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Future Strategy



Action Programme on Essential Drugs



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1. INTRODUCTION

This document presents the future strategy which appears to be the most appropriate for WHO Action Programme on Essential Drugs to its mandate to respond over the next five years. This strategy has been identified taking into consideration more than ten years of DAP experience in the field of national drug policies and essential drugs programmes.

The Action Programme on Essential Drugs (DAP)

The Action Programme on Essential Drugs acts as WHO's operational arm to assist in "the development and implementation by Member States of their drug policies, in the supply of essential drugs of good quality at the lowest possible cost, and in the development of training in the rational use of drugs"¹. It works in close collaboration with the WHO Regional Offices and other HQ programmes. The Programme supports comprehensive national drug policies and essential drugs programmes as a central component of the WHO Revised Drug Strategy.

The objectives of the Programme are summarized below:

- * to assist Member States in formulating comprehensive national drug policies in support of national health services;
- * to assist Member States in strengthening their technical, structural and human resource capabilities in selection, supply, distribution, local production, quality assurance, legislation, regulation, economic analysis, modes of financing, and rational use of drugs;
- * to assist Member States in implementing and evaluating all the components of national drug policies and essential drugs programmes;
- * to promote and facilitate the transfer of knowledge, expertise and technology;
- * to play a major international and national advocacy role in support of the essential drugs concept and the need for and methods of achieving a more rational use of drugs.

¹ Resolution WHA43.20, 1990.

- Increasing attention has been paid by governments to developing mechanisms to improve the availability of drugs, and many have tried to rationalize their drug sector. Most developing countries have drawn up limited lists of drugs under INNs for the public sector and developed national essential drugs programmes, often with the support of donors. Access to essential drugs of acceptable quality has increased.
- At global level, availability of generic drugs at lower cost on the international market and the services offered by such non-profit organizations as IDA, ECHO, UNICEF Supply Division, have increased competition and contributed to a lowering of drug prices.
- Governments, often for cost containment reasons, have become more aware of the problems linked with irrational prescribing and use of drugs. The academic world has become more conscious of its responsibilities and of the dangers of insufficient training, the concept of rational use of drugs has gained greater support. The public has also been sensitized to these issues through the important role played by consumer groups in advocating the provision of more and better drug information to the public.
- Finally, the concept of comprehensive national drug policies, covering both public and private sectors, gained ground and found application in a number of developing countries.

An evaluation of the Action Programme was performed in 1989 by an independent group which concluded that "DAP has been successful in its advocacy and communications role and has played an important technical support role in many countries. The evidence shows that the strategies employed by DAP have had a major impact on the understanding, acceptance and implementation of the essential drugs concept."

5. WHERE LESS SUCCESS HAS BEEN ACHIEVED

Despite these advances, strategies developed in the 1980s were not successful in solving some of the issues:

- Access to essential drugs remains limited and inequitable in many countries; the structural weaknesses of the drug public sector and its poor performance continue to handicap the functioning of the health system. Although procurement and distribution have improved in a number of countries, progress has been challenged by the economic crisis and the structural adjustment process. MOH budgets for drugs have often decreased in real terms and alternative financing methods including cost sharing, taxation and alternative drug supply systems are still not fully implemented and evaluated. The issues of equity and access to drugs for the poorest of the poor have not always been addressed adequately.

- Planning, programming and budgeting capacities are still limited in many least developed countries and the trained human resources to conduct the managerial process for establishing national drug policies, including the regulatory aspects, are scarce.
- A number of essential drugs programmes are insufficiently institutionalized and not integrated into national health policies; they continue to be fully supported by donors, and strategies designed in the 1980s to ensure their long-term sustainability have to be reviewed.
- Current drug utilization is still a cause of great concern, leading to a wastage of resources. Implementation of corrective measures and interventions has been rather slow.
- Cooperation and coordination among the partners involved, inside and outside WHO, to develop a common policy framework have been successful to a certain extent but need to be strengthened.
- Improvement in regulation is a priority and consequences of this low level of regulation are, *inter alia*, an increase of drug prices at the retail level, a concentration of the distribution network in the main towns, a shift to less essential drugs with a higher profit margin, and an irrational use of drugs and resources in general. The EDC has scarcely reached the private sector, which is playing an increasing role in the provision of drugs.

Many of these failures are linked to the development process and to new problems and challenges. The pharmaceutical sector belongs to a wider system and structural constraints within countries, outside the drug sector, contribute to the failure of many programmes and projects. Secondly, the imbalance which exists in the area of pharmaceuticals all over the world, i.e. a strong supply side dominated by transnationals exercising overwhelming influence on consumption, and a demand side consisting of poorly informed public and prescribers, is even greater in developing countries where the administration has often limited resources and negotiating power. This imbalance has contributed greatly to the difficulty of implementing rational drug policies. Thirdly, due to the sensitivity of the issues, it has not been possible for WHO to enunciate and promote a very clear and cohesive global policy that seeks to redress the imbalance of the use, production and distribution of pharmaceuticals in developing countries. Fourthly, the formulation and adoption of national drug policies (NDPs) frequently leads to strong resistance on the part of some stakeholders at national level, even though the process of policy development has included all interested parties. However, 10 years is a very limited period and, despite this short period, an increased number of countries are moving toward national drug policies. The challenge for the Programme in the next few years is to assist them efficiently, taking into consideration the new situation of the 1990s.

6. THE WORLD DRUG SITUATION AT THE BEGINNING OF THE 1990s: NEW PROBLEMS, NEW CHALLENGES

The problems facing the health sector today, with respect to ensuring access to essential drugs and rational use of drugs, are increasingly complex and take place in a rapidly changing environment; they certainly call for new and innovative strategies. Problems differ between regions and countries, nevertheless the main issues relate to:

- * **Availability of resources:** Due to the world economic crisis, the purchasing power of households has decreased in many countries, especially in Africa; this decrease seems to have contributed to the increase of malnutrition and of various diseases (ARI, cholera, etc.) and therefore to the demand on the health services and on drugs. This demand is exacerbated by population growth in some regions and by the spread of AIDS. This increase of demand took place when the decrease of revenue led to a decrease in the financial accessibility of households to drugs. At the same time, structural adjustment policies, by increasing the price of imported drugs and in reducing public expenditures, led in many countries to an aggravation of drug shortages in the health facilities.

Demand is therefore growing while resources, public or private, are decreasing or static; for the foreseeable future, this trend will be maintained in many countries and the challenge will be to help countries to make the best use of the limited public funds and of the private sector.

- * **Technical efficiency:** Training of human resources and management capacity to ensure the best use of existing resources at all levels and the sustainability of national drug policies remain inadequate in many countries. Training in health economics, which has the potential to increase the efficiency of utilisation of scarce resources, is particularly deficient.
- * **Relationship of the public and private sectors:** In most developing countries, the private sector is increasingly taking over drug supply from the public sector, either as a deliberate state policy or because finance for the public sector is lacking. The profile of the pharmaceutical sector has therefore changed and access is being influenced accordingly. At the same time the state often has little control over the private sector, and therefore cannot enforce compliance with its policies, nor does it fully draw upon the potential for collaboration with the private sector and the pharmaceutical industry in NDP implementation. The legal framework is often inadequate or outdated.
- * **Quality of health services:** In most of the developing countries, there is a serious lack of adequately trained health personnel (especially pharmacists) and this shortage particularly affects primary health care. In addition, many developing countries have difficulty funding adequate numbers of public sector health personnel. While primary

health care is still not fully developed in most developing countries, and provision of drugs at the periphery remains a major concern, many countries also suffer from inefficiency and waste of resources at the secondary and tertiary levels. As a result of the inequitable allocation and distribution of health care resources, public health services in many poorer countries cannot meet the needs of the population they are intended to serve.

- * **Rational use of drugs, knowledge and management:** In most countries, the use of drugs through prescription or self-medication is far from rational. In many, if not most, developing countries, training in drug use is still insufficient, information reaching the prescribers and consumers is far from satisfactory, drug management remains weak and drug promotional practices continue to give cause for concern.
- * **Role of international aid:** The present world drug situation is characterized by the growth of interest of major development agencies in supporting the drug component of health services (WB, UNDP, Regional Development Banks, EC, UNICEF, bilateral agencies, etc.). However, often lack of coordination, absence of clear strategies, lack of internal policy consistency, and absence of specific in-house expertise within these agencies leads to low integration of aid in national drug policies, and to low investment in setting up policy framework and structures. A typical example is the lack of a clearly defined policy on drug financing mechanisms. These factors reduce the impact of such aid, even when it represents an important and growing part of the pharmaceutical market in a country. Drug donations also continue to be a problem when donors do not pay enough attention to the national requirements of recipient countries. In certain cases aid may even conflict with overall government drug policies.
- * **Quality assurance of drugs:** Substandard drugs and counterfeit drugs continue to be a concern; efforts and collaboration at national and international levels still need to be reinforced to better understand the extent of the problems and to find ways to fight them.
- * **The New Independent States (NIS):** These have added to the number of countries with serious problems in the field of drug supply and drug regulation. Their problems are aggravated by limited government capacity to ensure planning and implementation of drug policies, despite the widescale availability of a great number of qualified professionals and institutions.

In conclusion, many countries face a crucial problem: how to improve access to and efficacy of health care services, including drugs, in making best use of the limited resources available. This calls for new priorities and strategies at country and global level by all partners involved. In this new environment, what should be the role of DAP? What implications do these changes have on DAP programmatic policies and strategies and on its mode of operation?

7. WHERE DOES WHO/DAP'S COMPARATIVE ADVANTAGE LIE?

The financial resources available to DAP have increased significantly over the years. DAP's budget for the current biennium 1992-1993 is US\$ 24.8 million and this represents an enormous expansion of activities supported by increasing commitments from the Programme's donors. The WHO/DAP's comparative advantage in NDP development and implementation lies in the strong partnership which has evolved between the developing countries, donors and DAP. The Programme believes that it has enabled and facilitated this partnership through the development of a sound and reliable programmatic framework for the implementation of activities, an efficient management system, strong financial control and timely, accurate and transparent financial reporting. Given the difficulties countries are undergoing, demands on DAP are likely to increase; at the same time, due to overall financial constraints, and like other WHO programmes, DAP's resources may remain limited. DAP will also seek to complement and support other organizations which play a part in assisting drug supply and use in developing countries.

The available strategies for DAP must operate within the overall mandate of the World Health Organization. WHO is the parent of the essential drugs movement. Its constitutional mandate from Member States, its distinctive competence in setting global standards and norms, and its operational experience and credibility at country level, cannot be replicated by any other UN organization. DAP itself has its own field of competence and assets: committed, experienced staff; acceptability in countries related to the mandate and operations of WHO in national drug policy development; intensive and wide-ranging experience in national policy development, assessment and review, and in technical support; outstanding information and training materials on all aspects of national drug policies; good collaboration with other WHO programmes; and general acceptability with old and new partners. DAP implements its activities in collaboration with WHO's Regional and Country Offices where in some cases there is limited capacity.

The strategy proposed below takes into consideration a) the assets of WHO/DAP as well as the role of other partners over the next few years; b) the main issues faced by countries today described under section 6.

8. NEW DIRECTIONS FOR DAP

This chapter provides an overview of the approaches that DAP should follow over the next five years to best fulfill its role.

8.1 Global functions

DAP should strengthen its activities at this level to facilitate its major role in country support and to provide increased technical advice and global advocacy. These global functions are the specific responsibility of WHO; no other agency has the mandate, expertise and commitment to carry them out. In addition, DAP will need to cooperate more fully with other WHO bodies and UN organizations, such as UNICEF and the World Bank.

Technical advice

DAP will work with experts from all regions on the development of technical and strategic guidelines, "how to" booklets, reviews of experiences on the various aspects of pharmaceutical systems. These experts and DAP will be informed on country situations through the monitoring system developed by DAP on the world drug situation. This information system, based on indicators applied in a sample of representative countries, will provide DAP with current data on the progress in implementation of policies and strategies at country level. Based on this system, on the results of problem solving operational research and on country experience, DAP will develop and update materials for advising Member States on policy formulation and strategies and on various technical areas. Technical areas identified as being of high priority for study and development are:

- * *Policy including financing:* guidelines on the formulation and implementation of national drug policies; development of appropriate legislation relating to the supply, quality assurance and rational use of drugs; appropriate level of drug expenditures, cost-effectiveness of drug expenditures; equity issues; pricing and financing schemes to improve affordability and stimulate availability of essential drugs under generic names;
- * *Supply and logistics:* best practices and systems for cost-effective public and private procurement, distribution, storage;
- * *Quality assurance:* effective quality assurance and regulatory control systems based on appropriate drug legislation and adapted to the socioeconomic level of developing countries; guidelines on the various modes of regulating and monitoring the pharmaceutical sector and on better use of resources for enhancing the role of the state;

- * *Rational use:* drug selection and information, formularies and cost-effective interventions to rationalize drug prescribing and use, public education strategies, and training in drug management and use;
- * *Other issues:* response to emergency situations in the world and to the current situation in NIS.

Under each technical area, the role of the private sector and the ways to make best use of the contribution of this sector will be carefully studied and its limitations and advantages specified.

Development and training of human resources will remain a key strategy of the Programme for building national capacity, in all of the above mentioned areas of intervention. In addition, DAP will focus on the evaluation of its experience and strategies in national drug policy development and implementation.

Global advocacy

DAP will actively advocate the approaches and main elements of national and international strategies which have been validated by its various advisory bodies and by its research component. It will continue to promote the essential drugs concept, including rational use of drugs, as a technically sound and realistic approach both to optimizing drug supply systems and to making drugs accessible to the whole population. It will closely cooperate and coordinate its work with that of other WHO programmes (e.g., DMP, ICO, disease control and strengthening health services programmes) and will develop with them a unified WHO response to the overall health problems faced by developing countries. With external agencies it will promote more strongly a unified approach to national drug policies based on WHO principles and the acquired body of knowledge.

8.2 Country support

DAP's global functions are essential and can only be done by WHO; activities at country level will continue to be the backbone of DAP's work. Country support will remain the focus of DAP's activities in the future, as: i) it is part of the constitutional mandate of the Organization to respond to requests from Member States for technical cooperation; ii) there is still a great need for flexible technical advice and support, tailored to the individual needs of Member States; iii) the Programme has the capacity to respond quickly to countries' requests; and iv) the credibility of the global drug policies developed by DAP and its advocacy nationally and internationally can only flow from its involvement at country level. However, this country support strategy should include the building up of expertise outside the Programme, in other agencies, at national and regional levels, so that increasingly technical support can be shared.

The main objective of country support has been to assist countries in designing and implementing national drug policies based on country needs and thorough situation analyses to increase equity in health care and to build national capacity. Strategies have included strengthening the health care infrastructure, improving the management of scarce resources, promoting the rational use of drugs, and developing human resources. These activities are funded by unspecified and specified funds, together with some regular budget funds.

DAP will adopt a flexible and pragmatic approach in its response to countries requesting technical support. This will be based on government commitment, assessment of needs, past performance, likelihood of success, the involvement of other agencies and availability of funds.

In future, three types of country support are envisaged:

1. Most support will concentrate on **long-term policy and strategy development**. DAP will assist governments to design and monitor national drug policies and national action plans as part of a wider national health policy. This process of assessment, planning and monitoring will foster coordination between all partners involved in the pharmaceutical sector. It will allow for better use of resources, long-term sustainability and increased coherence. In certain cases, when DAP has an advantage over other partners, the Programme will also assist in implementation. Such technical activities will differ according to national needs that will always be part of a comprehensive plan in which major drug policy elements have been reviewed in full.
2. DAP will provide **intensified support in a limited number** of countries. These countries will be representative of various stages of development of their pharmaceutical sector and of their national drug policies. These countries will serve as examples and will assist in clarifying the policy development process. The information used for developing materials, guidelines, training modules will also be generated from these countries.
3. DAP will support the **implementation of specific technical activities**, where appropriate, at the request of countries supported by donors. Such activities should be clearly separate in terms of budget, including administrative support costs.

In addition to the activities already described, DAP country support will be broadened to address new issues mainly related to the efficient use of scarce resources and appropriate financing mechanisms for drugs within the health sector. Specifically, DAP will assist countries, to:

- analyze the resources available to the health sector and their allocation between health care priorities (in collaboration with SHS and ICO), the level and cost effectiveness of expenditure by the public sector on drugs, and the appropriateness of this level.
- strengthen national capacity through systems development and training.
- develop rational drug use policies to optimize the use of scarce drug resources.
- define strategies to guide the role of the private sector, to improve efficiency and complementarity in the public and private sectors at all levels; to cover the most vulnerable groups, and to enhance government capacity to ensure access to needed drugs at the lowest possible cost.

9. PROGRAMME OUTLOOK

The Programme will maintain its present 4x4x4 operational framework, summarized below:

Areas of work: country support; development work; operational research; management activities.

Technical areas of intervention: policy and management; supply and logistics; rational use; quality assurance.

Underlying principles: a need-driven, pragmatic approach; building capacities through improved infrastructures and human resource development; promoting decentralized decisional operational responsibility; integrating essential drugs into overall health care systems.

Within this framework, DAP will increasingly work with a network of experts and advisers and with centres of excellence and collaborating centres. These centres could serve as "think tanks" which would collate and analyze knowledge and experience in drug policy development and implementation, that could later be translated into broadly applicable technical strategies and methods. Other centres could be used to develop some of the material that DAP is now initiating, doing itself or with the help of short-term consultants. A similar approach would be taken for operational research. The proposed Technical Support Panel (TSP) will provide a pool of expertise and advice which DAP can draw upon as required.

The plan and budget for biennia 1994-1995 and 1996-1997 will be prepared in the context of new directions for DAP and will include both the financial and human resources necessary to implement new activities or intensification of some existing activities. DAP has

proven able to cope with the significant expansion of its resources in the last decade and could have handled additional resources had these been available.

What is important here is to focus on the prioritization of DAP's resources. This must also take into account the Programme's funding structure whereby of its total budget for 1992-93, 10% is regular budget funded and 90% extrabudgetary funded. The extrabudgetary funds are currently split approximately 50/50 between unspecified and specified funds. Within specified funds the degree of specification may vary.

The Programme's resources will be prioritized so that the activities under global functions (section 8.1) will be funded from regular budget and unspecified funds. In addition - as at present - DAP will continue, where appropriate, to use some specified funds for global functions. Country support activities (paragraph 8.2) should be funded as follows:

- Type 1:** long-term policy and strategy development: from regular budget and unspecified funds;
- Type 2:** intensified support in a limited number of countries: from unspecified/specified funds;
- Type 3:** implementation of specific technical activities: from unspecified/specified funds. Such activities should be implemented by DAP within a well defined financial structure.

In summary, the Programme's strategy for the next five years will be to build on experience gained in the last decade and to adapt its technical support to face the challenges of the nineties, particularly those posed by a deteriorating economic situation and a changing public/private sector balance. While maintaining its country support function, which provides DAP with the experience, knowledge and credibility to undertake its work in support of national drug policies and rational use interventions, the Programme will fine tune its support according to need, commitment and resources. The Programme will broaden its network of technical advisers and partners by use of the TSP as needed in order to develop and implement an extensive range of technical tools and guidelines for use at country and global level. It will also strengthen its advocacy and leadership to develop a common understanding of pharmaceutical policy issues at global and country level, particularly among all development agencies working in this area.

While adaptation to meet the needs of the nineties will be fundamental to Programme strategy, its goal remains unchanged: equity of access by all people to safe and effective essential drugs, and the rational use of drugs throughout the world.

Annex I

ACRONYMS

AIDS	acquired immunodeficiency syndrome
ARI	Acute Respiratory Infections (WHO Programme of Control of)
DAP	Action Programme on Essential Drugs
DMP	Drug Management and Policies (WHO Division of)
EC	European Community
ECHO	Equipment for Charity Hospital Overseas
EDC	essential drugs concept
HQ	headquarters
ICO	International Cooperation (WHO Office of)
IDA	International Dispensary Association (Netherlands)
IEC	Information, Education and Communication
INN	international non-proprietary name
MOH	Ministry of Health
NDP	national drug policy
NGO	nongovernmental organization
NIS	New Independent States
PHC	primary health care
SHS	Strengthening of Health Services (WHO Division of)
TSP	Technical Support Panel
UN	United Nations
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
WB	World Bank
WHO	World Health Organization

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