



Drug Policy at the 55th World Health Assembly May 2002

“Ensuring Accessibility of Essential Medicines” Resolution EB109.R17

Access: the problem

More than one-third of the world's population lacks regular access to essential medicines¹, many people need to pay out-of-pocket for medicines they can access, regulatory authorities often face incredible difficulties in carrying out their mandate and financing for health is still very limited: in some countries, it is less than US \$2 per person per year. In spite of ad hoc donation programmes, promises of differential prices, international accords and so-called public-private-initiatives, the poorest nations continue to suffer from lack of access to medicines.

A key moment for WHO & Access

Recently, a number of developments have changed the global setting for access to medicines. These can be turned into concrete steps by WHO:

- WHO is participating in the collection of price information data and developing a methodology to collect and analyse price information.
- The prequalification process for HIV/AIDS-related medications has yielded initial results.
- Because of the Doha Agreement, WHO can play a significant role in the implementation and interpretation of pro-public health intellectual property laws.
- WHO's model list of essential medicines has been revised to become more independent, transparent and evidence-based.

Specifically, WHO should support the following means to improve access to medicines:

Equitable prices

People in every country have a right to affordable medicines. Governments have an obligation to enact laws, regulations and policies that ensure access to affordable essential medicines for all of their citizens, and in

particular the poor. They can use various mechanisms to achieve equitable prices, including *promoting generic competition, enacting and implementing pro-public health national trade legislation as allowed by TRIPS, and implementing differential pricing policies.*

Generic competition

Pricing studies have shown unequivocally that generic competition is the most effective way to ensure lasting price reductions. In Brazil, where generic competition for antiretrovirals was introduced in 1997, there has been a constant trend of decreasing prices as generics are introduced.¹¹ Globally, this trend is illustrated with a "typical" three-drug cocktail of zidovudine, lamivudine and nevirapine. Before an Indian generic pharmaceutical company announced its price reductions, this combination of medicines cost up to US\$10,000 per patient per year. Shortly after the announced price reduction, multinational pharmaceutical companies lowered their prices. When other generic companies announced even lower prices, the multinational companies responded by lowering their prices even more. As in all market situations, the introduction of competition drives prices down in a sustainable manner that is free from extraneous conditions.

Pricing studies: The WHO has begun several projects related to drug pricing. This work should be supported and broadened. Price lists should be updated on a regular basis.

Prequalification process: NGOs congratulate the WHO on its work with the prequalification of drugs for HIV/AIDS. This work needs to be supported and expanded to include medicines for diseases such as malaria and tuberculosis. Member states need to recognise the significance of the prequalification process and take advantage of the results of the work undertaken

by WHO. National drug regulatory programmes should recognise the prequalification of medicines under WHO's programme.

Post Doha: TRIPS & public health

The only way to pave the way for generic competition is for countries to fully utilise the provisions in TRIPS that allow them to put citizens before corporate patent privileges. In November last year, 142 countries affirmed the priority of public health over private intellectual property at the 4th WTO Ministerial Conference in Doha, Qatar.

Key excerpts from the Doha Declarationⁱⁱⁱ

- "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."
- "...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."
- "We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

NGOs commend the Executive Board on its recommendation that WHO needs to take a proactive role in the implementation of the Doha Declaration.

TRIPS: the question of exports of medicines.

Paragraph 6 of the Doha Declaration on TRIPS promised that the WTO would find a solution to the problems countries face when trying to obtain low cost generic medicines, and domestic production is not efficient. There are technical problems with the exact language in paragraph 6 of the Doha Declaration, which reflect some of the confusion regarding the nature of problem. But now there is a better understanding of these issues, and a growing consensus among public health experts over the appropriate solution. Developing countries and NGOs have asked the WTO to clearly recognise the right of countries to authorise the export of health care products, without the consent of the patent owner, so long as the legitimate rights of the patent owners (if any) are protected in the country where the products are ultimately used by patients. To clarify, NGOs accept the notion that patent

owners will be compensated in the country of consumption, under WTO TRIPS rules, but want assurances that patients can obtain the most efficient global suppliers. This debate is about how the WTO will interpret Article 30 of the TRIPS, the provision now used to allow countries to waive patent rights for experimental purposes, personal use, compassionate use, or for pre-approval testing (the Bolar exception). NGOs and developing countries are asking that Article 30 be used for exports of medicines and other health care products, for example, if the importing country can certify that such use is needed for domestic public health purposes. The WHO has been on the sidelines on this important debate, and should support further the notion that Article 30 of the TRIPS be used to allow such exports, for example, by providing the WTO with a well reasoned rationale for allowing Article 30 to be used for exports.

Differential pricing

Differential pricing has been going on for years. Many studies have shown that, in some cases, people in developing countries pay *more* for medicines than people in more developed countries. In the United States, Pfizer's fluconazole costs US\$12.20 per tablet but in Guatemala, it costs up to US\$27.60 per tablet.^{iv} Two years ago, the multinational pharmaceutical companies resisted differentiating their markets in favour of poorer countries. Now, because of recent actions by some countries to challenge patents, pharmaceutical companies are looking at differential pricing as the solution to the pricing problem. However, this is not necessarily the best solution. Differential pricing programmes often come with conditions attached.

Reported industry-imposed conditions on differential pricing agreements

- extra processing fees
- limited geographic distribution
- limited provider distribution
- disclosure of consumer information to companies
- unacceptable delivery terms and/or product dating

For differential pricing to work, citizens and governments need to be able to buy the needed medicines without unfair conditions.

Differential pricing can be part of the solution only if people, governments or donors are in a position to bargain competently and under fair conditions with companies over price.

Companies should not be allowed to set conditions or limit the time frame for the price reductions on essential medicines. No company should be able to insist that people, governments or donors forego normal rights, such as medical record confidentiality or the ability to legislate and regulate for public health in order to achieve reduced prices. Furthermore, differential pricing needs to be part of a systematic solution and not based on ad hoc responses from industry.

WHO at country level

WHO must engage more extensively at country level to assist governments in adopting pro-health strategies related to access to medicines, including assisting with intellectual property law revisions and negotiations with pharmaceutical companies. This would complement WHO's strategy to increase staffing and expertise at country level. WHO must also continue to work closely with civil society and the NGOs welcome the stated commitment to do so in Resolution EB109.R17.

Model essential medicines list

The 12th model list on essential medicines (EML, previously known as EDL) is an 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. As competing research-based pharmaceutical companies are unlikely to make FDCs, this is a unique opportunity for generic drug companies to assist in the war against AIDS.

The new process for adding or deleting medicines to/from the list is more transparent, uses evidence-based systematic reviews, and is faster. WHO should continue this important work, in spite of the efforts of some member states to dilute the process. It is encouraging that cost will no longer be a barrier to inclusion on the list. However, the expansion of the EML must be linked with measures to ensure that

medicines are affordable to those who need them.

The value of the EML lies in its political signal and how effectively it can be adapted and implemented at country level. WHO should strengthen its country support and advise local experts how to implement the essential medicines concept. At every level, the use of the EML must be linked to efforts to make essential medicines more affordable and available.

Public-private initiatives (PPIs)

NGOs are concerned about the lack of progress on WHO's commitments related to the revision of guidelines meant to steer its interactions with the commercial sector. The document EB 107/20 indicates that Executive Board members at a retreat last November put forward a number of suggestions to focus WHO work in this area. The revised guidelines that EB members clearly called for are still not available.

PPIs have direct consequences for access. Consumers, governments and donors are being asked to negotiate with pharmaceutical companies on conditions of differential pricing schemes and donations. Furthermore, it is not clear whether or not the desired public health outcomes of large-scale initiatives to improve access, including GAVI, the Global Fund and others, are at risk because of unaccountable private-sector involvement. It is unclear on what basis WHO decides that a given PPI is the best way to increase access to medicines.

WHO must take measures to identify the risks and benefits of PPIs and should analyse, in a transparent manner, the health and social outcomes and sustainability of these initiatives. WHO is and must remain the centre of technical expertise and the global agency for the protection and promotion of public health. WHO must ensure that no relationship with industry compromises its technical responsibilities or its credibility.

References

- i Brundtland, G.H. Conference on Increasing Access to Essential Drugs in a Globalised Economy, 1999
- ii Pérez-Casas, C. et al. 2000. HIV/AIDS medicines pricing report. Setting objectives: is there a practical solution. Geneva: MSF Access to Medicines Campaign
- iii Declaration on the TRIPS Agreement and Public Health. Doha WTO Ministerial Conference, 2001.
- iv The Lancet, 356:9427: 16 December 2000

Recommendations for Action For WHO:

Equitable prices

- WHO should provide technical assistance to member states to enact sustainable and systematic policies that encourage equitable prices, including generic competition, the utilisation of TRIPS safeguards and differential pricing *without* conditions.

Quality

- WHO must continue and speed up its work in prequalifying manufacturers of pharmaceuticals and raw materials for HIV/AIDS drugs. The list must be extended to include drugs for other major killer diseases such as malaria, tuberculosis and other infectious diseases.

Databases

- WHO must continue to develop databases on essential drug prices linking these with information from the prequalification process and the World Intellectual Property Organization (WIPO) for patent status information.
- WHO should continue to actively disseminate pricing information in a timely manner.

TRIPS & Public Health

- WHO should continue to play an active role as an official observer at the WTO and continue its interactions with WIPO
- WHO should continue to assist member states to develop and formulate pro-health laws and regulations, including providing models for compulsory licensing, parallel importing, generic manufacture and other TRIPS-compliant measures that will help overcome current barriers to accessing essential medicines.
- WHO should continue its work with the Network for Monitoring the Impact of Globalisation and TRIPS on Access to Medicines.

Essential medicines list process

- WHO should provide assistance to member states in creating and implementing treatment guidelines and formularies using the new EML.

Public-private initiatives (PPIs)

- WHO should publicly issue its revised guidelines and related tools on PPIs (as called for by the EB more than one year ago) to member states and for public comment. WHO should create an independent expert group to conduct a comprehensive analysis of the benefits and risks of PPIs, identify positive and negative PPI characteristics and evaluate their impact on public health systems and WHO's independence and integrity. The group should then make recommendations to WHO based on their findings. The expert group should have equitable representation from the global South and public interest groups and the process should be made completely transparent.

Collaboration with civil society

- WHO should continue its commitment to work closely with NGOs.

Recommendations for Action For Member States:

Equitable prices

- Member states should adopt regulations that require companies to identify components of price in a transparent manner when responding to tenders or otherwise negotiating prices with governments. Member states should be cautious about accepting deals that include unreasonable conditions as part of what should be a normal buyer-seller relationship. Emphasis should be placed on the development of systematic solutions to ensure equitable prices.

Quality

- Member states should eliminate barriers to access to medicines and raw materials, including overly rigid and/or expensive regulatory requirements, import tariffs on medicines and unnecessary margins on prices. Member states are urged to recognise WHO's prequalification results as an acceptable standard of quality.

TRIPS & Public Health

- Member states should take full advantage of the 4th WTO Ministerial Conference "Declaration on TRIPS and Public Health", adopted in Doha in November 2001, to implement the safeguards provided in the TRIPS agreement –i.e. compulsory licensing, parallel imports, early working (Bolar) provisions, etc. These should be made operational within their national legislation and implemented in a manner to minimise barriers to their use.

Essential medicines list

- Member states should adapt their national EML to reflect changes in WHO's new list. Measures must be taken at country level to ensure that medicines on the list are used according to rational drug use policies. Furthermore, essential medicines at country level must be made affordable and accessible to all citizens.

Public-private initiatives

- Member states should take a leading role in overseeing PPIs, especially concerning essential medicines, to ensure that the relationship and negotiations protect citizens, are without undue conditions imposed by industry and lead to systematic solutions to increase access to medicines.

Collaboration with civil society

- Governments should implement national drug policies based on the essential drugs concept that are formulated and implemented with the substantive involvement of citizens and NGOs.

Essential Medicines: WHO Definition

Essential drugs are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford.
