



PILLS AND POCKETBOOKS:

Equity Pricing of Essential Medicines in Developing Countries

(Adapted from a presentation made by Ellen 't Hoen, Médecins Sans Frontières, at the WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, April 2001)

Introduction

Too often in the countries where Médecins Sans Frontières (MSF) works, we have been forced to watch our patients die because they cannot afford the drugs that could improve, extend, or save their lives. Price is not the only reason why people do not get the medicines they need, but it is a major barrier. The high cost of many life-saving drugs not only keeps patients from getting treatment, but also discourages health ministries from improving the quality of patient care through the use of newer and better medicines. While the \$406 billion-strong drug industry researches, develops, markets, and prices medicines for the industrialised world, there is no mechanism to make newer medicines affordable to developing countries. Newer drugs, which are usually under patent and more expensive than those off-patent, are expected to become even more expensive with the implementation of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in all Members, scheduled to be completed by 2006.

MSF believes that essential drugs are not a luxury that should be reserved for the wealthy. Rather, access to essential medicines should be guaranteed as a critical component of the human right to health.

Equity pricing: what is it and how can it be achieved?

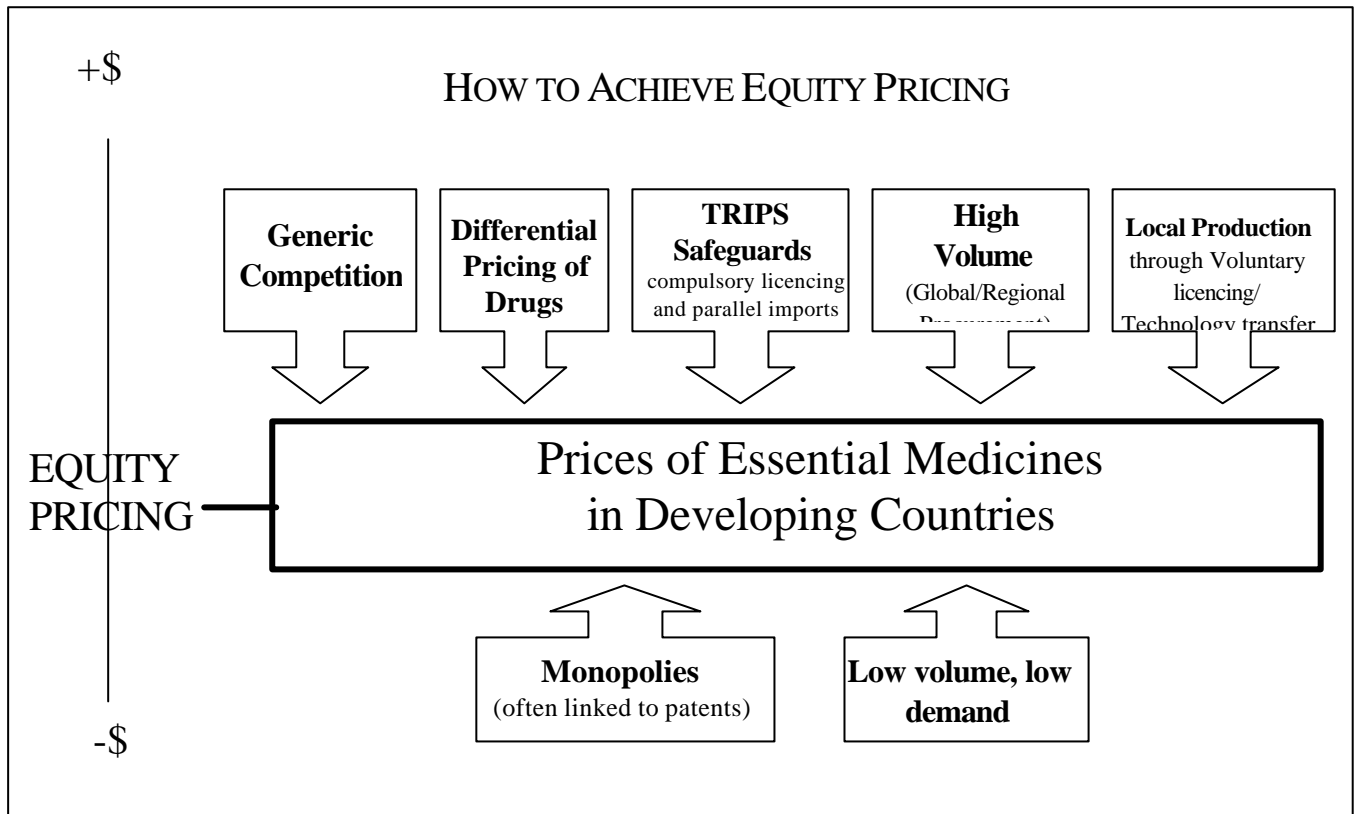
Essential medicines should be priced in developing countries based on the principle of “equity.” MSF uses the term “equity pricing” to describe policies that ensure that, from the point of view of the community and the individual, the price of a drug is fair, equitable and affordable, even for a poor population and/or the health system that serves them. Equity pricing is based on the principle that the poor should pay less for, and have access to, essential medicines.

The terms “differential,” “tiered,” “preferential,” and “discounted” pricing, and “market segmentation” are also often used to describe the practice of charging lower prices in different markets. However, they do not necessarily result in affordability or equitable access to a product. Rather, they are commercial terms for pricing practices aimed at maximising the profits of the seller. While these practices *may* lead to equitable access to medicines, they do not necessarily mean that even the lowest prices charged will be affordable.

Any new pricing policies for medicines must aim to achieve *equity* pricing if they are to have real impact in the lives of patients.

No single strategy will be sufficient to achieve and sustain equity pricing. Rather, what is needed is a comprehensive system of mutually supportive strategies. These strategies are:

- Encouraging **generic competition**
- **Differential pricing** of drugs
- Adopting **TRIPS safeguards** into national legislation
- Creating high volume/high demand through **global/regional procurement**
- Encouraging **local production** through voluntary licencing and technology transfer

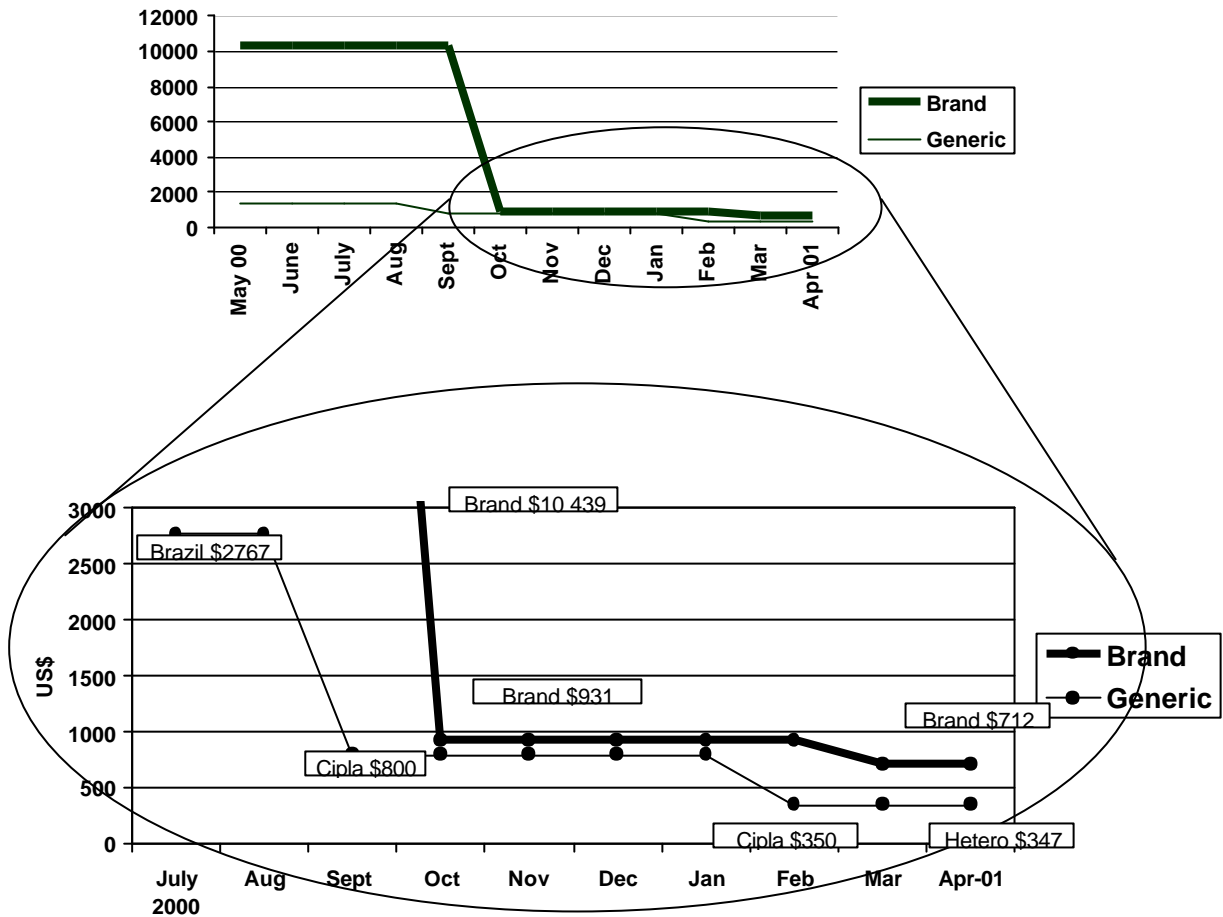


1. Generic competition: necessary and effective

Generic competition is one of the most powerful tools that policymakers have to lower drug prices in a sustainable way. Lessons can be learned from Brazil where the price of AIDS drugs fell by 82% over 5 years as a result of generic competition. The prices of drugs that had no generic competitor remained stable, falling only 9% over the same period.¹ Even more dramatic results can be seen in the price of AIDS triple-therapy for developing countries, which fell from US\$10,000 per patient per year to as low as US\$350 in one year due to generic competition (See chart below). Encouraging generic competition requires a pro-public health interpretation of TRIPS and active efforts by countries to use compulsory licencing. Countries should design and use “fast-track” administrative procedures for compulsory licencing to make the most of this tool. (See #3 below)

¹ Brazil Ministry of Health, 2000.

The Effects of Generic Competition
Sample AIDS triple-combination: lowest world prices
(stavudine (d4T) + lamivudine (3TC) + nevirapine)



2. Differential pricing: a promising but incomplete strategy

Differential pricing policies, also often labelled “market segmentation,” “tiered pricing,” “preferential pricing,” or “discounted pricing,” refers to the voluntary lowering of prices by drug makers for lower-income markets. The past year has seen growing support for a differential pricing system that would systematically sell patented drugs at reduced prices to developing countries. Recent announcements made by pharmaceutical giants on discounts for AIDS drugs are one example. However, it is critical to recognise that such discounts were offered only after immense international public pressure began to jeopardise the industry’s image. While differential pricing can yield rapid results and would signify real progress, it is an extremely vulnerable strategy on its own.

Differential pricing has a number of **weaknesses**, including:

- A dangerous reliance on the will of companies whose main objective is to maximise their profits.
- The requirement of strict separation of markets to prevent lower-priced drugs from flowing back into high-income markets. (Fears of re-importation should be kept in

perspective, given that past experiences with differential pricing for contraceptives and vaccines did not result in products flooding back into wealthier markets. While MSF supports measures such as special packaging or regulations to prevent re-importation into certain markets, such measures should not put too heavy a burden on developing countries, nor should they run counter to the goal of the system itself.)

- The absence of guarantees that the drugs will be priced at the lowest possible level and will be available on a predictable, long-term basis.
- It does not encourage sustainability or autonomy in developing countries.
- It could be used to extract reciprocal concessions, such as more stringent intellectual property protection, which could paradoxically make essential medicines more expensive in the long-term.

To have the most **benefit**, a differential pricing system should:

- Have transparent prices, rules, and regulations.
- Set minimum basic conditions to determine the eligibility of developing countries. The system should not be restricted to just the least-developed countries, but include developing and middle-income countries as well.
- Be a truly global system, not an initiative that is limited in time and place.
- Operate in a timely and efficient manner.
- Offer the lowest possible prices – using marginal cost of production as a guideline for the least-developed countries.
- Extend beyond the public sector to the private and NGO sectors. (In many developing countries patients get their medicines outside the public sector)
- Cover *all* medically essential drugs – not only those for relatively high-profile diseases such as HIV/AIDS, malaria, or tuberculosis.

In the past, differential pricing has been successfully implemented for vaccines and oral contraceptives, with drugs costing as much as 200 times less for poor countries.² Millions gained access to these products, while producers were able to increase their sales and prevent the mass re-importation of cheaper products into wealthier markets. The success of this example should be built upon.

3. TRIPS safeguards: creating a balance

TRIPS threatens public health in developing countries by giving patents on medicines for a minimum of 20 years, granting a monopoly to patent-holders during that time. This will lead to further increases in drug prices and negatively impact the developing world's ability to produce affordable generic alternatives to branded drugs. Countries can counter rising drug prices by building TRIPS-compliant safeguards into their national laws, including compulsory licencing, parallel importation and measures to accelerate the introduction of generics.

How do the safeguards work? Governments can reduce prices by granting compulsory licences for the production or importation of lower-priced generic versions of patented products. Using parallel importation, they can also buy patented products at the lowest price offered on the world market by the patent-holder. Finally, they can accelerate the introduction of generics – which are usually more affordable than patented products – through the use of a “Bolar provision.” (A Bolar

² Guilloux, Alain and Moon, S. “Hidden Price Tags. Disease-Specific Drug Donations: Costs and Alternatives.” Access to Essential Medicines Campaign, Médecins Sans Frontières, October 2000: 26.

provision allows a generic producer to conduct all tests required for marketing approval in advance, so that a generic can be put on the market as soon as the patent expires.) Unlike differential pricing, these safeguards give some control over drug prices back to developing countries. A key challenge in the coming months will be to begin putting these safeguards into action.

4. Global/regional procurement and distribution: pooling resources

Global procurement and distribution can also help lower drug prices by guaranteeing high demand and reliable payment for large quantities of drugs. Bulk purchasing will also make it easier to negotiate lower prices. Furthermore, the UN can support developing countries in addressing quality issues by pre-qualifying producers who participate in the global/regional procurement system. Within the UN – particularly at UNICEF – there is extensive experience and expertise with bulk procurement. To ensure that global procurement does not negatively impact local manufacturing capacity, encouraging the development of local generic production should be an explicit part of this strategy.

However, patents may pose a barrier to the use and transport of globally procured drugs. For example, the lowest priced antiretroviral drugs are currently produced generically in India, but today they cannot be used in countries where these products are under patent. This barrier could be overcome by allowing for patent exceptions for globally procured medicines.

5. Encouraging local production: a long-term sustainable solution

Lower prices can also be achieved by supporting the local production of drugs through voluntary licencing and technology transfer. This is a long-term, sustainable strategy that has the added benefit of stimulating the economic development and autonomy of developing countries. The success of this strategy hinges on the willingness of patent-holders to grant voluntary licences. In practice, a patent-holder is more likely to grant a voluntary licence if a country has a strong compulsory licencing system.

Under TRIPS, developed countries are obligated to transfer technology to least-developed countries.³ Industrialised countries should extend technology transfer as well to countries that already have some manufacturing capacity, as these will be the best candidates to start manufacturing drugs that are out of reach mainly because of price.⁴ If exportation of drugs produced under either voluntary or compulsory licences is allowed, this strategy can also benefit the many developing countries that lack production capacity, as producing countries can then become regional suppliers.

Conclusions

In summary, there will not be one single measure that will achieve equity pricing. Rather, a mix of mutually supportive strategies will be required to have real impact. A potent combination of generic competition, differential pricing, use of TRIPS safeguards, global/regional procurement, and local production has the potential to achieve dramatically lower prices for essential medicines and make a meaningful difference in the lives of patients. In the longer term, policymakers will

³ TRIPS, Article 66.2

⁴ For further recommendations on technology transfer, see “Statement from Médecins Sans Frontières, Campaign for Access to Essential Medicines at the Health Issues Group DG TRADE,” Brussels, 26 June 2000. Available at www.accessmed-msf.org.

have to find ways of reconciling the way the pharmaceutical market is currently regulated with the many public health needs that continue to go unmet.

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