Medicus Mundi Schweiz
Gesundheit für alle

MMS Bulletin #93
HIV/AIDS: Behandlung und Pflege

Prices, generics and patents

Antiretroviral medicines as core of HIV/AIDS treatment

Von Julien Reinhard

It is often said that access to HIV/AIDS medicines is only one part of HIV/AIDS treatment, that other elements such as education of healthcare personnel, infrastructure, healthcare systems are important, too. This is correct but it misses the most important point: Without medicines there is simply no treatment against HIV/AIDS.

To tell it differently: one can say that HIV/AIDS treatment today is organised around the provision of antiretroviral medicines to patients. One can alleviate the lack of physicians by training people to provide the medicines, one can simplify treatment guidelines, one can adapt the biological monitoring of patients according to where they are in the different phases of treatment. But without medicines, there is nothing to adapt: there is simply no treatment at all. Access to antiretroviral medicines is therefore essential.

Developing countries need medicines at the most affordable prices in order to scaling up HIV/AIDS treatment to the greatest number of people.(1) Why? Because the great majority of people in developing countries has only limited resources and has to pay the treatment out of its own pocket.(2) And because governments and NGOs that want to treat people living with HIV/AIDS have also limited resources. This aspect is particularly important as one seeks to establish free treatment for the poorest.(3)

Let us keep in mind that today only 300 000 people in developing countries have access to HIV/AIDS treatment, while more than 6 million need a treatment. Lower prices for ARVs means more patients under treatment in developing countries. Affordability means more access.

The recent price reductions and their limitations

In the past five years the price of antiretroviral medicines (ARVs) used in first-line treatment has been reduced dramatically. In 2000 a first-line tritherapy using brand name medicines was still over 10'000 US$ per patient per year in developing countries. Today one tritherapy using generics is available for less than 140 US$ per patient per year under the Clinton Foundation's programme.

As a result the high pricing of antiretroviral medicines in developing countries disappeared from the front pages of the newspapers. Does it mean that it is not an issue anymore ? No.

One should keep in mind that the price of treatment per patient per year is still over 100 US$ in resources-limited countries. Lowering prices is still necessary. The prices of second-line treatments are much more expensive than the prices of first-line treatments. However second-line treatment will become more and more important in developing countries with the development of HIV/AIDS treatments.

Best prices for WHO recommended first-line treatments in resources-limited countries (d4T or ZDV+3TC+NVP or EFV) range from less than 140 US$ to 640 US$ per patient per year.

Best prices for WHO recommended second-line treatments in resources-limited countries (TDF or ABC+ddI+LPV/r or SQV/r or NFV) are still over 1000 US$ $ up to 2000 US$ $ per patient per year. And it is only the best prices !

That situation is mainly due to the high cost of protease inhibitors in developing countries. In particular Roche's essential protease inhibitors (nelfinavir and saquinavir) continue to be sold between 900 US$ and 3200 US$ per patient per year in poor countries (prices from Basle). The Déclaration de Berne is still campaigning in order that Roche reduces its prices in developing countries.

Price reductions of brand name medicines and the role of generic competition

Under the pressure of public opinion in industrialised countries pharmaceutical companies have reduced the price of their ARVs in developing countries and have adopted differential pricing policies for developing countries. It is important to keep in mind that those policies are different between companies: eligible countries may differ (middle-income countries are often excluded), as well as eligible buyers, delivery conditions, etc.(4)

The recent experience have demonstrated that generic competition is a much more efficient way to obtain continously cheaper medicines than voluntary reductions by pharmaceutical companies.

Generic companies provide the cheapest prices for first-line treatment ARVs. Moreover generic competition makes it difficult for pharmaceutical companies to justify their high prices. Generic competition works more efficiently when the demand is high as it is the case for first-line

treatments. In order to get the most affordable prices, developing countries must make use of generic and must benefit from it.

Prejudices against the use of generics are still common. Their quality is often questioned. It is important to be informed that the World Health Organization has established a voluntary prequalification programme open to all producers of generics or brand name products. This programme guarantees the quality of generic medicines (as well as brand name products).(5)

Patents, generic competition and access to medicines

The first original patents date back to 1985 for the older HIV/AIDS medicines as zalcitabine or zidovudine. Today, antiretrovirals are still under patent in many countries. Those patents provide to their holders the exclusive rights to produce and market the product for at least 20 years. Those monopolistic rights enable the producers to charge an high price and to prevent the generic competition. It is only once the patent has expired that generics are allowed to be sold and that generic competition can start.

Pharmaceutical companies patent their new medicines in developing countries too. For example a PhRMA survey in 2001 showed that four important ARVs were patented in more than 20 African countries.

Patents on HIV/AIDS medicines are a problem in resources-limited countries since they prevent generic competition, i.e. the most effective tool to obtain HIV/AIDS medicines at low price in order to increase access to HIV/AIDS treatment.
Providing generic ARVs in a certain country requires to ascertain that those medicines are not under patent in the country. However in the great majority of the developing countries the absence of patent on a medicine is not sufficient to have access to generics since those countries have none or very limited production capacity for pharmaceutical products and have then to import the 100% of their medicines including generics.

Consequently the use of generic medicines in poor countries also depends on the patent situation in countries with an generic industry like India, China, Brazil, etc. which can produce and export generics.(6)

The international framework for patent protection keeps strengthening

While the case of HIV/AIDS demonstrates the need for cheap medicines in poor countries and the efficiency of generic competition in this regards, in the past ten years the international legal framework relating to patent protection has been strengthened. The 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) has imposed to all Member States

of the World Trade Organization (146 Member States in 2004), industrialised as developing countries as well, the same obligation to grant a 20 years patent protection on medicines. Until then many developing countries did not have patents on medicines.

This agreement mainly profits to the pharmaceutical giants which hold the great majority of patents on medicines: not only a patent enable them to charge higher price on this medicine in developing countries but it also provide them the legal means to prevent generic competition in those countries.

Now the pharmaceutical industry says that it will not patent its HIV/AIDS medicines in poor countries like Least Developed Countries. But it refuses to renounce to its patents on its HIV/AIDS medicines in the developing countries with an efficient generic industry.(7)

At present the cheapest generic ARVs are produced by the Indian generic industry, because there was no patent on medicines in the country in the past. However from 2005 India will have to grant patent protection for the new HIV/AIDS medicines in conformity with the TRIPs agreement.

The TRIPs agreement allows mechanisms that enable the States to balance the exclusive rights of the patent holders. The most powerful instrument is the compulsory licence that enables a State to authorise other producers to produce a patented medicines without the agreement of the patent holder (article 31 of TRIPs). But under pressure of their pharmaceutical industry industrialised countries have tried to prevent the poor countries to translate those mechanisms into their legislation and to use them.

In 2001 39 pharmaceutical companies had to withdraw their complaint against the South African medicines law under the pressure of the international public opinion. The subsequent mobilisation of developing countries and NGOs before and during the WTO ministerial conference in Doha led to the adoption of a declaration on the TRIPs agreement and public health. Paragraph 4 of the declaration states that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" and that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." Paragraph 5 (b) mentions that the WTO Member States have the "right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".

Unfortunately that declaration has not weakened the pressure of the pharmaceutical industry and of the industrialized countries to keep strengthening the international patent legislation. During the past two years WTO Member States labouriously negotiated to change a provision of the TRIPs agreement that prevents the countries without pharmaceutical production capacity to produce in another country a medicines under compulsory licence. Industrialized countries, including Switzerland, fought for a solution with the highest safeguards for the patent holders. As a result the final compromise sets a burdensome, complicate and ambiguous mechanism that might probably remain unused by the countries that would need it.(8)

Switzerland has recently committed itself to change its patent law to allow such compulsory licences for export. The Déclaration de Berne will carefully monitor that commitment.

Moreover today Switzerland and the other industrialized countries are negotiating with developing countries bilateral agreements which impose patent protection provisions that go further than the TRIPs agreement, i.e. provisions that strengthen the rights of patent holders in order to make more difficult and to delay the introduction of generics. In December 2003 the Swiss parliament has ratified a free-trade agreement with Chile which contains such provisions. Several similar bilateral agreements are under negotiations.

The need to change the international legal framework and to give the priority to the right to health

Developing countries needs a international legal framework for patent protection that enables them to use the generic competition in order to increase access to new essential and life-saving medicines (like ARVs) for their population. This is the conviction and the commitment of the Déclaration de Berne which is working for several years to change the international position of Switzerland in order that our country commits itself to give the priority to the right to health for all, in particular to the right of all in developing countries to access to medicines. The Swiss position should not be limited anymore to the protection of the short term interests and profits of its pharmaceutical industry. In April 2003 the Déclaration de Berne has launched with more than 40 Swiss NGOs the campaign "Healthcare®: a right for all, in developing countries as well"(9)

A coherent policy in favour of HIV/AIDS treatment in developing countries cannot ignore those essential international aspects.

Julien Reinhard is secretary of the Déclaration de Berne (DB; EvB). Contact: info@ladb.ch. The Déclaration de Berne is a Swiss non-governmental organization with 19 000 members. Through research, public education and advocacy work, it has promoted more equitable, sustainable and democratic North-South relations since 1968. (www.ladb.ch).

Notes

(1) There is the same problem of affordability with HIV/AIDS diagnostics tests, especially the ones to monitor the HIV/AIDS treatment.

(2) 2.8 billion human beings live with less that 3 US$ a day, and 1.2 billion live with less than 1 US$ a day. (Human Development Report 2002. NY: PNUD, 2002) In developing countries, 80% of the people pay their medicines out of their own pocket (WHO, Financing Health in Developing Countries. Quoted from: Oxfam Briefing Paper on GlaxoSmithKline. Dare to Lead: public health and company wealth. Oxfam, February 2001; p 14).

(3) In a majority of developing countries, the yearly health expenditure (public and private) per capita is less than 250 US$ (Estimations based on the data for 1997. Macroeconomics and health. Report of the Commission on Macroeconomics and health. December 2001, p. 56.). In 66 countries, there are even less than 100 US$ per capita. (WHO Medicines Strategy: Framework for Action in Essential Drug Policy 2000-2003. WHO: Geneva, 2000)

(4) For more details see the excellent guide regularly updated by Médecins Sans Frontières: Untangling the web of price reductions. 5th edition. December 2003, www.accessmed-msf.org/documents/5theditionuntangling.pdf

(5) List of prequalified medicines, including HIV/AIDS related medicines: http://mednet3.who.int/prequal

(6) Two useful documents about the patent situation of HIV/AIDS-related medicines in developing countries: UNAIDS & WHO. Patent situation of HIV/AIDS-related drugs in 80 countries. Geneva: January 2000; 16 p., www.who.int/medicines/library/par/hivrelateddocs/patentshivdrugs.pdf; MSF. Drug patents under the spotlight. Sharing practical knowledge about pharmaceutical patents. Geneva: May 2003; 37 p., www.accessmed-msf.org/documents/patents_2003.pdf

(7) See the letter from Roche to Déclaration de Berne dated 2 April 2004. Our correspondence with Roche can be seen on the Déclaration de Berne website: www.evb.ch/index.cfm?page_id=2898

(8) For more details, see the website of the Déclaration de Berne: www.evb.ch/index.cfm?page_id=2519

(9). For details: http://www.ladb.ch

Kontakt

Deutschschweiz
Medicus Mundi Schweiz
Murbacherstrasse 34
CH-4056 Basel
Tel. +41 61 383 18 10
info@medicusmundi.ch

Suisse romande
Medicus Mundi Suisse
Rue de Varembé 1
CH-1202 Genève
Tél. +41 22 920 08 08
contact@medicusmundi.ch

Bankverbindung
Basler Kantonalbank, Aeschen, 4002 Basel
Medicus Mundi Schweiz, 4056 Basel
IBAN: CH40 0077 0016 0516 9903 5
BIC: BKBBCHBBXXX