TRIPS Workshop for the WHO African Region
21–23 AUGUST 2001 (HARARE)

A workshop on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the implementation of TRIPS safeguards in relation to pharmaceuticals was organized by the WHO Regional Office for Africa in Harare, Zimbabwe, from 21 to 23 August 2001, in collaboration with the Department of Essential Drugs and Medicines Policy. It was intended to be the first in a series of meetings aimed at providing practical information to Member States on TRIPS and implementation of TRIPS safeguards. This activity comes under WHO’s mandate—following World Health Assembly and Regional Committee resolutions—to assist countries on TRIPS issues in order to improve access to drugs.

The meeting contributed to the development of strategies for implementing TRIPS safeguards in relation to health in general and to pharmaceuticals in particular. Specifically, the meeting:
- Reviewed TRIPS safeguards within the context of pharmaceutical legislation;
- Proposed principles of model legislation and guidance on implementing TRIPS safeguards; and
- Proposed a framework for implementing TRIPS safeguards at national level and the type of support required.

The 52 participants were from 15 countries of the WHO African Region and included senior officials from pharmaceutical services, and from legal, trade, patent and finance offices. Experts on WTO/TRIPS issues were also present, together with representatives from Médecins Sans Frontières, the African Regional Industrial Property Organization and the Consumer Project on Technology. WTO was invited but was unable to attend.

Dr Ebrahim M. Samba, Director of the WHO Regional Office for Africa, officially opened the meeting urging “African countries to develop appropriate legislation that will enable them to draw maximum benefits from provisions in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement which allow, among other things, for the parallel importation of medicines and compulsory licensing”. He stated that implementing these safeguards was necessary because the Region carried the heaviest burden of infectious diseases such as HIV/AIDS, malaria and tuberculosis. From the discussions it was clear that the need for institutional capacity building on TRIPS issues at country level is very urgent. Intensified technical support to countries, as well as provision of reliable information, are also crucial.

Countries were urged to:
- ensure inter-agency cooperation on TRIPS and public health decision-making;
- identify TRIPS and public health focal points for information dissemination;
- establish country capacity building programmes on TRIPS safeguards;
- enhance regional collaboration on TRIPS and public health issues;

The purpose of Essential drugs in brief is to share information on the latest country support provided or coordinated by the extended Drug Action Programme team (country, regional and HQ offices).

It is an informal instrument aiming to share our experiences with colleagues within and outside WHO, who are active in the implementation of national drug policies at national and regional levels.
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- incorporate TRIPS safeguards into national legislation;
- monitor the impact of international trade agreements on access to medicines.

WHO was requested to continue supporting countries to achieve these objectives through technical support both at the country and regional levels.

AFRICAN REGION

Developments in the South African Drug Action Programme

The South African Drug Action Programme (SADAP) is being actively implemented with the support of WHO. The Pharmaceutical Cluster of South Africa’s Department of Health is putting great emphasis on issues such as selection, distribution, procurement, financing, GMP inspection, management information systems and training of pharmacists’ assistants.

Norms and standards for management of pharmaceutical expenditure, procurement and distribution—now devolved from the provinces to local level—are being developed as benchmarks by stakeholders from all levels in the health system. The need for these norms and standards was identified as a priority in maintaining and improving the drug supply system during the transfer of responsibilities. They will set out key principles and objectives—by defining an outline of the services that need to be delivered—so as to maximize consistency, while allowing for local variation. A workshop with about 50 participants took place in August to address these issues. A comprehensive computerized pharmaceutical management information system is being developed in parallel with this process. The norms and standards and the information system will allow for variation, but will nevertheless ensure that management decisions on drug supply will be based on reliable data.

SADAP is also supporting drug regulation through strengthening of the GMP inspectorate and by reviewing comments on the pharmaceutical legislation that is now being finalized, following the court case concluded earlier this year. This legislation encompasses a number of issues designed to promote the Government’s policy of improving access to medicines. It allows for and regulates: generic substitution; parallel importation; international tendering; and price regulatory measures.

REGION OF THE AMERICAS

Vaccine registration and drug donation in emergency situations in Central American and Andean group countries

The National Drug Regulatory Authorities (DRAs) of Central America (seven countries) and the Andean Group (six countries) of the American Region, met in February and August 2001 respectively, and issues discussed included vaccine registration and drug donation in emergency situations. Even though drug registration is a requirement for importing drugs, it is often waived for vaccine imports. This requirement was discussed and provisions made to facilitate vaccine registration through review of national legislation, as part of the drug regulatory harmonization process. The group also identified the need for training for site inspection as part of the quality assurance programme of the DRAs.

Both groups of DRAs also analysed their role in drug donations in emergency situations. In each of the countries, the Minister of Health has led the coordination effort of international and national aid agencies. Many NGOs have participated actively in the process, but DRAs have hardly been involved at all. Following assessment of drug donation management during recent emergencies in Bolivia, El Salvador and Peru, the DRAs decided to discuss their role and responsibilities in managing drug donations. Problems observed during many previous emergencies persist: short expiration dates; inadequate labelling; unidentified drugs; and drugs not included on the national essential drugs list. The groups concluded that DRAs must participate more actively if drug donations are to be managed more effectively. The potential roles of schools of pharmacy and national associations of pharmacists also need to be evaluated.
EASTERN MEDITERRANEAN REGION

Promoting Rational Drug Use—first course in Tehran

This training course, hosted by the Faculty of Pharmacy of the Tehran University of Medical Sciences, was attended by 29 participants from 12 countries. It included local experts, WHO staff from Headquarters and the Regional Office, and consultants. Tehran proved to be an excellent venue for this type of training activity, with motivated staff and several examples of successful local rational drug use interventions that have already taken place (including a prescription database system for medical auditing). The involvement of the WHO Collaborating Centre for Research & Training on Rational Drug Use, Yogyakarta, Indonesia (based at Gadjah Mada University), proved to be extremely beneficial, especially in terms of developing “bilateral” cooperation between the two universities.

Meeting of the Regional Advisory Panel on Nursing and Consultation on Advanced Nursing Practice and Nurse Prescribing
BHURBAN, PAKISTAN, JUNE 2001.

The meeting, attended by 22 participants, from Bahrain, Cyprus, Iran, Iraq, Jordan, Lebanon, Oman, Pakistan, Saudi Arabia, Sudan, the United Arab Emirates and Yemen was the first joint meeting to be held between representatives of the disciplines of nursing, medicine and pharmacy in the Region. The objectives were to:

- identify the factors and issues creating the need for nurse prescribing;
- develop a regional policy framework for nurse prescribing to assist Member States; and
- develop a mechanism to strengthen the collection of evidence and information for nurse prescribing.

The meeting concluded that quality health care services, including prescribing of an appropriate range of essential drugs, at the first level of the health care system, should be available to health service clients. In many settings, nurses are the backbone of the primary health care system, and as such should be authorized and able to prescribe within the scope of nursing practice. Specific recommendations to WHO included:

- assistance to Member States in their efforts to identify, formalize and strengthen the roles and responsibilities of all health care providers involved in prescribing, with an emphasis on rational use of drugs;
- initiation and coordination of demonstration projects and case studies to evaluate the impact and cost-effectiveness of using different categories of health care providers, with special emphasis on nurses, in prescribing and rational use of drugs.

EUROPEAN REGION

Third International Training Programme in Pharmacoeconomics
BUDAPEST, 20–30 MAY 2001

WHO/EURO organized the Third International Training Programme in Pharmacoeconomics, ‘Evidence, Money and Drug Selection’, which was held in Budapest from 20–30 May 2001. The course was organized by the WHO Collaborating Centre at the University of Newcastle and hosted by the Hungarian Institute of Pharmacy. Thirty-nine participants from 31 countries attended, with the majority of participants coming from the target audience of Eastern Europe. Facilitators came from Birmingham University (UK), Newcastle University, Sydney University, Australia and WHO/EURO and Headquarters.

Pharmacists Against Smoking

In April 2001, a survey with the title “Pharmacists Against Smoking” was carried out within the EuroPharm Forum “Smoking Cessation” task force. The European Commission supports this initiative financially. Fourteen thousand questionnaires were sent out to 12 participating countries to evaluate the attitude of pharmacists to smoking in general, and with regard to their customers in particular. The average response rate was 37%. The questionnaires are now being analysed and the final report will be sent to the Commission on 15 September 2001.

Inspection of TB drug manufacturers in the Russian Federation

A joint inspection of selected TB drug manufacturers in the Russian Federation was conducted, in July 2001, by WHO, the Ministry of Health and the Ministry of Industry & Technologies to assess compliance with good manufacturing practices (GMP) requirements. The inspection was organized within the framework of WHO assistance to the Russian Federation to strengthen its pharmaceutical quality assurance system. Further inspections are scheduled to take place.
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SOUTH-EAST ASIA REGION

Meeting of the Ministers of Health, Maldives, 20–22 August 2001

Pharmaceuticals were discussed extensively at the Meeting of the Ministers of Health, held at the Bandos Island Resort from 20–22 August 2001. The focus was on providing essential drugs of adequate quality at affordable prices to all sectors, including the private sector. While the Ministers acknowledged that the Region has the capacity to manufacture and supply the required essential drugs, this has not been achieved for many reasons. The record in the government sectors has been reasonable, but the record in the private sector leaves much to be desired. Comprehensive publicly-funded insurance (the “macro” component) for all citizens would be a good target, but many problems could prevent it from being attained. In addition, activities focused on prescriber/user (“micro”) need to be integrated into the macro approach. For smaller countries such as Bhutan and the Maldives, bulk procurement schemes (BPS) are a viable option, and WHO collaboration in this area was requested. However, technical issues, such as harmonization of registration, would need to be sorted out before such a scheme could be worked out.

It was also recommended that the state provide unbiased drug information for both prescribers and consumers. Otherwise, the only available information on drugs would be that provided by manufacturers and sellers whose primary motivations are profit-oriented. Governments should therefore allocate a certain proportion of their drug budget for providing drug information. In other words, the drug budget must be used not only for “hardware” (drugs), but also for “software” (drug software). It was also recommended that “civil society”, as represented by informed consumer groups, should be involved in decisions regarding drugs.

WESTERN PACIFIC REGION

Workshop on Pharmaceutical Bulk Purchase for Small Pacific Island States

WHO provided technical and financial support for a ‘Small Pacific Island States Workshop on Collaboration with Fiji in Pharmaceutical Bulk Purchase’, held in Nadi, Fiji, in April 2001. Aimed at improving access to and availability of essential drugs in Pacific Island countries, the workshop was organized by the Government of Fiji and attended by participants representing Fiji and the Small Island States (including Kiribati, Nauru, Niue, the Marshall Islands, Tokelau, Tuvalu and Vanuatu).

National training workshops on problem-based pharmacotherapy teaching

In order, to increase awareness of rational drug use teaching in medical curricula, national workshops on problem-based pharmacotherapy teaching were held in China and Malaysia. The workshop in China was organized by the CHINA CLEN (Clinical Epidemiology Network) at the West China University of Medical Sciences in Chengdu, and was attended by over 70 clinical teachers in China. The workshop in Malaysia was organized by the Universiti Kebangsaan Malaysia (UKM), from 11 to 18 August 2001, and was attended by teachers from clinical and pharmacology disciplines from all over Malaysia.