

General Policy Issues

WHO roundtable with the research-based pharmaceutical industry

On 21 October 1998, Dr Gro Harlem Brundtland, the newly elected Director-General of WHO, met with key figures of the research-based pharmaceutical industry to explore ways in which access to affordable, innovative and essential drugs can be improved. The roundtable was attended by the chief executive officers of major pharmaceutical companies which included American Home Products, Glaxo Wellcome, Novartis, Pasteur-Mérieux-Connaught and SmithKline Beecham, together with representatives of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The meeting offered an opportunity for both sides to address issues of public health concern and to determine common ground. WHO's goal is to build a constructive dialogue with the private sector, and harness support to improve access to drugs and vaccines for populations in need.

Global partnerships for health

Gro Harlem Brundtland
Director-General
World Health Organization

A roundtable, as we intend to apply the word in WHO, is not a single event but a method of work. It derives from our commitment to meet with broad constituencies involved in public health at the global level and address key issues relevant to the fulfilment of our mandate in combating ill-health and building healthy populations.

I have invited representatives of the research-based pharmaceutical industry to a roundtable because I believe that we have a common aim in health. I am convinced that we can collaborate effectively if we deal with our differences and address them directly and openly as we did in the meeting on the Revised Drug Strategy held earlier in October*. Then, after an initial breakdown in communication, Member States reached a consensus on important issues which are also of concern to the pharmaceutical industry. How did this come about? Because of broader access to information, more time to listen, and a greater commitment to build bridges.

* Meeting of the ad hoc Working Group on the Revised Drug Strategy convened by WHO from 13 to 16 October 1998. *WHO Drug Information*, 12(4): 209 (1998).

Let me underline where WHO stands: we are committed to national drug policies and the concept of essential drugs and vaccines. The Action Programme on Essential Drugs has been our main instrument in helping governments implement these concepts. When the action programme was established in 1975, very few countries had adopted national drug policies. The developing countries were faced with serious problems of availability, cost, quality, and rational use of drugs. Today, nearly 90 countries have national drug policies in place or in preparation. The WHO Model List of Essential Drugs has been widely adapted by national authorities and three out of every four countries in the world now have an essential drugs list.

WHO plays a key supporting role by helping countries to assess their needs, identify problems and find solutions. WHO sets norms, standards and regulations for implementation by regulatory authorities, while quality assurance of pharmaceuticals is an overriding concern. Nowhere is the responsibility or challenge greater. Of course, operational research is a core function and so is safety monitoring. The two are closely linked. WHO works with partners around the world to monitor the use of drugs — not only to sound the alarm when faced with emergencies and outbreaks but to share the good news when progress has been made against a major disease.

WHO's global vaccination programme has achieved an immunization rate of 80% for all children in the

world. This is a success both from an industry and a public health perspective. However, we need to move on with new vaccine research and development and WHO is actively engaged with the World Bank, UNICEF, leading foundations and industry to pave the way to new breakthroughs in vaccine development and delivery. This kind of joint project has also been established in other areas. For example, the Medicines for Malaria Venture has recently been set up and will be incorporated into the Roll Back Malaria initiative. I hope that WHO and the pharmaceutical industry can work together to strengthen this particular component.

Still much remains to be done. One-third of the world's population lacks access to essential drugs. Those concerned with public health or equity will agree that this is truly unacceptable. Despite the large sums spent on research and development, less than 1% is directed to providing treatment for those diseases that strike developing countries. Frankly, this does not make sense. The price of drugs — especially for the newer products — puts them out of reach in the majority of developing countries. We must work together to ensure development of new drugs for major public health threats. The challenge is there. But we must also create an infrastructure to ensure that drugs for killer diseases like tuberculosis and malaria are provided to those in need.

Emerging diseases, growing drug resistance, global economic instability and uncertainty about the public health impact of new trade agreements are all relevant key issues. WHO will be present in all of these arenas. Health is an integral part of our way of life, how our world evolves, how human resources are nurtured, how trade expands and economies grow, and how environments perish or survive. The pharmaceutical industry has the responsibility for developing, producing and selling pharmaceutical products — drugs and vaccines. WHO has the responsibility for helping countries acquire access to essential drugs. The pharmaceutical industry is in the business of making a profit. But we are in the business of seeing to it that the most vulnerable — who have little or no purchasing power — are allowed equitable access to medicines.

WHO sees great potential in this roundtable as a first step in a serious attempt to build a sustainable mechanism and provide affordable, essential drugs of quality to the needy. We look forward to forging a strong, durable and committed partnership with those having a common purpose in health.

Public health and the pharmaceutical industry

Richard B. Sykes, President, International Federation of Pharmaceutical Manufacturers Associations and Chairman, Glaxo Wellcome, United Kingdom

The research-based pharmaceutical industry and the World Health Organization share a common goal of fighting disease and improving health. With this essential unity of purpose, it seems clear that we should be working closely together wherever it is feasible to do so. I am confident that the discussions which have taken place during this WHO roundtable will be a first step towards a closer partnership based on dialogue and mutual understanding.

We all agree that medicines have made a tremendous contribution to the improvement of health care during the 20th century, and particularly during the 50 years that WHO has existed. Of course, much effort still needs to be concentrated on ensuring that the benefits of modern medicine are made available to all in need. The pharmaceutical industry will play its part in helping to achieve this goal. However, our primary focus is and will continue to be the scientific and technological research needed to produce new medicines to respond to health problems that have so far eluded treatment.

As we go forward into the 21st century, we have every reason to be confident that the medical progress witnessed so far will continue and accelerate. Prospecting for new medicines has entered an era of unprecedented opportunity and offers new insights into areas unimagined until now. Within the industry, much is being done to ensure that we harness this new science and technology and deliver medicines of real value.

The contribution of genetics

Genetics is a vital newcomer to the drug discovery process and helps explain many things that we have observed in practice. The study of genetics offers an entirely new approach by identifying factors that influence an individual's susceptibility to a certain disease. This new knowledge derives from the international human genome project devoted to sequencing the three billion DNA bases in humans.

This tremendous effort will bring about significant improvements in the provision and practice of health care. Intransigent health problems such as

asthma and heart disease, which are increasing at an alarming rate throughout the world, will be understood. Genetic testing will enable individual patients to be targeted for specific treatment to maximize efficacy and minimize side-effects. In other words, drugs can be tailored to people for maximum response.

Effective prevention

In the future, the use of genetics will allow us to screen for susceptibility and we will be able to identify which individuals will develop diseases long before the symptoms appear. This genetic information can then be combined with known conventional risk factors. Although in many cases these benefits can only be provided within a sophisticated medical infrastructure, this new understanding of genetics will prove of great potential value in the fight against diseases of the developing world.

For example, the complete *Mycobacterium tuberculosis* genome sequence has now been published, and the sequence of every potential drug target and antigen is now available. Sequencing of the *Plasmodium falciparum* genome will be of great significance in paving the way for the development of a DNA vaccine against malaria. What, then, needs to be done to ensure that the tremendous potential for the development of new and better medicines is actually realized and that people throughout the world will benefit from them?

The realities of research and development

From an industry perspective, effective protection of intellectual property is essential if billions of dollars are to be invested each year in the research and development of new medicines. Currently used techniques are vastly more efficient and productive than ever before, but the technology that underpins these is very expensive. By contrast, copying and manufacturing medicines are very cheap. Unless companies are assured of intellectual property protection during the limited period conferred by patents, they simply will not be able to find the funds to pay for future research and development. The industry is pleased that progress was made in this regard during the meeting of the ad hoc Working Group on the Revised Drug Strategy convened by WHO from 13 to 16 October 1998*.

There is growing recognition that special measures are needed to encourage research and development for diseases such as malaria and tuberculosis. The involvement of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) in the new WHO Medicines for Malaria Venture demonstrates industry's willingness to find new ways forward. Similarly, legislation has successfully been introduced in the United States to provide incentives to companies developing orphan drugs and the European Union is now setting up a similar system. Regulatory authorities and WHO may wish to explore such an approach for tropical diseases since this would harness the industry's skills and resources for new drug development in an important area.

With regard to the problem of ensuring access to patented medicines, we need to look at ways to encourage companies to offer prices which reflect the economic reality of individual countries. This could be done by offering prices which are lower in developing countries than in more affluent parts of the world. However, if customers in the better-off countries were to import the lower priced medicines, industry would be unable to bear the burden. Parallel trading has understandable attractions for health care providers faced with tight budgets, but its long-term consequences can only be damaging.

Adequate funding is a key precondition for successful public health management and for the continuing supply of new medicines. Equally, there has to be a clear recognition from health care providers that the price paid for medicines will ultimately affect the funds available for further research and development. The pharmaceutical industry cannot be expected to take sole responsibility for ensuring that the least well-off have access to their medicines. This is a vital role for multilateral agencies who must work in close partnership with us. The UNAIDS HIV Drug Access Initiative and the new Medicines for Malaria Venture offer examples of potential opportunities for this kind of partnership.

These are exciting times for the research-based pharmaceutical industry. It is our desire to share our achievements through true partnerships — particularly with WHO — and to ensure that the benefits of modern science and technology are truly available to all peoples of the world.

* See *WHO Drug Information*, 12(4): 209 (1998).