WHO Interview

Making medicines and health technologies safe and accessible

WHO

Vladimir Lepakhin

Dr Vladimir Lepakhin gained his MD at the First Moscow Medical Institute in 1964 and his PhD in 1968. He headed the Department of General and Clinical Pharmacology of the People's Friendship University in Moscow from 1985 to 1998 and for 15 years was Director of the USSR and Russian Drug Authority. He served from 1989 to 1992 as deputy health minister in the former Soviet Union and later, the Russian Federation. He joined WHO in 1998.

Scientific advances have resulted in a vast array of drugs and health technologies to prevent or treat diseases. One of WHO's roles is to advise and support countries in the provision of these drugs and technologies. When Dr Vladimir Lepakhin became Assistant Director-General for the Health Technology and Pharmaceuticals cluster of departments in 2003, the debate centred on access and affordability. But as the number of new health products grows, WHO is focusing more than ever on their quality and safety.

Q: What is the role of your cluster of departments?

A: Our main task is to help countries achieve a supply of medicines and health technologies that are affordable, high quality, safe and efficacious. At the same time we assist countries to ensure that these medicines and technologies are used appropriately. Until recently, we spoke mainly about access and affordability. Now we have started to pay more attention to quality and safety. Medicines are a doubled-edged sword, they can save lives but they can also kill. According to scientific publications, in the United States alone 100 000–200 000 people die every year due to drug-related complications.

Q: Why do so many people suffer or die from taking medicines?

A: There are several reasons. There are many substandard and counterfeit medicines on the market. Another problem is that many new drugs are highly potent. The more biological activity, the greater the chances of more effective treatment but also of more serious adverse reactions. At the same time, pre-marketing evaluation of drugs is not enough to discover all possible adverse drug reactions. This is why more and more products are withdrawn. Everyone talks about Vioxx, but this is not the only example. Some drugs are withdrawn after 1–5 years on the market, sometimes after 10–20 years.

Q: How do you decide which company's products get on the essential medicines list?

A: Products are not decided by company but evaluated on the basis of efficacy, safety, quality and affordability. This list provides suggestions. It's up to countries to decide what to include on their lists. Some developing countries with little regulatory capacity adopt the whole list, others adapt it to their health priorities.

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Q: Why did WHO establish a prequalification list of products?

A: We realized that many products on the pharmaceuticals market are substandard. We compile this list for UN agencies to purchase drugs mainly for HIV/AIDS, tuberculosis and malaria treatments that meet unified standards of quality, safety and efficacy. When we started in 2001 we were criticized. Critics said it was not in the WHO constitution or required by a World Health Assembly resolution and that WHO was not a drug agency. But experience has proved we were right. Only 1 in 5 products submitted to us pass our pre-qualification scrutiny and are included on the list. We evaluate products, manufacturing sites and clinical studies. An important part of this work is training people from drug regulatory authorities in developing countries to do this evaluation themselves.

Q: Why is WHO concerned about "irrational" use of drugs?

A: About half of all drug-related problems are due to irrational use. This can start at any stage from prescription by the doctor or advice from a pharmacist to use by patients. Self-medication is very common, practically all families use drugs by themselves. We have a programme to monitor drug-related complications. More than 80 countries have joined it and their national centres have helped us compile a database of more than three million reports of adverse reactions.

Q: Flexibilities introduced into the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement have made medicines potentially more accessible, but are countries making full use of these?

A: So far very few countries — only Indonesia, Malaysia, Mozambique and Zambia — are using these flexibilities. The idea was good, but its effectiveness will be tested in practice. Many countries do not understand these flexibilities and that's why we have a special project to advise and show them how to use these. It's just the beginning.

Q: Are patents a barrier to improving access to essential medicines?

A: Patents are needed because it is complicated and costly to develop new medicines. We need innovative products because there is no effective treatment

for some diseases and more and more cases of drug resistance. Patent and price are not the only barriers in improving access. Lack of public health insurance forces people to pay for medicines themselves. Supply and delivery problems also lead to drug shortages.

Q: What challenges do we face with health technologies?

A: Health technologies cover a diverse area: blood transfusion and safety, medical equipment, diagnostics, surgery, anaesthesia, organ transplantation and so on. WHO has much experience in blood safety, but started working on transplantation recently. Here we advise governments on the technical aspects as well as the ethical concerns relating to organ donation, transplantation and trafficking.

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Q: What is WHO doing to stop the sale of counterfeit medicines?

A: The quality of products on the market in each country is the responsibility of national drug regulatory bodies. We assist and support countries to strengthen their pharmaceutical legislation, drug standards and requirements, national drug regulatory performance at all stages: from production, distribution and sales to their use. Quality assurance should be built into the entire process. We have prepared guidelines for countries on distribution and laboratory services. We give workshops in Africa and Asia and have produced 20 training modules on CD-Rom in English, Chinese, Japanese and Spanish.

Q: Are generic medicines less safe or efficient than patented medicines?

A: Many generic medicines meet all requirements, which means they're equivalent to the patented originals, but others do not. The generics industry is highly developed in both industrialized and in some developing countries.

Q: What are the common misconceptions about your work at WHO?

A: Some people think WHO is a supranational organization that creates and imposes norms and standards. WHO is an international organization, not a regulatory authority. Our role is to combine knowledge, skills and expertise to create international norms and standards and to assist countries in their implementation by providing information, training and capacity building.

Q: What is WHO's view of traditional and alternative medicines?

A: Traditional medicines have been used in all countries, some for centuries. Self-medication with herbal medicines is popular both in developed and developing countries. In some countries, traditional medicine comprises up to 80% of primary health care. Sometimes traditional medicines are the only ones people can afford. Unlike modern medicines, these were often not studied in accordance with today's scientific requirements. But without good study and information this can be dangerous, for example, when they interact with other medicines that people may be taking. That's why it is WHO's responsibility to evaluate these products and limit any damage by providing reliable information and expertise.

Q: WHO has been accused of giving conflicting drug recommendations?

A: Indeed, some time ago, there were different medicines on our list of essential drugs to those included in treatment guidelines of other departments. We have done a lot to harmonize these through collaboration. Now we are speaking more and more with one voice. ■

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