

# Generics Policies and Access to Drugs in Developing Countries

Juan Rovira  
Senior Health Economist  
Health Nutrition and Population  
The World Bank  
12/02/2003

*The findings, conclusions and recommendations expressed in this document reflect the opinions of the author and not necessarily the position of the World Bank*

## **Introduction**

The concerns of consumers and policy makers for the rising costs of pharmaceuticals in both developed and developing countries explains the increasing interest for generic drugs and policies.

What are generic drugs? Generics might be defined as drugs that

- 1) are not subject to patents or other forms of exclusive marketing rights in a given jurisdiction,
- 2) have a proven therapeutic interchangeability with a reference drug (based on bioequivalence or any other accepted proof of therapeutic equivalence), and
- 3) are sold under an international non-proprietary name.

There is not an internationally agreed definition of generic drug.<sup>1</sup> The term generics is often applied and legally defined to refer to drugs that are sold under brand names and have no proof of equivalence. In order to avoid confusion we'll refer to these categories of drugs as "branded generics" and "similar", respectively.

There are obvious public health and economic advantages in the use of generics: first, there is a guarantee of a standard quality for a multisource product. Second, the introduction of generics tends to lower drug prices. Generic drugs are sold at prices close to the cost of production, because they allow price competition to work. Selling products by an international non-proprietary name eliminates the incentives for companies to increase the demand for their own products by investing in marketing aimed at differentiating their products and attain consumer loyalty. But the introduction of generics also drags down the prices of the branded versions of the drug. For that reason, the World Bank requires its borrowers to use the INN or generic name in bidding documents.

---

<sup>1</sup> WHO often uses the term "multisource" as a synonym of generic.

## **Generic Policies**

Generic policies can be best analyzed by focusing on their role in improving access to three separate categories of drugs:

1. Off-patent drugs
2. On-patent drugs for diseases that are prevalent both in developed and developing countries
3. Drugs for diseases mainly prevalent in low-income countries, i.e. neglected diseases.

The obvious target of a generics policy is the set of drugs that are not subject to any exclusivity marketing rights, patents or otherwise. Most of the drugs in the WHO's Essential Drug List, which are assumed to be the highly cost-effective therapies for a broad list of diseases, are off-patent in all countries. Still, a large proportion of the population in low-income countries does not have adequate access to them.

The strategies required for implementing a generics policy for off-patent drugs are in the hands of the national authorities: quality control, generic substitution, reference pricing, etc. This does not mean that the implementation of a generics policy might not face problems and opposition. Consumers, prescribers and insurers might oppose it because they might associate generics with substandard quality drugs. Implementing good quality assurance programs and educating the public can of course change perceptions. Prescribers might derive additional private benefits from prescribing branded products (originators, generics or similars). A large proportion of the profits of most companies, even of those involved in research and development (R+D) comes from branded off-patent products. The producers of branded drugs are not likely to welcome savings for consumers and insurers that constitute a loss of income for them.

Implementing a successful generics policy requires a comprehensive strategy that addresses the whole life cycle of the product and all parties involved: policy makers, drug regulatory agencies, pharmaceutical industry, health insurers and providers, prescribers, wholesalers, pharmacists and consumers.

The first step is to set up the legal framework. The registration process should guarantee the quality of generic drugs and might facilitate the launching of new generics by providing fast-track registration and lower registration fees for this category of products. Quality assurance mechanisms should apply to the whole supply chain of generics and branded drugs. Generic manufacturers are assumed to operate on average at smaller profit margins than R&D based companies.

They nevertheless are for-profit companies that will not enter a market unless a likely appropriate profit is expected.

Generic manufacturers do not have an incentive to advertise their products, because the very use of non-proprietary names makes it difficult for them to recover the resources invested in that activity: they compete in prices. Unless governments become proactive in disseminating information and educating consumers and prescribers, ignorance and misinformation on generics are likely to prevail, and its use might not increase, in spite of their advantageously low prices and good quality. A clear long-term commitment by the government to a generics policy is an essential factor in reducing uncertainties and favoring the investment required to increase generic supply.

Countries might use financing mechanisms for promoting generic drugs use. If consumers pay the same amount for a branded drug than for a generic version of the same drug, they are likely to choose the branded option, especially if it is the product of the originator. Reference pricing is a financing mechanism whereby all drugs which are assumed therapeutically equivalent are reimbursed the same amount irrespective of its price: consumers have then a clear economic incentive to choose the cheapest drug, which often is a generic version, because they pay the lowest charge -or no charge at all - for the prescribed drug. Procurement by competitive bidding using non-proprietary names does also favor generic products.

At the distribution level generics might be promoted by means of generic substitution. This implies giving the pharmacist a certain degree of capacity for providing the least costly therapeutic equivalent of a certain product prescribed to a consumer. Generic substitution has to address the actual or perceived concerns of the prescribers for their responsibility for the patient's health. Prescribers are usually reluctant to giving up their "right" to choose the product they think best suits their patients' needs. An approach that seems to work in practice with limited conflicts is to ask the physician to explicitly write on the script that the brand prescribed should not be substituted: few prescribers are sufficiently committed to a brand to make the additional effort requested to preclude substitution.

Physicians might also receive incentives for cost-effective prescribing, which in practice implies prescribing the generic version of a drug: a simple approach to setting up physician incentives is to establish a bonus for those that attain a certain target of generic prescribing. A more sophisticated approach is, for instance, the UK National Health System budget-holding mechanism, whereby doctors are allocated a fixed budget for drugs according to the size and

characteristics of their patients' population. Any savings on the budget can be used for activities that the doctor values.

Fixed mark-ups give the pharmacist a negative incentive for dispensing the low price products and, consequently, for generic substitution. A fixed prescription fee, not related to the price, would easily avoid this perverse incentive.

Many consumers and prescribers have a negative perception of the quality of generics. This perception can be reversed by a strict quality assurance policy and a sustained effort to inform the target population of the actual effectiveness and quality of generics.

### **Patents, Generics and Innovation.**

In the context of the present international policy discussion, the focus of the debate on generics points to the impact of intellectual property rights of drugs that are patent protected in developed countries, on R&D incentives and on accessibility in developing countries. In the absence of intellectual property rights all products are potentially generics. This is supposed to reduce or keep prices low and increase accessibility. It also gives the opportunity to a local industry with limited or no R+D capacity to compete with the patent-holding companies.

There is also the issue of the neglected diseases. These are, by definition, diseases whose actual and potential treatments are not backed-up by a sufficient purchasing power. As a consequence, intellectual property rights become a secondary problem regarding accessibility. Theoretical proposals and actual initiatives point to partnerships among industry, public sector, international organizations and donors as the mechanisms to set up demand-pull and supply-push strategies can overcome the lack of insufficiency of a market demand. Still, any solution should consider how the property rights of the innovation will be allocated or, alternatively, what kind of R&D financing and incentives are required if no patents are granted.

Patents grant the innovator exclusive rights on the innovation, which often allow the patent-holder to enjoy a monopoly position. During the period of patent protection the innovator is able to charge higher prices than it would under competition. This allows to recover the resources invested in R+D. The R+D based industry often claims that a growing share of generics at low prices might harm the rate of R+D and innovation. The situation is often pictured as an

unavoidable trade-off between short-term affordability of on-patent drugs and innovation and hence long-term availability and affordability of new therapies.

No one denies that intellectual property rights constitute an incentive for private companies to invest in R+D. There is, however, less consensus on whether intellectual property rights are the only or, at least, the most efficient tool to attain the maximum social benefits from R+D and innovation.

Beside the issue of affordability, there are other concerns on possible negative effects of a strong intellectual property rights system. There is no evidence, for instance, that a longer duration of patents would result in more investment in R+D. Intellectual property rights might be a barrier to, or at least, discourage innovation in fields that have large number of patents. Companies often engage in defensive R+D and intellectual property rights strategies that are less concerned with therapeutic advances than with protecting the monopoly attained by a previous innovation. The management of intellectual property rights systems is becoming increasingly sophisticated and costly, especially for developing countries. The rising litigation costs are an obvious example.

Similarly, there is no evidence that the introduction of intellectual property rights systems similar to those existing in developed countries will increase pharmaceutical production and R+D in developing countries, although it might be true for some emerging developing countries. Intellectual property rights systems are perceived as more beneficial for developed than for developing countries. The optimal characteristics and strength of an intellectual property rights system probably depends on the level of development and industrial capacity of the country. As a consequence, the trend towards the international standardization of intellectual property rights is perceived as a North-South conflict.

## **The Way Forward**

The recent decision of the Council for TRIPS on the implementation of paragraph 6 of the Doha declaration on the TRIPS Agreement and public health has clarified the concerns of developing countries without manufacturing capacity in relation to how they can effectively use compulsory licensing as a tool for improving accessibility to key medicines. The agreement reached is neither perfect nor the final solution, but will hopefully be an important step towards the development of a dialogue that ensures the implementation of sustainable mechanisms aimed at increasing accessibility of the poor in developing countries to valuable

therapeutic innovations, while providing the incentives for the private and the public sectors to invest in R+D.

Given the present evidence of the effects of IPR on developing countries, it is probably safe for these countries to avoid any TRIPS plus change in their IPR legislation and policy and to make the maximum use of the flexibility of the TRIPS agreement (compulsory licensing, no data exclusivity, Bolar provision, etc). It will also be necessary to continue exploring proposals and initiatives looking at alternative incentive and property rights systems to the present ones (public financing, liabilities, non-exclusive property rights, open source approaches, etc).

But it is also essential to pay adequate attention to other key factors that have been often neglected in the heat of the debate on patents.

The most important probably is the issue of quality assurance. Most developing countries lack the human and economic resources required in order to set up a regulatory system that guarantees the quality of the drugs. The WHO prequalification initiative for HIV-AIDS products has provided a solution for that category of drugs, but it is uncertain whether it is a sustainable approach that can be generalized to all drugs.

Finally, there are justified concerns and little evidence on the capacity of the industry to producing the amount of quality drugs required in order to attain the Millennium Development Goals or, more generally, to substantially scaling-up the accessibility to drugs. Many countries seem to assume that local production of drugs is a solution to accessibility, but there is limited evidence supporting that belief. Local production is often associated with more expensive and lower quality drugs than what the country could obtain by importing the drugs. Moreover, local production is sometimes aimed at exports and does not have any impact on accessibility among the population in producer country. The most likely scenario is that a limited number of multinational generic manufacturers from a few emerging countries - India, China, Brazil - will become the main international suppliers of generics to developing countries.

Drugs are and will remain in the future a key factor in improving the health and in attaining the MDG. It is therefore of the utmost importance to ensure the access to drugs for the population in developing countries, specially for the most disadvantaged groups, which are the most difficult ones to reach.

## **References**

Dean Baker and Noriko Chatani. Promoting Good Ideas on Drugs: Are Patents the Best Way? The Relative Efficiency of Patent and Public Support for Bio-Medical Research, CEPR, October 11, 2002. [www.cpr.net](http://www.cpr.net)

IFPMA. TRIPS, Pharmaceuticals and Developing Countries: Implications for Health Care Access, Drug Quality and Drug Development. Geneva, 2000.

Mamphela Ramphele and Nicholas Stern. Generic Drugs Can Make the Money Last. NYTimes. March 1, 2003

Maria del Val Diez Rodrialvarez (Coord.). Genéricos. Claves para su conocimiento y comprensión. Editores Médicos, SA. Madrid, 1999

WHO. Pilot Procurement and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality, September 5, 2003  
<http://www.who.int/medicines/organization/qsm/activities/pilotproc/suppliers.doc>

The World Bank. Global Economic Prospects and the Developing Countries. 2002. Chapter 5: Intellectual Property: Balancing Incentives with Competitive Access.