Multisource drug policies in Latin America: survey of 10 countries

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Abstract Essential drug lists and generic drug policies have been promoted as strategies to improve access to pharmaceuticals and control their rapidly escalating costs. This article reports the results of a preliminary survey conducted in 10 Latin American countries. The study aimed to document the experiences of different countries in defining and implementing generic drug policies, determine the cost of registering different types of pharmaceutical products and the time needed to register them, and uncover the incentives governments have developed to promote the use of multisource drugs. The survey instrument was administered in person in Chile, Ecuador and Peru and by email in Argentina, Brazil, Bolivia, Colombia, Costa Rica, Nicaragua and Uruguay. There was a total of 22 respondents. Survey responses indicated that countries use the terms generic and bioequivalence differently. We suggest there is a need to harmonize definitions and technical concepts.

Keywords Drugs, Generic/classification/legislation; Therapeutic equivalency; Drug and narcotic control; Legislation, Drug; Latin America (*source: MeSH, NLM*).

Mots clés Médicaments génériques/classification/législation; Equivalence thérapeutique; Contrôle drogues et stupéfiants; Législation pharmaceutique; Amérique latine (*source: MeSH, INSERM*).

Palabras clave Medicamentos genéricos/clasificación/legislación; Equivalencia terapéutica; Control de medicamentos y narcóticos; Legislación de medicamentos; América Latina (*fuente: DeCS, BIREME*).

الكلمات المفتاحية: الأدوية الجنيسة (غير المحدَّدة الملكية)، تصنيف الأدوية الجنيسة، تشريعات الأدوية الجنيسة؛ التكافؤ العلاجي؛ مكافحة المخدِّرات والمواد المسبِّبة للإدمان؛ تشريعات المخدِّرات والمواد المسبِّبة للإدمان؛ أمريكا اللاتينية. (المصدر: رؤوس الموضوعات الطبية– المكتب الإقليمي لشرق المتوسط).

Bulletin of the World Health Organization 2005;83:64-70.

Voir page 69 le résumé en français. En la página 69 figura un resumen en español.

يمكن الاطلاع على الملخص بالعربية في صفحة 69.

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. Financial affordability is the main barrier to access (*1*–*5*). In Latin America the cost of medicines has increased at a rate faster than inflation. The number of pharmaceutical units sold in many countries in the region decreased despite increased drug expenditures, confirming that access to medicines has become more difficult (*3*, *6*, *7*). To ensure that countries have access to needed medicines at an affordable price, WHO has recommended the use of essential drug lists to guide drug selection, registration and procurement by governments; it has also recommended the implementation of policies to promote the use of generic drugs (*4*, *8*–*10*). The need to increase the availability of and access to generic drugs has gained visibility with the failure of antiretroviral therapy to reach patients in the developing world (*1*). In response to these problems and recommendations, many countries in Latin America have recently taken steps to increase the use of cheaper off-patent drugs.

This article reports the result of a survey conducted in June 2003 in several Latin American countries. The aim was to document their pharmaceutical policies. In this paper we present data on the existence of generic or multisource drug policies, the cost and time needed to register the different types of pharmaceuticals, and the incentives used to promote the use of generic or multisource drugs.

Methods

The survey tool was developed by the authors and was based on indicators that the Pan American Health Organization had wanted to use in its pharmaceutical observatory initiative (EC Seoane Vázquez, unpublished data, May 2003). The survey included a combination of 82 qualitative and quantitative questions.

The survey was financed by a US$ 6000 grant from The World Bank as part of an initiative to develop strategies to increase access to affordable medicines in developing countries. The funding was used to meet with survey respondents face to face and to attend meetings at The World Bank's headquarters in Washington, DC. We had less than one month to collect the information and decided to administer as many questionnaires as possible. The questionnaires were administered in person in Chile, Ecuador and Peru by Roberto López Linares. Questionnaires were administered by email to respondents in Argentina, Brazil, Bolivia, Colombia, Costa Rica, Nicaragua and Uruguay.

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Ref. No. **03-009381**

(*Submitted: 4 November 2003 – Final revised version received: 31 May 2004 – Accepted: 3 June 2004*)

Email respondents had a maximum of 10 days to complete the questionnaire and provide supporting documentation. Survey respondents included at least one person working in the national drug regulatory agency and/or one expert on pharmaceutical policies in each country. We had at least two respondents per country except in Brazil where we had only one respondent; thus there were 22 respondents in total.

Data were gathered during the second and third week of June of 2003, except in the case of Brazil from which information was obtained in January 2004. The information collected in the questionnaire was complemented with information obtained from archival documents and the web sites of the regulatory agencies (most of them located within the ministries of health) of the countries studied.

The definitions used in the survey (Table 1) were offered by a group of experts convened by The World Bank and, as will be discussed, we found these definitions to be inappropriate and that their use limited the possibility of making comparisons across countries. For our purposes a generic product had to be bioequivalent to the proprietary (original) drug. WHO uses the term multisource. According to WHO guidelines, multisource pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable. Two products are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage form; if they meet the same or comparable standards; and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence because differences in the excipients or the manufacturing process, or both, can lead to differences in product performance. Two pharmaceutical products are therapeutically equivalent if they are pharmaceutically equivalent and, after administration in the same molar dose, their effects with respect to efficacy and safety are essentially the same, as determined by appropriate bioequivalence, pharmacodynamic, clinical or in vitro studies (*11*).

Table 1. **Definitions used in survey of 10 Latin American countries to classify different types of pharmaceutical products**

Source	Type of drug	
Originator[a]	Branded original drugs on patent[b] Branded original drugs off patent Generic original drug[c] (uses INN and is off-patent)	
Secondary source (off-patent)	Bioequivalent to the original drug	Branded generic drugs INN (proper generic drug)
	Not bioequivalent to the original drug	Branded similar drug[d] INN (similar drug or copy)

[a] The originator is the company that holds the patent on a product.
[b] A branded original drug is a product sold by an originator or by a company licensed or authorized by an originator.
[c] Generic original drug refers to an original drug sold under an International Nonproprietary Name (INN). A generic drug is a pharmaceutical product that is off-patent in the country where it is sold or for which the patent rights have been modified in such a way that it can be produced without the patent holder's consent (e.g. due to compulsory licensing); its therapeutic equivalence to the proprietary drug has been certified in the country where it is sold on the basis of bioequivalence or a similar testing; it is sold under a nonproprietary name. If sold under a brand name it will be labelled as a branded generic.
[d] A similar drug (or copy) is a pharmaceutical product that is off-patent but for which there is no proof of bioequivalence. It may be sold under a brand name or under an INN.

Results

Types of pharmaceutical products

The first finding was that the term generic is used differently across countries and it may even have different meanings within a country depending on the context in which the term is used (Table 2). Bolivia, Chile, Colombia, Costa Rica, Ecuador, Nicaragua and Peru classify pharmaceutical products into two categories: those identified by brand names and those identified by the International Nonproprietary Name (INN) recommended by WHO or any other nonproprietary names defined by the country or recognized internationally. In these countries pharmaceutical products in the latter category are referred to as generic drugs, and the term generic itself is used to indicate that the product is nonproprietary. All products with nonproprietary names are off-patent; brand name products can be on-patent or off-patent.

In Argentina, Brazil and Mexico the term generic is reserved for products that are off-patent and have been demonstrated to be interchangeable with the proprietary product; that is, they have the same efficacy and safety. In these countries pharmaceutical products are classified into three categories: innovative drugs (proprietary products); similar drugs or copies (products that are pharmaceutically equivalent to the proprietary product — that is, they contain the same active substance(s) in the same dosage and are intended to be administered by the same route but may have a different excipient, form, size or shelf-life); and generic drugs (products that have been proven to be therapeutically equivalent and interchangeable with the proprietary drug). Generic and similar drugs may be labelled with brand names or with nonproprietary names; innovative (proprietary) drugs usually are identified with a brand name. In Mexico the official term is interchangeable generic (genéricos intercambiables). Chile uses the term interchangeable generic to indicate that the Chilean Institute of Public Health has certified that the product is bioequivalent to the proprietary drug (*15*).

Drug registration

The length of time it takes to approve drugs in each country is shown in Table 3. All countries in Latin America, except Brazil, Chile and Cuba, have shorter drug approval times than more developed countries, such as Australia (17 months), countries in the European Union (14–30 months), Canada (17 months) and the United States (14–18 months) (*16*). Peru's drug regulatory agency (Dirección General de Medicamentos, Insumos y Drogas or DIGEMID) has only 7 days in which to act, and if during this period DIGEMID does not respond to the request for approval, the drug is automatically registered. Brazil and Colombia encourage the registration of generics and similar drugs by having shorter approval times.

The cost of registering a product is low in Latin America (Table 3). Even Brazil's comparatively high fee is low compared to fees charged in developed nations; it is only one fifth the fee charged by Australia (US$ 126 500) and is significantly cheaper than the average in the European Union (US$ 200 000) or the United States (US$ 309 647), although the United States

Table 2. **Types of pharmaceutical products and definitions of products used in 10 different Latin American countries**

Country	Type of pharmaceutical products
Argentina (*12*)	**Innovative drugs** ***Similar drugs (or copies).*** These have the same active ingredient, concentration, pharmaceutical form and dosage and are used for the same indications as the innovative product. They are equivalent to the innovative product but may differ in size, shape, packaging and period of activity. These are pharmaceutically equivalent to the innovative drug. They may use a brand name ***Generic drugs.*** These are drugs that have been proven to be bioequivalent to the innovative drug. They are off-patent and tend to be identified by an INN[a]
Brazil (*13*)	**Innovative or reference drugs** ***Similar drugs.*** These have the same active ingredient, concentration, dosage and pharmaceutical form as the reference drug. They are used for the same indications. They are equivalent to the reference drug but may have different size, shape, packaging and excipients. Needs to be identified with a brand name ***Generic drugs.*** These are interchangeable with the reference drug and have been proved to have the same efficacy, security and quality. They are produced after patent expiration and are identified with an INN or Brazilian nonproprietary name
Mexico (*14*)	**Innovative or reference drugs** ***Generic interchangeables.*** These are interchangeable with the reference product as certified by the Health Secretariat. They are off-patent and are identified by an INN ***Similar drugs.*** These drugs have the same active ingredient as the reference product and may be identified with a brand name or an INN
Bolivia, Chile, Colombia, Costa Rica, Ecuador, Nicaragua, Peru[b]	**Branded drugs.** These are proprietary drugs and similar or copy drugs ***Generic drugs.*** These use an INN or others internationally recognized names. They are off-patent

[a] INN = International Nonproprietary name.
[b] Information provided by survey respondents.

waives the fee for generic applications (*16*). Argentina, Brazil, Chile and Venezuela encourage the use of generic and similar drugs by having lower registration fees.

National generic policies

The First Latin American Conference on the Economic and Financial Aspects of Pharmaceuticals recommended that Latin American countries develop policies on generic drugs (*17*). Ecuador and Brazil have laws regulating the use of generic drugs. Part of the national health law discusses the use of generic drugs in Argentina, Chile, Colombia, Costa Rica, Mexico, Nicaragua, Peru and Uruguay

As shown in Table 4, Argentina, Bolivia, Chile, Colombia, Ecuador, Mexico, Peru and Uruguay also have laws or executive decrees that require prescriptions to be written using INN designations. No country in the region mandates substitutions of proprietary drugs by generic or similar drugs, and Brazil allows only the substitution of proprietary drugs by generic drugs.

Discussion

One of our most important findings was that the term generic means different things between and within countries. With the exception of Brazil, which has about 1033 generic pharmaceuticals, the markets in the rest of the Latin American countries studied have few drugs proven to be therapeutically equivalent or interchangeable with the proprietary product. The result is that generic drug policies relate to the use of similar drugs (or copies), and in daily speech most policy-makers, consumers, and many health professionals use the terms generic and similar interchangeably, which further confuses the issue.

Indiscriminate use of the term generic in Argentina is a good example of the confusion that can be produced. When in 2002 the Minister of Health announced his initiative to promote the use of generic drugs (resolution 326 and law 25.549) national and provincial medical associations pointed out that none of the drugs sold in the country as generic had proven bioequivalence as required by law. The Argentine pharmaceutical market did offer many similar drugs under branded and INN names, and the intent of the initiative was to stimulate competition among drug producers so that expensive branded originals could be replaced with similar drugs. The government expected that the new initiative would promote competition and lower prices, resulting in increased accessibility (*18*).

The ambiguity of the term generic was one of the reasons why some medical associations and consumer groups opposed the policy. For them the quality of the similar drugs was questionable. Although the term generic includes a quality component the government had limited its mandate to prescribing by generic name (that is, it used the word generic to indicate that prescriptions had to be written using nonproprietary names) and substituting similar drugs for proprietary drugs. For obvious reasons the pharmaceutical industry also opposed the policy. All those who opposed the generic initiative used this opportunity to claim that similar drugs or copies could be unsafe and of poor quality, and that the ministry did not adequately regulate the production of drugs (*19*).

Many parties have an interest in how pharmaceutical products are classified. Some countries in the region have developed a typology that includes three types of drugs: original, similar and generic. The others use a binary classification of branded and generic products. WHO has proposed a differ-

ent typology: single source and multisource pharmaceuticals. Single source pharmaceuticals correspond to the original drugs (usually on-patent), while multisource drugs can be produced by multiple pharmaceutical firms and include drugs that are pharmaceutically equivalent and may or may not be therapeutically equivalent to the original drug. Single source drugs are usually identified with a brand name, and multisource drugs can be identified by the INN or by brand names. The merging of the categories of similar drugs and generic drugs offers several advantages.

Drug regulatory agencies have to ensure that the supply of medicine is safe and that medicines are efficacious for treating the ailments for which they will be prescribed. In the case of multisource drugs, however, there is no agreement on the tests that each pharmaceutical product should undergo in order to be considered to have met acceptable efficacy and safety standards. For some products it is sufficient to document that the new product is pharmaceutically equivalent to the original drug; in other cases therapeutic equivalence needs to be proven. Therapeutic equivalence can be proven by clinical trials, in vitro or through pharmacodynamic studies. The type of testing used has significant implications in terms of costs, technical capacity and time. Consequently, those parties interested in restraining competition advocate for lengthy testing and those interested in expediting the availability of cheaper versions of drugs argue for limited testing that is sufficient to guarantee the efficacy and safety of most drugs.

Our study documented high levels of confusion among our respondents (all of whom were working in regulatory agencies or were pharmaceutical experts). Therefore, it is not useful to maintain the classification of pharmaceutical products commonly used in Latin America. The classification of products that we used in our survey was inappropriate but because there is a lack of consensus on classifying these products, we would have encountered the same problem if we had selected a different typology. Interestingly, our respondents also had different interpretations of the word bioequivalence. For some the term implied that clinical trials had to be conducted to ensure that the generic product was pharmaceutically equivalent and its bioavailability was the same or similar enough to have essentially the same effects as the proprietary drug. Others used the terms bioequivalence and interchangeability indiscriminately and asserted that for a drug to be classified as a generic it had to be interchangeable with the reference product. Documents from Chile (*15*) specify that the test of bioavailability can be done in vitro.

Our findings suggest that countries are trying to reach agreement on the type of testing that needs to be done before the commercialization of multisource drugs can be approved. Argentina, Brazil, Chile and Costa Rica have developed lists of the pharmaceutical products that need to be tested for therapeutic equivalence, and these countries have often identified the corresponding tests needed. This is a first step. Ideally such a list would include all products and the types of tests needed, if any, before a drug can enter the market. The tests for many products will be simple and inexpensive.

The case of Brazil highlights some of the difficulties encountered in making these types of determinations. Brazil passed resolution number 391 in September 1999; it stated that for a product to be registered as generic there was a need to prove bioequivalence. Subsequently, the requirement for proving bioequivalence was modified (in February 2002 by resolution 10 and in March 2002 by resolution 84). Resolution 10 included a list of medicines that for safety reasons could not be registered as generic drugs. (Uruguay has a similar list and Colombia is considering adopting one.) Resolution 10 also mandated the creation of a guide to substitute bioequivalence testing with other tests to demonstrate the interchangeability of the new product with the reference drug. In addition, resolution 84 modified the list of products identified in resolution 10. Other issues under discussion in Brazil include the determination of the minimum number of volunteers needed to demonstrate bioavailability and bioequivalence in clinical trials.

It is impossible to carry out comparative cross-national studies of generic policies as a result of the lack of consensus on the meaning of the term generic. For example, in our study we found that it was impossible to make cross-national comparisons of the share of generic sales as a proportion of each country's pharmaceutical market or even to compare the number of registered generic and similar products.

Table 3. **Time and cost of registering a drug in 10 Latin American countries**

Country	No. of months to register	Cost (US$)[a]
Argentina[b]	3–4	1000 for original drugs 333 for generic or similar drugs
Bolivia[b]	1	50
Brazil[b]	Original: 12–14 Similar: 8–12 Generic: 6–8	2700–27 000 for original drugs (the price depends on the size of the manufacturer) 7000 for a similar drug 2000 for a generic drug
Chile[b]	8–12	1300 for original drugs 800 for generic or similar drugs
Colombia[b]	Original: 6 Similar or generic: 3	1200 for new registration 1000 to renew market authorization
Costa Rica (*16*)	1.5	500
Cuba (*16*)	12	700
Ecuador[b]	1	1339 for imported drugs 535 for drugs manufactured locally 344 for those included in the essential drug list
Guatemala (*16*)	NA[c]	6
Mexico[b]	Original: 3 Similar: 20 to 60 days	800
Nicaragua[b]	3	485 for imported drugs 166 for drugs manufactured locally
Peru[b]	7 days	89
Uruguay[b]	6	500
Venezuela (*16*)	6	1270 for original drugs 215 for generic drugs

[a] Costs are in 2003 US dollars.
[b] Information provided by survey respondents.
[c] NA = Not available.

Table 4. **Summary of legislation on drug prescribing and substitution by generic or similar drugs in 10 Latin American countries**

Country	Regulations		Conditions
	Prescribing	Substitution	
Argentina	Prescriptions must include the generic name (regulations in 1992 and 2002) but may include a brand name	Allowed but not mandatory	In some cases, if the INN[a] does not appear in the prescription, the cost of the prescription is not reimbursed by the third party payer
Bolivia	Must use INN (1996) but may include a brand name	Allowed but not mandatory	None
Brazil	The use of INNs is mandatory in the public sector	Allowed but not mandatory	Substitution is permitted only between originals and generics; similar drugs cannot be substituted for original drugs
Costa Rica	Social Security (CCSS) prescriptions may only mention INN (cannot mention brand name)[b]	Allowed but not mandatory	None
Chile	Public sector prescriptions may only mention INN[c]	At the discretion of the patient and the pharmacist	None
Colombia	Social security system prescriptions must include an INN and may include a brand name	Allowed but not mandatory	Discussions are under way about whether to prohibit the substitution of original drugs with narrow security margins (those that can cause harm if not produced carefully and administered properly)
Ecuador	In the public system the use of an INN is mandatory	Pharmacist may offer a generic or similar drug as a substitute for the prescribed medicine but it is not mandatory to do so	None
Mexico	Ministry of Health prescriptions must use an INN but may include brand name	If the physician prescribes a brand name the pharmacist must supply the branded drug	The patient may request a generic drug
Nicaragua	In the public sector an INN must be used	Prescriber and patient have to agree to the substitution of a generic or similar drug for the prescribed medicine but it is not mandatory to substitute	The prescriber and the patient must come to an agreement on whether to substitute a generic or similar drug
Peru	In the public sector an INN must be used	Allowed but not mandatory	Substitution allowed if the generic or similar drug is chemically and pharmacologically equivalent
Uruguay	INN used	Allowed but not mandatory; the consumer decides	None

[a] INN = International Nonproprietary Name.
[b] The CCSS provides coverage for 90% of the population.
[c] Chile's public sector covers 75% of the population.

It is not enough to say that a given pharmaceutical product produces the same pharmaceutical or therapeutic effect as the original. Regulatory agencies need to ensure that manufacturing follows international standards of good manufacturing practices), and they need to ensure the quality of the pharmaceutical supply. Some authors have raised doubts about the capability of drug regulatory agencies to do so (*1*, *20*, *21*). The importance of ensuring the quality of the medicines supplied cannot be overemphasized, especially in view of the increasing presence of counterfeit drugs. Ensuring the quality of the pharmaceutical supply is a prerequisite for the success of any policy on generic or similar drugs, and it is an important component of efforts to lower the cost of drugs. In Latin America the fees charged for drug registration are low compared to the charges made in other countries; if they were raised the revenue could contribute to strengthening the capacity of the drug regulatory agencies. Along with allowing additional trained personnel to be hired, these increased revenues would enable the agencies to better perform their regulatory tasks.

Conclusion

Countries in Latin America need to harmonize their basic vocabulary on pharmaceutical products and agree the technical procedures needed to ensure the quality of multisource products. Drug regulatory agencies need to be strengthened so that the population can have confidence in the quality of the drug supply. Agreeing on basic principles would also facilitate the exchange of information, the ability to build on one another's experience and the study of how different pharmaceutical policies affect the affordability of and access to pharmaceuticals. ■

Funding: This study was partially funded by The World Bank.

Conflicts of interest: none declared.

Résumé

Politiques en faveur des médicaments multisources en Amérique latine : enquête portant sur 10 pays

En tant que stratégies permettant d'améliorer l'accès aux produits pharmaceutiques et de maîtriser les coûts sans cesse plus élevés de ces produits, on a encouragé les listes de médicaments essentiels et les politiques en faveur des génériques. Le présent article rapporte les résultats d'une enquête préliminaire menée dans 10 pays d'Amérique latine. Cette enquête visait à recueillir des informations sur les expériences de différents pays dans la définition et la mise en œuvre de politiques de promotion des médicaments génériques, à déterminer le coût d'homologation de différents types de produits pharmaceutiques et le temps nécessaire à cette homologation, et à décrire les mesures incitatives mises au point par les gouvernements pour promouvoir l'utilisation de médicaments multisources. L'enquête a été administrée par un enquêteur au Chili, en Équateur et au Pérou et par courriel en Argentine, au Brésil, en Bolivie, en Colombie, au Costa Rica, au Nicaragua et en Uruguay. Vingt-deux personnes au total ont répondu. Les réponses ont indiqué que les pays utilisaient différemment les termes générique et bioéquivalent. Une harmonisation des définitions et des concepts techniques serait nécessaire.

Resumen

Políticas sobre medicamentos multiorigen en América Latina: encuesta de 10 países

Las listas de medicamentos esenciales y las políticas sobre medicamentos genéricos son algunas de las estrategias que se han promovido para mejorar el acceso a las preparaciones farmacéuticas y frenar el rápido aumento de sus costos. Este artículo presenta los resultados de una encuesta preliminar realizada en 10 países latinoamericanos. El estudio tenía por objeto documentar las experiencias de diferentes países en lo tocante a la definición y ejecución de políticas sobre medicamentos genéricos, determinar el costo del registro de diferentes tipos de productos farmacéuticos y el tiempo necesario para registrarlos, y descubrir los incentivos desarrollados por los gobiernos para promover el uso de los medicamentos multiorigen. El instrumento de la encuesta fue administrado en persona en Chile, el Ecuador y el Perú, y por e-mail en la Argentina, el Brasil, Bolivia, Colombia, Costa Rica, Nicaragua y el Uruguay, con un total de 22 encuestados. Las respuestas obtenidas indican que los países usan los términos de genérico y bioequivalencia de distinta forma. Sugerimos que es necesario armonizar las definiciones y los conceptos técnicos.

ملخص

سياسات تعدد مصادر الأدوية في أمريكا اللاتينية: مسح أجري في عشرة بلدان

الملخص: لقيت سياسات قوائم الأدوية الأساسية والأدوية الجنيسة (غير المحدَّدة الملكية) تشجيعاً بالغاً كاستراتيجيات لتحسين فرص الحصول على المستحضرات الصيدلانية ووقف الارتفاع المتسارع في تكاليفها. وتعرض هذه المقالة نتائج دراسة مسح أولية أُجريت في عشرة من بلدان أمريكا اللاتينية. وقد استهدفت هذه الدراسة توثيق تجارب مختلف البلدان في تعريف وتنفيذ سياسات الأدوية الجنيسة، وتحديد تكاليف تسجيل مختلف أنماط المنتوجات الصيدلانية والوقت اللازم لتسجيلها، والكشف عن الحوافز التي حدَّدتها الحكومات لتعزيز استخدام الأدوية المتعدِّدة المصادر. وقد تم توزيع نماذج استبيان المسح على المستجيبين بالتسليم باليد في شيلي والإكوادور وبيرو، ومن خلال البريد الإلكتروني في الأرجنتين والبرازيل وبوليفيا وكولومبيا وكوستاريكا ونيكاراغوا وأوروغواي. وبلغ إجمالي عدد المستجيبين ٢٢ شخصاً. وقد دلت الإجابات التي قدمها المستجيبون في المسح على أن البلدان تستخدم مصطلح "الجنيسة" ومصطلح "التكافؤ البيولوجي" للدلالة على مفاهيم مختلفة. ونقترح في هذه الدراسة ضرورة العمل على تحقيق الانسجام بين التعريفات والمفاهيم التقنية.

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