WORKSHOP FOR HEADS OF DRUG REGULATORY AGENCIES IN CCEE/NIS

WORLD HEALTH ORGANIZATION
Regional Office for Europe
COPENHAGEN

TARGET 31

QUALITY OF CARE AND APPROPRIATE TECHNOLOGY

By the year 2000, there should be structures and processes in all Member States to ensure continuous improvement in the quality of health care and appropriate development and use of health technologies.

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WORKSHOP FOR HEADS OF DRUG REGULATORY AGENCIES IN CCEE/NIS

Report on a WHO Meeting

Hillerød, Denmark
14–16 April 1994

1994

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ABSTRACT

A workshop for drug registration officers from countries of central and eastern Europe and newly independent states (CCEE/NIS) participating in the 7th International Conference of Drug Regulatory Agencies (ICDRA) was held prior to the conference. This was the first time that the WHO Regional Office for Europe had brought together senior drug registration officers to consider matters of common interest and to agree on a common approach to ICDRA itself. The participants touched on such important issues as national drug policies, registration, licensing, legislation, organization and management, budget, human resources, quality control, information, international regulations, adverse drug reactions and monitoring. A number of country presentations provided the opportunity for representatives to share experiences in key areas. This exchange identified priorities and will help prevent similar mistakes from being made in future reform of the health care systems in CCEE/NIS. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, launched by WHO headquarters, was discussed with special interest. The participants underlined the importance of the meeting and requested that similar workshops be held in the future. Participants requested that a support programme be established by WHO and prepared a master plan for activities and targets. They also prepared a joint statement to be presented at ICDRA-7.

Keywords

DRUG AND NARCOTIC CONTROL
LEGISLATION, DRUG
QUALITY CONTROL
CONGRESSES – organization and administration
CCEE
NIS

CONTENTS

INTRODUCTION

A national drug policy is an important element of an overall health policy and should be aimed at improving the health care of a population through the rational use of appropriate drugs. However, in the countries of central and eastern Europe (CCEE) and the newly independent states (NIS) of the former Soviet Union regulations on drugs have not been fully developed and there is little experience with implementing a drug policy in a free market economy.

The Division of Drug Management and Policies, WHO headquarters, was to hold the 7th International Conference of Drug Regulatory Agencies (ICDRA) in April 1994. In preparation for the conference, the WHO Regional Office for Europe, in collaboration with WHO headquarters and the Danish College of Pharmacy Practice, held a workshop for the heads of drug regulatory agencies of CCEE/NIS. The workshop took place in Hillerød, Denmark, from 14 to 16 April. It was attended by 13 representatives of CCEE/NIS and WHO staff. Annexes 1 and 3 list the working papers and participants, respectively.

The objectives of the workshop were to:

- review past recommendations and plans
- exchange information and experience
- update knowledge and skills
- plan joint activities and means for collaboration
- prepare joint input for ICDRA-7
- develop a long-term support programme for drug regulatory agencies in CCEE/NIS

The workshop was opened by Dr Marc Danzon, Director, Country Health Development. He underlined the role of the Regional Office in bringing together different countries so that they may exchange experience and analyse country-specific problems in order to find the most efficient way to improve the situation, for instance, in the pharmaceuticals sector.

Dr Ten Ham, WHO headquarters, Division of Drug Management and Policies, presented the history of ICDRA meetings,

underlined the importance of collaboration between WHO headquarters and the Regional Office and of good intercountry relationships, which should be a prerequisite for rational decision-making by national drug authorities.

DISCUSSION

The representatives of countries in a transitional phase shared their experiences regarding the development of a market-oriented pharmaceutical sector. One of the most important and common problems was the lack of a clearly defined drug policy and legislation. They felt that harmonization and compliance with directives issued by the Commission of the European Communities and with other international standards was the most viable way of reaching mutual recognition of drug quality. Differences in requirements for drug registration procedures were considered a barrier to forming effective partnerships.

Some countries confirmed that there were problems with the registration of drugs in a free-market economy and with the licensing and control of natural medicines, especially in those countries with long traditions of using such medicines and where there was a shortage of legal drugs. Some of the participants emphasized the "over-registration" of phytopharmaceuticals and homeopathic drugs as a current problem in regulating drug flow and implementing the rational use of drugs.

The WHO collaborating centre for drug information and quality assurance in Budapest, Hungary offered assistance to other CCEE in the form of quality control services, training courses, information exchange and experience in implementing the essential drugs philosophy. The possibility of forming such a partnership was considered a positive initiative.

Specific issues associated with the transition from a centralized system to a regional system were discussed by representatives of NIS. Advice from countries that had already developed structures for drug regulatory agencies was summarized into recommendations for implementation of a national drug policy in NIS.

Participants had the opportunity to share their experiences of drug reimbursement and drug pricing systems. The Danish system of reimbursement and criteria for reimbursement were discussed. Different regulations for drug pricing systems were presented.

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and the WHO programme for international drug monitoring were discussed and all the participants showed great interest. They expressed a wish to obtain to information on these activities and to have the opportunity to join them.

Lectures were delivered by representatives of the Danish National Board of Health and the Danish College of Pharmacy Practice on topics such as rational drug use, good clinical practice, international requirements for clinical trials and good manufacturing practice. It was recognized that the lack of sufficiently trained and equipped personnel in these areas in most of the countries present at the workshop poses a real problem. The participants had the opportunity to receive information about the special training programme in good management practice for professionals from CCEE launched by the Danish College of Pharmacy Practice.

The importance of improving coordination among bodies, organizations and funding agencies was stressed so that financial resources could be used in a more effective way.

WHO's pharmaceuticals programme for CCEE/NIS was presented. Its aim is to focus action on specific country needs (and not to duplicate the initiatives of the other agencies).

CONCLUSIONS AND RECOMMENDATIONS

Some of the most important points for further consideration were national drug policies, licensing, legislation, organization and management, budget, human resources, quality control, information, international regulations, monitoring. The importance of international collaboration, with special emphasis on regional cooperation, was also noted.

Similar workshops should continue to be held. Hungary has agreed to host one in 1995.

Recommendations from the participating countries regarding the structure of future workshops (for example, restriction of subjects for presentation, necessity of inviting outside speakers and the preparation of guidelines for presentations by participants) were taken into consideration.

The participants requested a WHO-organized long-term support programme, and a master plan for future activities and targets was prepared.

They also agreed on a statement that would be submitted to ICDRA-7 (Annex 2).

Annex 1

WORKING PAPERS AND BACKGROUND MATERIAL[a]

Working papers

PRE/ICDRA/6	Drug regulatory legislation in the Slovak Republic – Process of harmonization, L. Martinec
PRE/ICDRA/7	Bulgaria experiences in the transitional phase, G. Guencheva

Background material

EUR/ICP/DSE 165	*Drug information*: report on a WHO meeting. Copenhagen, WHO Regional Office for Europe, 1991
EUR/ICP/DSE 168	*Drug information*: report on a WHO meeting. Copenhagen, WHO Regional Office for Europe, 1992

[a] Copies can be obtained from the Pharmaceuticals unit, WHO Regional Office for Europe, Scherfigsvej 8, DK-2100 Copenhagen Ø, Denmark.

WHO/PHARM 82.4,4 — *Certification scheme on the quality of pharmaceutical products moving in international commerce.* Geneva, World Health Organization, 1994

WHO/PHARM 84.23,5 — *A brief overview of WHO's activities in the drug field with emphasis on PHA activities,* Geneva, World Health Organization, 1993

WHO/PHARM 92.2.559 — *Quality control methods for medicinal plant materials.* Geneva, World Health Organization, 1992

WHO/PHARM 94.565 — *WHO guidelines on stability testing of pharmaceutical products containing well-established drug substances in conventional dosage forms.* Geneva, World Health Organization, 1994

WHO/PHARM 94.568 — *Quality of selected drugs at the point of use in developing countries: report on the joint WHO/UNICEF study.* Geneva, World Health Organization, 1994

TRS No. 790	*WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-first report.* Geneva, World Health Organization, 1990
TRS No. 790,6	*Guiding principles for small national drug regulatory authorities.* Geneva, World Health Organization, 1990
TRS No. 825	*The use of essential drugs. Fifth report of the WHO Expert Committee.* Geneva, World Health Organization, 1992
DRVE-2	*Status report of the programme for pharmaceuticals in CCEE/NIS 1993.* Copenhagen, WHO Regional Office for Europe, 1994.

Annex 2

DECLARATION OF THE WHO/EURO PRE-ICDRA WORKSHOP, 14–16 APRIL 1994, HILLERØD DENMARK

At the above workshop for drug registration officers from countries of central and eastern Europe and the newly independent states of the former Soviet Union attending the 7th ICDRA meeting in the Netherlands, the participants discussed pharmaceutical questions arising from the development of new structures for official control of medicinal products in the countries of central and eastern Europe and the newly independent states.

The participants, representing 13 countries, RESOLVED that when taking decisions on official control of the registration, distribution and supply of medicines, governments must apply the following principles.

1. International standards shall be followed in organizing drug regulatory agencies (DRAs) as independent professional government bodies responsible and accountable for decisions and actions.

2. The help of experts or expert committees of medical, pharmaceutical or other health professions shall be used whenever necessary.

3. The experts or expert committees may serve as advisory bodies but final decisions shall be made by DRA professionals.

4. The decisions made by DRAs shall be highly professional, independent of any influence, and in accordance with WHO guidelines.

5. To achieve the goal of the representatives of ensuring that DRAs in countries of central and eastern Europe and newly independent states shall be able to comply with international standards in drug policies and regulations, DRAs need proper exchange of information in such areas as computerization, the development of organizational structures and training of personnel.

In addition, those representatives from countries of central and eastern Europe and newly independent states that had benefited from donations of drugs and medical supplies in the past, RECOMMENDED that donations of drugs should follow official WHO guidelines on donations.

Annex 3

PARTICIPANTS

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