Access to medicines should not be a luxury for the rich but a right for all.

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Introduction

Infectious diseases kill 17 million people each year, and more than ninety percent of these deaths occur in the developing world.[2] The leading causes of illness and death in Africa, Asia and South America, regions that account for four-fifths of the world's population are HIV/AIDS, respiratory infections, malaria and tuberculosis.

In particular the magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat the diseases or alleviate suffering. Each day 8000 people die of AIDS in the developing world. The reasons for the lack of access to essential medicines are manifold, but in many cases the high prices of drugs throw up a barrier to needed treatments.

Too often in the countries where Médecins Sans Frontières (MSF) works, we have been forced to watch our patients die because they cannot afford the drugs that could improve, extend, or save their lives. MSF believes that essential drugs are not a luxury that should be reserved for the wealthy. Rather, access to essential medicines should be guaranteed as a critical component of the human right to health.

Factors that affect access to medicines

There are many factors that affect the availability ad accessibility of essential medicines. Pécoul et al[3] identified four main issues associated with the inaccessibility of drugs for populations in the greatest need:

1) Poor-quality and counterfeit drugs. Counterfeit drugs are illegally produced medicines that mimic in appearance authentic mostly known trademark products. Counterfeit drugs are a result of criminal activities often carried out by well organised illegal organisations. Poor-quality or substandard medicines are those produced with little or no regard for quality

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[2] World Health Organization. The World Health Report 2000. Geneva: WHO, 2000

[3] Pécoul B., Chirac P., Trouiller P., Pinel, J. (1999) Access to essential drugs in poor countries. A lost battle? *JAMA*, *Vol*: 281: 361-367.

standards. The production of poor quality drugs is not necessarily a result of criminal activity but may be due to oversights in manufacturing or lack of controls. MSF teams in the field have been confronted with batches of medicines that had no active ingredient at all.

2) Lack or availability of essential drugs due to fluctuating production or prohibitive cost. Drug companies abandon the production of effective and needed drugs when they are commercially not of interest. For example the production and availability of oily chloramphenicol, a suitable and low priced drug for use in epidemic bacterial meningitis has been unsure because the company stopped production and transferred the technology to another company. Another example is eflornithine, an effective treatment for sleeping sickness (African trypanosomiasis). Sleeping sickness is a fatal neurological disease. 300.000 people suffer from the disease and a further 50.000 people living in sub-Saharan Africa are at risk of infection. The production of eflornithine was abandoned because of lack of commercial gain. Eflornithine was developed in the mid-seventies as an anti cancer agent by a drug company. The company received US approval for the treatment of sleeping sickness in 1990 but abandoned production in 1995 when the drug was not turning an adequate profit. MSF has been involved in securing the production and procurement of the drug. In 2001 Aventis announced to restart the production of eflornithine and reached an agreement with WHO to donate the drugs. MSF is supplying the drugs through its supply centre. The agreement between WHO and Aventis was accelerated by the media attention surrounding the launch of Bristol-Myers Squibb's (BMS) Vaniqa, an eflornithine-based product for slowing the growth of women's facial hair.

3) Lack of field based research and development (R&D) programmes for new drugs for the developing world. Despite the enormous burden of disease, drug discovery and development targeted at infectious and parasitic diseases in poor countries has virtually ground to a standstill. Of the 1223 new drugs approved between 1975 and 1997, 13 (less than 1%) were specifically to treat tropical diseases.[4] Developing countries where three-quarters of the world population lives account for less than 10% of the global pharmaceutical market.

4) Potential consequences of the World Trade Organisation (WTO) agreements on the availability of medicines, in particular the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In the recent years the magnitude of the AIDS crisis in the developing world has drawn attention to the grave inequity in access to essential medicines needed for HIV/AIDS. Most HIV/AIDs medicines are relatively new and are produced by the patent holder in what is effectively a monopolistic situation. The problems caused by the high HIV/AIDS drug prices offer us a snapshot of how availability of new essential medicines may

[4] Trouiller P, Olliaro P. (1999) Drug development output from 1975 to 1996: What proportion for tropical diseases? *Int Journ Infect Diseases. Vol*: 3: 61-63.

be affected by patents in the future. Once the TRIPS Agreement is fully implemented the cost of all new medicines will depend on price setting by the patent holder.

Price

Price is not the only reason why people do not get the medicines they need, but it is a major barrier. The high cost of many life-saving drugs not only keeps patients from getting treatment, but also discourages health ministries from improving the quality of patient care through the use of newer and better medicines. Newer drugs, which are usually under patent and more expensive than those off-patent, are expected to become even more expensive with the implementation of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in all Members, scheduled to be completed by 2006 in most developing countries. Industrialised countries needed to be TRIPS compliant by the year 1996.

Generic medicines

Generic medicines are copies of original medicines which are chemically and pharmaceutically identical to the original product. Sometimes they are also referred to as "multi –source medicines" because there usually are multiple producers. The official WHO definition of a generic medicine reads:

"A pharmaceutical product usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights. Generic drugs are marketed either under a non-proprietary or approved name rather than a proprietary or brand name."

In general prices of generic medicines, are significantly lower than prices of patented, or single-source products. A generic company does not carry the cost of the development of the drug. Another important reason is that generic competition brings the prices down. Lessons can be learned from Brazil where the price of AIDS drugs fell by 82% over 5 years as a result of generic competition. The prices of drugs that had no generic competitor remained stable, falling only 9% over the same period. [5] In the United States the average price of prescription brand name drugs is three times the price of the generic drugs.[6] Other dramatic results can be seen in the price of AIDS triple-therapy for developing countries, which fell from US$10,000 per patient per year to as low as US$209 in two year due to generic competition.[7]

The monopolies created by the patent system prevent price competition by delaying the introduction of generic versions and lead to higher drug prices. In the past countries could choose for public interest

[5] Brazil Ministry of Health, 2000.

[6] Prescription Drugs and Intellectual Property. National Institute for Health Care Management. Issue Brief August 2000.

[7] From Durban to Barcelona: Overcoming the Treatment Deficit. Médecins sans Frontières, Campaign for Access to Essential Medicines. July 2002.

reasons to exclude medicines from patentability. The Indian patent law for example provides for pharmaceutical process patents but not for product patents. This has allowed the growth of a substantial pharmaceutical industry in India, which is producing much of the generic medicines available throughout the world.

The TRIPS Agreement and the future of generic medicines

With the Conclusion of the Uruguay Round in 1994 and the establishment of the World Trade Organisation (WTO) in 1995 the TRIPS Agreement became the international standard for the protection of intellectual property. All WTO member countries are obliged to amend or adopt their national intellectual property laws to conform to the TRIPS Agreement.

TRIPS sets out minimum standards and requirements for the protection of intellectual property rights, including trademarks, copyrights, and patents. The implementation of TRIPS, initially scheduled for 2006 by most WTO Members, is expected to impact the possibility of obtaining new essential medicines at affordable prices. TRIPS requires all WTO Members to provide a minimum of 20 years of patent protection. TRIPS does not allow to distinguish between products. This means that life saving medicines fall under the same patent regime as more trivial products such as computer games or toys. Countries can no longer adopt patent systems that may be more suitable to their level of industrial and economic development.

It is unlikely that TRIPS will encourage adequate R&D in developing countries for diseases such as malaria and tuberculosis, because poor countries often do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry.[8]

Enforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which developing countries depend. The number of new essential drugs under patent protection will increase, but the drugs will remain out of reach to people in developing countries because of high prices. Increased patent protection leads to higher drug prices.[9] As a result, the access gap between developed and developing countries will widen.

Developing countries are under pressure from industrialized countries and the pharmaceutical industry to implement patent legislation that goes beyond the obligations of TRIPS. This is often referred to as "TRIPS plus." TRIPS plus is a non-technical term which refers to efforts to extend patent life

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[8]See MSF Access to Essential Medicines Campaign and The Drugs for Neglected Diseases Working Group, *Fatal Imbalance; The Crisis in Research and Development for Drugs for Neglected Diseases* 10–18 (Sept 2001), available online at <http://www.msf.org/source/access/2001/fatal/fatal.pdf>

[9]See F. Michael Scherer and Jayashree Watal, *Post Trips Options for Access to Patented Medicines in Developing Countries* 11 (WHO Jan 2001), available online at <http://www.cmhealth.org/docs/wg4_paper1.pdf> (reporting on three independent studies that found a mean price increase of well over 200 percent with the introduction of product patents).

beyond the twenty-year TRIPS minimum, to tighten patent protection, to limit compulsory licensing in ways not required by TRIPS, or to limit exceptions which facilitate prompt introduction of generics.[10]

Correcting the balance

Concerns about the public health affects of the TRIPS Agreement have been brewing from the day the TRIPS Agreement was adopted. In 1998 under protest of the pharmaceutical industry the WHO published a report "Globalisation an access to Drugs. Perspectives on the WTO/TRIPS Agreement". The report stresses that the protection of intellectual property rights is not an end in itself but has a functional role to play in the fulfilment of public policy objectives. Policies pursued must therefore aim to make drugs available. The report points out that drugs play a significant social role in that they are an integral part of the realisation of the fundamental human right to health.[11] At the failed WTO Ministerial conference in 1999 in Seattle Venezuela tabled a proposal to exclude essential medicines from patentability. However the issue gained huge international interest as a result of the court case brought in 2001 by 39 pharmaceutical companies against the South African government to stop the implementation of the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (Amendment Act) on the basis that it would not be compliant with the TRIPS Agreement. South Africa was not the only country that had come under pressure from industrialised countries and the multinational pharmaceutical industry for attempting to bring drug prices down. In Thailand in 1998 under the threat of increased import tariffs of wood and jewellery the United States forced the Thai government to abandon measure that were meant to protect affordability of medicines.[12]

Increased criticism

Today critical voices on the TRIPS Agreement sometimes come from unexpected quarters. Justice Laddie a member of the UK patents Court said in an interview in Legal Week in July 2002:

> "*Whether you are the richest or the poorest country in world, you have to sign up to TRIPS to join the WTO club. I personally have the deepest possible misgivings over this as it applies to the developing countries. The rules mean that developing countries, unable to benefit from Western innovations such as life-saving drugs due to their cost, are also prohibited from making cheap copies of such goods locally*".

Some drug companies have responded by the criticism and threats to their patents by offering drugs at lower or so called tiered prices for developing countries. GlaxoSmithKline (GSK) announced in 2001

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[10]See World Health Organization, *Globalization, TRIPS and Access to Pharmaceuticals* 4 (March 2001), available online at <http://www.who.int/medicines/library/edm_general/6pagers/PPM03%20ENG.pdf>

[11] See Germán Velasquez and Pascale Boulet, *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement* (WHO 2nd ed 1999).

[12] Global trade and access to medicines: AIDS treatment in Thailand. David Wilson, Paul Cawthorne, Nathan Ford, Saree Aongsonwang. Lancet 1999; 354: 1893-95

that it would make all its antiretroviral products available at differential prices in the least developed countries and sub-Saharan African countries. Also other drug companies have made discount offers, however there is no uniform tiered pricing system and policies with regard to eligibility differs enormously per company. Most companies do not have a clear lower price policy for developing countries outside Africa. Pfizer has a separate view. In response to a survey carried out by OXFAM, VSO and Save the Children Pfizer said [13]: "*For many patients in least-developed countries, medicines at any price are unaffordable. That is why Pfizer supports donation programs*". While in certain situations donations can offer relief it can hardly be argued that it contributes to a sustainable long-term solution. A careful analysis shows that generic competition remains the most effective means to lowering drug prices. Prices for ARVs are the lowest in countries that pursue a deliberate policy to increase generic competition, local generic production and show readiness to override patents when necessary. [14]

From Seattle to Doha

The TRIPS Agreement and access to medicines issue was at the heart of the discussions of 4th World Trade Organisation (WTO) Ministerial Conference in Doha. Developing countries asked for more flexible rules on intellectual property to ensure the protection of public health especially ensuring the availability of medicines.

The 4th WTO Ministerial Conference in November 2001 in Doha adopted the "Declaration on TRIPS and Public Health", which affirmed the sovereign right of governments to take measures to protect public health.

The most important paragraph of the Doha declaration reads:

> "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitments to the TRIPS Agreement, we affirm 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." [15]

The declaration is an important political and legal document that gives primacy to public health over private intellectual property and clarifies WTO Members' rights to override patents if they form a

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[13] Beyond Philantropy: the pharmaceutical industry, corporate social responsibility and the developing world. OXFAM, VSO, Safe the Children. London 2002.

[14] See: Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries. June 2002 2nd edition. Campaign for Access to Essential Medicines, Médecins sans Frontières.

[15] World Trade Organization, Doha Ministerial Declaration on the TRIPS Agreement and Public Health, para 4, WTO Doc No WT/MIN(01)/DEC/2 (2001) ("Doha Declaration" or "Declaration").

barrier to access to medicines. This is an important step to ensure that intellectual property protection serves the broader public interest beyond that of the commercial sector. The declarations clarifies the right of countries to set patents aside for example by using compulsory licensing and to adopt parallel import policies that allows for the importation of the lowest priced branded products. In addition the declaration grants Least Developed countries the option to exclude pharmaceuticals from patentability to at least 2016. The Doha declaration took away the insecurity caused by legal actions such as in South Africa and the trade pressures in Thailand.

Is the tide turning?

The debate on the need to take measures to increase access to the medicines for people in developing countries is taking on a global dimension. There are encouraging signals that the tight is turning.

The global debate on access to medicines has encouraged generic and brand name drug companies to offer key medicines at lower prices. Today, the cheapest generic combination therapy offered to developing countries costs a little over 200 USD. Three years ago the price of triple therapy was 15,000 USD.

The European Commission is working on a tiered pricing regulation that would ensure a more systematic approach to tiered pricing of newer medicines.

There is greater transparency in drug price information thanks to the UNICEF, UNAIDS, WHO/HTP, MSF pricing database.[16]

This years updated 12th model list on essential medicines (EML, previously known as EDL) of the World Health Organisation is another important step forward. The Essential Medicines Committee added 10 antiretrovirals to the core essential medicines list and highlighted the importance of fixed-dose combinations (FDCs) of certain antiretrovirals.
Previously essential medicines were often excluded from the WHO essential medicines list on the grounds that they were too expensive. This new policy is a recognition of the fact that high prices should not be taken for granted and that countries are encouraged to take measures to bring the cost down. WHO is also helping countries to access more affordable medicines through the pre-qualification of manufacturers and through the publication of treatment guidelines to encourage the rational use of the medicines.

Challenges remain

However many challenges remain. Despite the greater awareness and the Doha declaration countries have not taken advantage of the flexibilities spelled out in the declaration. Countries should start

[16] Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS. Joint UNICEF, UNAIDS, WO/HTP, MSF project. May 2002. Fourth edition. Available on the website: www.accessmed-msf.org

issuing compulsory licenses to allow for production or import of medicines that are priced out of reach of their population. LDC's should were necessary amend their laws to exclude medicines from patentability. The WTO has not found a solution for allowing production for export of generic drugs to countries who need them. Funding mechanism such as the Global Fund should expressly encourage strategies that overcome access barriers including those caused by patents.

There is a need for a systematic approach to tiered pricing for new essential medicines. Despite the fact that some drug companies offer discounts for some their drugs, they object to regulation that could lead to a tiered pricing system.

Global funding for health lags far behind the need. For example the Global Fund to fight AIDS, TB, and Malaria so far has only received 10% of the estimated required funds needed per year to tackle AIDS alone. The total amount required per year to fight AIDS, TB and Malaria is 10 billion US$.

Another area were attention is urgently needed is the lack of R&D into new drugs for specific health needs of the poor. Recent studies claim that the R&D cost of a commercial drug company per new pharmaceutical product is $802 million.[17] The Global Alliance for Tuberculosis Drug Development, a not-for-profit entity for R&D for TB drugs, estimated that the total R&D cost for a new TB drug, including the cost of failure is between US$ 115 mill and US$ 140 million[18]. The high R&D cost claimed by the commercial pharmaceutical sector poses some key questions: Is the present system for funding R&D the most efficient, and is it sufficient to rely on the intellectual property systems to fuel innovation? Clearly in the area of neglected diseases it is not. In an increasingly globalized economy additional international mechanisms need to be developed to address health needs in developing countries that are neglected by the market. This will be the key challenge for the coming years. Essential drugs should not be a luxury reserved for the wealthy but should be reinforced as a critical component of the human right to health.

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17 See: http://www.tufts.edu/med/csdd/images/NewsRelease113001pm.pdf. These data have come under heavy criticism. See for example IRS Data Shows Drug Industry Cost Estimates Exaggerated. Press release by James Love. November 30, 2001. See: http://lists.essential.org/pipermail/ip-health/2001-November/002481.html. See also the paper by James Love: "How much does it cost to develop a new drug" at http ://www.cptech.org/ip/health/econ/howmuch.html

18 See for details: http://www.tballiance.org/3_costs.cfm?rm=economics&sub=costs