product. The manufacturer will then be less interested in trying to increase prices in the first place. Regulatory authorities can use some other tools to control abusive price increases for these unpatented drugs. One technique is to punish the firm by switching all possible sales away from that manufacturer, whether for that drug or for others also. A second is to design contracts with long-term price clauses that allow for modest, but not excessive, price increases.

Summary

This paper has presented a very brief description of some of the issues present in pharmaceutical markets, and some of the methods used to control price. What should be clear is that there is no "one-size-fits-all" solution: Ecuador needs to use a whole toolbox in order to address the different kinds of problems that pharmaceutical markets create. And this implies that it is important to invest seriously in developing and sustaining regulatory and price control capacity in Ecuador to enable the country to meet the needs of its citizens in a way that respects its international obligations and its own constitutional mandate to prioritize health.

Acknowledgement

I acknowledge the financial support of the European Research Council under the Seventh Framework Program of the European Union (FP / 2007-2013) / ERC Donation Agreement no. 339239.

18. *Roberts EA, Herder M, Hollis A. Fair pricing of "old" orphan drugs: considerations for Canada's orphan drug policy. Can Med Assoc J [Internet]. 2015 Feb 23 [cited 2015 Oct 14];187(6):422–5. Available from: http://www.cmaj.ca/content/early/2015/02/17/cmaj.140308.extract*

19. *McCarthy M. Drug's 5000% price rise puts spotlight on soaring US drug costs. BMJ [Internet]. 2015 Sep 24 [cited 2015 Sep 25];351:h5114. Available from: http://www.bmj.com/content/351/bmj.h5114.abstract*

CHAPTER IV:

Drugs production and their availability in the market

ESSENTIAL DRUGS:
A perspective from the importance of their availability in the market

María Belén Mena*

Background

Drugs are a social asset; its existence logic should be posed at first instance as a service tool in favor of health and should be prioritized regarding the market interests.[1]

There are around two million people in the world who have no access to basic medicines. In Latin America, there are countries where almost 50% of the population does not have access either[2]. It is estimated that 75% of worldwide population has access to only 25% of the global drugs production. Most of the health systems need policies that assure the appropriate access and use of drugs. These policies shall be designed to reach universal drugs access and, particularly, access to essential drugs.[3, 4] "Essential drugs are those that are used to satisfy health attention needs of most of the population. They shall be available at any moment, in proper amounts, in the pharmaceutical forms that are required, and at an accessible price for the people and the community"[5].

Constitutional framework

Among the functions that the State has in the drugs scope, the most important are to regulate the pharmaceutical sector, to inform the population, and to guarantee the appropriate financing and provision of the necessary drugs.[6]

In the health field, the right to an efficient and integrated health system, accessible for everybody, has been defined, which includes among others, permanent access and availability to essential drugs. During the last decades, in Latin America the design and execution of minimalist social policies has been balanced from a social perspective. In health policies, this model has led to the definition of a benefits basic basket and to the orientation of Government resources only towards disadvantaged groups; in answer to this model, different actors have sustained the speech of the right to health; however, this invocation has been difficult to replicate in the daily life, the elements to boost a debate about the elaboration of a health policy with a human rights approach have been scarce.[7, 8, 9]

Regarding the construction of a public policy for drugs, the different pharmaceutical policies models are constituted in relation to the health perspective of each country; in a general way, three approaches have been posed. The first one, based on drugs access, rational use and quality components, focuses the political action on the final stages of the drugs life cycle, the disease attention, and the access. The latter is referred to aspects related to the economic variables of supply, competition and prices formation processes. A second approach is the "drug chain approach", which organizes the strategies according to the value cycle: from the research and development, its manufacturing, distribution and commercialization, to the supply, use and final waste disposal. Thus,

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1 *Tognioni, G. (2.010). Looking for Remedy, AIS-Nicaragua.*

2. *Ugalde A. Homedes N. (2007). Latin America: Capital Accumulation, Health and the Role of International Institutions. Salud Colectiva. Vol. 3, n. 1.. Available at http://www.scielo.org.ar/scielo.php?script=s185182652007000100000033&ing=es&nrm>ISSN. 1851-8265. Recovered on July 6, 2015.*

3. *Tobar, F. (2008). Generic Drugs Economy in Latin America. Panamerican Journal of Public Health. 59-67.*

4. *Sagrera, J (2006). El Medicamento y su entorno. Universidad de Barcelona. Disponible en: http://www.elsevier.es/sites/default/files/elsevier/pdf/1/1v60n1384a13012856pdf001.pdf recuperado el 20 de Junio del 2015. pdf/1/1v60n1384a13012856pdf001.pdf recuperado el 20 de Junio del 2015.*

5. *World Health Organization. (2011). Political perspectives on WHO drugs. Geneva: World Health Organization.*

6. *Pending Dario 2012.*

7. *Ase I. Burjovich, J. (2009). The Strategy on Health Primary Attention, progressivity or degressivity in the right to health? Salud Colectiva, Lanús, v. 5, n. 1. Available at http://www.scielo.org.ar/scielo.php?script=sci_artex&pid=S1851-82652009000100000038&lng=es&nrm=iso>. Recovered on July 2, 2015.*

8. *Office of the High Commissioner for Human Rights. (2008). International Pact of Economic, Social and Cultural Rights. Available at: http://www.unhchr.ch/spanish/htm/menu3/b/a.cescr_sp.htm. Recovered on July 2, 2015.*

9. *Costales-M (2014). Neoliberal policies in Latin America and their impact on the health sector: Ecuador case", in Observatory of Latin American Economy, N. 197. Available at http://www.eumed.net/cursecon/ecolat/ec/2014/neoliberal policies.html. Recovered on July 2, 2015.*

the implementation of innovation and industrial development strategies becomes more important. A third approach is centered on the health concept and, by extension, on drugs as a fundamental human right.[10, 11]

In Ecuador, what elements will construct this public policy? The Ecuadorian Constitution, together with the National Plan for Good Living, address the rights to health and drugs from a more global and systemic perspective that the former magna cartas.[12] In this context, the Ecuadorian Constitution is aligned with the Universal Declaration of Human Rights (1948), the International Agreement of Economic, Social and Cultural Rights (1966) and the Ata Alma Declaration (1978).

The Constitution of the Republic of Ecuador of 2008 establishes in its Article 363, numeral 7, that "the State will be responsible for guaranteeing the availability and access to quality, safe and effective drugs, for regulating their commercialization, and for promoting national production and generic drugs use that respond to the epidemiology needs of the population. Concerning drugs access, the public health interests will prevail over the economic and commercial ones"; in spite of the political agreements expressed in the Constitution and the above mentioned agreements, the lack of access to the required drugs is a problem that persists in the country.[13] The road is clear, implementation actions, through a Drugs National policy that integrates the elements that the Constitution guarantees, is an indispensable step for the construction of a Health National System that assures what has been established in the Magna Carta.

Current situation

Chart 1. Essential drugs supplied to reduce the two main causes of maternal deaths in Ecuador

Drugs	Offer		$ Cost (Range)
	Generic	Commercial	
Oxytoxin Parenteral Liquid 10 U/ml	2	2	(0,28-0,78)
Misoprostol Oral solid 200 ug	0	3	(0,38-2,03)
Methylergonovine Parenteral Liquid 0.2 mg/ml	1	1	(0,69-0,78)
Magnesium Sulfaphate 20%	2	0	(0,28-0,39)
Methyldopa oral solid 250 mg **	0	0	-
Methyldopa Oral solid 500 mg	0	0	-
Nifedipine Oral solid 10 mg	3	1	(0,07-0,76)
Hydralazine Parenteral liquid 20 mg/ml*	0	0	-

*Drug of difficult access because requirements for its commercialization in Ecuador are not met
** Registered with supplier, without commercialization

Source: *Mena, et.al. 2015, FESGO.*

Drugs production in Ecuador has generally had an erratic development. Even though from the "economic" point of view the revenue has increased, the pharmaceutical industry has registered in Ecuador an excess of "banal" drugs such as anti-flu drugs, fixed doses combinations of analgesics, vitamins, immunological system enhancers, among others. In the National Agency for Regulation, Control and Health Surveillance (ARCSA, for its

10. *Pending WHO 2008.*

11. *Seuba X. (2011). International Referencing of Cases and Better Practices in Pharmaceutical Policies of Medical Supplies and Appliances. Social Protection Ministry.*

12. *Pending Hermida C, 2011*

13. *Asamblea Nacional. (2008). Constitución de la República del Ecuado. Registro Oficial 449 del 20 de octubre de 2008.*

Spanish acronym), 13,451 products have been registered and catalogued as drugs, 69.6% of which are branded drugs and 30.4% have been registered as generic drugs;[14] with such amount of drugs, it is easy to presume that drugs supply for pathological conditions with emphasis in public health is covered, which partially occurs.

A recent study that analyzed the presence of essential drugs vital for the handling of postpartum hemorrhage (PPH) and pregnancy hypertensive disorder, according to the national recommendations mentioned in the protocols and guidelines of clinical practice emitted by the Public Health Ministry (MSP), found that at least one third of them presented some sort of irregular condition for its availability.[15]

Another similar case is the offer of antidotes; poisonings are charts that demand an opportune and immediate attention. Currently, at least 38.4% of antidotes that are included in the Basic Drugs National Chart, 9th Edition, are not available.

Chart 2. Essential drugs supplied of the group of antidotes in the Basic Drugs National Chart (CNMB), 9th edition review.

Drug	Indication	Available	Offerer
Pralidoxime	Poisoning due to Organophospates	NO	-
Dimercaprol	Poisoning due to arsenic, gold, mercury, lead	NO	
Protamine	Neutrolization of heparin effects	YES	RIVERO (Ar)/EDUARDO NEIRA
Naloxone	Opioids overdose	YES	CARLOS J. FINLAY (Cu)/ NORVILLE
Acetylsysteine	Poisoning due to paracematol, paraquet, doxorubicine, arsenic, CO, cyanid, carbon tetrachloryde, chloroform, mercury, nephrotoxicity by cisplatin	YES*	ZAMBON (It)/ RS: FARMAYALA
Flumazenyl	Benzodiacepin overdose	YES	SANDERSON (Ch)/ MEDISUMI
			RICHET (Ar)/ DIEMPEC DIF (Ur)/MEDISUMI
Hydroxocobalamin	Cyanid toxicity	YES	GROSSAMAN (Mex)/ FARMA Ec GINSBERG (Ec)/RS: SIONPHARM
Fomepizole	Methanol, ethilene and other glycols toxicities	NO	
Deferasirox	Iron poisonings	YES	GINSBERG (Ec)/SIONPHARM
Dantrolene	Malignant hyperthermia	NO	-
Activated Carbon	Gastrointestinal decontamination	NO	-
Methadone	Opioids dependence	YES	BIOSANO (Ch)/ PHARMEDIC
Atropine	Poisoning due to organophosphates	YES	PISA (Mex)/COMERCIOSA BIOSANO (Ch)/PHARMEDIC PHARMATECT (Col)/GENETIA

Fuente: *Base de datos de medicamentos ARCSA. 2015*
Elaboración: *MB Mena.*

When market constraints, such as offer, limit the access, it is required that the sanitary authority regulates the market; when an essential drug is not available, it becomes a constitutional right and can affect the patients' lives.

14. *Ortiz-Prado E, Galarza C, Cornejo Leon F, Ponce J. (2014). Access to drugs and pharmeceutical market situation in Ecuador. Rev Panam Salud Pública. 36(1):57-62.*

15. *Mena MB, Barba K, Leon W, Rojas, G, Maldona X, Simbaña, Gomez L, Erazo J. (2015). Essential Drugs Offer for two main causes of maternal death in Ecuador. Gynecology Ecuadorian Magazine. 22(1): 54-56*

Challenges

The production approach of the national pharmaceutical industry shall be based on health needs of the population; a key point could be to regulate the sanitary registration system by prioritizing what adds clinical value instead of congesting the technicians with analyses of banal drugs that abound in the national pharmaceutical market. Every proposal to change the productive matrix in the drugs area shall be analyzed from different points of view. Starting from the installed capacity and expertise, the efforts to favor the assurance of the constitutional rights to receive safe and efficient quality drugs are, among others, some of the topics to be addressed.

If the national pharmaceutical industry fails to supply essential drugs, the Government shall boost other purchase mechanisms like parallel imports, international purchases, purchases through regional organisms that centralize the purchases, etc.

Natinal Drugs Production

Oswaldo Pablo de la Torre Neira*

Introduction

The actors of the pharmaceutical sector are many, however, it is necessary to make a basic but key distinction regarding the two types of drugs suppliers in the national territory: the first ones are the national manufacturers, and the second ones are importers (even though a same actor can supply under both mechanisms).

The first group, the producers, are those that can generate more qualified employment, incorporate an aggregate value, increase national and foreign investment, and drive many other of the objectives that help to achieve the so longed economic growth of the country; they are at the center of the industrial policy, and they compete and complement the second group, the importers, distributors and marketers.

We define the pharmaceutical industry as the sector dedicated to the research and preparation of medicinal chemical products starting from the active principle (Active Pharmaceutical Ingredient, API), a substance with pharmacological activity extracted from a living organism that, once chemically purified and/or modified, is combined with other excipients to constitute what is called a drug or medicine and is used for the prevention, treatment and/or cure of symptoms and conditions related to diseases.

This industry is subject to a great variety of laws and regulations regarding drugs patents, tests and commercialization,[1] which are necessary in order to guarantee the security of these human consumption products, which use brings direct repercussions on health.

Brief global context

The pharmaceutical industry has its worldwide and historical development focus in countries like Germany, Switzerland and the United States, where the companies that lead nowadays the international market are born;[2] an interesting behavior has been revealed with the incursion of this industry in the emergent markets of the BRICMT group (Brazil, Russia, India, China, Mexico and Turkey), where, thanks to the rising openness and business environment, a large growth option has been seen in this markets.

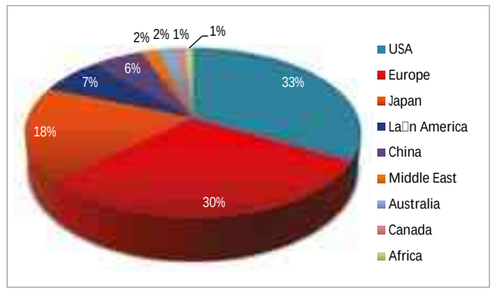
India and China play an important role in the manufacturing of API principally, followed by intermediate products for this industry,[3] and they produce more than 50% of the raw materials that are used by the pharmaceutical companies in the world.[4]

However, due to the explosive market growth, the regulations and control means are still lax; for this reason, certain European markets that imported their APIs from these countries have found the need to engage in extra efforts for their quality control, or, in some more extreme cases, to stop the trade of these APIs due to lack of guarantee.[5]

Countries with appropriate Government policies and critical production masses of APIs or finished products have increased their worldwide manufacturing participation and/or consumption: China, India, Italy, and Jordan in APIs; Brazil, Korea, Chile, Argentina, and Canada in finished products.

The worldwide market share is divided in the following way:

Illustration 1. International Market Share[4]



APIs manufacturing, and the pharmaceutical industry itself, have a significant importance at worldwide level due to the economic revenues this industry generates, and it is situated among the four most lucrative sectors within the world's economic scene.[6] The large pharmaceutical companies billed 610 thousand million dollars globally only in 2012.[7]

The pharmaceutical sector at the global level is a direct and indirect employment engine, as shown by the 520 thousand direct jobs generated by the 10 leading companies in the "Fortune" ranking in 2012.[8] Just like the number of employments, the yielding profits of this industry are very significant; only in 2012, the 10 first companies of the industry produced US$ 49,248.6 million in profits.

Situation in Ecuador

No active principles are produced in Ecuador, and, by evaluating the synthesis potential of pharmaceutical APIs, it was determined that there are high entrance barriers to the market of fine chemicals for APIs, like, for example, regulatory approval, high initial investment, and the need of an integrated supply chain; thus, the country would not have competitive advantages in the APIs synthesis market. With high scale production and incentives, the country could produce at a 15% lower cost compared to the USA; however, China would continue to produce a 15-20% cheaper. The social impact of APIs synthesis would be low; the impact on the payment balance is 60% of the income and, for each US$ 1 million in revenues, 1.5 employments would be generated, and an investment of US$ 3 million would be necessary. [9]

Therefore, national producers basically import APIs for the highly automated secondary manufacturing of dosed drugs, like tablets, capsules or envelopes for oral administration,

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1. *Available at: http://www.imbiomed.com.mxt/1/1/articles.php/method=showdetail&id_article=59568&id_section237&idejemplar=6023&_revista=144*

2. *Available at: http// www.pharmaphorum.com/2010/09/17/a-history-of-the-pharmaceutical-industry/*

3. *Available at: http://ecolin.es/finanzas-el-abismo-entre-europa-y-el-resto-del-mundo-es-cada-vez-mayor-con-respecto-a-los-riesgos-sectoriales/*

4. *Deltos Consult, February 2013, Proposal for a National Pharmaceutical Policy [Power Points slides].*

5. *Available at: http:// www.fernandotazon.com.es/2010/09/01/apis-de-india-y-de-china/*

6. *Available at: http:// salutamseny.wordpress.com/avier-padilla-la-industria-farmaceutica-y-el-mundo-global/*

7. *Available at: http:// currentpartnering.com/insight/top-50-pharma/*

8. *Available at: http://money.com.com/magazine/fortune/fortune500/2012/industries/21/*

9. *BAIN & Company, "Diagnosis of productive chains", 2015.*

injection solutions, ovules and suppositories, with a notable total increase of 62.81% in the sales of the denominated private sector (private pharmacies) from 2004 to 2010.

Total drugs consumption, both in the private and public sectors in 2013, reached the amount of USD 1,400 million, of which US$ 400 million correspond to national production, i.e., barely 28.57%, while the countries of the region produce at least 60% of the country's internal consumption. Of this 2013 consumption, USD 1,000 million corresponded to the private market and USD 400 million to public purchases. In 2014, the pharmaceutical market closed with a total of US$ 1,500 million, with a public purchases share of USD 400 million. The drug consumption per capita in Ecuador (USD 90 per person every year) is the same as the one in Colombia and higher from the one in Peru (USD 50 per person every year).

Chart 1. Sales growth of the private pharmaceutical sector in Ecuador[10]

AÑO	2004	2005	2006	2007	2008	2009	2010
Sales (private) MM	475	500	550	600	700	800	860
% increase		5,26%	10,00%	9,09%	16,67%	14,29%	7,50%

US$ 1,030 million of the total consumption of USD 1,500 million is imported, 69%, thus, the national pharmaceutical market share has a marked trend towards consumption of imported drugs due to the low supply of the national industry, although the used capacity is in average of approximately 20-28% of the installed capacity, which shows a great manufacturing potential to satisfy the national market.[11]

Based on these consumption figures: market growth, the underutilized installed capacity, and the fact that Ecuador imports more from neighbor countries with no comparative advantages, the potential for imports substitution for local formulation is of up to USD 1,050 million until 2025, considering the possibility of closing the gap with Colombia and Argentina. In 2013, barely USD 30 million was exported, and the exports potential could reach USD 250 million until 2025 if the gap with Argentina would be closed.

If Ecuador manages to substitute some additional USD 1,300 million annually, the socio-economic impact would be high; in the commercial balance it would be of USD 700 million per year, and 3,300 jobs would be generated; therefore, it is a priority to promote drugs formulation to reach the countries of the region that produce at least 60% of the consumption internally; additionally, the countries of the region export up to 15%, and Ecuador only 2%.

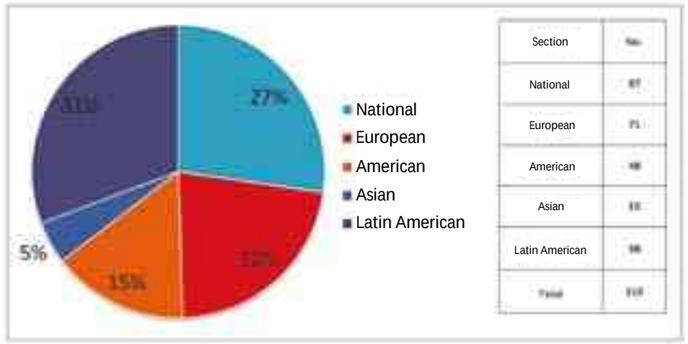
Since pharmaceutical products that are consumed in Ecuador are mostly imported, investments and capitals in the sector have great foreign influence, which reduces to 87 the enterprises of national origin, from 319 companies of the sector who participate in the market.

In our country, the total production cost is 15% higher than in Colombia; however, with a high production scale and incentives, it could reduce its production costs in 25%, and achieve competitiveness in the local market. With the right scale conditions and incentives, we could have competitive production costs (15% lower than Colombia in the internal market and similar costs for exports).

10. *http:// espae.espol.edu.ec/images/documentos/publicaciones/publicacionesmedio/Eye_Industria Farmaceutica 2011.pdf.International Marketing Services Antonio Quezada Pavon, SIB-Mipro Elaboration.*

11. *Institutional Memory of Industrial Chemical, SIB-Mipro, 2014.*

Illustration 2. Origin of the sector actors that operate in Ecuador[4]



Regarding occupation, in 2012, the sector employed in a direct way almost 5 thousand people and generated a profit of USD 41 million. Also, distribution and trade of drugs in the country during 2012 generated USD 80 million in profits and employed in a direct way more than 9 thousand people.[12]

Due to the demand of new products in order to satisfy the health needs of the worldwide population and counteract the health conditions that affect the population, research and development of innovative and new active principles that are effective, efficient and safe is a key element for the survival of the pharmaceutical industry. The Ecuadorian Government, through its different entities that participate in the pharmaceutical sector, is a primary protagonist in the development and control of the industry, in addition to providing the conditions and regulations for drugs commercialization in the country. Therefore, the proper gear of all the official government entities depends on a large degree on the performance of the pharmaceutical sector in the country; the most significant are:

Chart 3. Roles of the main actors in the Ecuadorian pharmaceutical sector[13]

Actor	Rol
Arcsa	Sanitary Registrations (Inscription, renewal, certification)
Conasa, MSP, IESS, IEPI, Senescyt, Solca	Test and publish agreed products, basic drugs chart
Enfarma, MSP, Senplades, Presidency of the Republic	Business policies and resolutions
Public and Private Health Entities, RIPS, Society	Satisfied users
National Government	Definition of national policy
IEPI	Authorization and registration of mandatory patents and licenses
MIPRO, Producers and their associations	Competitiveness, manufacturing and consolidation of the industry
MSP, MIPRO	Regulatory and executor
Senae, SRI	Fiscal control and taxes
SERCOP	Drugs purchase processes - SCIM

12. *Available at : http://www.ekosnegocios.com/empresas/RankingEcuador.aspx#*

13. *Available at: http.// www.enfarma.gob.ec/admcontenidos/docs_publicacion/enfarma_71_LINEAS%20ESTRATEGICAS%20ENFARMA%20EP.pdf. Updated by Mipro, alphabetical order.*

This inter-institutional articulation is being strongly promoted and the national government has simultaneously invited the industry to meet the challenges that the market and the consumer demand, to get rid of the dependence on low innovation and drug commercialization to venture in the proactivity and development of this industry; for this purpose, under the legal framework promoted by the National Public Procurement System in force since 2008, the reverse auction mechanism has been established, through which suppliers of equivalent goods and services bid in a public act or by electronic means through the public purchases Website, where the national industry has advantages to become supplier of the National Health System, for this reason, it is necessary to improve the drugs public purchase process through:

- Definition of clear quality criteria and delivery times as part of a long term strategy for the assurance of quality in the industry.
- Appropriate definition of “local production” and national aggregated value.
- Definition of clear criteria of local and foreign production prioritization.
- Establishment of collaboration processes with the private sector in order to increase the success of the public bidding.

We articulate the public purchases of the health sector, to increase the effectiveness in its acquisition and timely supply processes for the health centers of the country.

Photographic archive: Public Health Ministry of Ecuador.

CHAPTER V:

2015 Corporate Reverse Drugs Bidding

Corporate Reverse Drugs Bidding and the Right to Health

Santiago Vásquez*

Introduction

Public purchases constitute a fundamental element in the Ecuadorian economy because they add up to USD 10 thousand million[i] in transactions, which represented on average 10.8% of the country's Gross Domestic Product (GDP) and around 34% of the National General Budget (GSB) during the period 2011-2014.[1]

However, public purchase is not only important at the economic level, but it also represents an instrument through which the Ecuadorian Government acquires goods and services that allow it to guarantee the rights embodied in the Constitution of Montecristi,[2] one of these rights is, undoubtedly, the right to health. Under this perspective, the constitutional mandate determines that the Government will be responsible for guaranteeing the availability and access to good quality, safe and effective drugs for the population, and mentions that, regarding the access to drugs, the public health interests will prevail over the economic and commercial ones.[2]

From this context, during the last years the Ecuadorian Government has carried out many efforts to guarantee this access and, based on this experience, this article analyzes the drugs public purchase and the benefits that the 2015 Corporate Reverse Drugs Bidding generates for the country.

Public purchase of drugs in Ecuador

Public purchase planning allows the Government to carry out programmed purchase processes of goods and services in the medium and long term. Such processes are developed through the demand consolidation of public institutions for a determined good or service, which allows the Government to have more beneficial negotiation margins and generate fiscal savings in a significant way.[3] These savings represent a set of opportunities to allocate resources to the provision of other social services, and to the execution of new public investment.

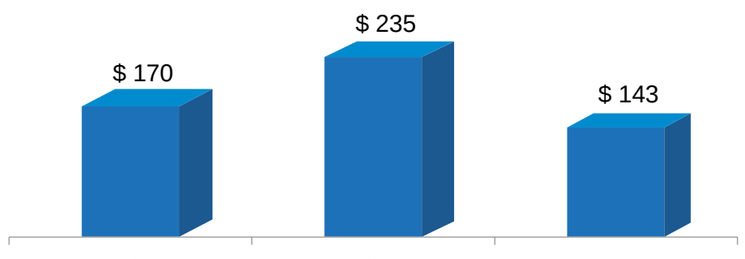
On the other hand, programmed public purchase gives the State's suppliers certainty scenarios that enable them to project their production based on the estimated governmental demand.

In drugs matter, Ecuador is a pioneer in the region in the implementation of this type of public purchase processes. This is because the first Corporate Reverse Drugs Bidding[ii] was carried out in 2011, procedure in which the drugs needs estimate in the health units belonging to the Integral Public Health Network (RPIS)[iii] was consolidated, and Framework Agreements were executed for a period of two years with the awarded public suppliers.

Additionally, this procedure had the purpose of establishing the first Drugs e-Inventory, which enables the health units of RPIS to purchase drugs through the Electronic Catalogue which is administrated by SERCOP.

Such has been the importance of the Drugs e-Inventory that of the total amount of public purchases of drugs during the period 2012-2014[iv] through the Government Procurement Official System (SOCE, for its Spanish acronym)[4], 86% was purchased through the use of this e-Inventory and the remaining 14% through Institutional Biddings.

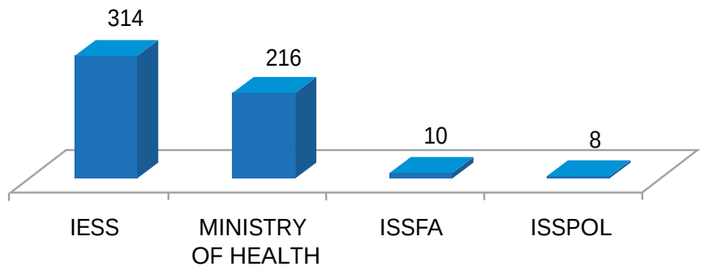
Chart 1: Drugs public purchase through the Drugs e-Inventory (USD millions)



Source: *Official System for National Procurement- SOCE*
Elaboration: *Direction of Studies, SERCOP*

From this 86%, which represents USD 547 million, the entities that generated more purchases during the aforementioned period were the Ecuadorian Social Security Institute and the Public Health Ministry, with 57% and 39% of the mentioned amount, respectively.

Chart 2: Public purchase of drugs through the Drugs e-Inventory by entities. Period 2012-2014 (USD millions)



Source: *Official System for National Procurement- SOCE*
Elaboration: *Direction of Studies, SERCOP*

1. *National Public Procurement Service (SERCOP), 2015. Executive Bulletin, September 2015.*

2. *Constituent Assembly 2008. Constitution of the Republic of Ecuador. Official Register 449 from October 20, 2008.*

3. *Arauz A., 2015. Productive matrix change in the new Ecuadorian economy.*

i. *During the period 2011-2014 the country has transacted through public purchases around USD 39 thousand million (SERCOP, 2015).*

ii. *The Corporate Reverse Drugs Bidding process is leveraged in what is stipulated in Chapter VII, Section II of the General Regulation of the Organic Law of the National Public Procurement System.*

iii. *The Public Integral Health Network is made up by the Public Health Ministry (MSP), the Social Security Ecuadorian Institute (IESS), the Army Social Security Institute (ISSFA) and the National Police Social Security Institute (ISSPOL).*

iv. *During the period 2012-2014, drugs public purchases through the Official Public Procurement System represented an amount of USD 639 million, i.e. an average of USD 213 million per year.*

4. *General Regulation of the Organic Law of the National Public Procurement System. Executive Decree 1700. Official Register Supplement No. 588 of May 12, 2009.*

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On the other hand, if the purchases of the Drugs e-Inventory are analyzed by supplier, the amounts show that six suppliers concentrate 53% of the purchases made during the period of 2012-2014 through this mechanism. Besides, from these five suppliers, one agglomerates 20.3% of the purchases, which evidently reflects the need for establishing measures to avoid and regulate this type of concentrations and enable a greater democratization of the public purchase of drugs for the next procedures that will be carried out.

2015 Corporate Reverse Drugs Bidding

The 2015 Corporate Reverse Drugs Bidding (SICM) is implemented with the principle that health and its attention are not only merchandise, but also a fundamental human right that must be guaranteed by the Government. Under this precept, SERCOP and RPIS have taken many actions for this new corporate auction procedure in order to guarantee total transparency and maximization of benefits for the country.

Totally electronic and transparent process

The combat against corruption in public procurement in the XXI century is carried out through the elimination of physical processes.

Therefore, the 2015 Corporate Reverse Drugs Bidding procedure is sustained on a zero-paper policy, which was made possible through the automation of data entry, which is carried out in an electronic way and through the inter-operability of the information systems. This allows guaranteeing the process' transparency and, above all, it avoids documents manipulation.

Greater competition

Establishing entrance barriers, like requesting enabling documents prior to the participation in a process, limits supplier participation and causes the market to be restricted to those companies that have been previously commercializing their products in the country.

The impact of these barriers is reflected in drug prices because, with fewer competitors, the possibility of obtaining savings in the drugs purchase is lower. Besides, it is evident in the current concentration of the purchases carried out through the Drugs e-Inventory.

For that reason, in the 2015 Corporate Reverse Drugs Bidding, the verification of enabling information will be carried out prior to the awarding of a contractual procedure. Namely, entrance barriers are no longer established for those suppliers that have not yet commercialized their products in the Ecuadorian market, this is because the verification of enabling information will be performed only to the supplier who wins the bid or the successful negotiation, prior to the awarding of the tender.

In this manner, it is assured that there is a greater number of companies participating in the auction, a scenario of greater competition among suppliers is established, and it is guaranteed that the awarded suppliers are those who have all the documentation in order.

Incentives for the national pharmaceutical industry

The 2011 Corporate Reverse Drugs Bidding contemplated an exclusive round for national suppliers; however, within this exclusive round, no difference was made between those suppliers who generate national aggregated value to their products and the suppliers who only commercialize the drug in the country. This provoked that around 60% of the awarded products to "national" suppliers had foreign origin.

Considering this scenario, for the 2015 Corporate Reverse Drugs Bidding, an exclusive round will not be established as an incentive mechanism because, as it was evidenced, it was not the most suitable to boost the national pharmaceutical industry. For this new procedure, an incentive policy was crafted to reward those suppliers who produce drugs locally and generate a determined national aggregated value in their products. A preference policy was designed through preference margins that encourage the national pharmaceutical industry, and allows it to compete in a better way with companies from the international pharmaceutical market.

Establishing referential budgets

A key element in the contracting procedures is the definition of a referential budget; this is because the quality of the market studies that are carried out to define this budget determines the public spending optimization.

For this reason, for the 2015 Corporate Reverse Drugs Bidding, the referential budgets were structured based on price studies that analyze both national and international sources, which allows to technically understand these budgets based on a regional compared prices analysis.

In this way, a greater participation of the suppliers is assured and, above all, the public spending quality is guaranteed.

Drugs sanitary control mechanism

The 2015 Corporate Reverse Drugs Bidding contemplates the importance of sanitary control mechanisms executed by the national sanitary authority, through the National Agency for Regulation, Control and Health Surveillance (ARCSA), for those drugs object of this procedure.

Control prior to the awarding is carried out at the moment of the issuance of the sanitary certifications, where it is verified that all products' information complies with the technical and sanitary conditions established to guarantee quality, safety and efficacy of the drugs that will be purchased by the health units of the Public Integral Health Network.

Additionally, during the Framework Agreements, ARCSA will be in charge of developing subsequent sanitary and pharmacovigilance controls that assure that the drugs dispensed in the health units of RPIS are in optimal conditions for the consumption of the population, and, in this way, guarantee the fulfillment of the constitutional mandate of the right to health and to the timely access to drugs.

Spaces for dialogue and participative control

The democratization of public purchase constitutes an imperative for the Government in each contractual procedure, and especially in those procedures with national significance like the 2015 Corporate Reverse Drugs Bidding. Therefore, for the development of the 2015 SICM, all the institutional capacities of SERCOP have been deployed with the purpose of generating spaces for a participative dialogue with all the public and private actors, scholars and citizens in general that are linked to the pharmaceutical sector and to the access to drugs, which have allowed citizens to form part of the contracting process and assume their role as key actors in the social control of public performances/interventions.

One of these spaces constitutes the Drugs Advisory Councils, where drugs suppliers, citizens and public actors interact. So far, three of these spaces have taken place in the main cities of the country (Quito, Cuenca and Guayaquil) with a participation of approximately 400 people.

On the other hand, two citizen discussion groups (Riobamba and Portoviejo) have been conducted, in which citizenship was informed about the process of the 2015 Corporate Reverse Drugs Bidding.

Additionally, with the support of the Market Power Control Superintendence, socialization workshops have been carried out (Ibarra, Esmeraldas, Cuenca, Guayaquil and Quito) with the Health and Drugs Observatory Network at national level, a space where teachers and students of the different universities and polytechnic schools of the country converge. Finally, the International Seminar “Public Access to Quality Drugs” took place with the participation of national and international experts, scholars, and public and private officers who converged from different perspectives to face the problems that limit the access to drugs in the country and the world.

These spaces where the procedure of the 2015 Corporate Reverse Drugs Bidding has been socialized, debated and democratized, and where valuable contributions have been received, have allowed to engage the academy, the public and private sector, and the citizens as key actors to guarantee the transparency and social control of this process of vital importance for the country.

Conclusion

Undoubtedly, public purchase constitutes an instrument that allows the assurance of effective access of the population to superior goods oriented to the achievement of good living. Under this precept, the 2015 SICM represents one strong mechanism that has the Ecuadorian Government to guarantee access to the population to a public and social good and service such as medicine. Therefore, it is of extreme importance that SERCOP guarantees that the process is carried out with total transparency and that, during its development, the public health interests prevail over the economic and commercial ones; therefore, we invite all the citizens to join this great effort and to conduct the social control that a process like this deserves.

Prevention and mitigation to the observations made in the special examination of the General State Comptrollership to the 2011 Corporate Reverse Drugs Bidding

Camila Restrepo Rojas* y Karla Ulloa**

In the year 2011, the National Public Procurement Service (SERCOP), formerly denominated National Public Procurement Institute (INCOP, Spanish acronym), published the first procedure of Corporate Reverse Drugs Bidding with the purpose of creating the first Drugs e-Inventory to satisfy the drugs needs of the Public Integral Health Network (RPIS), which is made up with the health units of the Public Health Ministry (MSP), the Armed Forces Social Security Institute (ISSFA), the Ecuadorian Social Security Institute (IESS), and the National Police Social Security Institute (ISSPOL).

Regarding this procurement procedure, the General State Comptrollership (CGE, Spanish acronym), as the technical organism in charge of controlling the use of Government resources, and the achievement of the objectives of public institutions and legal private entities that have public resources, as specified in article 211 of the Constitution of the Republic of Ecuador, and making use of its constitutional and legal powers, performed a special examination to this procedure with the purpose of verifying and evaluating the aspects relative to the financial, administrative, operative and environmental management after its execution; techniques and auditing procedures of the specified discipline were applied according to the examination matter; all this information is contained in an extensive report with its corresponding comments, conclusions and recommendations (Art. 19 of the Organic Law of the General State Comptrollership – LOCGE, for its Spanish acronym).

In this sense, CGE submitted to SERCOP the report No. DA4-0019-2012, which was approved on February 28, 2013, as a result of the special examination of the programming, pre-contractual and contractual processes for the drugs purchase for the Public Integral Health Network; it was carried out by the denominated INCOP, through the 2011 Corporate Reverse Drugs Bidding, in which many very important observations were pointed out that evidenced deficiencies in the organization and execution of the procedure.

Therefore, the National Public Procurement Service, because of the upcoming publication of the Corporate Reverse Drugs Bidding procedure for the year 2015 – SICM 2015 – has planned many preparation and preventive measures with the objective of mitigating and eliminating the error margins produced in the 2011 SICM.

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In this sense, prior to the execution of the 2015 SICM, action, prevention and contingency plans have been performed in order to mitigate the risks observed in the 2011 SIMC by the CGE, which are detailed as follows:

1. **The deficient filing system of the Reverse Auction files and the lack of collaboration for the timely submission of the information obstructed the control action carried out by CGE**

The first observation was that for the special examination implementation, CGE requested SERCOP the necessary information for the elaboration of the report; a punctual case were the resolutions concerning the conformation of working groups, which evidenced a lack of an opportune and agile statement, especially regarding the participants' identification data during the development of the auction, elementary information that the institution should have had in an ordered and integral way to identify and guarantee that the different stages were conducted by suitable officers, responsible for the actions taken in such jobs.

It should be emphasized that the free access to the information generated in public entities that manage State funds is considered a constitutional right that cannot and should not be violated (Art. 18 CRE), this is why SERCOP, with the purpose of preventing this deficiency presented in 2011, foresees for the 2015 SICM the implementation of a policy, through the expedition of an Internal Resolution, that rules the register, conservation and custody administration of the complete information of each one of the procedures to be carried out in the 2015 SICM, as well as the realization of an inventory which will contain indexes and references that speed up their search.

The regulations to be issued in the mentioned Internal Resolution will be part of the institutional information tool so the registration and custody of the documents of each procedure has a digital backup that cannot be susceptible to modifications or alterations, which will give transparency to the procedure, and it will also omit human errors during the files manipulation, thus guaranteeing the legitimacy principle of the processes.

These measures were also taken with the purpose of complying with what it is established in the Organic Law of the National Public Procurement System (LOSNCP), which provides that Contracting Entities shall create and keep a file for each procurement with the documents relating to the most significant facts and aspects of their preparation, selection, procurement and execution stages, as well as of the post contracting phase (Art. 36 LOSNCP).

Namely, the files that are generated due to the 2015 SICM in all its phases, in order to be considered complete, shall contain all the documentation established in the Law and other regulations, and if annexes shall exist, or other information relative to the procedure, it should also be added, except in case of the declaration of a void process or procedure cancellation, where the duly motivated corresponding resolution must be included, as well as the complete documentation up to the phase where it was declared void or cancelled.

Simultaneously, SERCOP will maintain a data base, as an Electronic Public Record, of the processed contracts with technical and legal provisions for its access at any moment, according to what is stated in the LOSNCP (Art. 97), with the purpose of making the procedures transparent and public, abiding the publicity principle.

It is important to emphasize that public information is a right of the people guaranteed by the Government and consecrated in the Constitution; therefore, all the information that emanates from or is in the power of the institutions, organisms, entities or legal persons of public right shall be considered as public, except for those exceptions that are foreseen by Law (Art. 1 Organic Law of Transparency and Access to Public Information – LOTAIP).

Regarding the lack of collaboration for the documentation submission for the 2011 SICM, the Executive Director of SERCOP, in order to mitigate this preoccupying situation, has issued a Circular with a mandatory character for all the public servants that conform the institution, which disposes mainly the opportune and upright provision of the documentation requested by the Control Organ for the efficient development of the activities of the corresponding Government auditing.

Additionally, a proper coordination shall exist between State entities, as it is a responsibility of the control organisms of the Government to conduct subsequent controls to the procurement procedures performed by the contracting entities within the scope of its competences (Art. 15 LOSNCP).

2. **There was no organization, planning or programming in the execution of the Corporate Reverse Drugs Bidding**

The SICM that the former INCOP executed in 2011 did not have enough programming or planning in order to evidence the systematic development of the procedure application, to determine and document the means to be used, to list the activities to be carried out, to technically define the determination of the referential budget, to establish the probable risks, to have an activities schedule, to assign responsibilities based on functions, among others that guarantee the achievement of the bidding objective under efficiency, effectivity and economy conditions, as well as to avoid process suspensions.

Regarding this matter, SERCOP, with anticipation to the procedure execution of the 2015 SICM, has conceived a continuous coordination with all the participating public entities with the purpose of planning the 2015 SICM, especially regarding execution times, goals, objectives, activities to be carried out, accurate and opportune definition of the requirements and needs of the health operative units, probable risks, referential budgets of the procedures, and the establishment of an exhaustive market study. For this purpose, it has designed a master plan called: "EXECUTION STRATEGIC PLAN" with the objective of implementing the guidelines and technical and operative parameters with the following main goals: total opening for national and foreign participation, as well as the automation of most of the phases of public procurement; the stages structure of the procedure to energize the procurement; and, the adhesion of specifications to guarantee the fulfillment.

An effective and permanent subjection of public procurement to the planning and budgeting systems of the Central Government will also be kept, as determined by the LOSNCP, and, for this reason, for the drugs purchase through the 2015 SICM, a strict planning between health institutions and SERCOP has been established,

thus, contributing to the achievement of the national and institutional objectives and needs.

Likewise, for the procurement procedure for drugs acquisition through the 2015 SICM, SERCOP has elaborated an **"INSTRUCTIVE FOR THE REGULATION OF THE CORPORATE REVERSE DRUGS BIDDING AND DRUGS PURCHASE THROUGH THE DRUGS e-INVENTORY"**, which regulates each one of the phases and stages of the auction with the purpose of homologating the procedure from the programming to the results, as well as the responsibility levels of the officers who will intervene in it and the responsibilities in which they are engaged due to the actions or omissions not fully adherent to the in-force legal regulation, and the periodical evaluations of the process to guarantee that the performed efforts are directed towards the fulfillment of the goals and objectives posed for the 2015 SICM.

On the other hand, prior to the 2015 SICM, Advisory Councils have been carried out, becoming very important socialization spaces for this great project, with Government suppliers, as well as with all the actors of RPIS, the observatories and citizens in general, thus, fulfilling what is provided in the Constitution of the Republic of Ecuador regarding the participation based on democratic principles.

For the execution of this participation, as established by the Constitution of the Republic of Ecuador, public audiences, oversights, assemblies, popular councils, advisory councils, observatories, and other instances promoted by citizens can be organized (Art. 100 CRE).

This guarantee established in the constitutional norm fulfills the double function of giving transparency and legitimizing the procurement process of the 2015 SICM, besides transforming us all into its actors, such as public sector entities, pharmaceutical companies, observers and citizens, and become "CO-RESPONSIBLE" for the execution of this procedure.

3. Inconsistencies in the procedures specifications and lack of consistency and fair treatment regarding the criteria applied by the members of the technical commission

In the 2011 SICM, the former INCOP presented deficiencies in the criteria unification by the officers who carried out the preparatory phase of the procedures and participated in it, especially in the tender specifications drafting; inconsistencies were also found in the criteria emitted by the members that conformed the Technical Commission, especially in the validation errors, offer evaluations, and proposals awarding phases. Namely, in a certain way the principles that rule the National Public Procurement System were infringed: fair treatment, equity and concurrence.

SERCOP, in answer to this, has foreseen for the 2015 SICM a new methodology regarding the procedure, it will be approved only after the procedure specifications have been agreed with all the actors of this procedure and after they contain the conditions and parameters required by them; they must also comply with the criteria and legal provisions issued by the Health National Council –CONASA, for its Spanish acronym-, the National Agency for Regulation, Control and Health Surveillance -ARCSA-, the National Council for the Fixing and Review of Human

Use Drug Prices ,and other entities related to the drugs purchase for human use and consumption; only under these conditions they will be approved for its later socialization and publication.

Besides, it is important to mention that the new methodology of the 2015 SICM includes the possibility of allowing possible bidders into the bidding session, and only the one that bids the lowest price, after **"PRESENTING ALL AND EACH ONE OF THE ENABLING DOCUMENTS DETERMINED IN THE LEGAL FRAMEWORK ESTABLISHED FOR THE DRUGS PURCHASE"**, will be awarded.

Additionally, this methodology allows SERCOP to define referential prices, tender specifications, activities schedule, legal, economic and financial requirements beforehand, in order for the process to have a systematic development for the publication, awarding, execution of general and framework agreements and timely supply of drugs to the health units and to determine the contractors non-compliances in such a way that together they benefit the health service users by reducing administrative costs, both for the engaged public entities and for the participant bidders.

Regarding the deficiency presented in the 2011 SICM, with respect to the criteria unanimity of the members and officers, SERCOP, for the 2015 SICM, has foreseen within its methodology to request the legal statement of the Legal Advisory Coordination in those cases where different criteria among the members of the Technical Commission appear for the qualification or disqualification of one or many offers, which will be featured in the awarding decree to demonstrate the legality, fair and equal treatment to all the bidders in the proceedings.

It is important to consider that the Technical Commission designated for the 2015 SICM, according to Article 78 of the General Regulation of the Organic Law of the National Public Procurement System (RGLOSNCP, for its Spanish acronym), will encompass a delegate of the Executive Director of SERCOP, who will be the chairman and will have a diriment vote; a technical delegate of the Public Health Ministry, in his/her capacity of maximum authority of the National Health System; a technical delegate of the General Director of IESS; a technical delegate of the General Director of ISSFA, and a general technical delegate of ISSPOL; additionally, the Legal Director of SERCOP, or his/her delegate, or the delegate of the requiring area, or his/her delegate, will act as the Secretary of the Technical Commission; and, a professional related to the contracting object designated by the maximum authority, or his/her delegate.

The reports of the Technical Commission will be addressed to the maximum authority or his/her delegate, and they will include the corresponding analysis of the process, the motivation, justification and recommendation for awarding or for declaration of void contracting process.

4. Referential budget established for the Corporate Reverse Bidding without a wide market analysis

In the 2011 SICM, the system that was applied to establish the budget and the drugs referential price was deficient; the lack of a wide market study which indicated the actual prices of the drugs to be purchased was also revealed; this

provoked that the referential prices of many drugs were established much higher than the actual market prices, and, consequently, the awarding of contracts were made with higher prices than those negotiated by the health operating units with the same supplier.

Currently, SERCOP, close to deploying the 2015 SICM, has performed a detailed market analysis and study with the objective of fixing a referential budget for each of the procedures by means of clear and real market figures. Through this study, SERCOP collected significant information that will be used to deal with market conditions, decisions making, and even to anticipate possible eventualities. The ultimate goal has been to obtain an exhaustive knowledge of the sector interlocutors, together with all the information regarding prices policy and commercialization.

Source	Variable	Description
MSP	REF STFP Price	They are obtained from the list that is recommended by STFP as referential for the prices to be used in the 2015 SICM
DIFFERENT SOURCES	Gob. Mediana International with PPP Multiplication	*Sample of the calculation carried out in the bases of the referential prices multiplied by the PPP factor*
SERCOP	Awarded ones in 2011 SICM	They are the prices awarded in the 2011 SICM
MSP	CNFRP in force Unit Ceiling	Public Sales Price PSP is used at public entities (15% lower than PSF) per unit
MSP	Pharmacies Historical 2013	Is the unitary price to pharmacy (obtained from the ratio between sales price and volume)
SERCOP	Adjudicated Historical data SOCE	Minimum price awarded for drugs in processes outside the drugs e-Inventory catalogue
MSP	Minimum Historical Price STFP Referential 2012-2014	It was obtained from the data bases submitted by MSP through letter number #.
CGE	COMPTROLLERSHIP ANNEX	Price was observed by CGE, issued in Report DA4.0019-2012
DIFFERENT SOURCES	Ceiling Minimum International Consumer	Minimum Sales Price to consumer found in International Sources

After this study, SERCOP performed several workshops where it was deliberated and a consensus was reached with representatives of the contracting entities about the methodology to be applied in the referential budget determination that will be used in this contracting procedures application, in which it was considered: historical purchase prices used by the entities that conform the Health System at national level (Public Purchases Web Site under different procedures from SICM), those fixed by the competent authority, namely those established by the Technical Secretary for Prices Fixing STFP, the ones that are valid in the market, reports of specialized magazines at national and international level and the one negotiated by international organisms with the purpose of using this instrument, referential prices ceilings are adjusted to the conditions and possibilities of the Government budget.

Also, SERCOP has comply with the legal regulation, since contracting entities according to what is provided in the Article 23 of the LOSNCP, shall carry out before the start of pre-contractual procedure, studies and complete, definite and updated designs, as well as plans and calculations and technical specifications shall be duly approved by the corresponding instances linked to the Contracting Annual Plan of the entity.

These studies and designs include mandatorily the methodology and determined parameters which have been defined previously to its publication as a necessary condition to start the contractual process. In this sense, SERCOP has carried out absolutely all the necessary studies to establish the referential budgets in a fair, balanced and reasonable way.

5. The drugs delivery schedule required by the contracting entities was not applied and bided in its totality at the beginning, nor were executed the framework agreements.

In the 2011 SICM, from the total of 524 required and published items to be bided, only 336 processes were awarded; however, many drugs could not be purchased because INCOP, currently SERCOP, neither consolidated the total demand of these entities nor properly programmed the process application of the 2011 SICM.

This caused that the totality of drugs forecasted by the IESS, ISSFA, ISSPO, MSP were not purchased through the 2011 SICM, situation that generated a shortage in the health units.

Therefore SERCOP, in the interest of positively accept this observation, for the 2015 SICM has created mechanisms that allow to speed up the awarding process, the agreement execution and the inclusion of drugs to the Drugs Electronic Inventory in order to enable the contracting entities to carry out their purchases.

For that purpose an action plan denominated “CONTINGENCY PLAN 2015 SICM ZERO VOIDS” with the aim of identifying alternatives and action schedules to enable an agile and efficient way to act in case one procedure by the grounds established in the LOSNCP and its General Regulation is declared void or cancelled.

This plan has the main objective that the cancelled or declared void procedures by grounds of the Law should be restarted timely until awarding is achieved and thus reach the goal and purchase the drugs that have been requested by the health units and avoid its shortage due to deficiencies in the 2015 SICM. This plan has emerged from the statistics study and historical data of previous drugs corporate biddings and it has been analyzed all the possible causes for which contracting procedures could be cancelled or declared void.

It is a legal provision that once the procedure is declared void, the maximum authority or his delegate can dispose its filing or its immediate reopening; likewise the LOSNCP mentions that the procedure can be declared partially void when the contracting process has been convoked with the possibility of partial adjudications or by items. The void declaration or cancellation will not give place to any compensation or indemnification to the bidders.

Both the Instructions and Tender Specifications elaborated for the deployment of the 2015 SICM have the objective to minimize the amount of void procedures, by requiring the bidders that in any possible cases they present their initial economic offer and participate in the process of electronic bid, under penalty of being sanctioned if they do not do it, even foreseeing what is pointed out in Article 45 penultimate subsection of RLOSNCP which provides that the initial economic offer obliges the bidder to fulfill the offered technical and economic conditions in case of being awarded.

Additionally, progress reports shall be displayed of the procedure status with the objective of evaluating them and, if it is the case, analyze the causes that motivated the procedure that is cancelled or declared void and execute opportune and corrective actions to reopen them and supply the contracting entities the required drugs by awarding for the timely delivery to health units.

6. Awarded drugs prices in the SICM are higher than the ones purchased by many Health Operating Units

This consequence was caused by the lack of a market study in the 2011 SICM and is linked to the aforementioned observation that lead to the drugs awarding at higher prices than the market ones and the ones purchased by many health units to the same suppliers awarded in the 2011 SICM and with the appearance of a significant difference in the amount to be paid by the contracting entities which represents a damage and impairment to the Government interest and resources.

Therefore for 2015 SICM, as it was already mentioned, a detailed market study has been carried out on the unit prices of each one of the drugs that are intended to purchase. Additionally, the Public Health Minister and General Directors of IESS, ISSFA and ISSPOL shall analyze the drugs prices adjudicated in the 2015 SICM which shall be compared to the purchase prices at national level with the purpose of establishing the existence of better offers and informing the authorities, so that the necessary measures could be adopted which should allow to extend such costs through the execution of the General Agreements to the remaining health houses.

As to the Executive Director of SERCOP, meetings and workshops are planned with those entities that require the drugs (RPIS) so that in any moment of the process, if better drugs prices are informed to the awarded of the 2015 SICM, the necessary corrective measures can be adopted to improve the prices without affecting the institutional budgets of the contracting entities and avoiding any damage to the Government interest that would result in a detriment to Ecuadorians in general.

Therefore, through this methodology referential prices are obtained that are according to the real market at national and regional level, which will generate important saving for the Ecuadorian Government. Additionally, the regulation that rules the drugs prices fixing will be considered such as the Regulation for the Drugs Price Fixing for Human Use and Consumption, based on the review and sales price control for the drugs for human use and consumption to final consumer which are commercialized inside the Ecuadorian territory; this was reflected in the Instructions for the 2015 SICM.

7. The information technology tool: the public purchase institutional Website has a deficiency

Inside the 2011 Corporate Reverse Drugs Bidding the information system of the institutional website for public purchases presented serious deficiencies due to the fact that no wide and complete information was reported about the contracting conditions; additionally, the website invited suppliers that were in arrears with the Government; this was even against the legal regulation.

Thereon, the LOSNCP foresees the general inabilities because of which one cannot obtain a contract with the Government; it determines also who are not enabled to celebrate contracts with contracting entities. If the intervention of an unapt bidder were found, it would be eliminated of the pre-contractual process without the right to any claim (Art. 63 LOSNCP).

Another deficiency that 2011 SICM showed was that if a bidder signed in to the public purchase institutional Website, the complete information could not be obtained because of lack of the record of the date, time and the responsible one for the significant information uploaded to the Website; this situation violated principles such as the transparency in public purchases. Another one of the greatest deficiencies was that the portal regarding the drugs purchase revealed a description of the product with the commercial name, being correct to name only the active principle with which the drugs is composed. I. e. there was no proper control and frequent monitoring in the procedures.

Therefore SERCOP, for the 2015 SICM has implemented a follow-up, validation and testing procedure of the computerized system application that supports the public purchases website, which will be applied by the Technological Innovation Coordination and its corresponding units in charge of the follow-up and functioning of the public purchase Website. Additionally, in a continuous way, reports will be generated about the functionality of the system that allows the correct and agile decisions making.

Additionally, SERCOP has foreseen that in the institutional public purchase Website the name of the drugs active principle shall be displayed to facilitate health units operators the purchase of the required drugs and avoid purchase orders to be annulled.

In the computerized system it shall also be implemented the necessary facilities to add information about partners and shareholders of the bidding companies that is registered in the Drugs registry of Suppliers, RUPM, with the purpose of knowing in a well-timed way the linking information between bidders and prohibitions established in the LONSC and its General Regulation.

Accepting the observations of the report carried out by the CGE about the 2011 SICM, the date, time and user responsible for the publication of the documents shall be published in the “results and files” of the process so that the system eases to establish the procedure responsible one in an automatic way; the real date and time of the different supplier´s status shall be established and not at the query time.

Finally, those suppliers that keep debts with the Government will be excluded from the invitation to the contracting process; SERCOP has an inter-institutional interoperability between IESS-SERCOP and SRI-SERCOP and other public entities; when one of the interoperated systems report debts automatically the RUP system disables the debtor bidder.

This means that the responsibility of maintaining the procedure integral information of the 2015 SICM will be fully executed since by law it is determined that the public

purchase portal shall contain, among others, the RUP, the list of the institutions and contracting parties of the SNCP, reports on the contracting entities, statistics, non-fulfilling contracting parties, the information about the public procurement status and it will be the only means to be employed to carry out any electronic procedure related to public procurement processes.

Conclusions

The National Public Procurement Service (SERCOP) aiming to aid the Government to guarantee the fundamental right to health to all Ecuadorians through economic, social, cultural, educational and environmental policies and the permanent, timely and without exclusion access to programs, actions and integral promotion and attention of health, sexual health and reproductive health and additionally considering that the supply of health services is ruled by the principles of equity, universality, solidarity, inter-culturally, quality, efficiency, precaution and bioethics, with gender and generational approach shall carry out a Corporate Reverse Drugs Bidding for the year 2015 for which an exhaustive planning has been performed that contains clear guidelines, general objectives and specific goals for the project organization.

It is a strategic action plan with enough detail of each one of the bidding phases; additionally, useful techniques and clear guidelines have been established to organize the job for each one of the public officers who will carry it out.

Finally, policies have been set to follow in the planning of the 2015 SICM as it provides a clear explanation about the connection between planning, follow-up and evaluation, which undoubtedly are a valuable contributions for drugs purchase in benefit of all the Ecuadorians.

Ecuador has endless possibilities with the purchase of high quality medicines at low cost

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