



Access to Essential Medicines, the Need for Fair Prices, and Better Research

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The World Federation of Public Health Associations (WFPHA) at its Annual Meeting of 19 April 2004 in Brighton pledges that essential medicines are an important part of any health care system. In many regions of the world large parts of the population are nevertheless lacking access to essential medicines. This became painfully clear with the emergence of the HIV/AIDS epidemic. Less than 2% of those in need in Africa got antiretroviral treatment in 2003.¹ High prices of medicines to treat HIV and opportunistic infections are a major barrier to the access to treatment. The globalisation of a patent system tailored to the needs of industrialised countries through the World Trade Organization (WTO) secures high prices globally. Safeguards in the WTO TRIPS-Agreement to protect public health like compulsory licensing have not solved the price crisis.

We recall the resolution on “Public health and Globalisation” (voted at the WFPHA Annual Meeting in 2001) which calls to “draw attention to international [...] disparities in health which are a consequence of global economic change.” The effects of the TRIPS agreement clearly contribute to enlarge disparities.

AIDS is not the only problem. Many people do not even have access to the most basic medicines. Furthermore there is little research on diseases like malaria, tuberculosis or sleeping sickness, which mainly hit poor populations.

It has often been argued that high prices are needed to finance research in to new important medicines. But the effectiveness of the existing system to reward research must be questioned. Too many new medicines offer no additional therapeutic benefit and even worse large parts of the world population lacks access to existing treatments and can only dream of getting new cures.

Health is a human right and the access to medicines is part of it. The World Federation of Public Health Associations therefore supports all measures that improve the access to essential medicines. It demands that the WTO TRIPS-Agreement is adjusted to cater for the needs of the poor. The WFPHA wants to foster the discussion about better systems to promote research for neglected diseases.

The scale of the problem

One third of the world population has still no regular access to lifesaving essential drugs².



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The situation with antiretroviral medicines is even worse: only 7% of the patients in developing countries are treated with antiretrovirals¹. “While in many developed countries over 70% of pharmaceuticals are publicly funded through reimbursement plans and other mechanisms, in developing and transitional economies 50–90% of drugs are paid for by the patients themselves. Medicines are the major out-of-pocket health expense for poor households in most developing countries.”³.

High prices for patented medicines and drugs which are produced by only few companies and an in-transparent market place medicines out of reach for two billion people in the world⁴. Prices are a major but not the only obstacle in providing medicines. Lack of trained staff, poor management, influences of promotion, little health education and subsequently irrational drug use add to the crisis of health systems. Solutions for these problems are well addressed in the WHO concept for a national drug policy⁵.

Even with reduced prices many countries will still need donor support for their health systems. More support for health and medicines will pay off not only in saving millions of lives but can also lead to wealthier societies with a much lower burden of disease and will help many countries to become self-sustainable in health⁶.

Medicines, prevention and public health

We want to emphasise that prevention of diseases is a key element of every health system. Nevertheless treatment remains a major task especially in societies with a high burden of infectious diseases. The World Health Organization’s concept of Primary Health Care therefore integrates prevention and treatment⁷.

Prevention and treatment often reinforce each other. The treatment of e.g. a tuberculosis patient will prevent numerous new infections. The option to be treated in case of severe illness is important for the credibility of health services and improves their possibilities to promote preventive and public health messages^{8,9}.

In the case of AIDS scientists¹⁰ and WHO advocate strongly for the combined effects of treatment and prevention: “Prevention will remain central to all HIV interventions. Universal access to antiretroviral therapy for everyone who requires it according to medical criteria opens up ways to accelerate prevention in communities in which more people will know their HIV status – and, critically, will want to know their status. As HIV/AIDS becomes a disease that can be both prevented and treated, attitudes will change, and denial, stigma and discrimination will rapidly be reduced. Rolling out effective HIV/AIDS treatment is the single activity that can most effectively energize and accelerate the uptake and impact of prevention.



Under 3 by 5, this will occur as part of a comprehensive strategy linking treatment, prevention, care and full social support for people affected by HIV/AIDS. Such support is critical – both to ensure adherence to antiretroviral therapy and to reinforce prevention.”¹¹.

The “availability of drugs and supplies also affects the productivity of health staff. When drug supplies fail to arrive, patient volume drops, and health workers are left idle. In many settings irregular drug supply is a greater constraint on program effectiveness than inadequate numbers or training of health workers.”⁹.

Human rights and access to medicines

The UN Commission on Human Rights emphasised in a resolution in 2001 that “access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”¹².

Patents and access

Though most essential medicines are no longer patented and available from multiple sources² there is a considerable number of important medicines that are still under patent and with prohibitive prices. “Access to drugs in poor countries requires prices at or close to production costs.”⁴. It is neither realistic nor ethically acceptable to expect poor countries to pay high prices for patented medicines.

Many developing countries did not accept patents on medicines or did only protect production processes.¹³ The TRIPS-Agreement forces all WTO-members to introduce 20 years of patent protection for pharmaceutical substances by 2005.¹⁴ This period is extended till 2015 for least developed countries.¹⁵

The use of safeguards in the TRIPS-Agreement as compulsory licensing and parallel imports have been cause for major disputes between large pharmaceutical companies - often supported by governments from industrialised countries – and developing countries.

This has not only caused unnecessary delay in the provision of important patented medicines but also discouraged other states to make use of TRIPS rules which could help to protect public health. While with the WTO Doha Declaration on Public Health¹⁵ in 2001 the situation for countries with own manufacturing capacities has improved, the WTO compromise on importing drugs under compulsory licenses achieved 30 August 2003 will help only little to alleviate the situation for poorer countries. It poses many unnecessary hurdles, requires



a second compulsory license by the exporting state and may prevent a commercially viable production of drugs.

Innovation

High prices for medicines are usually justified by the costs of drug development. Patents are a public incentive to promote innovation by giving the inventor a time-limited monopoly. Such a patent regime for substances has been introduced in most industrialised countries in the 1960ies and 1970ies.¹⁶

There are different concepts of innovation. While industry sees an innovation as a product which is patentable, and therefore commercially promising, from a public health point of view innovation means therapeutic advance¹⁷. Both concepts often do not match. The FDA classified only 23% of new drugs introduced in the US between 1990-2002 as a significant therapeutic improvement¹⁸.

There is an even larger gap when looking at research for diseases which mainly prevalent in poor populations. An analysis of the 1393 new drugs introduced 1975-1999 showed that less than 1%¹³ were against tropical diseases and only three against tuberculosis¹⁹. The Global Forum For Health Research²⁰ pointed out in 1998 that less than 10% of research is directed toward 90% of disease burden in the world.

There is not only a gap in the research priorities between rich and poor. There is also gap in knowledge about many medicines used in rich countries. The comparison of new drugs against established drugs and/ or non-medical interventions is often lacking. This makes it difficult to judge about the real value of new drugs. In this context the independence and transparency of research must be emphasised. Results of research must always be publicly available and researchers are bound to declare possible conflicts of interests.

The actual cost of pharmaceutical research is also a matter of dispute. This is an important area for debate because patents and high prices are justified that way. There is little independent evidence on the cost of research. The figure of 800 million US\$ per new drug quoted by industry is exaggerated.²¹ It is based on research of the Tufts Center for the Study of Drug Development (CSDD)²² which gets two third of its funds from the pharmaceutical industry.²³ The original study calculates the cash outlay as 403 million US\$ per drug. The rest of the sum are “opportunity costs” – money the companies actually did not spend. Furthermore tax benefits were not deducted which bring the actual sum down to around 250 million US\$. The sample used is not representative because only new molecular entities were included which were completely developed by industry. The US Office of Health



Technology Assessment judged about an earlier study by the same center²⁴ that bias cannot be discounted as the companies which gave the data knew about the purpose of the study²⁵.

The role of publicly funded research is often underestimated. The US National Institutes of Health (NIH) had a budget of over 20 billion US\$ in 2001. Public research is very successful. A study by the NIH showed that publicly funded research was key in the development of the five most sold drugs on the world market in 1995.²⁶ The same holds true for most AIDS drugs²⁷.

In times with limited budgets so called “Public Private Partnerships” between UN-organisations or governments and the private sector are becoming widespread. They often lack clear assignments and transparent and accountable structures.²⁸ It is important that the public mission of the UN does not get diverted and under undue influence of private interests.

Commitments and demands

The WFPHA urges all interested parties to do the utmost to improve access to essential medicines for all people in need irrespective where they live. Prices especially of patented medicines are often excessive and put them out of reach for many people. The TRIPS agreement makes access to newer treatments even more difficult. We demand from all WTO member states that they use the review of the agreement to find solutions that secure uncomplicated and quick access to cheap generic essential medicines. We emphasise that sustainable solutions are needed which do not depend on charity. WHO needs to take an active role to defend public health in the WTO.

We ask the industrialised countries to give substantial additional funding to improve health systems in developing countries. Funds should preferably be channeled through multilateral funding using in full the capacities of the competent organisations of the UN system, namely the WHO, UNAIDS and UNICEF.

The WFPHA supports WHO’s “3 by 5 initiative as an integrated approach to improve health care in developing countries. A great deal of operational research is needed along the implementation of “3 by 5” and WFPHA members are prepared to contribute to this challenge.

We ask all involved in the improvement of health systems in developing countries to stick to a holistic approach and to acknowledge the interrelatedness of prevention and treatment. We support the attempt by the WHO and others to create price transparency and urge the WHO to develop a comprehensive database on medicine prices to be regularly updated. We propose to expand the quality control system of WHO (pre-qualified generics) and to continue to help member states with the procurement, quality control, distribution, use and education in rational



drug use.

We are committed to foster a discussion about the direction of future drug and health research. This cannot be limited to improving research on neglected diseases but must critically evaluate the strengths and weaknesses of the existing systems to promote research. Part of this exercise should be an independent investigation in research spending and the cost of research.

Research in health and medicines is a public responsibility. If UN-Organisations enter in relationships with the private sector the roles of the involved parties must be clear. Purpose and expected outcome must be defined and the public accountability secured. Finally we recommend WFPHA member organisations take an active part in national and international debates about improving access to medicines and in fostering research that can help to improve the health of poor people.

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