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Health, Nutrition and Population (HNP) Discussion Paper

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Health, Nutrition and Population (HNP) Discussion Paper

Generic Drug Policies in Latin America

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Parts of this paper have been previously published in the WHO Bulletin, 2005: 83:64-70, Homedes N and A Ugalde, Multisource Drug Policies in Latin America: survey of 10 countries.

Abstract: The World Health Organization and pharmaceutical experts have recommended that Generic Drug Policies be implemented to improve the availability of affordable medicines. This document reports on the status of generic drug policies in Latin America. The data presented are based on several sources: a survey conducted in 2003, archival information, and official health and pharmaceutical policy documents. The survey revealed that countries use different definitions for the terms “generic and bioequivalence” severely curtailing the ability to make comparisons across countries. There is also ample variability in the periods allowed for drug registration and registration charges. Although most countries in the region are becoming increasingly dependent on pharmaceutical imports, many have sizeable local pharmaceutical manufacturing capacity. The need to adopt common definitions for technical terms, the urgency of improving quality controls and the importance of strengthening generic drug programs are highlighted.

Keywords: generic drugs, pharmaceutical policies, bioequivalence, quality, Latin America, pharmaceuticals, quality assurance, private sector.

Disclaimer: The findings, interpretations and conclusions expressed in the paper are entirely those of the authors, and do not represent the views of the World Bank, its Executive Directors, or the countries they represent.

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FOREWORD

Several inputs are indispensable in ensuring health services function properly. This includes pharmaceuticals, equipment, other consumables, capital, human resources, and knowledge. This publication – *Generic Drug Policies in Latin America* – by Núria Homedes, Roberto López Linares and Antonio Ugalde, reviews generic drug policies in Latin America. It is part of a series of publications on the role of pharmaceuticals as critical inputs to health services in low- and middle-income countries.

Drugs are often the most important cost driver of health care expenditure on hospitals and ambulatory care. Patients that have access to adequate and effective drugs at the time of need are more likely to be happy with the treatment they receive. When such drugs are not available or ineffective after use, patients will go elsewhere, even if they have to pay high prices to private providers, to get the care they think they need.

The availability of affordable and effective drugs is, therefore, one of the most visible indicators of the quality of health services. Satisfaction with the drugs received is a key determinant of utilization of health services and return visits in the public sector. And out-of-pocket spending on drugs is a major contributor to the impoverishing effects of illness.

Despite significant progress in increasing access to essential medicines in low- and middle-income countries during the past decades, many of the health services used by the poor still lack adequate supplies of basic medicines. Drug shortages and quality problems continue to undermine the performance of health systems throughout the developing world.

Many factors influence whether poor people can obtain affordable drugs of good quality. This includes issues related to pricing and procurement of existing drugs, new product development, patenting/intellectual property rights, manufacturing or import of drugs, macroeconomic constraints, and foreign exchange fluctuations. Without addressing these issues, many countries will fail to reach their poverty reduction and Millennium Development Goal targets.

This paper notes that countries use different definitions for the terms “generic and bioequivalence” which severely curtails the ability to make comparisons across countries. Although most countries in the region depend on pharmaceutical imports, many have sizeable local pharmaceutical manufacturing capacity. The authors highlight the importance of strengthening generic drug programs in the Latin American Region.

Alexander S. Preker

Lead Economist
Editor of HNP Publications

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INTRODUCTION

An increasing number of pharmaceuticals are available in the world market and yet many people in developing countries do not have access to medicines that can save lives and/or reduce suffering (1-5). To ensure that countries have access to needed medicines at an affordable price, WHO recommends the use of Essential Drug Lists and implementation of Generic Drug Policies (4, 6-8). In recent years many countries in Latin America (LA) have taken steps to increase access to cheaper drugs. This paper reports on the results of a survey conducted in several Latin American countries during June 2003 on the status of Generic Drug Policies.

METHODOLOGY

The survey tool was developed by the authors of this report and was based on a series of indicators developed by Enrique Seoane. The survey was applied face to face by Roberto López Linares in Perú, Chile, and Ecuador and by electronic mail in Argentina, Bolivia, Brazil, Colombia, Costa Rica, Nicaragua and Uruguay. Most e-mail respondents were subsequently contacted by telephone or by e-mail for further clarification of the information provided. Survey respondents included at least one regulatory agent and/or a pharmaceutical expert in each country, (with at least two respondents in each country except in Brazil where there was one respondent), for a total of 22 persons. E-mail respondents had a maximum of 10 days to complete the questionnaire and provide supporting documentation. All the data were gathered during the second and third week of June of 2003, except in the case of Brazil, whose information was submitted in January 2004. The information collected through the survey was complemented with information obtained from archival documents and government websites.

DESCRIPTION OF THE QUESTIONNAIRE

The questionnaire was administered in Spanish (See Annex 1 for the Spanish version and Annex 2 for the English translation). It included qualitative and quantitative questions and addressed the following domains of inquiry: types of pharmaceutical products registered in the country; existence of a generic/similar drug policy and the corresponding regulation; legislation for intellectual property protection; drug registration process; regulation of drug importation; local drug manufacturing capacity; and public and private pharmaceutical market.

The classification of drugs and the definitions used in the questionnaire were agreed by the Generic Consultative Group (GCG) convened by Joan Rovira and included 7 categories defined as follows:

Manufactured by the originator: Branded original drugs on patent [1]
 Branded original drugs off patent [2]
 Generic original drug (off patent, identified by the
 international non-proprietary name [INN]) [3]

Secondary source Drugs: Bioequivalent: Branded generic drugs [4]
 INN (Proper) Generic drug [5]

 Non-bioequivalent: Branded similar drug [6]
 INN (Proper) Similar Drug [7]

Originator refers to the company that holds the patent and the brand name of the drug.

Branded original drug refers to a product sold by the originator or by a company licensed or authorized by the originator.

Generic original drug refers to an original drug sold under INN (international nonproprietary name). It is assumed that it is off patent.

Generic drug is a pharmaceutical product that:

1. Is off-patent in the country where it is sold (or with patent rights modified in such a way that it can be produced without the patent's holder consent --e.g. due to compulsory licensing);
2. Is therapeutically equivalent to a reference drug (usually the innovator) and has been certified as generic in the country where it is sold, on the basis of bioequivalence or a similar test.
3. Is sold under (international) non-proprietary name. If sold under a brand name, it will be labeled as a Branded Generic.

Similar drug (copy): Pharmaceutical product that is off patent but there is no proof of bioequivalence. It can be sold under brand name (**Branded Similar**) or under INN.

RESULTS

TYPES OF PHARMACEUTICAL PRODUCTS

The first realization was that countries in Latin America (LA) use different definitions and could not respond to the questionnaire using the definitions proposed by the researchers.¹ In practice most countries (Bolivia, Chile, Colombia, Costa Rica, Ecuador, Nicaragua, Peru and Uruguay) classify pharmaceuticals under two categories (See Table 1):

¹ . For a more in-depth discussion of this issue see Homedes N and Ugalde A. Multisource Drug Policies in Latin America. Bulletin of WHO 2005; 83: 64-70.

1. Branded pharmaceuticals: included in this category are Branded Originals, Branded Generics, and Branded Similar or Copies. This category includes medicines that the GCG classified as 1, 2, 4 and 6.
2. Generics (using INN or country specific generic names): in this category, these countries include all the pharmaceutical products that are identified using the INN or country specific generic names, which would include the following products: Original Generics, Generics manufactured by pharmaceutical companies other than the originator, and Similar, corresponding to GCG categories 3, 5, and 7.

Brazil and Argentina classify their pharmaceutical products in three categories: Innovative or originals (GCG categories 1, 2); generics; and similars. In these two countries the term generic is reserved for pharmaceutical products that have been proven to be therapeutically equivalent to the original product. In Argentina, generic drugs can be identified with a brand name or with INN (GCG categories 4, 5); and in Brazil all generic drugs have to be identified with INN or a Brazilian non-proprietary name (GCG category 4). Similar products are pharmaceutically equivalent to the original drug but have been proven to be therapeutically equivalent. In the case of Argentina, similar products can be identified with INN or a brand name (GCG categories 6,7) and in Brazil they have to be identified with a brand name (GCG category 6).

Table 1: Types of pharmaceutical products found in different Latin American countries

Country	Drug Types	Corresponding GCG categories
Argentina (9)	Innovative drug	1, 2
	Similar drug (copy)	6, 7
	Generic drug	4, 5
Brazil (10)	Innovative or reference drug	1, 2
	Similar drug (copy): is identified with a brand name.	6
	Generic drug: is identified with INN or Brazilian non-proprietary name.	5

The term bioequivalence is also used differently by several of our survey respondents. For some respondents, bioequivalence implies the need to conduct clinical trials in human beings (Bolivia, Colombia, Perú). Other tests of therapeutic equivalence such as dissolution tests or in vitro studies are not considered sufficient to classify a pharmaceutical product as a generic. In other countries, such as Brazil and Argentina, a pharmaceutical product is classified as generic when the new product has proven to be therapeutically equivalent to the originator, independently of the test used to prove its equivalence. Clarifying the type of test needed for each product to prove that it is therapeutically equivalent to the original drug is essential in advancing the dialogue on generic drug policies in Latin America. Argentina and Brazil have made significant advances

along those lines but some technical details are still evolving. For instance, Brazil passed a resolution (no. 391) in September 1999 stating that the registration of a generic product required proof of bioequivalence. Subsequently in February 2001 (resolution 10) and March 2002 (resolution 84) the requirement of bioequivalence was modified. Resolution 10 determined that there was a need to create a list of medicines that would not be registered as generics (the list of excluded medicines) and mandated the development of a guide to substitute the requirement of testing for bioequivalence for the use of other tests of therapeutic equivalence. Resolution 84 eliminated some medicines from the excluded list (that is expanded the number of medicines that could be commercialized as generics) and clarified some of the procedures to be used to prove therapeutic equivalence. Other issues under discussion are the minimum number of volunteers needed to prove bioavailability and bioequivalence.

The lack of agreement across countries on these basic definitions prevented us from being able to make cross-country comparisons of basic indicators such as the proportion of generic products registered, or the share of the market that is controlled by generic products.

DRUG REGISTRATION

In many of the LA countries the amount of time that the regulatory agency has to register a product is very short. Peru requires the least amount of time for registration: only 7 days. If the regulatory agency fails to prove that a particular product may be harmful during this period of time, the product is automatically registered. Except for Brazil and Chile, which have between 8 and 14 months, the rest of the countries for which we obtained information have less than 6 months to register a product.

The only countries that offer incentives for the registration of generics/copies/similars are Argentina, Brazil and Chile (See Table 2). These three countries discount the registration application fee for generic drugs and in addition Brazil offers a shorter evaluation time for generic and similar products.

The cost of registering a product ranges between 50 dollars in Bolivia (for 5 years) and \$27,000 in Brazil. Argentina, Brazil and Chile offer significantly lower fees for the registration of generics and similars than for the registration of a new product. Chile and Colombia charge a different fee for registration than for re-validation. Ecuador offers a cheaper registration price to national companies (US \$535) and for essential drugs (US \$344) than to foreign companies (US \$1,339). Nicaragua also favors local producers (US \$485 for a foreign product and US \$166 for a nationally produced drug).²

² For a discussion on the costs of registering products in developed and developing nations see Kaplan WA and Laing R., "Paying for pharmaceutical registration in developing countries", *Health Policy and Planning*, 2003; 18 (3): 237-248.

Table 2: Time and cost for registering a pharmaceutical product in selected LA countries

	Number of months	Cost in US dollars (2003)
Argentina	3-4 months	\$1,000 for original drugs \$333 for generic/similar drugs
Bolivia	1 month	\$50
Brazil	Original = 12-14 months similar = 8-12 generic = 6-8	\$2,700-27,000 for original drugs (the price depends on the size of the manufacturer) \$7,000 for a similar drug \$2,000 for a generic drug
Colombia	New = 6 months Similar/generic = 3 months	\$1,200 new \$1,000 re-validation
Chile	8-12 months	\$1,300 for original drugs \$800 for generics/similars
Ecuador	1 month	\$1,339 foreign \$535 national \$344 essential drug
Nicaragua	3 month	\$485 foreign \$166 national
Peru	7 days	\$89
Uruguay	46 months	\$500

DRUG PRODUCTION

Mexico, Brazil and Argentina are the three countries with the largest pharmaceutical production capacity and they are important suppliers for the region. In terms of drug manufacturing capacity, Colombia, Chile, Venezuela and Uruguay are considered to be in an intermediate stage of development; and Peru, Bolivia, Ecuador and Central America are small producers (11). Although we did not gather any quantitative information, most interviewees mentioned that Latin America is becoming increasingly dependent on pharmaceutical imports. Moreover, the vast majority of active ingredients are imported (11,12).

Argentina has 280 laboratories and 25 of them control 75% of the market. The local industry produces 54% of the products and in the year 2000 this represented about 7.1% of a total market of 6,000 million Argentinean pesos (at that time 1 pesos = 1 dollar). It is worth noting that during the 1960s and 1970s Argentina produced active ingredients (12). During the late 1970s and the beginning of the 1980s the Argentinean pharmaceutical industry created distribution agencies (See Table 3) (13).

Table 3: Share of the market of each medicine distribution agency, until 1997

Distribution agencies				Not through a distribution agency
Disprofarma 25%	Farmanet 16%	Rofina 24%	SD 4%	31%
Parke Davis	Boehringer Ing	Roemmers	Sidus	
Elea	Bayer	Roche	Lasifarma	
Phoenix	Zeneca	Armstrong		
Sintyal	Gador	Syncro		
Bago	BYK	Boehringer Arg.		
Montpellier	Novartis Organon	Glaxo Wellcome		
Pfizer	Casasco	HMR		
Merck	Otros	Plough		
Schering Arg		Otros		
Eli-Lilly				
Sanofi				
RPR				
Otros				

Despite having a large number of public pharmaceutical production plants (See Table 4), owned by municipalities, provinces or the nation; the ministry of health has decided not to promote local production as a means of facilitating access to pharmaceuticals. There are other groups who consider that if there were better coordination among all producers it would be easier to guarantee access to medications for the entire population (13).

In Brazil, 70% of the pharmaceutical producers are foreign (that is more than 50% of the capital is foreign). The production of generics is in the hands of 37 national companies and 12 foreign companies.

Chile has 40 national laboratories, and of those 10 are generic manufacturers; the national laboratories control 56% of the market value and 79% of the volume. In 1995 all multinational producers left Chile and since then, products manufactured by multinationals are imported into Chile from their plants in Brazil, Mexico and Argentina. As a result drug imports of finished goods have been increasing by an annual average of 17%, from about 80 million US\$ in 1995 to US\$250 in 2002 (11).

Table 4: Most important public pharmaceutical production plants (13)

Ciudad de Buenos Aires	Provincia de Tucumán
Instituto Malbran (N)	Universidad de Tucumán (U)
Talleres Protegidos (M)	Siprosa (P)
Provincia de Buenos Aires	Provincia de San Juan
Universidad de La Plata (U)	Luis F. Leloir (P)
UTN de Pacheco	Provincia de San Luis
Ciencias Exactas de La Plata	Labs. Puntanos (P)
Lab. Central de Salud Pública, Dr. Tomas Perón (P)	Provincia de Río Negro
Lab. de Trenque-Lauquen (M)	Prozome (P)
Hospital Profesor Alejandro Posadas (P;N)	Provincia de Formosa
Hospital Eva Perón del Partido de San Martín (P)	Laformed (P)
Hospital Pte. Perón del Partido de Avellaneda (P)	Provincia de Corrientes
Hospital Penna de Bahía Blanca (P)	Sin información
Hospital de Olavarría (¿)	Provincia de Misiones
Ciudad de Balcarce (M)	Lab. Provincial Hospital Baliña (P)
Ciudad de Bragado (M)	Provincia de La Pampa
Provincia de Córdoba	Lab. de Gral. Pico (M)
Universidad de Córdoba (U)	Provincia de Salta
Hemoderivados (P)	Htal. Materno Infantil (P)
Lab. Municipal de Córdoba (M)	Provincia de Mendoza
de Río Cuarto (M)	Htal. Notti Guaymallen (¿)
San Francisco (M)	Provincia de Entre Rios
Provincia de Santa Fé	Htal. Heras Azodeco (¿)
Lab. de Rosario (M)	Htal. Diamante (¿)
Ciudad de Santa Fé (¿)	Lab. de las Fuerzas Armadas

Key: N: national; P: provincial; M: municipal; ¿: no information

Table 5: Share of the market by type of pharmaceutical industry, December 2002

	% of market value (US dollars)	% of market volume
American Producers	14.3	5.4
European Producers	29.7	16.0
National Producers	56.1	78.6

Source: Cavallone, Enrique: June 02, 2003

According to Cavallone (11) the Chilean pharmaceutical market is highly competitive and drug prices are relatively low. Eighty-six percent of the drugs are distributed through pharmaceutical chains.

Ecuador has 36 laboratories but only 9 comply with good manufacturing practices (GMP), 80% of the drugs are imported, and all national manufacturers are legally mandated to produce 20% of their total yield in generic form.

In Uruguay there are 20 multinational pharmaceutical industries and 40 national producers.

NATIONAL GENERIC POLICY

Ecuador³ and Brazil⁴ have Generic Drug Laws. Other countries such as Argentina⁵, Bolivia⁶, Chile, Colombia, Mexico (1998), Costa Rica, Nicaragua and Peru have a section of the national health law that discusses the role of generics.

Table 6: Generic Prescription and Substitution in Selected LA countries

	Prescription	Substitution	Conditions
Argentina	INN (1992 and 2002) but may include a brand name	Allowed, not mandatory	In some cases if the INN does not appear in the prescription there is no reimbursement
Bolivia	INN (1996)	Allowed, not mandatory	
Brazil	The use of INN is mandatory in the public Sector	Allowed, not mandatory	Substitution is only permitted between originals and generics, can not be done with similar drugs
Costa Rica	CCSS: INN	Allowed, not mandatory	Can not mention brand name in prescription
Chile	Public Sector: INN	At the discretion of the patient and the pharmacist	
Ecuador	Brand and INN	Have to offer, no mandatory substitution	
Peru	INN	Allowed, not mandatory	Chemically and pharmacologically equivalent
Uruguay	INN	Allowed, not mandatory	

The national drug policies require all physicians in Argentina, Bolivia, Peru, and Uruguay to write prescriptions using INNs. In Ecuador the prescribing physician can use either the brand name or the INN; in Costa Rica the Caja Costarricense de Seguro Social requires that prescriptions be written using INN; and the public sectors in Brazil and Chile require the use of INN. Most countries allow generic substitution by the dispensing agent but it is not mandatory in any of the surveyed countries. In Ecuador the pharmacist has to offer the possibility of substituting a generic product for the prescribed product but it is not mandatory. In Chile substitution is at the discretion of the patient and the pharmacist. In Brazil, substitution is only allowed between originals and generics but not with similar drugs.

³ Ley de Producción, Comercialización y Expedio de Medicamentos Genéricos 2000-12, published in the official registry 59, April 17, 2000.

⁴ Law 9787/1999; resolution RDC 135/2003.

⁵ Decreto Nacional N° 150/92; Decreto 486/02 (March 4, 2002)

⁶ Medicines Law, December 1996.

In Brazil, Chile (11), Argentina (14) and Peru, patients are increasingly requesting generic medicines. This is partly due to the increasing cost of drugs and suggests that, contrary to what was happening only a few years ago, consumers are starting to trust the quality of generic drugs.

GENERIC MARKET AND PRICE CONTROLS

Table 7: Generic Market in selected LA countries (2002)

	Types	% Units	% Value
Chile	Generics	39	8
	Branded Generics	39	49
	Original brand	22	43
Uruguay	Copies	89	60
	Original brand	11	40
Ecuador	Generics (20% of registered drugs, or 1529 of 8600)	9	8
	Branded (original and copies)	91	92
Peru	Generics	34	11 (1998)
	Branded (original and copies)	66	n.d.

The fact that the term generic means different things in different countries precluded us from getting detailed information on the share of the market accounted for by the different drug types. In Chile, Peru and Colombia the market is dominated by similar drugs. In Chile, the largest share of the market is for drugs sold under INN. It should be noted that in Chile the average unit cost of a brand product is US\$3.3 and the unit cost of a generic is US\$0.6. In Ecuador, the public sector can only purchase generics but there are exceptions. In several countries it is impossible to know how much of the market is generic and how much are copies.

It is also worth mentioning that in Chile about 90% of the pharmaceutical market is under the control of pharmacy chains; in Argentina 3 firms control about 65% of the distribution networks (storage and distribution, occasionally retail); and in Peru 35-40% of the market is under the control of pharmacy chains. At present, in Uruguay there are no pharmacy chains.

To regulate drug prices Ecuador uses price controls but the prices are fairly high, and Brazil requires that the price of a generic be at least 35% lower than the price of the original drug

DISCUSSION

Except in the cases of Chile and Brazil, survey respondents manifested their frustration with the limited capacity of the regulatory agencies to control the quality of the medicines available in Latin American markets. It was also felt that the perceived inability of the regulatory agencies to ensure quality is used to discredit the quality of generics. For example, in the case of Argentina, physicians opposed the law that requires them to prescribe using the INN saying that in Argentina there are no generics and suggesting that the quality of the pharmaceutical products classified as *similar*, are of low quality, and of dubious safety and efficacy. Francisco Rossi

documented how the increased presence of counterfeit drugs in Colombia was affecting the commercialization of generic products from India and Cuba (15). In Latin America, ensuring the quality of products that enter the pharmaceutical market is a pre-condition for the success of national policies aimed at decreasing the cost of pharmaceuticals through the use of generic or similar drugs (16). Regulatory agencies should be responsible for guaranteeing that all drugs available in the market are safe and efficacious for the treatment of the indicated conditions. Countries that have not determined which test should be applied to each drug to guarantee their efficacy and safety could benefit from the expertise of other countries in the region such as Brazil, Chile and Argentina.

In our view it would be inappropriate to infer that many medicines classified as *similar or copies* have lower therapeutic efficacy or are less safe than single source products or than other drugs that have proven to be interchangeable. Many of these drugs, if tested, would pass the threshold, but because the appropriate test for classification as *generic* has not been performed they are considered of lesser quality. As in the developed world, the use of similar drugs or copies is widespread, and only recently has the quality of these drugs been questioned. In countries such as Argentina, Chile, Colombia, Peru, Bolivia and Uruguay, similar drugs represent the highest percentage of sales volumes. In daily use, many policy makers, users and prescribing physicians consider the terms *similar* and *generic* to be synonymous, and countries that have aggressively implemented Generic Drug Policies such as Argentina and Chile, are promoting the use of similar drugs when the original drugs are off-patent.

It is important to study the capacity of the drug regulatory agencies to conduct their activities adequately. Most of our respondents implied that the agencies were weak in personnel and resources, but without adequate documentation on their current situation and an estimate of ideal staffing and equipment needs, it is very difficult to establish concrete development plans and allocate needed resources.

Developed countries that have implemented policies to decrease the cost of medicines have mandated pharmacists to substitute prescriptions of brand name drugs with cheaper generic/similar products. This is an effective strategy but it is difficult to implement in the region because in most countries, pharmacy clerks with little or no training in pharmacology dispense the vast majority of drugs. In addition, prescription only drugs are often accessible over-the-counter. Anecdotal information suggests that in the last decade, as a result of the economic crisis and health reforms, the number of people who self-medicate or use the pharmacy clerk as a source of medical advice has been increasing. The consequences of these practices for the health of the individual patient and for society –through increased risk of antibiotic resistance– are easy to imagine. This is a problem that requires forward thinking and identification of long-term solutions. In the short run, countries could benefit from training pharmacy clerks, and from developing and distributing guides listing the brand names and the names of the equivalent generic/similar products, such as those developed by the Peruvian Ministry of Health (17).

The region would also benefit from harmonizing basic definitions and technical concepts. The discrepancies in terminology prevented us from comparing the information gathered across the different countries. Harmonizing definitions is especially important in the context of the regionalization of markets and the increased number of bilateral and multilateral free trade

agreements, which aim to establish conditions for free circulation of pharmaceuticals among several countries of the region.

Latin America is a net importer of pharmaceuticals, especially of active ingredients. It may be time to do some strategic planning and decide if local production should be strengthened or not, and if the region would like to further integrate or diversify the pharmaceutical market. It is worth keeping in mind that regional and bilateral trade agreements may be used, as Brazil has done, to force technology transfer.

ANNEX 1

POLÍTICA DE GENÉRICOS EN PAÍSES DE AMÉRICA

NO OLVIDARSE DE ANOTAR EL CARGO DE LA PERSONA QUE PROPORCIONA LA INFORMACIÓN. SI HAY MÁS DE UN INFORMANTE, INDICAR LAS SECCIONES PARA LAS CUALES CADA PERSONA HA DADO LA INFORMACIÓN.

ANEXAR UNA HOJA CON NOMBRE, CARGO Y SEÑAS DE LOS INFORMANTES.

INDICAR TAMBIÉN LAS FUENTES DE INFORMACIÓN SI SE UTILIZAN DOCUMENTOS EXISTENTES

SI NO HAY INFORMACIÓN, DEJAR LAS CASILLAS VACÍAS. SI ES QUE NO SE HA PODIDO CONSEGUIR, INDICAR EN EL MARGEN QUE ESTÁ DISPONIBLE PERO SE TARDARÁ TIEMPO EN OBTENERLA Y QUIEN LA PUEDE FACILITAR.

DEFINICIONES:

Medicamento **original**: se refiere al producto que vende la firma innovadora u otra firma que ha recibido la licencia o la autorización de la compañía innovadora. Puede estar **bajo patente o fuera de patente**.

Medicamento **original genérico**: se refiere al producto que vende la firma innovadora (u otra firma que ha recibido la licencia o la autorización de la compañía innovadora), que **está protegida o no por patente** y se comercializa bajo DCI.

Medicamento **genérico**: se refiere al medicamento **bioequivalente e intercambiable** con un medicamento de referencia (generalmente el original) que se vende bajo DCI.

Medicamento **genérico de marca**: medicamento que se vende con una marca y es **bioequivalente** a un medicamento de referencia.

Medicamento **similar de marca**: medicamento para el que **no se ha demostrado bioequivalencia** con el original y se vende con una marca.

Medicamento **similar con DCI**: medicamento que se vende con DCI, pero que **no es bioequivalente**.

1. TIPOS DE MEDICAMENTOS QUE ESTÁN REGISTRADOS EN EL PAÍS

	Sí	No
¿Hay medicamentos originales de marca que están bajo patente u otro tipo de protección intelectual?		
¿Hay medicamentos originales de marca que no están bajo patente ni otro tipo de protección intelectual?		
¿Hay medicamentos originales genéricos (bioequivalentes) que están bajo patente u otro tipo de protección intelectual?		
¿Hay medicamentos originales genéricos (bioequivalentes) que no están bajo patente u otro tipo de protección?		
¿Hay medicamentos genéricos (bioequivalentes) que se venden bajo DCI?		
¿Hay medicamentos genéricos de marca (bioequivalentes)?		
¿Hay medicamentos similares (sin bioequivalencia) que se venden con marca?		
¿Hay medicamentos similares (sin bioequivalencia) que se venden con DCI?		

2. POLÍTICA DE GENÉRICOS

2.1. ¿Existe una política oficial relacionada a medicamentos genéricos? Sí () No ()

2.2 Nombre del documento oficial que contiene dicha política y fecha de publicación

.....

RECOGER COPIAS DE ESTE DOCUMENTO CON LA REFERENCIA BIBLIOGRÁFICA COMPLETA. SÍ EXISTE MÁS DE UNA POLÍTICA RECOGER INFORMACIÓN SOBRE TODAS ELLAS

3. LEGISLACIÓN Y REGULACIÓN SOBRE GENÉRICOS

3.1 ¿Existe una ley o disposiciones (dentro de una ley) relacionada a genéricos?

Sí () No ()

3.2 Nombre, número, fecha de la Ley

.....

3.3 ¿Existen regulaciones (normas, directivas, etc) relacionadas a genéricos? Sí () No ()

3.4 Nombre y fecha de la regulación o regulaciones

.....
.....

RECOGER COPIAS DE ESTOS DOCUMENTOS CON LAS REFERENCIAS BIBLIOGRÁFICAS COMPLETAS

3.5 ¿Existe una agencia u oficina reguladora con responsabilidad para medicamentos genéricos?

Sí () Nombre _____
No ()

4. POLÍTICA DE SIMILARES

4.1 ¿Existe una política oficial relacionada a medicamentos similares? Sí () No ()

4.2 Nombre del documento oficial que contiene dicha política y fecha de publicación

.....
.....

RECOGER COPIA DE ESTE DOCUMENTO CON LA REFERENCIA BIBLIOGRÁFICA COMPLETA. SI EXISTE MÁS DE UNA POLÍTICA RECOGER INFORMACIÓN SOBRE TODAS ELLAS

5. LEGISLACIÓN Y REGULACIÓN SOBRE SIMILARES

5.1 ¿Existe una ley o disposiciones (dentro de una ley) relacionadas a similares? Sí () No ()

5.2 Nombre, número, fecha de la Ley

.....
.....

5.3 ¿Existen regulaciones (normas, directivas, etc) relacionadas a similares? Sí () No ()

5.4 Nombre y fecha de la regulación o regulaciones

.....

RECOGER COPIAS DE ESTOS DOCUMENTOS CON LAS REFERENCIAS BIBLIOGRÁFICAS COMPLETAS

5.5 ¿Existe una agencia reguladora con responsabilidad para medicamentos similares?

Sí () Nombre de la agencia _____ No ()

6. LEGISLACIÓN Y REGULACIÓN SOBRE PROTECCIÓN DE PROPIEDAD INTELECTUAL

6.1 Fecha de la Ley de Protección de Propiedad Intelectual

6.2 Tipo de protección de patente:

	Sí	No
Compuesto: ingrediente activo (incluyendo formulaciones o usos del compuesto químico)		
Composición farmacéutica: ingrediente activo formulado para su uso como medicamento		
Indicaciones y usos de un ingrediente activo		
Proceso de producción		
Otros (especificar)		

6.3 Plazo de la protección patentaria

	Sí	No	Años de protección
Desde la presentación de solicitud			
Desde la aprobación de la patente			

6.4 Razones para la extensión de la patente y máximo número de años que se puede extender

Razones	Sí	No	Máximo No. de años de extensión
a. Por atrasos de la agencia reguladora de patentes			
b. Por el tiempo en ensayos clínicos			
c. Por el tiempo en recibir la aprobación			
d. Otras (explicar)			

6.5 Tiempo máximo total desde que la agencia reguladora aprueba un medicamento nuevo hasta que expira la patente (número de años) _____

6.6 ¿Hay extensiones de exclusividad en el mercado (protección sobre el uso de la información de la compañía innovadora para la aprobación de un medicamento genérico)?

Sí () No ()

Si las hay, son para:

	Sí	No	Máximo No. de años de extensión
Medicamentos huérfanos			
Moléculas nuevas			
Nuevas indicaciones			
Otras (especificar)			

6.7 ¿Existe la Provisión Bolar en la Ley de Propiedad Intelectual? (La Provisión Bolar permite que antes de la expiración de la patente otra compañía pueda usar el producto patentado y la información relacionada con él, para el desarrollo y registro de un producto genérico. Solo se comercializa el genérico después de la expiración de la patente).

Sí () No ()

Comentarios.....

6.8 ¿Existe la solicitud de registro provisional? (Es la que da a los inventores derecho a reclamar un trato preferencial cuando posteriormente entregan una solicitud. Este trato preferencial está basado en la fecha en que entregan los documentos para hacer una solicitud provisional)

Sí () Número de años por la patente provisional _____

No ()

Comentarios

6.9 ¿Existen las licencias obligatorias? Sí () No ()

Si existen, las razones o causas para otorgar una licencia obligatoria son:

	Sí	No
Porque no se produce en el país*		
Porque hay una emergencia sanitaria		
Por aspectos relacionados con la competitividad en el mercado		
Para uso por el sector público sin intereses comerciales		

*Número de años que pueden transcurrir antes de que se otorgue una licencia obligatoria _____

6.10. Importaciones paralelas

¿Existe legislación acerca del agotamiento de los derechos de propiedad?

Sí () es al nivel : Nacional ____ Regional ____ Internacional ____

No ()

6.11 ¿Existe un vínculo entre la oficina de registro de medicamentos y la oficina de patentes?

Sí () No ()

Comentarios

.....

6.12 ¿Hay algún debate en curso sobre asuntos relacionados con la protección de la propiedad intelectual en el país?

Sí () No ()

Explicar.....
.....
.....
.....

7. REGISTRO DE MEDICAMENTOS

7.1

- a. ¿Se requiere registro de medicamentos para su comercialización? Sí () No ()
- b. Número de principios activos (medicamentos) registrados
- c. Número total de especialidades farmacéuticas⁷ registradas a la actualidad
.....
- d. Número de medicamentos genéricos registrados a la actualidad
- e. Número de medicamentos similares MARCA registrados a la actualidad
- f. Número de medicamentos similares DCI registrados a la actualidad
- g. Tiempo para registrar un medicamento nuevo (meses)
- h. ¿Existe un proceso abreviado para registrar medicamentos genéricos? Sí () No ()
- i. ¿Se requieren pruebas de bioequivalencia para registrar un medicamento genérico?
Sí () No ()
- j. Tiempo para registrar un medicamento genéricomeses
- k. ¿Existe un proceso abreviado para registrar medicamentos similares (marca o DCI)?
Sí () No ()
- l. Tiempo para registrar un medicamento similar.....meses
- m. Costo de registro de un medicamento nuevo (innovador) (en dólares USA)
- n. Costo de registro de un medicamento de marca cuyo principio activo ya está en el mercado (en dólares USA)
- o. Costo de registro de un medicamento genérico (en dólares USA).....
- p. Costo de registro de un medicamento similar (en dólares USA).....

7.2 Facilidades que ofrecen al país para registrar medicamentos genéricos

- a.
- b.
- c.
- d.

7.3. ¿Qué pruebas se exigen para demostrar bioequivalencia?

- a.
- b.

⁷ Un mismo principio activo puede dar lugar a muchas “especialidades farmacéuticas”. Cada formulación (concentración, forma farmacéutica, etc.) es una especialidad farmacéutica.

- c.
 d.

7.4 ¿Existe en el país una lista prioritaria de productos que requieren demostración de bioequivalencia? Sí () No ()
 Comentar

SI SÍ OBTENER LA LISTA

8. COMERCIO INTERNACIONAL

- a. ¿Hay impuestos sobre la importación de medicamentos?
 Sí () % del FOB _____
 No ()
- b. ¿Se requiere licencia de importador? Sí () No ()
- c. Número de importadores de medicamentos _____
- d. ¿Se usa el esquema de certificación de la OMS para medir la calidad de medicamentos que entran en el mercado internacional? Sí () No ()

Si se usa la certificación de la OMS, se lo hace para:

	Sí	No
El registro del medicamento		
Los medicamentos que se van a exportar		
Para el registro se aceptan la certificación de la OMS que se ha otorgado en otros países		
Para las compras en el sector público se aceptan certificaciones de la OMS otorgadas en otros países		

9. FABRICACIÓN DE MEDICAMENTOS

9.1. Número total de compañías farmacéuticas extranjeras (extranjera significa que más del 50% del capital es extranjero).....

- a. Número de compañías extranjeras que producen genéricos
- b. Número de compañías extranjeras que producen similares

9.2 Número total de compañías farmacéuticas de capital nacional (nacional significa que más del 50% del capital es nacional)

- a. Número de compañías extranjeras que producen genéricos
- b. Número de compañías extranjeras que producen similares

9.3 Porcentaje del mercado de genéricos y similares del total del mercado farmacéutico:

	% del valor monetario	% del número de unidades
Genéricos (bioequivalente)		
Similares (marca y DCI)		

9.4 ¿Hay algún incentivo para la producción de genéricos? Sí () No ()

Si los hay, describirlos.....

10. DISTRIBUCIÓN DE GENÉRICOS

10.1 Número de mayoristas que distribuyen genéricos.....

a. Número de mayoristas privados.....

b. Número de mayoristas públicos.....

10.2 Porcentaje del mercado que controlan los 5 mayorista más grandes del país%

10.3 ¿Existen incentivos para que el sector privado distribuya medicamentos genéricos?

Sí () Especifique _____

No ()

11. PRESCRIPCIÓN DE GENÉRICOS

11.1 ¿Existe alguna regulación que obliga al prescriptor a prescribir en DCI?

En el sector publico	Sí ()	¿Puede el prescriptor añadir un nombre de marca?	Sí () No ()
	No ()	¿Puede el prescriptor legalmente impedir la sustitución de un producto de marca?	Sí () No ()
En el sector privado	Sí ()	¿Puede el prescriptor añadir un nombre de marca?	Sí () No ()
	No ()	¿Puede el prescriptor legalmente impedir la sustitución de un producto de marca?	Sí () No ()

11.2 Del total de medicamentos prescritos, ¿cuál es el porcentaje de medicamentos prescritos en DCI?

En el sector público%

En el sector privado..... %

11.3 ¿Existe algún incentivo para prescribir en DCI?

En el sector público Sí () ¿Cuáles?.....
No ()

En el sector privado Sí () ¿Cuáles?.....
No ()

12. DISPENSACIÓN DE GENÉRICOS

12.1 Porcentaje del mercado farmacéutico que controlan las cinco cadenas más grandes del país:

..... %

_____ No hay cadenas farmacéuticas

12.2 ¿Qué porcentaje de los medicamentos incluidos en la lista de medicamentos esenciales están disponibles en forma genérica?%

12.3 ¿Qué porcentaje de los medicamentos incluidos en la lista de medicamentos esenciales están disponibles como similar?%

13. SUBSTITUCIÓN POR GENÉRICOS

13.1 ¿Hay alguna ley o regulación que **permita** al farmacéutico sustituir la prescripción de un medicamento de marca por un genérico? Sí () No ()

13.2 ¿Hay alguna ley o regulación que **obligue** al farmacéutico sustituir la prescripción de un medicamento de marca por un genérico? Sí () No ()

13.3 ¿cuáles son la condiciones que ponen la ley o regulación para que se haga la sustitución genérica?

•

13.4 ¿Hay alguna ley o regulación que establezca que el farmacéutico puede realizar la sustitución de un medicamento de marca por un **similar**? Sí () No ()

13.5 ¿Hay alguna ley o regulación que obligue al farmacéutico sustituir la prescripción de un medicamento de marca por un **similar**? Sí () No ()

13.6 ¿cuáles son la condiciones que ponen la ley o regulación para que se haga la sustitución por **similar**?.....

13.7 ¿Están las farmacias obligadas a tener al menos una presentación de cada uno de los productos incluidos en la lista de los medicamentos esenciales?

Sí () No ()

13.8 ¿Están las farmacias obligadas a tener más de una presentación de cada uno de los productos incluidos en la lista de los medicamentos esenciales?

Sí () No ()

13.9 ¿Pueden las farmacias decidir cual de ellos dispensan? Sí () No ()

13.10 Cuando hay varios productos genéricos equivalentes al mismo medicamento de referencia ¿puede el usuario decidir que producto genérico se dispensa? Sí () No ()

13.11 ¿Existen catálogos (cartillas) que establecen la equivalencia entre los medicamentos de **marca y genéricos** y que se ponen a disposición de:

médicos	Sí () No ()
farmacéuticos	Sí () No ()
consumidores	Sí () No ()

13.12 ¿Existen catálogos (cartillas) que establecen la equivalencia entre los medicamentos de **marca y similares** y que se ponen a disposición de:

médicos	Sí () No ()
farmacéuticos	Sí () No ()
consumidores	Sí () No ()

13.13 ¿Existen incentivos para que las farmacias dispensen genéricos? Sí () No ()

En caso de Sí ¿cuáles son?

.....
.....
.....

13.14 ¿Existen incentivos para que las farmacias dispensen similares? Sí () No ()

En caso de Sí ¿cuáles son?:

.....
.....
.....

14. EDUCACIÓN SOBRE GENÉRICOS

¿Ha habido algún plan o campañas de educación a prescriptores, dispensadores y público general sobre genéricos? Explicar que actividades, para que actores, las características de los programas, y su duración ANEXAR DOCUMENTOS

.....
.....
.....

15. CONSUMO FARMACÉUTICO EN EL SECTOR PÚBLICO Y EN EL SECTOR PRIVADO (2002 o indicar el último año para el que hay información disponible)

	Sector Publico		Sector Público	
	En unidades	En dólares	En unidades	En dólares
Medicamentos de marca				
Genéricos				
Similares				

16. FINANCIAMIENTO DE MEDICAMENTOS

16.1 ¿Existe control de precios de los medicamentos? Sí () No ()

Si sí, explicar las características del control de precios

.....
.....
.....

16.2 ¿Existe un régimen especial de precios para el usuario del sector público (Ministerio de Salud o la Seguridad Social)? Explicar

.....
.....

16.3 ¿Hay algún incentivo financiero para que el usuario solicite genéricos? Explicar

.....
.....
.....

16.4 ¿Hay algún incentivo financiero para que el usuario solicite similares? Explicar

.....
.....
.....

17. COMPRA DE MEDICAMENTOS POR EL SECTOR PÚBLICO (2002 o indicar el último año para el cual está disponible la información)

	Genéricos		Similares		De marca	
	Unidades	Valor en dólares	Unidades	Valor en dólares	Unidades	Valor en dólares
Ministerio de Salud						
Seguro Social						
Otros (especificar)						

17.1 ¿Existe alguna política que impida a las instituciones del sector público la compra de medicamentos que no estén incluidos en sus formulario institucionales? Sí () No ()

Explicar y ANEXAR DOCUMENTO

.....

17.2 ¿Existe alguna política de compras para el sector público que de preferencia a la compra de genéricos cuando se pueden obtener al mismo precio que los medicamentos de marca?

Sí () No ()

Explicar y ANEXAR DOCUMENTO

.....

ANNEX II

QUESTIONNAIRE ON GENERIC DRUG POLICIES

THIS QUESTIONNAIRE IS A DRAFT. WE WOULD APPRECIATE YOUR ASSISTANCE IN IMPROVING IT. YOU CAN HELP BY LETTING US KNOW WHICH QUESTIONS ARE DIFFICULT TO UNDERSTAND OR TO RESPOND. ALSO, IF THERE ARE ADDITIONAL AREAS OF INQUIRY THAT SHOULD BE INCLUDED, PLEASE SHARE YOUR IDEAS.

DO NOT FORGET TO INCLUDE THE NAME OF THE INFORMANT. IF THERE IS MORE THAN ONE PERSON PROVIDING INFORMATION. PLEASE INDICATE WHICH SECTION/S HAS EACH PERSON RESPONDED.

PLEASE ADD A PAGE WITH THE NAME, TITLE, POSITION, E-MAIL AND ADDRESS OF ALL THOSE WHO HAVE PROVIDED INFORMATION.

IF YOU ARE USING ANY DOCUMENTS INDICATE THE FULL BIBLIOGRAPHIC REFERENCE.

IF YOU DO NOT HAVE THE INFORMATION LEAVE THE QUESTION EMPTY. IF YOU LEAVE THE QUESTION UNANSWERED, AND YOU KNOW THAT YOU CAN GET THE INFORMATION IF GIVEN MORE TIME, PLEASE INDICATE WHO CAN RESPOND TO IT AND BY WHEN. WE MAY BE ABLE TO WAIT FOR THE DATA.

DEFINITIONS:

Original drug: refers to the drug sold by the originator or another company that has received the license or the authorization from the originator. The original drug can be under patent or off patent.

Original generic drug: refers to the drug sold by the originator or another company that has received the license or the authorization from the originator. It may or may not be protected by patent, and it is sold under INN.

Generic drug: is the drug that is bioequivalent and interchangeable with the reference drug (usually the original drug). It is sold under INN.

Branded generic drug: is a generic drug (thus it is bioequivalent and interchangeable) and it is sold with a brand name.

Branded similar drug: drug that has not been proven to be bioequivalent with the original drug and that is sold under a brand name.

Similar drug: drug sold under INN, that has not been proven to be bioequivalent with the original drug.

1. TYPES OF DRUGS REGISTERED IN THE COUNTRY

	Yes	No
Are there branded original drugs under patent or under another system of intellectual property protection?		
Are there branded original drugs off patent or not under a system of intellectual protection?		
Are there original generic drugs (bioequivalent) under patent or another system of intellectual protection?		
Are there original generic drugs (bioequivalent) that are not under patent or another system of intellectual protection?		
Are there generic (bioequivalent) drugs sold under INN?		
Are there branded generic (bioequivalent) drugs?		
Are there branded similar (not bioequivalent) drugs?		
Are there similar drugs (not bioequivalent) that are being sold under INN?		

GENERIC POLICY

2.1. Is there an official generics' policy? Yes () No ()

2.2 If yes provide the reference to the document containing the policy, including the publication date.....

.....
 PROVIDE COPY OF THE DOCUMENT. IF THERE IS MORE THAN ONE DOCUMENT
 PROVIDE THE BIBLIOGRAPHIC REFERENCE OF ALL OF THEM

3. LEGISLATION AND REGULATION OF GENERIC DRUGS

3.1 Is there a law or any provision approved by the legislature related to generic drugs?
 Yes () No ()

3.2 Name, number and date of the law/s or provision/s

3.3 Are there any provisions approved by the government for the specific regulation of generic drugs? Yes () No ()

3.4 Name, and date that the regulation/s were issued

PROVIDE COPY OF THE DOCUMENTS. IF THERE IS MORE THAN ONE DOCUMENT
 PROVIDE THE BIBLIOGRAPHIC REFERENCE OF ALL OF THEM

3.5 Is there an agency or regulatory office with responsibility for generic drugs?
 Yes () Name _____
 No ()

4. POLICY FOR SIMILAR DRUGS (NON-BIOEQUIVALENT)

4.1 Is there an official policy for similar drugs? Yes () No ()

4.2 Name of the official document detailing this policy and publication date

.....

PROVIDE COPY OF THE DOCUMENT. IF THERE IS MORE THAN ONE DOCUMENT
 PROVIDE THE BIBLIOGRAPHIC REFERENCE OF ALL OF THEM

5. LEGISLATION AND REGULATION OF SIMILAR DRUGS

5.1 Is there a law or any provision (within a law) on similar drugs? Yes () No ()

5.2 Name, number and date of the law.....

5.3 Are there regulations (norms, directives etc) related to similar drugs? Yes () No ()

5.4 Name and date of the regulation/s

.....

PROVIDE COPY OF THE DOCUMENT. IF THERE IS MORE THAN ONE DOCUMENT
 PROVIDE THE BIBLIOGRAPHIC REFERENCE OF ALL OF THEM

5.5 Is there are regulatory agency/office responsible for similar drugs?

Yes () Name of the agency _____
 No ()

6. LEGISLATION AND REGULATION OF INTELLECTUAL PROPERTY PROTECTION

6.1 Date of the intellectual property protection law

6.2 Type of patent protection:

	Yes	No
Compound: active ingredient, including formulation or uses of the chemical entity		
Pharmaceutical composition: active ingredient formulated for use as a pharmaceutical		
Method of use: indication or use of an active ingredient		
Manufacturing process: method of production		
Other (specify)		

6.3 Period of patent protection

	Yes	No	Number of years of protection
From filing request for approval			
From patent approval			

6.4 Reasons for patent extensions and maximum number of years of extension

Reasons	Yes	No	Maximum number of years of extension
a. For delays of the patent regulatory body			
b. Time in clinical trials			
c. For time in receiving approval			
d. Other (specify)			

6.5 Maximum possible time from new drug approval by the regulatory body to patent expiration _____ years

6.6 Is there drug market exclusivity extension (protection from using the data of the originator company for approval of a generic competitor)? Yes () No ()

If yes, it covers the following

	Yes	No	Maximum number of years of extension
Orphan drugs			
New molecular entities			
New indications			
Other (specify)			

6.7 Is there a Bolar provision? (The Bolar provision allows the use of a patented drug and all pertinent information by a company other than the owner of the patented drug for the development of a generic drug and for filing a generic drug approval application. The generic product is not released into the market until the patent is expired.) Yes () No ()

Comments

.....

6.8 Is there Provisional filing? (Provisional filing allows inventors to claim a right of priority when they later submit a complete application, the priority is based on the filing date of the provisional application)?

Yes () Additional time due to the provisional application _____
 No ()

Comments.....

6.9 Are there compulsory licenses? Yes () No ()

If they exist, under which of the following conditions are they granted:

	Yes	No
No production in the country*		
Health emergencies		
Market competition issues		
Public non-commercial use		

*Number of years before a compulsory license may be granted _____

6.10. Parallel importing provisions

Is there a regimen of exhaustion?

Yes () at what level? National _____ Regional _____ International _____
 No ()

6.11 Is there a link between the drug registration office/body and the patent office/body?

Yes () No ()

Comments

6.12 Is there any issue related to intellectual property rights being debated in the country?

Yes () No ()

Explain

7. DRUG REGISTRY

7.1

- a. Is there a need for registration before a drug is commercialized? Yes () No ()
- b. Number of active ingredients registered
- c. Number of pharmaceutical entities registered ⁸
- d. Number of registered generic drugs
- e. Number of branded similar drugs registered
- f. Number of similar drugs registered with INN names
- g. Median time of approval of a branded originator drug (months)
- h. Is there an abbreviated process for the registration of generic drugs? Yes () No ()
- i. Is there a requirement of bioequivalence to a reference product for approval of a generic drug?
Yes () No ()
- j. Median time for approval of a generic drugmonths
- k. Is there an abbreviated process for the registration of similar drugs? Yes () No ()
- l. Median time for approval for a similar drugmonths
- m. Cost of registering a new original drug (in US dollars)
- n. Cost of registering a branded product which active ingredient is already in the market (in US\$)
.....
- o. Cost of registering a generic drug (in US\$).....
- p. Cost of registering a similar drug (in US\$).....

7.2 Does the government facilitate the registration of generics? Explain

- a.
- b.
- c.

7.3 What types of tests are required to demonstrate bioequivalence?

- a.
- b.
- c.

7.4 Is there a priority list of drugs that require to be tested for bioequivalence?

Yes () No ()

Comments

IF YES PROVIDE THE LIST

⁸ The same active ingredient can be used in several pharmaceutical entities. Each formulation (concentration, presentation) is a different pharmaceutical entity)

8. INTERNATIONAL COMMERCE

- a. Are there taxes for the importation of drugs? Yes () % del FOB ____ No ()
 b. Does the importer need a license? Yes () No ()
 c. How many drug importers are there? _____
 d. Are you using the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in international commerce? Yes () No ()

The WHO certification is used for:

	Yes	No
Drug registration		
Certification for export		
Use certification issued by other countries for drug registration		
Use certification issued by other countries for drug registration only for public sector procurement		

9. DRUG MANUFACTURING

9.1. Total number of foreign pharmaceutical companies (more than 50% of the capital is foreign).....

- a. Number of foreign companies that produce generic drugs
 b. Number of foreign companies that produce similar drugs

9.2 Total number of national pharmaceutical companies (more than 50% of the capital is national).....

- a. Number of foreign companies that produce generic drugs
 b. Number of foreign companies that produce similar drugs

9.3 Percent of the total market that is covered with generics and with similar drugs :

	% monetary value	% of number of units
Generics (bioequivalent)		
Similar (brand and INN)		

9.4 Is there any incentive for the production of generics? Yes () No ()

If Yes, Describe

10. GENERIC DISPENSING

10.1 Number of wholesalers that distribute generics

- a. Number of private wholesalers
 b. Number of public wholesalers

10.2 Percent of the market controlled by the 5 largest wholesalers in the country%

10.3 Are there any incentives for the private sector to dispense generic drugs?

Yes () Describe _____
No ()

11. GENERIC PRESCRIPTION

11.1 Is there any regulation mandating doctors to prescribe using INN?

In the public sector	Yes ()	Can the prescriber add a brand name?	Yes () No ()
	No ()	Can the prescriber legally preclude the substitution of a brand name product?	Yes () No ()
In the private sector	Yes ()	Can the prescriber add a brand name?	Yes () No ()
	No ()	Can the prescriber legally preclude the substitution of a brand name product?	Yes () No ()

11.2 Of the total number of prescriptions, how many are written using the INN ?

In the public sector%

In the private sector..... %

11.3 Is there any incentive to prescribe using INN?

In the public sector Yes () Explain.....
No ()

In the private sector Yes () Explain.....
No ()

12. DISPENSING GENERICS

12.1 Percentage of the pharmacy market controlled by the top 5 pharmacy chains: %

_____ there are no pharmacy chains

12.2 Percentage of drugs included in the essential drug list that are available in generic form.....%

12.3 Percentage of drugs included in the essential drug list that are available in similar versions
.....%

13. GENERIC SUBSTITUTION

13.1 Is there a law or a regulation allowing generic substitution by pharmacists? Yes () No ()

13.2 Is there a law or regulation requiring generic substitution by pharmacist? Yes () No ()

13.3 According to the law or the regulation, under which conditions should generic substitution be done?

-
-

13.4 Is there any law or regulation allowing the pharmacist to substitute a brand name by a similar drug? Yes () No ()

13.5 Is there any law or regulation requiring the pharmacist to substitute a brand name by a similar drug? Yes () No ()

13.6 According to the law or the regulation, under which conditions should the substitution with a similar drug be done?

-
-

13.7 Are pharmacies required to have in stock at least one product for each drug included in the essential drug list? Yes () No ()

13.8 Are pharmacies required to have in stock several products for each drug included in the essential drug list? Yes () No ()

13.9 Can pharmacies decide the generic product to be dispensed? Yes () No ()

13.10 When there are several generics in stock, can the consumer decide the generic product to buy? Yes () No ()

13.11 Is there a catalogue establishing the equivalence of brand names and generic drugs at the disposal of:

- | | |
|-------------|----------------|
| Physicians | Yes () No () |
| Pharmacists | Yes () No () |
| Consumers | Yes () No () |

13.12 Is there a catalogue establishing the equivalence of brand names and similar drugs at the disposal of:

- Physicians Yes () No ()
- Pharmacists Yes () No ()
- Consumers Yes () No ()

13.3 Are there incentives for the private sector to dispense generic drugs?

Yes () No ()
If Yes, explain

13.14 Are there incentives for the private sector to dispense similar drugs?

Yes () No ()
If Yes, explain

14. EDUCATION ON GENERICS

Has there been any program or campaign to educate prescribers, dispensers or consumers on generic drugs? If yes explain the program, actors, duration etc. ATTACH DOCUMENTS IF AVAILABLE

15. PHARMACEUTICAL CONSUMPTION IN THE PUBLIC AND PRIVATE SECTORS (Use 2002 figures, if not available note the most recent year for which information is available)

	Public Sector		Private Sector	
	In units	In dollars	In units	In dollars
Branded drugs				
Generics				
Similar drugs				

16. DRUG FINANCING

16.1 Are there price controls for drugs? Yes () No ()

If Yes, explain how prices are controlled

16.2 Is there a special pricing system for public sector users (Ministry of Health or Social Security)? Explain

.....

16.3 Are there financial incentives for the consumers to request generics? Explain

.....

16.4 Are there financial incentives for the consumers to request similar drugs? Explain

.....

17. DRUG PURCHASING IN THE PUBLIC SECTOR (use 2002 figures, if unavailable, note the most recent year for which information is available)

	Generics		Similar		Branded	
	Units	US dollars	Units	US dollars	Units	US dollars
Ministry of Health						
Social Security						
Other (specify)						

17.1 Is there a policy precluding prescribers in the public system to prescribe drugs not included in the institution's formulary? Yes () No ()

Explain and ATTACH DOCUMENTS

.....

17.2 Is there any purchasing policy in the public sector favoring the purchase of generics when the cost is equal to the cost of branded medicines? Yes () No ()

Explain and ATTACH DOCUMENTS

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REFERENCES

1. Kremer M. Pharmaceuticals in the developing world. *Journal of Economic Perspectives* 2002; 16 (4): 67-90.
2. Cortez R. Desarrollo de una estrategia social para Perú. BID-Centro de Investigación de la Universidad del Pacífico, Lima, Perú; 2001.
3. Gonzalez GG. Las vidas que no tienen remedios. *El Clarín*, July 25, 2001. Buenos Aires, Argentina; 2001.
4. World Health Organization. WHO medicines strategy: framework for action in essential drugs and medicines policy 2000-2003. Geneva; WHO, 2000.
5. Bapna JS, Tripathi CD, Tekur U. Drug utilization patterns in the Third World. *Pharmacoeconomics* 1996; 9: 286-294.
6. World Health Organization. How to develop and implement a national drug policy. Geneva: WHO, 2001.
7. World Health Organization. Progress of WHO Member States in developing national drug policies and in revising essential drug lists. WHO/DAP/98.7. Action Programme on Essential Lists. Geneva: WHO, 1998.
8. World Health Organization. Guidelines for developing national drug policies. Geneva: WHO, 1988.
9. ANMAT. La ANMAT y la bioequivalencia. [ANMAT and bioequivalence] *ANMAT Informa*, 2002, 10 (3-4): 33-64. In Spanish
10. Agência Nacional de Vigilância Sanitária (ANVISA). Ministério de Saúde. Medicamentos genéricos en Brasil. Aspectos regulatorios [Generic medicines in Brazil. Regulatory aspects]. Brasilia: ANVISA; c. 2002. Brasil (circa 2002). In Portuguese.
11. Cavallone, Enrique. Practical issues in creating and maintaining local pharmaceutical production in developing countries. Paper presented at the World Bank, June 2, 2003.
12. Tobar, Federico. Acceso a los medicamentos en Argentina: diagnósticos y alternativas. Fundación ISALUD. Buenos Aires, Argentina. 2002.
13. Comisión Pro-cátedra Libre de Salud y Derechos Humanos en la Facultad de Medicina de la Universidad de Buenos Aires. En una Argentina nueva es posible medicamentos para todos (segunda parte). Por una producción pública de medicamentos básicos esenciales. *Boletín Fármacos* 2003; 6(2):99-110.
14. Martín Cañás. Qué pasa con los genéricos de los laboratorios públicos argentinos? . *Boletín Fármacos* 2002; 5(2):18-20.
15. Francisco Rossi. Genéricos en Colombia. *Boletín Fármacos* 2002; 5(2):23-25.
16. Avalos, Angela. Guerra por calidad de medicinas genéricas en Costa Rica. *Boletín Fármacos* 2003; 6(1):18.
17. Ministerio de Salud. Medicamentos esenciales genéricos y sus alternativas de marca. DIGEMID. Lima, Perú. 2001.



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