

Introductory note: **The access to Essential Medicines Campaign**

Jean-Marie Kindermans¹ and Francine Matthys²

1 *MSF International, 37 Rue de la Tourelle, 1040 Brussels, Belgium*

2 *MSF, 94 Rue Dupréstraat, 1090 Brussels, Belgium*

Summary

To ensure access to essential medicines for disadvantaged populations there are at least three conditions to be met: drugs prices must be affordable for poor countries; research and development of drugs for tropical diseases must take place; and there is a need for health exceptions to trade agreements.

keywords medicines, access, research, development, trade

correspondence Jean-Marie Kindermans, MSF International, 37 Rue de la Tourelle, 1040 Brussels, Belgium. E-mail: jean-marie_kindermans@bi.msf.org

In its daily work, Médecins Sans Frontières (MSF) is constantly facing the ravages of infectious diseases and the lack of access to health care and medicines among populations in distress. In 1998, a campaign was launched to ensure access to essential drugs for disadvantaged populations (www.accessmed-msf.org). When in October 1999 MSF was awarded the Nobel Peace Prize, it chose to consecrate the prize money to neglected diseases highlighted by the campaign, which is constituted of three pillars.

Overcoming the barriers of access to medicines

A number of (new) drugs for treating tropical diseases are too expensive and others are no longer produced because the market is not profitable. According to the profit rationale that currently prevails, a medicine must be lucrative to be produced commercially. Many factors influence access to effective medicines (Pécoul *et al.* 1999), including quality of diagnosis; accurate prescribing, selection, distribution and dispensing of drugs; drug quality; capacities of health systems and budgets; and lack of research and development (R&D). But one of the fundamental barriers to access is price. Several factors can influence the price of a medicine, including patents, generic competition, production cost, taxes, tariffs and mark-ups, and R&D costs.

MSF is currently identifying manufacturers who are producing affordable quality drugs, negotiating better prices with manufacturers and supporting the countries' efforts to improve access to essential drugs. In the long term, MSF is looking for ways to restart the production of

drugs that are no longer being manufactured. MSF also advocates a global tiered pricing system based on the principle of equity that would offer lower drug prices to developing countries, making drugs truly affordable to patients, while maintaining prices in the industrialized world. This pricing system should benefit all developing countries and should be accessible for health care providers outside the public sector as well. But MSF also appreciates companies' concerns that equity pricing may be used to demand lower prices in industrialized countries. Therefore, it is willing to launch a public campaign to support the principle that developing countries should pay less for essential medicines and it accepts provisions to prevent the re-import of equity-priced drugs into high-income markets.

For the poorest countries, international funding will still be critical to subsidize drug purchases. MSF advocates more means for the procurement of drugs that could give leverage to the purchasing power of developing countries and donors.

To improve global price transparency, MSF supports the development of a data base on drug prices, quality and patent status. This data base should be managed by a UN agency, with patent information provided by the World Intellectual Property Organization.

Stimulating research and development of medicines

Research into tropical diseases has ground to a virtual halt. While pharmaceutical companies argue that patents are essential to continue financing R&D, they actually neglect

R&D of drugs to fight the major killer diseases of the developing countries. Of the 1223 new drugs developed since 1975, only 11 directly target a tropical disease (Trouiller & Olliaro 1999).

Using data gathered from the field, MSF tries to highlight the lack of effectiveness of old treatments and the limited resources currently allocated to tropical diseases. MSF wants to stimulate R & D efforts that focus on an internationally agreed-upon, need-driven agenda, which from the beginning aims at developing drugs that are *effective, safe, affordable and easy to use*. The applied strategies should preferentially be disease-specific. Furthermore, new funding has been called for, as well as the revision of legal and regulatory frameworks and a special international treaty to guarantee adequate R & D for neglected diseases in the future. MSF believes that investing in developing countries' capacity to research, develop and produce their own medicines will be a key part of a sustainable solution.

Health exceptions to trade agreements

The World Trade Organization's (WTO) agreement, Trade Related Aspects of Intellectual Property Rights (TRIPS), is the most important international agreement on protection of patents, copyrights, and trademarks. It is setting the rules for the sale of drugs within and between countries, treating medicines like any other product. Drug patents confer a market monopoly to pharmaceutical companies for any invention for a minimum of 20 years [World Health Organization (WHO) 1997; WTO 1995]. Only on expiry of the patent, other companies are allowed to produce it as a 'generic' drug. The resulting competition between several manufacturers often leads to a dramatic fall in price. Therefore, TRIPS is expected to affect the price of new life-saving drugs negatively and to further restrict access to patients in developing countries (Dumoulin 2000). MSF does not oppose patents but it contests the dire imbalance caused by TRIPS between the sanctity of patents and the health of people.

Nonetheless, within TRIPS there are safeguards to address this imbalance and MSF is supporting countries to use these safeguards, which include parallel imports, compulsory licences and strategies to accelerate the introduction of generics (Correa 2000a,b). Parallel imports is cross-border trade in a branded product without the manufacturer's permission – or, shopping for the best price on the global market. It is an attractive option for developing countries when the same branded medicine is being sold for different prices in different markets. Compulsory licences are provisions in patent law that allow public authorities to grant licenses to a third party without

the consent of the patent holder. Patent holders receive adequate compensation. Compulsory licences may be issued on various grounds of general interest, including public health, and are a common feature of patent law. Compulsory licences can be used as a leverage to introduce generics, to keep the possibility of generic competition real and to put pressure on companies to grant voluntary licences. Export under compulsory licence must be allowed for this safeguard to be meaningful for the poorest countries. Generic substitution and competition is allowed by the TRIPS agreement. Appropriate formulation and implementation of national legislation and regulations is needed in order to avoid any delay. The use of exceptions to exclusive rights, which permit early testing and approval of generics ('Bolar' provisions), voluntary licences and compulsory licences can also facilitate the prompt introduction of generics.

To ensure that trade policies do not harm public health, the first step is to guarantee that safeguards are included in the national legislation of developing countries. Among WTO member states, most developing countries had to implement TRIPS in their national legislation by 2000. Some countries that did not grant patents on pharmaceuticals before 1995 can do so up to 2005, and least-developed countries up to 2006. The second step is to support developing countries in using the options when needed. The duty of countries to protect the public health of their people must take precedence over the right of the commercial sector to make profits.

References

- Correa C (2000a) Développements récents dans le domaine des brevets pharmaceutiques: mise en oeuvre de l'accord sur les ADPIC. *Revue Internationale de Droit Economique* 1, 23–35.
- Correa C (2000b) In: *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (ed. R Weissman) South Centre, Geneva, pp. 65–102.
- Dumoulin J (2000) Les brevets et le prix des médicaments. *Revue Internationale de Droit Economique* 1, 45–69.
- Pécoul B, Chirac P, Trouiller P & Pinel J (1999) Access to essential drugs in poor countries. A lost battle? *Journal of the American Medical Association* 281, 361–367.
- Trouiller P & Olliaro P (1999) Drug development output from 1975 to 1996: What proportion for tropical diseases? *International Journal of Infectious Diseases* 2, 61–63.
- World Health Organization (1997) *Globalization and access to drugs. Perspectives on the WHO/TRIPS agreement. Health Economics and Drugs (Revised)*. World Health Organization, Action Programme on Essential Drugs, DAP series no. 7, Geneva.
- World Trade Organization (1995) *TRIPS agreement*. Article 33.