

OECD FORUM 2005

FUELLING THE FUTURE: Security, Stability, Development

Health and Development

Karim Laouabdia – Director, Access to Essential Medicines Campaign, Médecins Sans Frontières

Ladies and Gentlemen,

First of all I would like to thank the organisers for inviting me.

I want to discuss with you why medical advances in the *last* decades, that have resulted in considerable improvements in health and quality of life in developed countries, have left behind the majority of the world's population in developing and least developed countries. MSF is a medical humanitarian organisation, not a development agency. However as a field medical agency we have been witnessing for years the increasing difficulties our patients have to access effective and affordable treatments.

An assessment conducted in '99 showed that:

- Many existing treatments for tropical and infectious diseases were old and increasing resistance had reduced their efficacy
- The production of effective existing drugs was being abandoned or was about to be stopped
- New essential drugs were too expensive

This was seen as the result of the very nature of the pharmaceutical market and the way *it* was regulated.

The WTO/TRIPS Agreement (Trade Related aspects of Intellectual Property rights) that sets out 'minimum' standards of protection of IP rights including patents on pharmaceutical is the main barrier that hinders patients in developing countries to access existing life saving medicines and prevents investments in R&D for neglected diseases that do not offer a profitable market.

In 2001, in Doha, the WTO members expressed their concerns about the effects of IP protection on prices. They declared that "The Agreement can and should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and promote access to medicines for all.

Countries have the right to grant Compulsory License and to determine the grounds upon which such licenses are granted."

4 years later we can say that we have made hardly any progress and the situation is getting worse and worse for our patients.

1. Access to existing Drugs

The access to Aids Treatments is a good case study.

MSF field teams treat more than 30000 patients in Africa, Asia and Latin America.

2 key factors enabled us to put so many patients under treatment:

- the introduction of what we call a Fixed Dose Combination (3 drugs in 1 pill) produced by the Indian manufacturers. Producing a FDC, a true innovation that responded to the field needs, was impossible in industrialised countries because the patent holders were different.
- the 2nd factor was the drop of ARV prices: the marketing of Indian generics pushed down the ARV prices (triple therapy) from 12000 US \$ per patient /per year to around 150.

We know that high prices are the result of the lack of competition due to the patent that grants a monopoly (20 years) to the patent holder who is free to set the price.

Today the access to new ARV drugs (what we call the second line drugs and the ARV of tomorrow) is impossible for two reasons:

- India has changed its legislation to comply with its obligation under the WTO/TRIPS Agreement. In the future, drugs not yet produced by the generic manufacturers and any drugs invented after 2005 are likely to only be sold by originator companies. The lack of competition will undoubtedly lead to steep increases in the prices of any new medicines, be it ARV or antibiotics
- The signature of bilateral and regional trade agreements with the US undermine the Doha Declaration through "TRIPS plus" provisions that annul the achievements of Doha and confirm the lack of political support for the use of TRIPS flexibilities

Today MSF best prices, including PQ generics when available:

- Price for 1st line: NVP/3TC/d4T: 270 USD /pp/py
- Range of prices for 2nd lines (ZDV/Ddi/NFV to Lopv/r+ddi+ ZDV): 1040-1520 USD /pp/py

The 2nd lines cost 4 to 6 times more than the first line

2. R & D

The R&D system, based on the IP protection and patent, has failed to produce new drugs for neglected diseases.

20% of the world population represent 80% of the world drug market, that is worth 550 *Billions \$ in 2004.*

The worldwide spending on health R&D has never been so high: estimated at around US\$ 100 *billion.*

Since the 90's: the Private sector has become the biggest investor.

The Public funding is directed to basic research and through tax breaks for the pharmaceutical industry.

However little is translated into the development of new drugs because the expertise in the development of new medicines is concentrated in the private sector whose interest is to develop drugs for profitable markets.

As a consequence: less than 10% of global research spending is devoted to conditions that account for 90% of the global disease burden

IP protection and patent

The IP protection system and patent are supposed to stimulate innovations through high prices, the terms of the equation being:

High prices = high profits = high investments in R&D and therefore more innovations.

It's known that only 10% of drug sales profit is plugged back in R&D whilst 1/3 of the sales revenues are on marketing and administration.

And in terms of innovations, less than 5% of the drugs introduced in the US (1981 - 1991), by the top 25 pharmaceutical companies, were therapeutic advances. Of these 70% were developed with government involvement.

There are no mechanisms for directing these innovations, so many diseases are ignored. Therefore no matter how strong is the level of IP protection, R&D will not spontaneously happen for neglected diseases that do not offer a profitable return on investment.

Even more the system may hamper innovations; compounds or formulations that could show promises for the treatment of neglected diseases may not be developed.

For instance, we need child-friendly ARV formulations, but there is no commercial interest:

- The market is small in Western countries: around 100 new infections in Europe or N. America in 2004
- Whilst in Developing countries there have been 560,000 new infections in 2004

After a flurry of patents filed on the SARS virus, WHO declared that "such patents could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases."

3. Conclusion

Given our field experiences and the five-year fighting to get access to *essential medicines* we can conclude that the global rules that affect availability and R&D of medicines and health technologies should be driven by health needs rather than by commercial considerations.

We cannot accept that the majority of the world's population has no access to medical advances; **a paradigm shift is needed.**

The Philanthropic model cannot offer a sustainable solution; *it's a public responsibility. Political will is essential if a government wants to use the WTO/TRIPS flexibilities.*

We have seen that when there is enough concern and motivation, health research and development (R&D) can yield rapid results:

- The Severe Acute Respiratory Syndrome (SARS) outbreak in 2003
- The anthrax scare in the United States in 2001 led bio-defense research spending at the US National Institutes of Health (NIH) to increase from US\$ 53 million in 2001 to US\$ 1.6 billion in 2004.

Thank you