

Summary of Panel Discussion for “A European Perspective on the Future of Global AIDS Programs: A Conversation with Five AIDS Ambassadors”

Subject: Intellectual Property and Access to Medicines

Background:

In 1994, countries agreed to the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement as part of the formation of the World Trade Organization. The TRIPS Agreement included twenty years of patent (monopoly) protection for medicines. Until then, patent protection had only been implemented in developed countries, with developing countries relying upon low-cost, generic medicines to supply their health systems.

In subsequent years, there was concerted focus upon the TRIPS Agreement in various quarters of the AIDS community. As developed countries moved towards universal access to first-line anti-retroviral medicines to treat HIV and AIDS, it became apparent that high prices charged by pharmaceutical companies in developing countries, including nearly \$10,000 per patient per year in South Africa, was preventing scale-up of treatment.

Unprecedented competition between Indian generic pharmaceutical manufacturers ensured that prices for 1st line ARVs fell dramatically from \$10,000 USD per patient per year to approximately \$360 USD per patient per year (recently, prices for the typical first-line drug cocktail are only \$132 USD per patient per year). Increased civil society, public, governmental and media pressure upon the pharmaceutical industry and the US government produced two results in 2001: (1) an unprecedented increase in supply of ARVs to developing countries, and particularly across sub-Saharan Africa, and (2) an accord at the World Trade Organization in November 2001 (in Doha), which re-assured that intellectual property protections should never prevent any country from protecting public health.

Introduction by Dr Michel Kazatchkine:

Dr Kazatchkine, in his introduction to the panel, noted that intellectual property rules had presented a serious challenge to access to medicines in the previous decade, but today patent barriers did not present a challenge to access to first line medicines.

Yet, new challenges appear to threaten the viability of continuing to provide appropriate treatment to the growing numbers of AIDS patients across the developing world. In particular, Dr Kazatchkine noted three trends: (1) an inability of developing countries to use public health safeguards under the TRIPS Agreement to improve access to medicines, (2) a gradual increase in the levels of intellectual property protection due to the introduction of higher levels of intellectual property protection in free trade agreements and (3) the high cost of 2nd line anti-retroviral medicines, which often cost 10 to 30 times more than 1st line anti-retroviral medicines. Dr Kazatchkine noted that while access to medicines had fallen off the agenda of the AIDS community, it was likely to become a major issue again, particularly as increasing numbers of patients need access to 2nd line treatment.

Discussion

- One of the positive initiatives over the last few years has been the creation of UNITAID, an airline tax initiative that creates new funds to purchase medicines for HIV and AIDS, tuberculosis and malaria.

- There was a general discussion over the role of medicine prices in delivery of health care, which has often focused upon the role of infrastructure, health care workers and health care financing.
- European countries have adopted the Paragraph 6 compulsory licensing mechanism, which enables production and export copies of patented medicines from countries with generic manufacturing capacity to those countries with no ability to manufacture generic medicines. Yet this mechanism has not been used in Europe to ensure delivery of needed medicines from rich countries to poor countries that are constrained from obtaining medicines from low-cost sources due to technology, trade and patent barriers.
- WHO pre-qualification can be viewed as both a success and failure to ensure that new medicines are readily available in developing countries. Registration barriers often prevent new medicines needed to protect public health from reaching people in developing countries. Often a lack of technical expertise, financial assets and capacity prevents the approval of new medicines (or their generic counterparts) in developing countries. Thus, the WHO pre-qualification process is supposed to create a centralized mechanism to examine and review patented and generic medicines for their use in countries that have a reciprocal arrangement with WHO. Yet due to chronic understaffing and excessive drug applications, the WHO process is plagued by delays and lack of buy-in by developed countries. In particular, the US has ignored the WHO pre-qualification process and used its own food and drug administration to implement a fast track approval process for new medicines, and particularly ARVS needed for PEPFAR (President's Emergency Plan for AIDS Relief).
- New models of drug and vaccine development seem more promising than the older models. In particular, discussants noted the new found success of GAVI (Global Alliance for Vaccines and Immunizations), which had predictable, sustainable funding, targeted health objectives, sharing of research and development and the possibility of improving access to medicines in developing countries.
- At this point, while 2nd line ARV availability (as well as availability of new 1st line ARVs, and particularly Tenofovir), is an issue, it is a quiet issue since the number of patients needing these newer medicines has not reached a level that requires a significant proportion of overall funds. Furthermore, participants noted the continued unavailability of medicines to treat opportunistic infections, including those medicines which are off-patent today.
- Some participants expressed doubt that access to medicines, and particularly the high cost of new medicines, was a real concern in developing countries. Yet this was rebutted by others who noted that in some countries nearly the entire AIDS budget is being used for new AIDS medicines. In particular, Dr Kazatchkine noted the case of Brazil, which was spending over 60 percent of its national AIDS budget to pay for new AIDS medicines.
- The Norwegian embassy noted with dismay that access to medicines has not been considered from a wider perspective – namely that while AIDS is a major concern, developing countries were increasingly concerned with other access to medicines issues: including the availability of medicines to treat non-communicable diseases, to ensure availability of medicines for pandemics (for instance, patent protection on Tamiflu means

that many developing countries do not have reliable access for addressing a possible outbreak of avian influenza) and to ensure research and development for neglected diseases that predominantly affect developing countries (but for which little R&D has been conducted over the previous decades).

- The Pan American Health Organization noted that great inefficiencies still rested in the procurement mechanisms used in developing countries, and more sustainable mechanisms to procure medicines are needed.
- The Office of the Global AIDS Council noted that there had been too much of a fixation on intellectual property rights, and that participants, alongside patents, needed to consider other reasons why medicines needed immediately were not available in developing countries. In particular, it was noted that cotrimoxizole, which is not patented, was often not available in many countries needing immediate access.
- There was some concern that eventually the pharmaceutical companies may not continue innovating medicines for HIV and AIDS, especially as the disease burden continues to fall in the developed world. Thus, questions were raised about how to ensure that there were sufficient incentives to produce medicines for AIDS in the near future. Others expressed skepticism, noting that the high amount of political will and funding for AIDS, and new infections in developed countries, while not higher than before, ensured that a lucrative market would still be available to the pharmaceutical industry to incentivize production of these medicines.

Conclusion

The discussion finally settled upon three issues:

- 1) The high price of 2nd line anti-retroviral medicines, and its implications for future AIDS treatment
- 2) The importance of AIDS in ensuring access to medicines, while considering that AIDS exceptionalism may exclude discussion of access to medicines for other diseases and in other spheres.
- 3) The need to find new mechanisms and solutions to continue incentivizing effective research while ensuring access for all.