

PILLS AND POCKETBOOKS:

Equity Pricing of Essential Medicines in Developing Countries

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



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. 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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