Viewpoint

Global trade and access to medicines: AIDS treatments in Thailand

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The process of increasing globalisation is dominated by market influences that have a negative effect on public health in less-developed countries.[1] Laws that govern the importing of medicines and the patent protection of new discoveries are subject to an increase in globalisation. The possible effects in terms of access to medicines are well defined.[2]

In May, 1999, WHO was given a mandate to monitor the public-health consequences of international trade agreements.[3] Several less-developed countries have been under pressure from western governments to make changes in trade laws that would restrict their ability to produce or import drugs (www.cptech.org, accessed Nov 15, 1999). Non-governmental organisations have an important part to play in increasing awareness of these issues, and Médecins Sans Frontières has been active in bringing these issues to public attention.

The World Trade Agreements

The World Trade Agreements, signed in 1994,[4] were a decisive step towards a worldwide free-trade economy. In signing these agreements, member states of the World Trade Organisation have to abide by several multilateral agreements, of which the TRIPS agreements (Trade-Related Aspects of Intellectual Property Rights) probably has the greatest effect on access to medicines. TRIPS deals with patent law and sets some minimum standards such as 20-year patent protection for pharmaceuticals. In certain instances, such as public-health emergencies or unfair-pricing practices, TRIPS allows for the production of medicines by companies other than the patent holder (compulsory licensing). TRIPS also allows for the importing of medicines from countries other than the country of manufacture (parallel importing). Compulsory licensing and parallel importing are both widely practised by western countries. However, some less-developed countries have been pressured by western governments to ban compulsory licensing and parallel imports. We focus here on Thailand, where US trade pressure has limited access to affordable treatment for patients with HIV and AIDS.

Access to HIV treatment in Thailand

1 million people in Thailand (which has a population of 61 million) are infected with HIV. In 1995, a World Bank and WHO review advised Thailand to focus its limited drug resources for HIV on the prevention of perinatal HIV infection and management of opportunistic infections.[5] The Thai Ministry of Public Health (MOPH) identified the need to formulate a policy of rational use of antiretroviral drugs[6] and issued guidelines for the clinical management of HIV infection that focused on prevention and treatment of opportunistic infections.[7] Short-course zidovudine to limit perinatal transmission is to be implemented as a result of a study by the Centers for Disease Control and Prevention.[8] The MOPH also funds small-scale research projects but these benefit small numbers only and do not guarantee long-term treatment for participants.[9] In reality few patients can afford antiretroviral treatment. The monthly price for a course of zidovudine, lamivudine, and indinavir is $US675, whereas the typical monthly wage of an office-worker is $US120.

Generic drugs in Thailand

There are legitimate concerns about the quality of therapeutic agents in less-developed countries. In Thailand, there have recently been reports of deaths as a result of a new rabies treatment.[10] Although a limited study by UK researchers did not find any pattern of substandard quality for pharmaceuticals imported from less-developed countries,[11] the researchers commented that improved control at a regulatory level with less-developed countries is required. A critical assessment of the extent of the problem is needed.

The generic pharmaceutical industry in Thailand formulates and packages drugs from imported raw materials. Bioequivalence studies are required for generic product registration.[12] Reports on Thailand's pharmaceutical industry are available from the website of the UN agency in charge of industrial development (www.unido.org, accessed Nov 15, 1999).

Fluconazole is a key drug in the management of cryptococcal meningitis, an opportunistic infection that affects one in five patients with AIDS in Thailand. Until recently, Pfizer was the sole supplier of fluconazole in Thailand, charging a daily price (dosage of 400 mg) of $US14. In 1998, fluconazole was released from the safety monitoring programme (the safety monitoring programme confers a period of market exclusivity) in Thailand and is now supplied by three local pharmaceutical companies. The price has fallen to 5% of the 1998 price, which represents a potential annual saving to Thailand of $US3.1 million in the treatment of cryptococcal meningitis. Compliance with treatment has also improved because more patients can afford the drug.

This example shows the difference that generic competition can make in terms of price and accessibility of medicines in less-developed countries.

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Antiretroviral drugs are cost-effective in a less-developed country.[13] Thailand's Government Pharmaceutical Organisation has supplied generic zidovudine since 1993. The resulting competition has led to a fall in monthly cost (600 mg per day) from $US324 in 1992 to $US87 in 1995.

Attempts to produce other drugs have been less successful, such as the Government Pharmaceutical Organisation's plan to supply generic didanosine. Research and development of didanosine was funded by the US National Institutes of Health and exclusive production rights in the USA were granted to Bristol-Myers Squibb. The planned production of didanosine in Thailand was supervised by Bristol-Myers Squibb but buffer formulation in production was blocked when Bristol-Myers Squibb secured a product patent for the new formulation in 1998. This company remains the sole supplier in Thailand selling didanosine at a monthly cost (400 mg per day) of $US136. The agreement between the US National Institute of Health and Bristol-Myers Squibb includes a reasonable-pricing clause, which seems to have been overlooked in this case.[14] In response to our requests, the US Department of Health and Human Services has verbally agreed to review implementation of this clause.

US pressure to change patent law in Thailand

Thailand is capable of producing good-quality cheap generic drugs, but local production has been limited by trade pressure from the US government.

The US government regards TRIPS as a minimum standard, and in bilateral discussions commonly asks for additional commitments,[15] with threats of trade sanctions to achieve its objectives.[16,17] The USA is the destination of a quarter of exports from Thailand[16] so these threats are taken very seriously.

In 1992, under threat from the USA to limit textile imports,[17] the Thai government passed a law to introduce product patent protection. As a safeguard, the Thai government created the Pharmaceutical Patent Review Board, which had authority to collect economic data, including the production cost of pharmaceuticals. The US Trade Representative Office objected[18] and in 1998, under threat of increased tariffs on imports of wood products and jewellery,[16] the Pharmaceutical Patent Review Board was disbanded and measures were taken that led to limiting of the right to issue compulsory licenses for pharmaceuticals.

The role of WHO

At the World Health Assembly in May, 1999, WHO was given a mandate to monitor the public-health consequences of International trade agreements. This new responsibility is contained within the Revised Drug Strategy, the WHO policy designed to ensure equitable access to essential drugs and to good treatment. The Revised Drug Strategy is a comprehensive policy that addresses all those involved, including member states and industry. The role of WHO, however, seems to be limited to monitoring the consequences of the World Trade Organisation agreements such as TRIPS. This will be of little comfort to countries subjected to international trade pressure.

After the adoption of the Revised Drug Strategy, a statement from the Thai delegation to WHO strongly recommended that the WHO support access to drugs by actions in areas of technology transfer, local production, elimination of counterfeit drugs, and human-resource development. The delegation also identified the need to develop indicators to assess the positive and negative effects of trade agreements on public health in less-developed countries. Assessment of the future effect of the Revised Drug Strategy will not be possible without such indicators.

The United Nations Development Programme (UNDP) has pointed out that less-developed countries are merely passive recipients of the effects of globalisation rather than its beneficiaries,[1] and in 1992 and 1998 Thailand responded passively to trade pressure from the USA. However, the terms of the Revised Drug Strategy require member states to initiate requests for help; this help is unlikely to have a significant effect in less-developed countries unless consumer and advocacy groups pressure governments into action.

Conclusion

Pressure from the US government has forced Thailand to limit compulsory licensing and parallel importing, both of which are rights allowed for under TRIPS and used to great extent by western governments, including the US.[15] Other less-developed countries have been subjected to similar pressure, in particular South Africa (for a list of countries, see www.cptech.org).

An attempt to confer to WHO a role in monitoring international trade agreements was strongly opposed at the 1998 World Health Assembly: US State Department representatives threatened to withdraw WHO funding when faced with aggressive WHO support for improved access to patented medicines in less-developed countries. The adoption by unanimous consensus of the Revised Drug Strategy this year was, therefore, welcome news.

International trade agreements determine what can be done in terms of production and importation of medicines, so it is important for less-developed countries to understand fully the implications of these agreements. Equally, western governments need to receive a more balanced input of information when formulating trade policies that have public-health consequences.

Non-governmental organisations can be more flexible than WHO and have an important part to play in defending the rights of less-developed countries at local and internatonal level. Médecins Sans Frontières has been active as part of the Thai Non-Governmental Organisation Coalition on AIDS in bringing trade issues to public attention.[21] Similarly, the AIDS Treatment Action Campaign has done much work in defending South Africa from US trade pressure. However, it remains to be seen whether WHO and non-governmental organisations will be able to prevent western trade pressure from forcing less-developed countries to forego rights to produce and import medicines that are prohibitively expensive in today's market.

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