MSF Briefing: 6th WTO Ministerial Conference, Hong Kong, December 2005

Access to Essential Medicines and the WTO:
Case Study CHINA

Introduction

As in many countries where Médecins Sans Frontières (MSF) works, access to essential medicines is an important problem in China. China began granting product patents on medicines in 1993, and fully implemented the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 2001 as a condition of joining the WTO. Since 2003, MSF has been running HIV/AIDS treatment and care projects in China's Guangxi and Hubei Provinces; MSF now provides antiretroviral (ARV) therapy to about 335 people living with HIV/AIDS, including 25 children. One of the key challenges in providing quality medical care has been getting access to the appropriate drugs. Intellectual property protection, among other factors, has had wide-ranging impacts on public health and access to medicines in China including: restrictions on drug choice, lack of availability of needed drugs, and high prices for branded drugs.

Restrictions on Drug Choice

Like many other countries in the region, China faces a growing AIDS epidemic. The latest government estimates indicate China has about 840,000 HIV positive people, 80,000 of whom are living with AIDS. In 2003, the government launched a national programme to provide free ARV drugs, and as of late 2005, was treating about 16,000 people. When the programme began, the drug regimen chosen was stavudine (d4t)+didanosine (ddI)+nevirapine (NVP); these three drugs were available generically in China, as patents did not block local production. However, the World Health Organization (WHO) does not recommend using this regimen due to the toxicity profile of the combination of d4t and ddI.[1] Instead of ddI, WHO recommends using lamivudine (3TC). However, GlaxoSmithKline (GSK) has a monopoly on 3TC in China, and had not made the drug available in the dosages required to treat AIDS when the national programme began. The situation changed in December 2004, when the government changed its national protocol to adopt the WHO-recommended combination of d4t+3TC+NVP, having reached a confidential supply agreement with GSK. Nevertheless, the impact of the lack of availability of 3TC lingers – doctors have attributed high levels of side effects and negative effects on patient adherence to the lack of 3TC.

NOT AVAILABLE: Fixed-Dose Combinations

GSK's monopoly on 3TC in China also blocks access to the fixed-dose combination (FDCs) ARVs widely used in other countries. FDCs are a combination of two or three ARVs in one pill. MSF provides 3-in-1 FDCs to 70% of new patients in its programs internationally. One example of an FDC commonly used to extend life and rapidly scale-up treatment in developing countries is the combination of d4T/3TC/NVP. FDCs are an important medical and public health advance, in that they improve adherence by making lifelong ARV treatment easier to take for patients, and reduce the risk of developing resistance by making it impossible to take only a partial dose of a triple combination. However, this FDC cannot be manufactured or sold in China because of monopoly rights on just 1 out of the 3 drugs in the combination – 3TC.

NOT AVAILABLE: Key 2nd-line Drugs

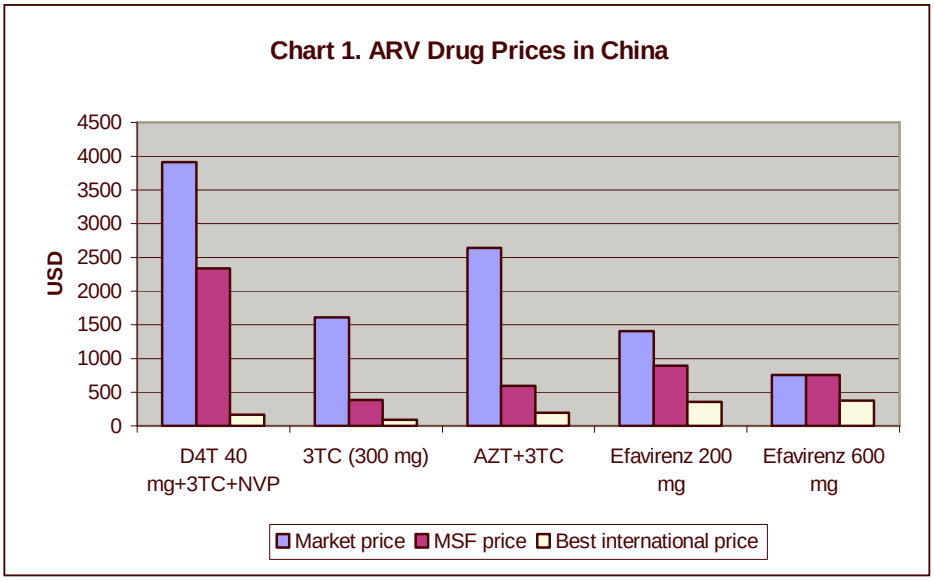
Experience from places where ART has long been widely available, such as Brazil, the US or Europe, shows that after a few years, many patients develop resistance to the "first-line" of ARV drugs and must then switch onto a "second-line" regimen. However, in China, many second-line drugs are simply not available because the companies controlling the patents have chosen not to market them. These include tenofovir, lopinavir/ritonavir (LPV/r), saquinavir, nelfinavir, and ritonavir. Patients desperately needing access to the drug LPV/r, for example, might go to Hong Kong to find it, where it

[1] "Scaling up Antiretroviral Therapy in Resource-Limited Settings: Treatment guidelines for a public health approach. 2003 Revision." Geneva: WHO, 2004. p13.

is available at about $4600 per patient/year. But this is neither an accessible price, nor a sustainable solution for Chinese patients needing 2nd line therapy. The per capita income of Hong Kong is 21 times that of mainland China.[2]

NOT WORKING: Voluntary differential pricing

Another problem China faces is that it does not benefit from many of the discounted prices that drug companies sometimes offer to developing countries, in a system called "voluntary differential pricing." Like other countries categorized as (lower) middle-income, such as Guatemala, Honduras or Thailand, China often does not get access to the prices offered to Least Developed Countries, which results in drugs being priced at wealthy-country levels. Chart 1 illustrates prices paid for branded drugs in China (market price and MSF price) compared to the best international prices available.



TOO COMPLICATED: Treatment for Children

The promise of the TRIPS Agreement was that patent protection would engender increased research & development for medicines. However, as there is little profit in HIV/AIDS medicines for children in developing countries, few companies are investing R&D dollars in this area. The resulting lack of simple, easy-to-use versions of AIDS drugs for children make pediatric treatment too complicated. The few drugs that do exist in syrup or powder formulations are impractical to use: a child must take three different quantities (often large volumes) of three different and often foul-tasting syrups.

PRODUCTION CAPACITY: Chinese Generic Firms

The irony of many of these access difficulties is that capacity to generically produce nearly all needed first and second-line ARVs exists in China. China is currently the leading producer of the raw materials necessary for ARV production, and has significant capacity to scale-up production volumes of both raw materials and finished-products. China has recently adopted into national law the WTO decision ("August 30th") allowing production of drugs under compulsory license predominantly for export. However, China has not yet issued a compulsory license for a medicine so patents continue to block production of many drugs.

Conclusions

MSF's difficulties getting access to the right drugs to treat HIV/AIDS in China reflect a more global problem: intellectual property protection is continuing to significantly restrict access to medicines. Thus far, the solutions proposed by the WTO have not proven effective in addressing the fundamental roots of these problems. MSF calls on WTO Members to re-affirm their political commitment to the Doha Declaration on TRIPS and Public Health (2001 WTO Ministerial), fully implement the declaration in national law and drug procurement policies, and find robust and workable ways to eliminate the negative effects that drug patents have on access to essential medicines.

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[2] GNI per capita in: Mainland China: 1290 USD. Hong Kong: 26,810 USD. (World Bank, 2004).