



# Action Programme on Essential Drugs

*Issue Paper on*

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**Assistance to Eastern Europe  
and the Republics of the  
Former Soviet Union**

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World Health Organization  
Geneva

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## **1. Introduction**

In consideration of the prospect that the donor community wishes to provide additional funding for increased levels of activities in the Countries of Central and Eastern Europe (CCEE) as well as New Independent States (NIS) - which encompass a number of the republics of the former Soviet Union - the Management Advisory Committee (MAC) requested the Action Programme on Essential Drugs (DAP) to prepare an issue paper for the 1994 meeting, outlining the implications for the Programme in terms of provision of technical assistance and of personnel.

The CCEE and NIS are in political and economical transition affecting all governmental sectors. Lack of sufficient financial resources for the public sector, including health, is one of the predominant constraints. The provision of health care is handicapped by lack of drugs and maximum attention will need to be given to assure that deterioration in population health status does not occur. There have been some reported instances of reappearance of epidemics of previously well-controlled diseases.

The limitation of funds highlights the importance of focusing on development of an appropriate framework for a comprehensive national drug policy including optimal management for, in particular, drug procurement, distribution and rational use of drugs.

## **2. Background**

The drug supply policy of the former Soviet Union was typified by a division of responsibility for production of drugs among the member states of the Council of Mutual Economic Assistance (COMECON) and its centralized drug supply system procured needed drugs from those various COMECON manufacturers. Further, drug production was not a major area of investment and the pharmaceutical industry did not benefit from financial and technical support to allow its development to modern and accepted international standards. Thus, while many of the CCEE have a long tradition of local drug production, only a narrow spectrum of drugs have been produced in any one country.

With the cessation of functioning of a centralized drug supply system, the NIS face a situation in which the processes of drug production and distribution must be restructured and, most importantly, each country must formulate its own comprehensive national drug policy.

The pharmaceutical sector in a number of CCEE and NIS countries is characterized by:

- a) a breakdown of the centralized production and distribution system leading to uneven accessibility;
- b) an absence of clearly defined drug policies and legislative framework;
- c) need for the development of revised drug pricing and financing systems;
- d) lack of satisfactory quality assurance systems;
- e) insufficient and outdated drug information and education;
- f) lack of training in modern therapeutics.

To these characteristics must be added the undoubted risks inherent in a situation of *unregulated* privatization.

## 2.1 Reports and decisions in earlier meetings of the Management Advisory Committee

1991 A proposal was made to the Management Advisory Committee (MAC) in 1991 to commit US\$ 1.5 million for provision of assistance to Countries of Eastern Europe and the former Soviet Union. It was recognized that the proposal for a more significant level of activities in CCEE was dependent on additional funding. During 1991, DAP helped in development of drug policies in Albania, Czechoslovakia and Poland on request of the governments and the European Regional Office. For this, the Programme used a small amount of regular budget funds.

1992 In the DAP Report of the Biennium 1990-1991<sup>1</sup> the new situation in Eastern Europe and former Soviet Union was described, in part, as follows:

"Following the relaxation of central control and the diversification of markets in many CCEE, public health agencies have been left poorly equipped to assess national conditions of supply, quality and use. New government officials are in need of management training since the significant turn-over of government officials has left many government offices without sufficient experienced personnel.

In many countries, social plans ensuring free provision of health care have remained in place while the free market reforms in the drug sector have caused health care costs to sky-rocket. High costs of medicines on the free market, compounded by the economic consequences of improper drug use,

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<sup>1</sup>DAP/MAC(4)/92.4

are driving drug costs upward and are threatening the financial viability of government health care institutions. In some cases, drug costs are estimated to be 70% of government health care budgets.

Whereas in the past international trade was mostly limited to Eastern Europe and the former Soviet Union, today there are significant social and market pressures for Western goods - including medicines. Often of higher cost than domestically produced and regulated drugs, increasing demand for Western medicines has accentuated the demands for limited foreign exchange. As more components of the drug sector are privatized, a confusing variety of drugs with different trade names has become available and there has been a vast multiplication in the number of drug sales outlets.

The transition to free-market economies also exposes these countries to a wider problem which includes all aspects of drug regulation, drug prescribing and use. Comprehensive national drug policies are needed in order to ensure that necessary medicines of acceptable quality, safety and efficacy at reasonable prices are available on a long-term basis, and that they are prescribed and used in a proper way."

The budget proposals for the biennium 1992-1993 to the MAC included US\$ 480,000 for country support in the European Region. The Committee acknowledged the need for support in the Eastern European countries and approved DAP's initiatives for technical support. The MAC expressed the view that it was important to differentiate between technical support and provision of support for supplies. While DAP should continue to analyze the situation in the European Region, resources should not be diverted from needy developing countries.<sup>2</sup>

1993 DAP reported to the MAC in February 1993 (Progress report 1992) that the situation in some of the CCEE was now similar to that of the developing world. DAP had received requests for assistance from Member States and from the Regional Office for Europe. In accordance with conclusions drawn by the MAC in February 1992, the Programme's response had been limited to the provision of technical assistance in the form of assessment missions with no further financial commitments.

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<sup>2</sup> Only US\$ 30,000 was obligated (from the regular budget) in 1992-1993

### **3. Present situation in CCEE and NIS**

A general situation analysis is given in the following sections under the classification of programme areas used by DAP.

#### **3.1 Policies and management**

In both CCEE and NIS there is generally a lack of clearly defined drug policies and legislative frameworks partly resulting from the dissolution of the Soviet Union and the disruption of COMECON.

The management and regulation of the pharmaceuticals sector had been centralised in Moscow. Upon independence of the republics, the NIS are in a situation where no legal framework is in place specific to each individual state. Most CCEE have also not established properly functioning legislation and regulation of the pharmaceutical sector.

There is little evidence of essential drugs principles being followed in procurement and prescribing of drugs. Essential drugs lists are not in operation in many countries. Drug committees that could select drugs and influence and control the quality and cost of prescribing practices have either not been developed or responsibilities in this area have not been defined.

There is minimal use of generic drugs which are often subject to considerable suspicion concerning quality. In contrast, brand-name drugs, often recently marketed and expensive, are prescribed extensively.

The CCEE and NIS face the task of developing new drug policies; it is most likely that a diversity of decisions will be taken among them. There is an expressed need for provision of unbiased information reflecting the experiences of other countries relating to the development of the drug policies.

#### **3.2 Supply and logistics**

The drug supply policies of CCEE and NIS have changed from a centralized system of drug procurement from manufacturers in COMECON countries to independent policies in the various states. While some of the CCEE have a tradition of local drug production, none can claim self-sufficiency for the whole range of drugs needed by their health care systems.

Countries which have local drug manufacturing capabilities are now engaged in restructuring production and identifying internal and other markets. Countries without local production must establish drug procurement systems; their experience in this domain is very limited.

Drug distribution systems for the public sector health care systems are to be developed. Here, as in other areas of the pharmaceutical supply system, the influence of privatisation policies may have a critical impact especially where drug policies and goals for the sector remain undefined.

All the NIS and some of the CCEE receive donations of drugs from major donor agencies and nongovernmental organizations. Some of the donations are uncoordinated, unsolicited and may not correspond to the health needs of the population. Drug donations are seldom based on the essential drugs criteria and may be of varying quality. Moreover, the prescribing habits of doctors may be influenced by drug donations.

While drug donations may help solve some of the acute problems of availability of drugs, they do not solve longer-term problems of drug supply. In addition, such negative effects of donated drugs as the undermining of national drug production and distribution systems cannot be ignored.

There is an urgent need to establish relevant drug selection criteria and policies in all of CCEE and NIS which can be used not only as guidelines for donations but also as policy guidelines for national drug procurement for the health care systems.

Pharmacy services in primary health care in many countries are rapidly changing from state-run pharmacies to private pharmacies. In general, and in part because of the substantial growth in this area, private pharmacies are inadequately regulated and inspected. Some of the private pharmacies are believed to supply unregistered imported drugs in breach of existing practices or legislation and some also dispense prescription drugs without proper authorization.

### **3.3 Quality assurance**

Quality assurance systems generally need upgrading in most CCEE and NIS. With the shift from state-run activities to private initiatives in production, wholesale and retail distribution, the capacities for inspection, regulatory and quality control needs to be expanded.

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is used in only very few of these countries but it is highly desirable that the CCEE and NIS participate in it as quickly as is feasible.

### **3.4 Rational use of drugs**

There is no systematic procedure for collecting or analysing drug utilization data in the majority of CCEE and NIS although such data is needed to monitor and control the use of drugs.

There is also no tradition of drug information centres or pro-active distribution of independent drug information. There is a severe shortage in general of up-to-date

international medical and pharmaceutical literature. Furthermore, drug formularies, which serve as reference manuals for doctors and pharmacists and contain at least the minimum of drug information required for safe, effective and economical prescribing are non-existent. Therapeutic or treatment guidelines are not available.

Drug prescription and use in CCEE and NIS is based on outdated pharmacotherapeutic principles and, compounded by a lack of information about modern pharmacotherapy, may result in inappropriate selection and use of drugs. Modern therapeutics do not feature in the education and training of doctors and pharmacists.

### **3.5 Summary of key problems**

Although most CCEE and NIS face basically similar problems, there are differences in focus and importance, as well as in levels of economic development and the degree of autonomy that existed in the former socio-economic system. Thus, areas of support must be pragmatically tailor-made to each individual environment. However, the problems facing CCEE and NIS have a strong resemblance to those experienced in developing countries in other parts of the world and can be summarised as follows:

- a) resources for health care including drugs are limited and have been decreasing since the emergence of independent states;
- b) lack of clearly defined drug policies impedes the development of efficient drug supply systems;
- c) lack of drug legislation, a regulatory and enforcement system responding to the present needs and new situation may create problems with the safety and efficacy of drugs available on the market;
- d) lack of prescribing policies or consensus guidelines for primary and secondary care while at the same time many new drugs are being marketed and prescribers have little information about them;
- e) lack of up-to-date drug information for doctors, pharmacists and nurses causing delay in introducing rational drug use;
- f) outmoded education and lack of training in modern therapeutics.

## 4. Activities carried out in CCEE and NIS

### 4.1 WHO Regional Office for Europe

As a result of the radical geo-political changes which have taken place in the European region over the past few years, the Regional Office for Europe has reoriented its programmes to include increased support to the CCEE and NIS.

At its Fortieth Session in September 1990, the Regional Committee of the WHO Regional Office for Europe (EURO) considered the need for a programme of intensified cooperation in health with special focus on CCEE. In establishing this programme, designated EUROHEALTH, Member States made a commitment to pursue the basic WHO Health for All strategy in these countries. An immediate concern of EUROHEALTH is to improve the poorly performing health care systems and to address the challenge of reducing health inequities. Funding will come from both the EURO regular budget and extrabudgetary funds solicited in support of the programme of intensified cooperation.

EUROHEALTH comprises a list of twenty-one projects covering domains identified by CCEE as priority needs. Among the wide-ranging issues represented in the twenty-one projects is Drug Utilization and Supplies which includes among its objectives the formulation of national drug policies, designing mechanisms for review of drug utilization and support in securing adequate supplies of life-saving and other essential drugs.

In order to address EUROHEALTH projects related to pharmaceuticals, a Programme for Pharmaceuticals in CCEE/NIS was established within the EURO initiative in 1993. In the first instance, the Programme has benefitted from managerial and financial support from the Danish Pharmaceutical Association allowing it to establish model projects in Albania, Bulgaria and Lithuania. The EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS supports activities in more than ten countries in central and eastern Europe with a dominant focus on development of drug policies, legislation and drug information systems.

The Programme for Pharmaceuticals in CCEE/NIS includes country-specific and intercountry activities where the same assistance is provided to several countries with an element of cooperation between them. The Programme for Pharmaceuticals collaborates closely with DAP and employs its guidance and strategies in development of country-based activities. The situation in the CCEE and NIS differs from that in some developing countries in respect to the human resources available; most countries have trained medical and pharmacy staff but there is a lack of managerial skills.

Activities in the NIS have been limited to fact finding missions in a few of the countries, development of guidelines for supplies of life-saving drugs and, on request, ad hoc support relating to drug selection.

Activities in Belarus and Georgia will begin in 1994-1995 through limited country funds made available from the regular budget. The funds are sufficient to cover only such initial activities as preparation of project proposals and preliminary consensus building on development of drug policies.

Expansion of activities by the EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS will require extrabudgetary funding since a very limited regular budget is available in 1994-1995.

## **4.2 Action Programme on Essential Drugs**

DAP has received requests for assistance for CCEE and NIS from the EURO and directly from Member States. In accordance with a 1993 MAC proposal to DAP, the Programme's response has been primarily to provide technical assistance by means of assessment missions, without additional financial implications, but also the provision of extensive documentation on development of a national drug policy, legislation and other areas relating to drug supply systems. A DAP staff member also contributed expertise in two missions to Albania, including review of a proposed World Bank project in Albania.

In February 1994 a workshop was convened in Moscow on "Implementation of a National Drug Policy" in which forty-five officials from the Ministry of Health participated. The workshop was facilitated by three professionals from DAP and one from EURO.

### **4.2.1 The Mongolian experience**

The political and economic systems in Mongolia were, earlier, practically identical to those of other republics of the former Soviet Union. Until 1990 the country was heavily dependent on the then-USSR for its supply of drugs, medical equipment and vaccines. Physicians and pharmacists were accustomed to purchasing large numbers of drugs - many of them non-essential - deriving from the former Soviet Union and COMECON countries.

Subsequent to the rapid changes in the political and economic systems in 1990, Mongolia faced an acute shortage of essential drugs.

Following a request for support at the World Health Assembly in 1991 from the Minister of Health of Mongolia, DAP sent a three-member mission to the country to undertake an in-depth situation analysis on the drug supply system. Its aim was to identify priority problems and to prepare a project proposal for a National Drug Policy and Essential Drugs Programme in Mongolia.

A project proposal for 1991-1994, prepared by the mission, was submitted to the Government of the Netherlands which accepted to provide funds. The budget for the first two years was for a sum of US\$ 600,000; it included all elements of a comprehensive Essential Drugs Programme.

Quite early on in the programme in Mongolia it was evident that national staff could assume a large measure of responsibility for its development. Through fellowships, highly qualified staff were provided updated information on the pharmaceutical sector and subsequently utilized in training activities in Mongolia. Management and administrative costs (e.g. one United Nations Volunteer) have been minimal.

In the context of the CCEE and NIS, the development of the Essential Drugs Programme in Mongolia has been a useful experience for DAP and can serve as a practical model for other countries in the region with similar backgrounds.

During the course of a joint WHO/UNICEF mission to the NIS, DAP was able to assess the pharmaceutical sector in Kyrgyzstan and Tadjikistan where the situation is very similar to Mongolia, i.e. drug shortages and complete lack of drug policies. Development of a national drug policy was recommended as a priority activity. Experience from Mongolia has demonstrated that a good quality comprehensive essential drugs project can be developed and implemented for approximately US\$ 600,000 for a two-year period.

### 4.3 Other agencies

Other organizations such as the World Bank and the CEC PHARE Programme (the original designation for a Commission of the European Community programme of technical support for Poland, Hungary Assistance in Reconstruction of the Economy which has been subsequently expanded to include other countries although its earlier-used acronym has been retained) have provided support on a loan or grant basis for activities relating to the restructuring of the pharmaceutical sector. In addition, the countries have been in a position to carry out parts of the restructuring with their own resources.

The CEC TACIS Programme (Commission of the European Community programme of Technical Assistance to the Commonwealth of Independent States; although their designation has been changed to NIS the original acronym has been retained) is supporting, in principle, the restructuring of the health care sector in NIS. Activities are in the initial stages under this programme and a few countries have been identified as pilot project areas, namely Moldavia and a few regions of the Russian Federation.

The World Bank is also providing assistance; in general, such assistance is on a loan basis to CCEE and NIS. The World Bank normally seeks the technical support of WHO for its activities which include the health sector and, generally, from DAP for activities relating to the pharmaceutical sector.

## **5. General observations on future activities**

The quality and availability of pharmaceuticals are public policy issues where WHO can provide unbiased policy and technical guidance, information and experience from other countries which may facilitate the process of developing new systems in CCEE and NIS. The approach and experience of the Action Programme on Essential Drugs has proved valuable in a number of countries where problems are comparable to those presently faced in CCEE and NIS.

With its EUROHEALTH Programme for Pharmaceuticals for CCEE/NIS, EURO has begun the process of assisting these countries, particularly CCEE, in restructuring the pharmaceutical sectors. The springboard for these activities is the essential drugs concept as promulgated by DAP.

Provided that adequate financial and human resources are made available to DAP, it can support the activities of the EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS particularly in view of the sound links already established with many of the CCEE and NIS. Furthermore, as part of the EUROHEALTH Programme for Pharmaceuticals, liaison offices in all the CCEE and NIS countries are being established which will facilitate collaboration between EURO and the Member States.

Certain CCEE and NIS have urgently requested support from WHO on drug policies, legislation and drug information; priority should be given to these technical areas.

While the EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS can provide limited support in response to requests from the CCEE, there are greater difficulties in supporting the NIS as the problems in general are more severe. Jointly DAP and the Programme for Pharmaceuticals in CCEE/NIS could offer technical assistance to a wider range of countries in the region.

## **6. Recommendations**

In mid-1993, DAP and the EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS began a series of inter-office staff consultations in Copenhagen and Geneva to discuss ways and means to collaborate in providing technical assistance and development activities in the CCEE and NIS. Priority areas are considered to be activities leading to development of a drug policy framework.

## 6.1 Enhanced collaboration between EURO and DAP

The ongoing collaboration between DAP and the EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS should now be enhanced to allow provision of country support, especially to develop drug policy frameworks, in a limited number of NIS and to assist in development work in some CCEE. Areas of development work already identified to be strengthened will include issues in pricing and financing, human resources and pharmacy practices.

In order to support the enhanced collaboration between the two offices proposed above, one person will be needed full-time for coordination and administration including convening planning, monitoring and review meetings and to undertake country missions as needed.

The costs for this staff would be shared between DAP and EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS and is estimated to be around US\$ 130,000/year. The staff member would also be closely involved in the implementation of activities proposed below; implementation of activities would be the primary responsibility of the EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS.

## 6.2 Budget proposal for collaborative activities in 1994-1995

It would be well worthwhile for development of essential drugs programmes in CCEE and NIS if funds of around US\$ 800,000 were made available to DAP under the 1994-1995 budget for the development of programmes in collaboration with EUROHEALTH Programme for Pharmaceuticals in CCEE/NIS. Accessibility of adequate numbers of qualified staff at the national level would allow a continuing development of activities encompassed in a national drug policy following a period of initial training and transfer experience from well-developed essential drugs programmes.

At least one year must be devoted to developing a comprehensive national programme; it would be preceded by a in-depth situation analysis and preparation of a detailed project proposal, including plans for development of each activity.

A realistic budget proposal in 1994-1995 for development of essential drugs projects in five countries is the following:

Initial activities leading to preparation of project proposals in 5 countries (US\$ 50,000 each)	US\$ 250,000
Costs of development activities for the biennium in 2 countries	<u>US\$ 600,000</u>
TOTAL	US\$ 850,000

The total costs for 1994-1995 to prepare project proposals for five countries and for development activities in two countries would amount to US\$ 850,000. Added to this sum should be the costs, proposed above, for one staff member for coordination, administration and project implementation shared between DAP and EURO.

## **7. Conclusion**

In conclusion, the extensive experience and expertise of DAP in formulating and implementing comprehensive national essential drugs programmes together with its extensive documentation system will neatly mesh with the Regional Office initiative, the EUROHEALTH Programme for Pharmaceuticals in CCEE and NIS, which aims to help countries to restructure their pharmaceutical sectors and to formulate and implement national drug policies.

## List of Acronyms

CCEE	Countries of Central and Eastern Europe
CEC PHARE	Commission of European Community: Poland, Hungary Assistance in Reconstruction of Economy (covers now the whole CCEE)
CEC TACIS	Commission of European Community: Technical Assistance to the Commonwealth of Independent States
CIS	Commonwealth of Independent States
COMECON	Council for Mutual Economic Assistance (= CMEA)
DAP	Action Programme on Essential Drugs, WHO
DMP	Division of Drug Management and Policies, WHO
EURO	Regional Office for Europe, WHO
EURO HEALTH	EURO Health Programme for CCEE/NIS
NIS	New Independent States
WHO	World Health Organization