The World Health Report
HEALTH SYSTEMS FINANCING
The path to universal coverage

Technical Brief Series - Brief No 1

IMPROVING ACCESS TO ESSENTIAL MEDICINES AND CREATING EFFICIENCIES BY ENCOURAGING THE UPTAKE OF GENERIC MEDICINES

WHAT IS AT STAKE?

Effective health services cannot be achieved without equitable universal access to essential medicines. In most low- and middle-income countries, access to essential medicines for the treatment of the most common diseases is inadequate. Low availability of essential medicines is often caused by a lack of public resources or under-budgeting, inaccurate demand forecasting, and inefficient procurement and distribution.

As well over 90% of essential medicines are available as generics, access to essential medicines is tightly linked with the question of generics uptake. Recent surveys in over 40 countries showed that availability of generic medicines was only 42% in the public sector and 64% in the private sector. A strategy that systematically promotes low cost generics will increase availability of essential medicines and consumer access to them.

When generic medicines are of assured quality, there is a potential for patients and health systems to achieve equivalent health outcomes at a lower cost. Patients purchasing medicines in the private sector pay, on average, 2.6 times more for originator brand than for their lowest-priced generic equivalent, and in some countries ten fold price differentials occur. An analysis covering 18 medicines in 17 largely middle-income countries revealed that costs to patients could be reduced by an average of 60% by switching from originator brands to the lowest priced generic equivalents. This shows that the potential efficiency gains from a more systematic use of generics are important - in all countries, at all income levels.

WHAT COULD BE DONE?

In Europe, many countries have a significant generic market share. In 2006, Denmark, Germany, Latvia, the Netherlands, Poland, Slovakia, Slovenia, Turkey and the United Kingdom each had more than a 50% market share for generics by volume. These countries have put in place different measures and strategies that have facilitated the entry of generics to markets, such as abridged ("fast track") medicine marketing applications and provisions for advanced permission for preparatory work before patent expiration.

In the **United States of America**, the Hatch-Waxman Act from 1984, has been inducing faster access to the generic market by for example granting a 180-day market exclusivity right for the first generics manufacturer. Evidence suggests that the delay between patent expiry and generic product entry to market has dropped from more than three years to less than three months for high revenue medicines. In the USA the pressure for cost containment from the public Medicaid programme and from the private health insurers have been one of the motors of the generics policy.

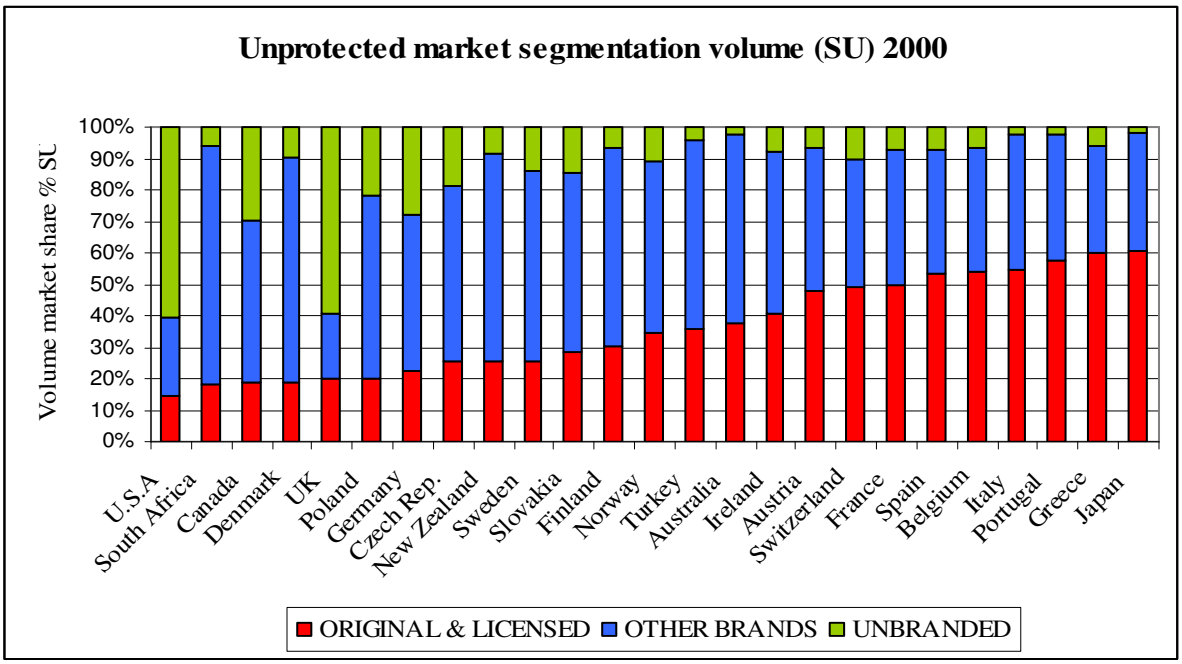
The United Arab Emirates has reduced the price of many originator brands and generics. To improve the availability of generics in the private sector, the regulatory authority has implemented a priority track for generic product applications where there are less than 6 generic equivalents on the market.

The use of generics can also be supported by substitution strategies allowing, incentivizing or requiring pharmacists to dispense a generically equivalent product in place of the originator brand. In Sub-Saharan Africa around 80% of countries have legal provisions for generics substitution while in South and Western Asia only 40 per cent of countries have adopted these type of measures. It has been estimated that in France generic substitution has saved the National Health Insurance and the complementary insurance companies €1.32 billion (around US$2 Billion) in 2008 alone.

KEY ISSUES FOR POLICY MAKERS

As Figure 1 shows, there are important variations in generic uptake between countries. This shows that opportunities exist for countries at all income levels to increase generic uptake and by consequence achieve cost savings and improve the affordability of treatment for their populations.

FIGURE 1. 2008 GENERIC UPTAKE AFTER PATENT EXPIRY IN 2000



Several policy options to promote the use of generic medicines exist, these include:

- preferential registration procedures;
- generic substitution strategies;
- financial incentives for generic prescribing and dispensing;
- education and promotion of generic acceptance to professionals, patients and the general community;

- national clinical guidelines that recommend generic essential medicines, and social marketing of generic essential medicines through the private sector;
- Prequalification of generic manufacturers and publication of the quality assurance documentation of such manufacturers;
- Fast-tracking of regulatory approval of generic medicines.

The **quality and safety of medicines** for all essential medicines, originator or generic, require a functional national regulatory authority which is adequately resourced and staffed, and with legal powers to inspect facilities and products and to enforce the regulations. This also includes regulatory measures to encourage and enforce ethical promotion.

Regular **monitoring of medicine availability, price, affordability** and use is also required to assess and modify policy interventions.

FURTHER READING

The Global Partnership for Development at a Critical Juncture. MDG Gap Task Force Report 2010. New York: United Nations; 2010. Available from: http://www.un.org/millenniumgoals/pdf/10-43282_MDG_2010%20(E)%20WEBv2.pdf.

Strengthening the Global Partnership for Development in a Time of Crisis. MDG Gap Task Force Report 2009. New York: United Nations; 2009. Available from: http://www.un.org/esa/policy/mdggap/mdg8report_engw.pdf.

Delivering on the Global Partnership for Achieving the Millennium Development Goals. MDG Gap Task Force Report 2008. New York: United Nations; 2008. Available from: http://www.un.org/millenniumgoals/pdf/MDG%20Gap%20Task%20Force%20Report%202008.pdf.

Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. Lancet 2009;373:240-49.

World Health Organization, Health Action International. Measuring medicine prices, availability, affordability and price components. 2nd edition. Geneva: World Health Organization and Health Action International; 2008. Available from: http://www.haiweb.org/medicineprices/manual/documents.html