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**ACTION
PROGRAMME
ON
ESSENTIAL
DRUGS**

**Monitoring and
evaluating national drug
policies and measuring
the effects of DAP's
work**



World Health Organization

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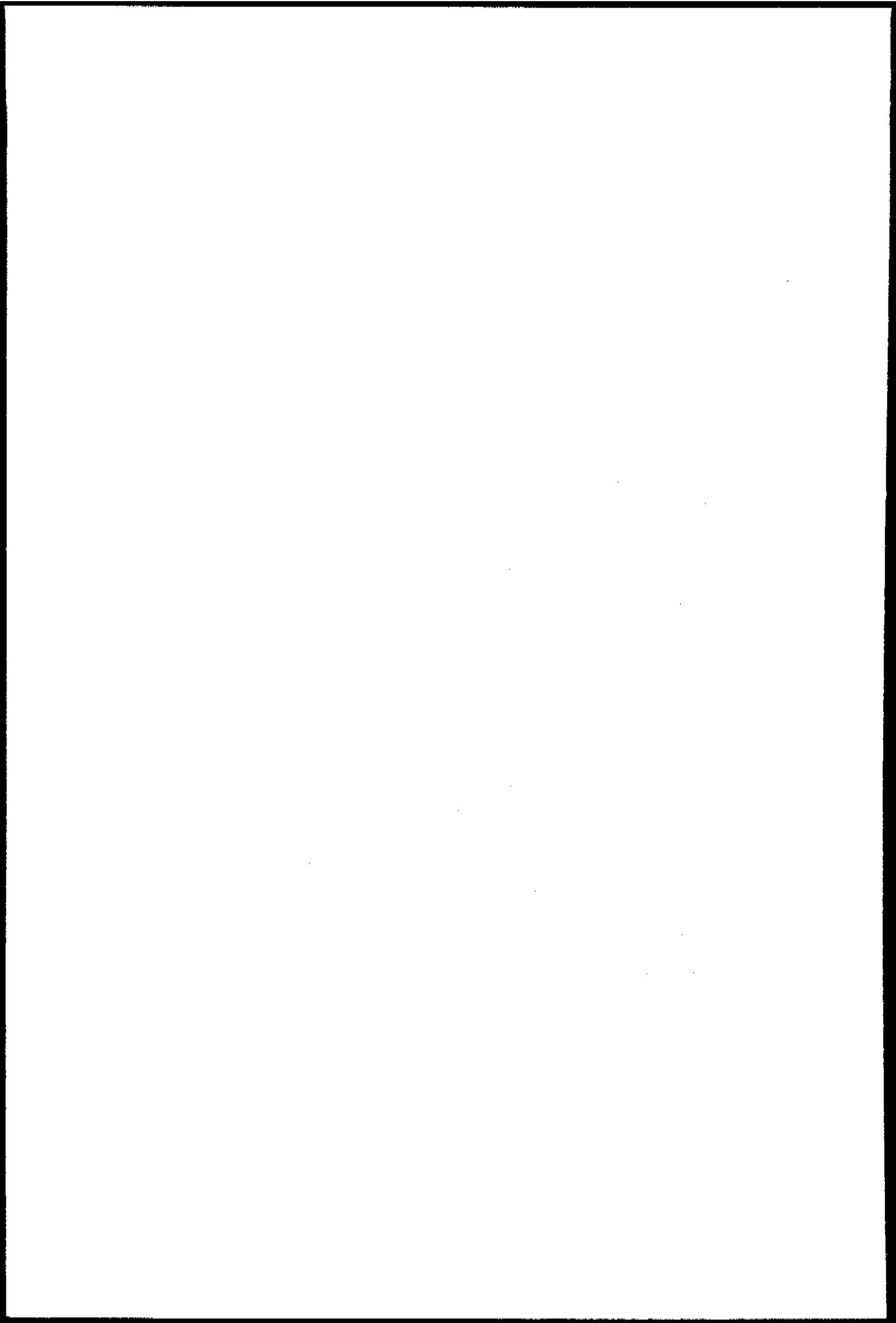
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Executive summary

Introduction

Although the progress in reducing poverty and in increasing access to health services and essential drugs is remarkable in many parts of the world, more than a quarter of the world's people lack access to basic health facilities and essential drugs. These people live mainly in developing countries, but not exclusively; countries of Central and Eastern Europe and of the Commonwealth of Independent States (CIS) have seen a reduction of access to health services and drugs due to poverty and lack of insurance systems and an increase in morbidity and mortality. Even in developed countries a significant proportion of the population now suffers from poor health due to lack of secure access to health facilities and drugs.

Advances therefore have been uneven and new global pressures are further threatening access to drugs.

To tackle these problems and ensure equity of access to and rational use of drugs, new strategies/reforms have been initiated in many parts of the world. They include:

- developing more sustainable drug financing mechanisms and broadening financing options;
- improving the performance of the public sector, mainly at health services level through cost containment measures and training of staff;
- decentralizing to local government and through the establishment of autonomous bodies (e.g. autonomous central medical stores, or autonomous drug regulatory authority);
- increasing the role of the private sector, mainly in drug delivery;
- strengthening the role of the state in information and regulations;
- securing access to expensive new patented drugs through mechanisms acceptable under the new agreement on trade-related intellectual property rights (TRIPS);
- implementing cost effective interventions to secure a more rational use of drugs.

In such a complex environment and with progress not easily traceable to one factor, governments need to monitor the performance of their drug sector and to evaluate the effects of their policies on the overall objectives of the national drug policy. They need also to evaluate why some policies work and others do not work and how and when to adjust them. The WHO Action Programme on Essential Drugs (DAP) should be able to adapt itself to the new challenges and to

assess on a regular basis the relevance and the adequacy of the support provided to countries.

For a number of years, countries and DAP have been active in better monitoring and evaluating their own work. However, an analysis of these activities shows that (1) governments and other important players do not have all the tools needed to evaluate the effects of reforms in the pharmaceutical sector and to interpret changes; (2) the Action Programme on Essential Drugs could be much more systematic in its approach to assessing whether its work is sufficiently relevant to countries' needs and whether its support contributes to measurable changes in the national situation.

The paper will therefore review these two aspects. It will specifically look at (1) monitoring and evaluating national drug policies and (2) measuring the effects of DAP's work.

Monitoring and evaluating national drug policies

The ultimate goal of a national drug policy is: equity of access to essential drugs, rational use of drugs and drug quality. In order to achieve this goal, a number of components of the pharmaceutical system need to be in place and functioning. These key components, which can be seen as intermediate objectives of the policy, are implemented through various strategies and measures.

Monitoring and evaluation should be adapted to the country's situation and should assess changes in the light of the objectives of the NDP. This means they should assess to which extent:

- the intermediate objectives of the policy are performing well;
- the reforms and measures implemented have an effect on the final objectives of the policy.

In view of the above, the paper suggests that for monitoring and evaluating NDPs there is a need to combine two methods:

- *Quantitative methods* (mainly indicators) (1) to assess the performance of the policy and the effects of changes on the NDP objectives; (2) to identify areas needing further action and areas progressing well; (3) to identify strengths and weaknesses of the policy; and (4) to understand certain aspects of the policy by interpreting data and identifying trends.
- *Qualitative methods* to assist in the analysis of policy-making processes, including to systematically analyse the support and opposition to the policy and the opportunities and obstacles to change.

A number of tools already exist to carry out successfully such monitoring and evaluation; they include various selections of indicators and methods for analysing policies. These tools are described in more detail in the paper. Although tools and methods are available they are either not used enough or not complete enough. Therefore there is a need to improve tools and methods and to encourage a "culture of monitoring" in which staff at all levels of the drug sector

understand and participate in the success of monitoring and evaluation activities. The paper goes on to suggest areas where more work needs to be done.

As many different organizations and individuals are involved in implementing a national drug policy, the methods used for monitoring and evaluating the policy should be seen as representing an assessment of many initiatives. Some may be attributed to the Ministry of Health, others may be initiated by other partners.

However, policy-making including development, implementation and monitoring/evaluation of the national drug policy is the responsibility of the state. It is therefore the responsibility of the senior management personnel in the Ministry of Health to steer the monitoring and evaluation efforts. All the partners should be associated with these efforts at least when developing the methods and the indicators which will be used to monitor and evaluate the initiatives developed under the policy. The fact that the Ministry of Health is responsible for these activities does not mean that the actual work has to be done by the Ministry of Health. This will depend on the country context and the human and financial resources available.

The paper reviews some of the alternatives on how and where monitoring and evaluating activities should take place. It argues that a successful development, implementation and monitoring/evaluation of a national drug policy can be achieved only by strengthening the role of the state and Ministry of Health in standard setting, monitoring and evaluation of outputs.

Bilateral agencies, international organizations and WHO/DAP should support institutional capacity-building in monitoring and evaluation through direct support to activities and through training of government staff and other individuals, as few people, mainly in least developed countries, have experience at a strategic or policy level.

Measuring the effects of DAP's work

The Action Programme has developed programme targets and indicators since 1994. It has also carried out evaluations in a large number of countries on a regular basis and results have been incorporated in policies and plans. However, the measurement of the real "impact of DAP's work" has not been carried out in a systematic manner.

The new WHO Essential Drugs Strategy provides DAP's objectives and strategies. The Programme's ultimate goals are that essential drugs be equitably accessible to everybody, that drugs all over the world be of acceptable quality, and that drugs be used rationally. Achieving these goals will contribute to the reduction of the morbidity and mortality.

In order to reach these overall goals, DAP has identified two global strategies:

- *Country programme development* (CPD) which includes direct technical cooperation with countries.

- *Policy and technical development* (PTD) which includes the identification, development, provision, and advocacy of technically and strategically sound policies, strategies, tools, and approaches to be used and adopted by all countries.

The paper proposes methods for assessing the effects of DAP's work. These include both new methods as well as current methods which need to be applied more systematically. In addition, as a good monitoring system is fundamental to successful evaluation, it also suggests how monitoring in DAP can be improved. It includes therefore methods to assess:

- the effectiveness of DAP's work in implementing the activities under each of the global strategies: CPD and PTD;
- the direct effects of DAP's work through an analysis of the work under each of the global strategies: CPD and PTD;
- the indirect effects of DAP's work on the pharmaceutical situation in the world.

The methods proposed stem from a compromise between what is desirable and what is feasible. Evaluation is a necessary exercise but at the same time it is costly and time-consuming. The paper tries to focus on relatively low cost and non-complex evaluation methods, which may not provide detailed answers to everything we want to know but which will be sustainable in the long run and open to improvement.

These methods are explained in the paper and summarized in the following table.

In order to successfully apply these methods, the paper proposes ways to strengthen the culture of monitoring and evaluation with the staff of DAP at all levels — country, region and headquarters.

Operational implications

The suggestions made in this paper have important implications for DAP in terms of financial and human resources. DAP will not carry out all the activities; however, the coordination, the advocacy, and the implementation of the activities will create additional workload for the staff of the Programme.

Some activities have already been planned for 1998-1999. It is suggested that as soon as the MAC has reviewed the proposals and agreed on them, a detailed workplan will be prepared which will outline how activities will be organized, and propose collaboration with different organizations in carrying out the plan. It is expected that monitoring and evaluation activities in countries supported by specified funds will be covered by these funds; for other activities, unspecified and regular budget funds will be used. A preliminary estimate suggests that the total amount spent on all these activities, including staff, should not exceed 3% of the total DAP budget. This amount does not cover activities such as the network of sentinel countries whose mandate goes far beyond the sole monitoring and evaluation role.

DAP monitoring and evaluation approaches			
Objectives/questions	Type of information collected	Frequency of collection	Sources of information
Measuring the effectiveness of CPD and PTD			
To what extent does DAP achieve its targets?	Quantitative data on targets.	Each year.	DAP monitoring system/Proposed plan and budget.
What are the factors which explain the extent to which DAP is able to achieve its targets?	Qualitative information (critical analysis).	Biennial.	DAP staff, regional advisers, eventually experienced individuals.
Have the activities been executed efficiently?	Qualitative assessment linked to financial data.	Biennial.	Country evaluation, DAP documents, DAP monitoring system.
Measuring the direct effects of CPD			
Has the country made a gain from cooperation with DAP?	(a) Review of intermediate and final objectives in type 1, 2, 3 countries. (b) In-depth evaluations. (c) Surveys.	Biennial. Three per biennium. Every four years.	Country plans of action. Country reviews. Country reports + interviews. 20 people at country level/20 people at global level.
Measuring the direct effects of PTD			
Is the material known? Has it been developed with extensive participation of future users? How far have the concepts/policies advocated by the Programme been adopted by countries and other agencies?	Quantitative and qualitative.	Biennial.	DAP monitoring and information system.
Is it used? By whom is it used? Is it relevant to the most pressing needs of countries?	Quantitative and qualitative.	Every four years.	Evaluations. Surveys.
For materials related to training or applications of methodologies: • Have they been followed by training and/or any implementation activity by DAP? • Has there been uptake by others for training and/or research?	Quantitative and qualitative.	Every four years.	Evaluations. Surveys.
Measuring the indirect effects of DAP's work			
Global access to essential drugs.	Quantitative data.	Every four years.	Questionnaire.
Collection of selected indicators.	Quantitative data.	Biennial.	Questionnaire.
Creation of a network of countries.	Quantitative + qualitative methods.	Ongoing.	

Conclusions

This paper presents approaches and methods to evaluate pharmaceutical reforms at country level and to better assess the role of DAP and its contribution to national action. It tries to keep a balance between the need to better know the effects of the actions of the various players on the final objectives of a NDP with the costs in human resources and time taken by evaluation activities. It is suggested in this paper that descriptive analysis of the actions taken and of their effects is a cost-effective way to identify strengths and drawbacks of actions taken at national level and by DAP and can lead to recommendations for policy changes. This has been done successfully in the past by DAP. There will always be a need for hard data which are often difficult to collect and analyse. In view of this, the paper advocates that more importance be given by governments, international agencies and others to training of staff at all levels in monitoring and evaluation and in the use of the results of these activities.

In conclusion, it should be remembered that even when using valid methods and asking good questions it is often very difficult to be sure that the changes observed are due to the interventions or to the reforms; changes do not take place in a laboratory. The pharmaceutical sector is complex, with many external and confounding factors, such as the macroeconomic situation and the international treaties, influencing the final outcome. Therefore, even if progress is evident over a certain period, it is often difficult to relate cause and effect. Operational research is needed to identify more precise tools to assess causality links and to ensure that the evaluation efforts contribute by their accuracy to more equitable access to essential drugs, mainly for the poorer people.

1. Introduction

This paper aims (1) to review and discuss methods which can be used by countries to measure the effects of pharmaceutical reforms within the framework of national drug policies and (2) to review existing approaches and identify new methods for evaluating the effects of the work of the WHO Action Programme on Essential Drugs.

1.1 Facing critical problems

When the Action Programme on Essential Drugs was launched 17 years ago, the most critical problem faced by countries in their pharmaceutical sectors was the lack of drugs in the public sector, especially for primary health care. Although countries were spending between 20 and 40% of their scanty health budget on imported drugs, most people in rural areas and urban slums had no access to the drugs. Use of drugs was already a great concern at that time but it was felt that before concentrating on rational drug use, availability of drugs should first be secured. Therefore the main questions were: Which drugs should be purchased with a limited budget? How could drugs be provided to the periphery and to the urban poor? How could a country reduce its expenditures of limited foreign exchange on imported drugs while enlarging pharmaceutical coverage?

The essential drugs concept (EDC) was a core answer to the key issues identified. The strategies developed by the Action Programme focused on this concept which was advocated as the most appropriate tool to make the best use of resources in selection, procurement, storage, distribution and use of drugs. Through the application of the concept, the formulation of essential drugs lists and the establishment of drug policies and management programmes relevant to the health needs of populations, significant saving could be made by rationalizing purchase, storage, distribution and use of drugs. Attention was mainly geared towards the public sector and the development of essential drugs programmes. Most countries and organizations supported the essential drugs concept. Most countries now have a list of essential drugs. Organizations such as the World Bank have included the essential drugs concept in their recommendations to countries. In terms of expanding awareness and implementation of the essential drugs concept, DAP has been widely successful^{1,2}.

However, although the progress in reducing poverty and in increasing access to health services and essential drugs is remarkable in many parts of the world, more than a quarter of the world's people lack access to basic health facilities and essential drugs. These people live mainly in developing countries, but not exclusively; countries of Central and Eastern Europe and of the Commonwealth of Independent States (CIS) have seen a reduction of access to health services and drugs due to poverty and lack of insurance systems and an increase in morbidity and mortality. Even in developed countries a significant proportion of the

population now suffers from poor health due to lack of secure access to health facilities and drugs.

Advances therefore have been uneven and new global pressures are further threatening access to drugs. Among the main dangers are:

- slow economic growth, stagnation and even decline in some 100 developing and transition countries³;
- continuing conflicts in many countries;
- the rise of such threats as HIV/AIDS;
- poor performance of many health systems.

In the drug field, these problems exacerbate a situation characterized still by low access to essential drugs in many countries; rising drug expenditures in both the public and private sector; and a use of drugs which is often highly irrational.

1.2 Developing innovative strategies/reforms

To tackle these problems and ensure equity of access to and rational use of drugs, new strategies/reforms have been initiated in many parts of the world. They include:

- developing more sustainable drug financing mechanisms and broadening financing options;
- improving the performance of the public sector, mainly at health services level, through cost containment measures and training of staff;
- decentralizing to local government and through the establishment of autonomous bodies (e.g. autonomous central medical stores, or autonomous drug regulatory authority);
- increasing the role of the private sector, mainly in drug delivery;
- strengthening the role of the state in information and regulations;
- securing access to expensive new patented drugs through mechanisms acceptable under the new agreement on trade-related intellectual property rights (TRIPS);
- implementing cost effective interventions to secure a more rational use of drugs.

Experience in most of these areas is limited, because of the small number of countries which have tried to implement these measures and the short period of time they have been implemented. In some policy areas, such as cost containment measures, an important number of experiences have been collected in the last 20 years, mainly on interventions using the essential drugs concept as a basis for such rationalization⁴. In others, like broadening financing options, the measure which has been studied in greatest depth is the introduction of user fees. But even here, a lot of uncertainties remain on the implications of user fees on access and use of drugs and on how and when it is most appropriate to introduce such fees⁵. Cost effective interventions in RUD are well documented; however little is known on how to introduce them successfully⁶. Autonomous

bodies, being CMS or new drug regulatory authorities, have been in existence for too short a time in developing countries to allow definitive conclusions to be drawn.

Finally the TRIPS agreement is still not completely implemented and its full effects will not be seen for a few years^{7 8 9}.

1.3 Monitoring and evaluation: current approaches

In such a complex environment and with progress not easily traceable to one factor, governments need to monitor the performance of their drug sector and to evaluate the effects of their policies on the overall objectives of the national drug policy. They need also to evaluate why some policies work and others do not work and how and when to adjust them. The WHO Action Programme on Essential Drugs (DAP) should be able to adapt itself to the new challenges and to assess on a regular basis the relevance and the adequacy of the support provided to countries. It is also important for DAP to accumulate experience from countries in order to learn from failures and successes and assist countries accordingly.

A number of countries, mainly countries with large donor support, have introduced monitoring systems to review progress according to plans. Zimbabwe is a good example of a country which has developed methods and indicators for monitoring implementation of the national essential drugs programme (ZEDAP) and for assessing problems and redefining strategies¹⁰. Many more countries have carried out assessments of their pharmaceutical sector either when a new project was implemented or on an ad hoc basis. For instance, twelve countries^a have embarked on a comparative analysis of their national drug policies using quantitative measures (standardized indicators) and qualitative evaluation strategies (political mapping). This research, done with the support of DAP, Karolinska Institute and Harvard School of Public Health, seeks to monitor and evaluate the performance and the effects of the strategies initiated in the public and private sectors to achieve national drug policy objectives¹¹.

Some of the countries involved in the research are setting up systems which will allow them to continue to monitor and evaluate their NDP on a regular basis, e.g. the Philippines collects data in a systematic way on the main areas of its NDP. With the exception of these countries, there are however a relatively limited number of countries in the world which systematically monitor and evaluate the reforms undertaken in the pharmaceutical sector. Australia is the first developed country to do so¹². Finally, the results of many of these exercises are not fully utilized to change policy or adjust strategies. This is due partly to the fact that it is often difficult to determine clear causal links between the result of an indicator and a new policy. Only plausible conclusions about cause and effect can be reached. This allows room for slowing down the process of reforms, mainly in an area like the drug policy where conflicts of interest exist.

^a Bulgaria, Chad, Colombia, Guinea, India, Mali, Philippines, Sri Lanka, Thailand, Viet Nam, Zambia, Zimbabwe.

The Action Programme on Essential Drugs has been active since its inception in assisting countries to better monitor and evaluate their policies. To this effect, it developed methods for monitoring specific aspects of NDP^{13 14} or more recently for monitoring the performance of the various components/strategies of a national drug policy and for measuring the policy's progress towards the achievements of objectives¹⁵. It has also developed simple qualitative indicators to assess country situations and to compare countries among themselves¹⁶. To measure progress in implementation of its own activities and use of resources, the Action Programme on Essential Drugs has developed programme targets and indicators since 1994.¹⁷ It has also carried out evaluations in a large number of countries on a regular basis and results have been incorporated in policies and plans in the countries evaluated. In some cases, major changes were undertaken following evaluations. For instance, in Tanzania the CMS was made autonomous following the recommendations of evaluations carried out jointly by MOH, DANIDA and WHO¹⁸.

However, the measurement of the real "impact" of DAP's work has not been carried out in a systematic manner although there has been much anecdotal evidence of its usefulness and relevance. An external evaluation, carried out in 1989 by DANIDA and other main donors², reviewed the work of DAP and provided useful recommendations for improvements. In addition, DAP was one of the tracer programmes selected in the review of "The World Health Organization's support to programmes at country level" carried out on behalf of the Oslo group in 1997¹⁹. Results of this evaluation are still to be considered by DAP and incorporated as needed in its own practice.

1.4 Purpose and scope of the paper

It is clear from the above that (1) governments and other important players do not have all the tools needed to evaluate the effects of reforms in the pharmaceutical sector and to interpret changes; (2) the Action Programme on Essential Drugs could be much more systematic in its approach to assessing whether its work is sufficiently relevant to countries needs and whether its support contributes to measurable changes in the national situation. The paper will therefore review these two aspects. It will specifically look at (1) monitoring and evaluating national drug policies and (2) measuring the effects of DAP's work.

This paper has been requested by the Management Advisory Committee. The primary audience is, therefore, the members of the MAC who will discuss and comment on the proposals made in this paper. However, it is expected that the final beneficiaries of efforts in monitoring and evaluating NDPs will be:

- *Member States*, which may benefit from further work on monitoring and evaluation; mainly government senior managers and other non government parties who advise health policy-makers and need to analyse current situations and trends. In addition, Member States may benefit from more systematic evaluation of DAP's support to countries.
- *The Action Programme* including the regional offices which will be in a better position to determine whether its policies and strategies are

appropriate and relevant to country needs, and which will be able to better document effects of reforms on the drug sector.

- *The governing bodies of WHO*, which will be in a better position to assess the work of the Action Programme on Essential Drugs. Indeed, during the past few years, the governing bodies have passed a series of resolutions emphasizing the need for better monitoring and regular evaluation of the Organization's work.
- *Donors and other international organizations*, which will be able to use the approaches designed by DAP in their own practice. In addition, they will be able to use the results of the evaluation process when formulating strategies and policies.

This paper will not propose methods for assessing impact of national drug policies on current health outcomes. This evaluation of impact is not feasible in developing countries because of the lack of large health databases and the difficulty of establishing causality links between improvement of health indicators and increased supply and rational use of drugs. Even in developed countries where investigators have access to national health insurance databases, hospital morbidity databases and death registers, this evaluation is problematic^b.

^b Australia is one of the few countries which has initiated such an evaluation and results of the work will be published in 1998 (personal communication from Dr J. Primrose).

2. Monitoring and evaluating national drug policies

2.1 Setting the scene

Pharmaceuticals have made an important contribution to global reductions in mortality and morbidity. Making drugs available to the people and ensuring they are rationally used should be, thus, a priority for every government. It is now widely accepted that each country should make a positive effort to achieve optimal availability and use of drugs to patients and consumers. However, many governments confront a host of problems in their efforts to ensure the availability and rational use of safe and effective drugs. In trying to overcome these problems, many have formulated national drug policies (NDPs) that specify national pharmaceutical goals and provide a framework for all parties involved.

Regardless of a country's specific circumstances, a national drug policy takes into account all elements of the pharmaceutical sector and all actors of this sector: the government who acts in the public interest; those who take or consider taking medicines; those who prescribe medicines; those who dispense medicines; those who make, market, distribute and sell the drugs. As governments develop and implement these policies, monitoring and evaluation have become important tools for assessing progress, revising strategies and providing policy-makers with the evidence they require to support the drug sector. These exercises are even more important than before as new innovative strategies are launched in most countries as described in the introduction.

However, as already stated, few developing countries monitor^a and evaluate^b on a regular basis the effectiveness, relevance and effects of their policy. Some countries with a well-designed policy implemented for a few years monitor carefully whether activities are executed according to plans, but even these countries have difficulty in looking at the relevance and effects of their policy. A limited study undertaken by DAP on drug monitoring and evaluation found that monitoring was indeed being carried out in many countries²⁰. The finding of the study sharply revealed the tension between respondents' evident desire to monitor and evaluate the policies they implemented and the difficulties posed by the persistence of long-standing obstacles in the social sector of developing countries, especially the lack of resources and political will to institutionalize an ongoing monitoring and evaluation process.

^a Monitoring refers to reviewing, on a continuous basis, the degree to which activities are completed according to plans.

^b Evaluating refers to assessing as objectively as possible the degree to which policies and strategies fulfil their stated goals.

Respondents reported confronting data collection problems typical of environments with chronic resource constraints: limited funds, under-staffing, inadequate technical resources. Results from the questionnaire also indicated that commitment to the notion of monitoring was shallow. Integrating data collection with routine work presented a further challenge, in part because it was difficult to convince overworked staff to assume additional tasks -- such as gathering information for indicators -- which were time consuming and whose usefulness was not immediately evident.

Respondents additionally reported confronting obstacles to successfully translating the conclusions of the monitoring process into policy. There were repeated complaints that the lack of political will at the national level and the constraints imposed by limited resources not only hindered monitoring itself, but often represented insurmountable obstacles to effective change. These frustrations were expressed by respondents engaged in monitoring activities and put forth by those respondents *not* using indicators to explain the lack of monitoring and evaluation in their countries.

This chapter therefore outlines methods for monitoring and evaluating NDPs and suggests ways to improve the present situation.

2.2 What to monitor and evaluate?

As pharmaceutical systems in developing and transition countries have undergone many changes in recent years, it is useful at this stage to begin by asking the question: what needs to be monitored and evaluated?

The ultimate goal of most governments is: equity of access to essential drugs, rational use of drugs and drug quality. In order to achieve this goal, a number of components of the pharmaceutical system need to be in place and functioning. Experiences from countries have permitted the identification of the components which are needed to achieve the goals of an NDP^{21 22}. They are listed in Box 1. These key components, which can be seen as intermediate objectives of the policy, are implemented through various strategies and measures.

Indeed, a nation's drug policy, although it may have many similarities with the drug policies of other countries, must be appropriate to the situation in which it is going to be used; therefore, the "right" policy will differ by country in its priorities, strategies and approaches. For instance, in the least developed countries, in the absence of any insurance system, provision of essential drugs will still be the responsibility of the state; on the contrary, in a middle income country equitable access to drugs will be ensured by expanding compulsory health insurance. Monitoring and evaluation should reflect these differences and should be adapted to the country's situation. Changes should be assessed in the light of the objectives of the NDP. The assessment should concern to what extent:

- the intermediate objectives of the policy are performing well;
- the reforms and measures implemented have an effect on the final objectives of the policy: "Do people who need drugs have access to them and are they used rationally?"

**Box 1: Key components of a national drug policy
(intermediate objectives)**

1. Working within the framework of a well-developed NDP, linking drug research/registration, production, procurement, and distribution with real health needs.
2. Improving the functioning of the drug regulatory authority in order to ensure that drugs are registered properly, and that pharmaceutical establishments are licensed and inspected according to well defined procedures.
3. Developing facilities to control the quality of drugs on the market.
4. Implementing an essential drugs list to guide drug selection, procurement, and prescribing.
5. Developing good procurement and distribution systems which ensure that drugs are available where they are needed.
6. Developing sustainable drug financing and pricing mechanisms (e.g. maintaining a significant drug allocation in the health budget, developing insurance or other solidarity systems, regulating prices in the private sector, promoting competition through increased availability of generics, etc.).
7. Implementing printed information (NDF and treatment guidelines), a drug information unit, current training and continuing education materials, etc. to ensure the rational use of drugs.

2.3 How to monitor and evaluate NDPs?

In view of the above, there is a need for combined approaches. Obviously, quantitative methods play a key role in assessing NDPs, mainly indicators.

These indicators should be of various types:

- *Structural or input indicators*

They seek to reflect the extent to which an infrastructure or any other key structure has been established or exists which facilitates the implementation of the policy. These indicators are qualitative and are expressed in the form of questions. Once these indicators have been answered affirmatively, they generally cease to provide a measure of further progress. They are therefore mainly useful at the earlier stages of the policy development (structural or input indicators). Some additional questions can be asked on the extent to which things work.

- *Process indicators:*

They seek to measure the degree to which activities are being effectively implemented and the progress over time. In certain cases, these indicators

provide measures of the effect of the activities in influencing changes. They provide more meaningful measures than the first ones and can also be used to measure progress in specific areas/strategies.

- *Outcome indicators:*

They seek to measure the results achieved and the progress toward the stated goals of the policy.

However, the assessment of the policy should go beyond an analysis of the content of the policy: "its technical components". It should examine the process of the policy implementation and the institutional and political contexts in which the policies are implemented. Indeed policy reform is not only a technocratic process; it is a political process and it needs to be managed adequately²³.

A reason for not achieving the objectives of an NDP can be lack of resources and management skills but more often it is the fact that reforms in the pharmaceutical sector are political and changes are difficult to implement since a large number of interest groups is likely to resist such policies. Without understanding the processes which explain why a planned policy is not implemented or does not work, governments and other actors will not be able to solve some of the problems they face.

There is therefore a need to assess more carefully how changes are carried out, who is favouring or resisting the changes and other factors that affect implementation. Quantitative data on the context within which a policy is developed are necessary but more importantly qualitative methods such as policy analysis are needed²⁴.

In conclusion, in order to monitor and evaluate NDPs today there is a need to combine:

- *Quantitative methods* (mainly indicators) (1) to assess the performance of the policy and the effects of changes on the NDP objectives; (2) to identify areas needing further action and areas progressing well; (3) to identify strengths and weaknesses of the policy; and (4) to understand certain aspects of the policy by interpreting data and identifying trends.
- *Qualitative methods* to assist in the analysis of policy-making processes, including to systematically analyse the support and opposition to the policy and the opportunities and obstacles to change.

2.4 Existing tools for monitoring and evaluating NDPs

A number of tools and methods already exist at global and country levels. They include:

- *Indicators for monitoring NDPs¹⁵:*

The set developed by WHO/DAP includes four types of indicators (background, structural, process and outcome). The structural and process indicators assess the implementation of NDP by measuring progress in seven key priorities (see Table 1). These indicators are explicitly aimed at

monitoring the dynamic processes associated with the development and implementation of national drug policies. Underlying the WHO/DAP indicator set is a conceptual approach which attempts to understand the links between the nature and operation of structures and processes in the drug sector, and outcomes, so as to be able to offer proposals for achieving desired results.

Table 1: Organization and content of WHO indicators for monitoring NDP

Background information	Structural indicators	Process indicators	Outcome indicators
Quantitative	Qualitative	Quantitative	Quantitative
Population data Economic data Health status data Health system data Human resources Drug sector organization	Legislation and regulation Essential drugs selection and drug registration Drug allocation in the health budget/public sector financing policy Public sector procurement procedures Public sector distribution and logistics Pricing policy Information and continuing education on drug use		Availability of essential drugs Accessibility of essential drugs Quality of drugs Rational use of drugs

The indicators have been used in DAP's comparative analysis of national drug policies. The study found that:

- A high percentage of the indicators were relevant and useful to country situations and did not require substantial modification. The various categories of indicators achieved their goals. The outcome indicators provided a good picture of the national situation in relation to the four NDP objectives. The structural and process indicators allowed for the assessment of the level of implementation of the main components of their NDP. The indicators revealed new things about policy and illustrated the importance of using certain types of data such as the financial data. They also demonstrated that indicator-based research is a helpful tool for focusing action on deficiencies and for finding solutions based on data and analysis.
- A few additional indicators were constructed by country teams to better cover certain components of the pharmaceutical policy (e.g., rational use of drugs). New indicators were suggested for specific components or for additional objectives (e.g., decentralization policies).
- *Rapid pharmaceutical management assessment*²⁵:

The set developed by Management Sciences for Health contains a smaller number of indicators and focuses more on obtaining an accurate snapshot of

the pharmaceutical sector broadly defined. There is greater emphasis on identifying current strengths and weaknesses in the sector and less interest in tracing their sources. The MSH indicators are organized into eight categories, the first five of which are counterparts to the seven priorities identified in the WHO/DAP indicator development process. The eight topics are: Policy, Legislation and Regulation; Formulary/Essential Drug Lists and Drug Information; Ministry of Health Budget and Finance; Ministry of Health Pharmaceutical Procurement; Ministry of Health Pharmaceutical Logistics; Patient Access and Drug Utilization; Product Quality Assurance; and Private Sector Pharmaceutical Activity.

These two sets can be used by countries as models when developing their own indicators.

- *Selected indicators:*

WHO/DAP developed a reduced set of indicators (see Annex) which could be used for the continuous monitoring of the world drug situation. This was done through an informal meeting which involved participants from Ecuador, Ghana, Indonesia, The Philippines, South Africa and experts from MSH and WHO²⁶. The compilation at the global level of this national-level data will allow the Programme, countries, and other partners to review trends and progress and to identify common patterns and differences in NDP development and implementation. Furthermore, it will enable lessons to be drawn which will assist Members States, the Programme, and other organizations to adjust or design strategies and policies.

Countries with limited resources can use this reduced set of indicators to monitor their own drug situation.

- *Country indicators:*

At country level, a number of sets of indicators have been developed, e.g. in Australia, Laos, Zimbabwe, etc. for covering different aspects of the policy. Unfortunately, these sets are not always easily available to other countries.

- *Manual on monitoring:*

In order to assist countries, WHO/DAP is preparing a manual on the process of implementing indicator-based monitoring in the drug sector²⁶. Although countries have used indicators to monitor progress against objectives and targets, few of them have succeeded in creating an organized system for collecting, processing, reporting, and using information on NDP on a continuous basis. A brief manual is needed to provide assistance on the practical aspects of organizing and managing such a system.

- *Policy analysis:*

Finally, policy analysis has been carried out in some of the countries involved in the comparative analysis of NDP, through the use of "Policy-Maker". Policy-Maker is a method developed by the Harvard School of Public Health with the support of a large number of organizations including WHO/DAP. It is a tool for describing the political processes involved in formulation and

implementation of policies; it also helps in developing strategies to manage the dynamics of policy decisions²⁷.

2.5 Who should monitor and evaluate NDPs?

Many different organizations and individuals are involved in implementing a national drug policy. The methods used for monitoring and evaluating the policy should be seen as representing an assessment of many initiatives, some which may be attributed to the Ministry of Health, others which may be initiated by other partners.

However, policy-making including development, implementation and monitoring/evaluation of the national drug policy is the responsibility of the state. Public policy-makers are responsible for the overall governance of the health sector including the drug sector. It is therefore the responsibility of the senior management personnel in the Ministry of Health to steer the monitoring and evaluation efforts.

All the partners should be associated with these efforts at least when developing the methods and the indicators which will be used to monitor and evaluate the initiatives of the policy. The fact that the Ministry of Health is responsible for these activities does not mean that the actual work has to be done by the Ministry of Health. This will depend on the country context and the human and financial resources available.

In many cases in the past these activities were carried out as part of essential drugs programmes. The advantage was that these programmes had more resources as they were often supported by donors, they were closer to the sources of information and they already collected data for programme monitoring. The drawback was that they monitored only activities under the programme, which basically meant drug supply in the public sector. When there is no other viable option, the Ministry of Health can continue to rely on these programmes as long as there is an effort to redefine and extend methods to cover all key aspects of the policy. This is not an optimal solution but it can work if the terms of reference for the monitoring and evaluation activities are clearly defined.

A second approach is for the Ministry of Health to contract the actual work of collecting and analysing data to a university already involved in data collection in the health field. In the research discussed previously on comparative analysis of national drug policies, two country teams (India and Viet Nam) were from university and they will probably continue to carry out the monitoring/evaluation activities for the Ministry of Health.

When the drug regulatory authority is a department of the Ministry of Health, often monitoring and evaluation is carried out by a unit of the department. However, NDP formulation, implementation and monitoring/evaluation is not only a regulatory issue and needs the input of many other sectors inside and outside the Ministry of Health. It is therefore important that the unit in charge is clearly identified as a policy-making body.

When the drug regulatory authority is a separate technical entity under the supervision of the Ministry of Health, it is preferable to keep a policy unit in the Ministry of Health. In certain cases, when the drug regulatory authority has more resources, the exercise of monitoring and evaluation can be left with them while the decision-making aspects remain with the Ministry of Health.

In any case, successful development, implementation and monitoring/evaluation of a national drug policy can be achieved only by strengthening the role of the state and Ministry of Health in standard setting, monitoring and evaluation of outputs/outcomes. This reform cannot be done in isolation; at country level, it should be closely linked to the health sector reforms which are generally geared toward the same objectives.

Bilateral agencies and DAP have an important role to play in this regard in assisting the Ministry of Health at national level to reorganize itself. More specifically, in the pharmaceutical field, bilateral agencies, international organizations and DAP should support institutional capacity-building in monitoring and evaluation through direct support to activities and through training of government staff and other individuals, as few people, mainly in least developed countries, have experience at a strategic or policy level.

2.6 Gaps and next steps

Although a number of tools and methods are available they are either not used enough or not complete enough. Therefore there is a need to improve tools and methods and to encourage a "culture of monitoring" in which staff at all levels of the drug sector understand and participate in the success of monitoring and evaluation activities.

Some of the following proposals were discussed during an informal consultation organized by WHO/DAP to share experiences in monitoring and evaluation²⁶, others arise from requests from regions and countries; others from research projects carried out in previous years. They include:

- Advocating the utilization of indicator-based monitoring and evaluation of the drug sector and the assignment of resources to that end.
- Promoting monitoring and evaluation as part of a "package" which includes a pharmaceutical policy and work-plan. If not viewed as an integral part of the strategic planning process, monitoring and evaluation activities should not be assigned scarce time and money.
- Identifying and promoting strategies to more successfully translate findings into policy.
- Preparing a guide to existing materials on monitoring (manuals, lists of indicators, appropriate literature) which includes a discussion of where they have been used, benefits and limitations, etc.
- Devising "modules" of indicators for monitoring at different levels (e.g., in health facilities) or on specific issues (e.g. how to measure equity of access to drugs, how to measure the effects of decentralization of drugs supply, how to assess capacity-building, etc.).

- Developing and offering a training course on monitoring and evaluation for policy-makers. In addition training of mid-level staff is a vital component of monitoring because the process is dependent upon accurate data collection.
- Developing further policy analysis methods adapted to the drug sector.
- Developing research on the policy process by identifying indicators to measure opposing and enabling factors.
- Developing operational research on improved methods and techniques to detect more sharply the effects of reforms/interventions and the causality links²⁸.
- Using the Essential Drugs Monitor and other publications to advocate monitoring and evaluation; reporting and soliciting articles on experiences in this field.

A number of these suggestions are already part of the plans of work of DAP for 1998-1999²⁹ including promotion and advocacy, training of policy-makers and senior management staff, and research on improved methods. For others, such as the production of modules for evaluating specific aspects of an NDP, further discussions are needed with the different partners of the Action Programme on ways to implement them.

3. Measuring the effects of DAP's work

3.1 Scope of work and definitions

Monitoring and evaluation are two complementary but distinct parts of the DAP management cycle. Monitoring refers to reviewing, on a continuous basis, the degree to which programme activities are completed and targets are met. This allows corrective actions to be taken during programme implementation. As said earlier, DAP has developed programme targets and indicators and ways to measure progress in implementing its programme of work. Each of the products listed in the 1996-1997 Proposed Programme Plan and Budget of DAP (PPB) and in the 1998-1999 PPB have a plan for implementation, including a list of activities leading to the completion of the product, a timetable with targets, milestones for tracking progress, and a corresponding budget.

Evaluation refers to assessing as objectively as possible the degree to which policies and strategies fulfill their stated goals. It should answer the questions: "Does the policy or strategy work? And if so, to what extent does it work?" The main goal of DAP being to ensure that people in need have access to and can benefit from the quality essential drugs that are appropriate to their health conditions, the evaluation should assess the difference DAP support makes to national action. One important limitation to this exercise is the fact that there are a large number of players which influence the pharmaceutical situation globally and at country level; DAP is only one of them. It is therefore often difficult to directly attribute achievements to DAP.

This chapter outlines methods for assessing the effects of DAP's work. These include both new methods as well as current methods which need to be applied more systematically. In addition, as a good monitoring system is fundamental to successful evaluation, it also suggests how monitoring in DAP can be improved. It includes therefore methods to assess:

- The effectiveness of DAP's work. This can be summarized in three questions:
 - (1) To what extent does DAP achieve its targets?
 - (2) What are the key factors that explain the extent to which DAP does or does not achieve its targets?
 - (3) Have activities been executed efficiently, and have costs been appropriate to the level of benefits?
- The effects (direct or indirect) of DAP's work on improving the availability, affordability, quality, and rational use of drugs. This can be translated into two questions:

(1) Does DAP's work make a difference?

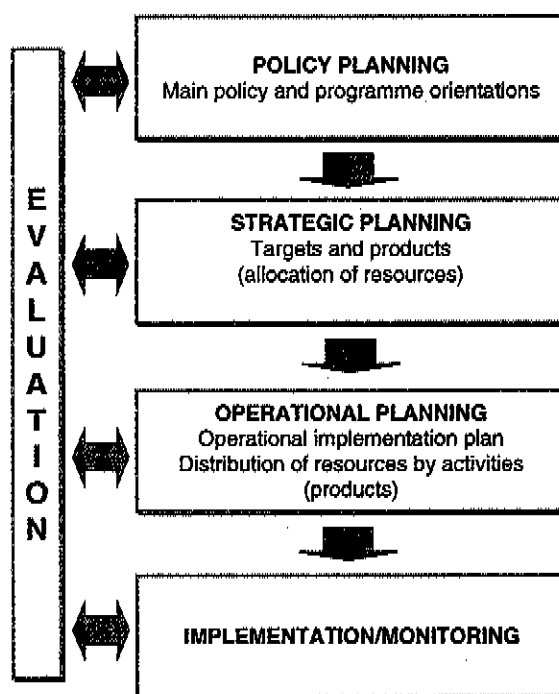
(2) Is the type of support provided appropriate (i.e. relevant to the main problems faced by countries) and adequate (can it be done differently or better)?

The methods proposed stem from a compromise between what is desirable and what is feasible. Evaluation is a necessary exercise but at the same time it is costly and time-consuming. The paper tries to focus on relatively low cost and non-complex evaluation methods, which may not provide detailed answers to everything we want to know but which will be sustainable in the long run and open to improvement.

These new methods will become part of the managerial process of DAP which includes:

- the definition of DAP's long-term goals, and main orientations (policy/strategies);
- the formulation of products and targets to be achieved during the biennium and the allocation of resources (strategic planning);
- the formulation of detailed planning of activities to achieve products within the plans of action and the distribution of resources by activities (operational planning);
- the systematic monitoring of progress and expenditures which relates regular monitoring of activities to financial reporting.

Managerial process



(Adapted from: Conducting policy and programme evaluation in WHO. Geneva, WHO, 1997. PPE/97.3).

3.2 What to measure: the policy framework

The new WHO Essential Drugs Strategy gives DAP's objectives and strategies³⁰. The Programme's ultimate goals are that essential drugs be equitably accessible to everybody, that drugs all over the world be of acceptable quality, and that drugs be used rationally. Achieving these goals will contribute to the reduction of morbidity and mortality.

In order to reach these overall goals, DAP has identified two global strategies:

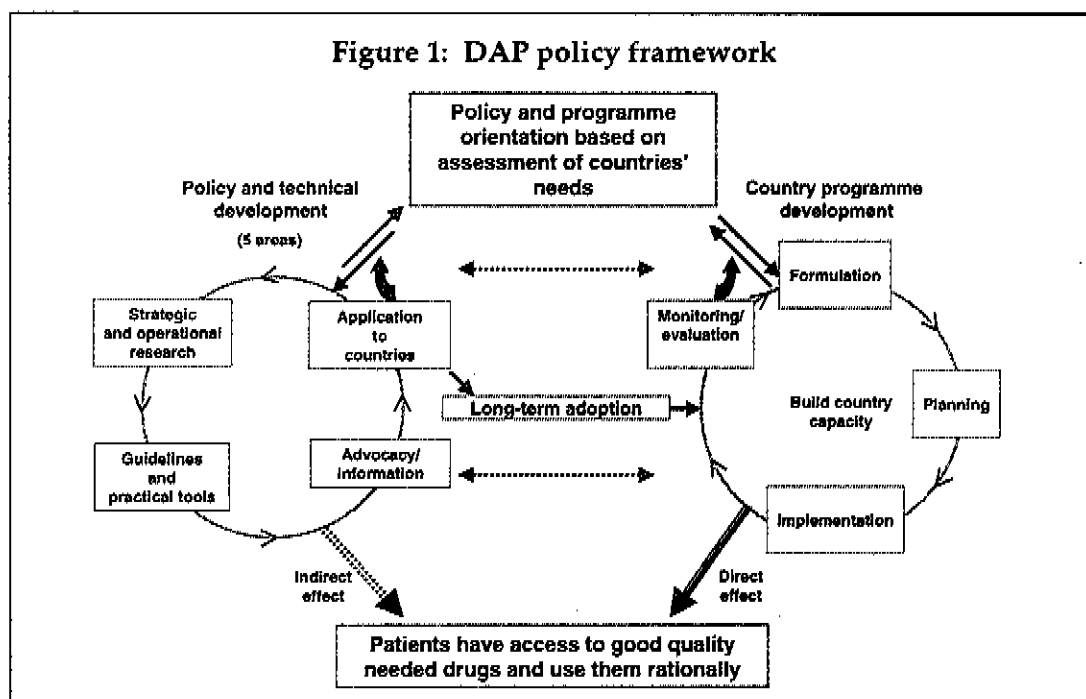
- *Country programme development* (CPD) which includes direct technical cooperation with countries. The specific objectives of CPD are to:
 - (1) Strengthen Member States' capacity to develop, implement and monitor national drug policies, in order to assist them in reaching the overall goals of access, quality, and rational use.
 - (2) Enhance knowledge and technical expertise of all stakeholders at global, regional, and national levels in strategies to develop, implement and monitor national drug policies.

Technical support is provided to a limited number of countries which are categorized into three groups based on a set of criteria developed by the Programme.

- *Policy and technical development* (PTD) which includes the identification, development, provision, and advocacy of technically and strategically sound policies, strategies, tools, and approaches to be used and adopted by all countries. Work is undertaken in five areas, which relate to the main problems encountered by countries and to the major objectives of national drug policies. These areas are: national drug policy process and monitoring; health economics and drug financing; access, drug management, and supply strategies; rational use of drugs; and regulation and quality assurance capacity.

These strategies will be pursued through the following key approaches:

- *Partnerships and collaboration* — to strengthen links with all concerned partners.
- *Strategic and operational research* — to generate, collect, analyse and disseminate research findings and experiences from around the world.
- *Guidelines and practical tools* — to develop manuals, guidelines, and training materials to be adapted by countries;
- *Human resources development* — to support the development of human resources as a key contribution to the sustainable development of the pharmaceutical sector.
- *Advocacy and information* — to disseminate and promote best practices and relevant information and materials.



We propose to use this framework as a basis for the evaluation and to measure:

- the effectiveness of DAP's work in implementing the activities under each of the global strategies: CPD and PTD;
- the direct effects of DAP's work through an analysis of the work done under each of the global strategies: CPD and PTD;
- the indirect effects of DAP's work on the pharmaceutical situation in the world.

3.3 Measuring the effectiveness of CPD and PTD

To what extent does DAP achieve its targets?

DAP currently develops plans of action which outline quantified targets and indicators. For instance, in the Proposed Programme Plan and Budget 1996-1997¹⁷ a specific target is: "quality assurance and regulatory control mechanisms will be built into the pharmaceutical systems in 15 countries receiving DAP support". The extent to which this target is achieved is measured with an indicator which has been defined as follows: "Number of countries with DAP support that have quality assurance and regulatory control mechanisms built into their pharmaceutical system". More attention will be paid in the future to the definition of targets and indicators, notably by qualifying the level of achievement. An example is given in Box 2.

Box 2: Example of objectives and targets in drug quality assurance for overall monitoring

Objective	Support countries in strengthening quality assurance and regulatory systems.
Target for end 1998	Increase capacity in Member States with greatest need to develop an effective drug quality assurance system.
Target group	Senior and mid-level managers in the drug regulatory authorities.
Quality	Training and technical advice provided according to WHO standards.
Numerator	Number of countries in need with personnel trained in setting up quality assurance systems.
Denominator	Number of countries in need.
Level of achievement	60% of countries in need have senior and mid-level managers with competence in QUA by end 1998.

What are the factors which explain the extent to which DAP is able to achieve its targets?

Knowing simply whether DAP activities succeed or fail is less useful than knowing why and where they succeed or fail. Failures and delays may be linked to inappropriate human resources, to over-ambitious objectives and targets, to problems at the country level or to other factors. Qualitative methods will be used to document the reasons for success and failure of key activities in CPD and PTD. This analysis will be done primarily by the Programme with the regional advisers every two years. In certain cases -- for instance, a target is not met in a large number of countries and the Programme does not understand why -- the Programme will require the opinion of individuals with extensive experience in the area concerned and, when necessary, organize focus group discussions in selected countries.

Have the activities been executed efficiently?

Analysing the efficiency of work performed will be facilitated in the next biennium, as it will be possible to link each product/activity with the funds spent. With that tool in hand, the Programme will be able to review if the resources are being used as well as possible, e.g. the level of the support provided to a country in relation to the cost, or the amount of resources spent for producing guidelines. It is proposed to review efficiency of support to countries while evaluating the effects of DAP support to countries, i.e. three country evaluations per biennium (see para. 3.4). For products under PTD, DAP will select each biennium three important products finalized during the previous four years and will perform an economic evaluation. The results will be presented to the MAC in a chapter on monitoring and evaluation of the report of the biennium.

3.4 Measuring the direct effects of CPD and PTD

Success in achieving immediate targets provides few clues to the real effects of DAP work in terms of improving the drug situation. For instance, the fact that 20 countries receive support from DAP in strengthening quality assurance and regulatory systems does not allow conclusions to be drawn on the quality of the support and the positive changes of the situation. However, identifying the direct effect of DAP work is not easy. It will be measured through a mixture of qualitative and quantitative methods, keeping a balance between the costs and benefits of evaluation. Different methods will be needed for each global strategy; and these are treated separately below.

Direct effect of CPD

Evaluation of DAP work in this area should be linked to the assessment of achievements at the national level. However there are important limitations to this exercise:

- Since information systems at the country level are often not developed to provide the necessary information, DAP may not be able to get all the data it needs.
- There are a number of players at the country level in the pharmaceutical field and achievements cannot usually be directly attributed to any one of them. In order to really understand what works and does not work in DAP support, there is a need to focus on DAP's work. When feasible, a distinction should be drawn between achievement and constraints which originate within countries and those which originate due to DAP support. In other words it is important to measure the difference DAP support makes to national action in solving some of the critical problems.

The main question is therefore:

- Has the country made a gain from cooperation with DAP?

It is proposed to answer this question through three approaches.

By reviewing in the countries where DAP is directly involved if intermediate and final objectives of a NDP are improving over time:

Intermediate and final objectives as discussed under 2.2 will be reviewed by using the indicators developed within the Programme, mainly the ones contained in the WHO Manual on Indicators for Monitoring National Drug Policies and the selected indicators (see Annex). The indicators will be used according to the type of support provided by DAP as explained below and shown in Table 2. A certain level of flexibility is however necessary as DAP support to countries should be adapted to the specific national context.

In type I countries, DAP support is intended to assist MOH and other partners in developing and planning a national policy or an essential drugs programme. Key additional activities such as establishing or updating an EDL or a drug legislative framework can be part of this support. Only a few indicators (e.g. the

ones marked with an asterisk in the Annex) will be collected regularly as part of monitoring of the activities. They will be included in the country plans of action and the results will be considered at the end of the biennium during the country reviews by the DAP professional responsible for the country and the national team. An example is provided in Box 3. The same team will also assess the relevance, quality and adequacy of the support provided and of the various products. The information will be stored in the DAP database at regional and headquarters level.

Box 3: Example of objectives, targets and products for type I countries

Objective: To increase country capacity in drug policy development and its operationalization

DAP targets:

1. By the end of 1999, DAP will have provided technical support to MOH for policy definition.
2. By the end of 2000, DAP will have cooperated with the MOH and other stakeholders to develop a strategy for drug policy consensus-building .

Products/indicators:

1. A national drug policy and masterplan for implementation.
2. A strategy for consensus-building on the national policy.

In type II countries, support is provided to strengthen the key components of the pharmaceutical sector, including monitoring. In these countries, at least all the selected indicators will be collected regularly; additional indicators using the WHO policy indicators as a model will be constructed and collected as needed. The biennial reports will include an analysis of the progress achieved and of the problems encountered. Special attention will be given to reviewing the role of DAP. As for type I countries the information on the selected indicators will be stored in the regional and headquarters database.

Finally, in type III countries DAP supports some specific activities. In each country, the selected indicators will be used in accordance with these specific activities as part of the biennium plan. Generally, specific activities should fall into one of the components and be covered by some of the selected indicators. However, if an activity is more sophisticated, a new indicator will be developed taking the WHO policy indicators as a model. As for the other countries, the analysis will be done at the end of the biennium. Data on the specific activities will be stored in DAP. When feasible, the selected indicators will also be collected and stored in the DAP database.

Country support type	Description	Monitoring/evaluation approaches
I: Long term policy and strategy development	<ul style="list-style-type: none"> • advocacy of the EDC, • national policy development, • programme development, • comprehensive framework for further support. 	<ul style="list-style-type: none"> • Few indicators from Annex, i.e. N°1 (a+b), 2, 7 (a+b). • Review of progress.
II: Intensified support in a limited number of countries	<ul style="list-style-type: none"> • advocacy, drug policy, • quality assurance, • supply and logistics, • rational drug use, • programme management. 	<ul style="list-style-type: none"> • All selected indicators and some additional ones as needed. • Review of progress.
III: Support to implementation of specific technical activities, e.g.:	<ul style="list-style-type: none"> • EDL, • international contacts, • research projects, • programme evaluation, • any other technical activity. 	<ul style="list-style-type: none"> • Few indicators as in type I countries. • Additional indicators according to activities carried out. • Review of progress.

By making in-depth evaluations of the effects of DAP support:

The regular reviews are not sufficient to assess thoroughly the effects of DAP support. They cannot provide enough insight into the exact role of DAP in influencing the national action in the direction of a more equitable access to essential medicines, mainly to poorer people. Indeed at country level there are many different interests which influence every aspect of the pharmaceutical sector from legislation to pricing or procurement policies. Only an in-depth evaluation can lead to an understanding of how DAP is able to influence positively the process of developing and implementing changes and the actors involved in policy reforms.

In each biennium the support of DAP will be evaluated in one country of each type (I, II and III). This means a total of three evaluations per biennium. Countries to be evaluated in type I and II will be selected randomly, with the exception of the geographical location. Countries from each region should be represented over a period of six years. For type II countries (all of them being financed by specified funds) the selection will also take into account the requests of the donors.

These evaluations should be participatory and DAP will develop guidelines to perform them in a "standardized" manner in order to be able to compare results

over time and between countries. These evaluations will look at effectiveness, efficiency, relevance, adequacy and sustainability of DAP support. They will also assess the main approaches used by DAP at country level: promotion and advocacy, and strengthening of institutional capacity. The first approach will be assessed by measuring the extent of the uptake by countries of concepts and strategies advocated by DAP. The second approach will be assessed by analysing what has been the influence of DAP on the development of human resources at different levels. It is suggested in this paper that simple methods such as analytical description of the changes and of the processes will be able to detect major achievements and problems and to evaluate the role of DAP's support.

In order for these evaluations to be fruitful, the Programme in the years to come will improve its "pre-support" assessment (baseline survey, definitions of objectives, targets and products) and will continue to promote monitoring as an essential tool for assessing performance and progress.

These evaluations will be carried out with the support of independent international and local consultants experienced in both evaluation and pharmaceutical policies. The funds needed for such an exercise will come from a specific separate allotment for type I and III countries (for which funds will be raised) and from the funds of each project for type II countries.

Through a survey of 20 people at country level and 20 people at the global level:

Experts in pharmaceutical policy will be requested to provide their opinion on the work of WHO in CPD and on the relevance and adequacy of DAP support.

The experts will be selected for their knowledge of processes related to the formulation and implementation of NDPs. The first group will comprise persons from countries at various levels of development and with different pharmaceutical coverage; it will include policy-makers, senior managers, and mid-level managers. The second group will comprise persons from different types of institutions: multilateral donors such as the World Bank and the European Union; the United Nations system such as UNICEF and other programmes in WHO; nongovernmental organizations; research and consulting groups; universities; and the pharmaceutical industry.

This exercise will be carried out through an anonymous open-ended questionnaire every four years. The preparation of the questionnaire and the analysis of the results will be done by a WHO Collaborating Centre.

Direct effects of PTD

Policy and technical development is a broad term for all DAP's activities which do not involve direct support to specific countries. It covers therefore a wide range of activities which aim at providing countries and organizations all over the world with the best technical and scientific advice. It includes research, production of guidelines, methodologies and other tools, advocacy, information and training. It is carried out through partnerships and collaboration with various organizations at global and country level.

The direct effects of such products are in most cases difficult to measure especially over a short period. There are however a few exceptions: the WHO Model List of Essential Drugs is one of them. Twenty years after the first model list most countries have a national list of essential drugs; The "Guidelines for developing national drug policies"²² have been widely used by countries. Many countries have a policy which contains most of the components described in the guidelines. However it is to-day still difficult to link the use of the guidelines and the development of NDPs to improvement of the pharmaceutical situation.

Because of these difficulties, at this stage the Programme will be rather modest in assessing the direct effects of PTD and will use proxy measures to do so. The work in each of the five areas of PTD will be assessed through different methods, presented in Table 3.

Questions	Methods
1. Is the material known?	Number of copies printed, distributed and/or sold.
2. Has it been developed with extensive participation of future users?	Assessment done by DAP.
3. Is it used?	This will be reviewed during the country evaluations and through the surveys described earlier.
4. By whom is it used?	This will be reviewed during the country evaluations and through the surveys described earlier.
5. Is it relevant to the most pressing needs of countries?	This will be reviewed during the country evaluations and through the surveys described earlier.
6. For materials related to training or applications of methodologies: <ul style="list-style-type: none"> • Have they been followed by training and/or any implementation activity by DAP? • Has there been uptake by others for training and/or research? 	<p>This will be reviewed during the country evaluations and through the surveys described earlier.</p> <p>This will be reviewed during the country evaluations and through the survey described earlier.</p>
7. How far have the concepts/policies advocated by the Programme been adopted by countries and other agencies?	Assessment by DAP through contacts with DAP partners and through web based surveys.

Data will be collected every two years when methods are not too complex (e.g. questions 1, 2 and 7) and every four years for questions where a survey is needed. Analysis will be done in DAP and presented to the MAC every four years. This analysis will be a useful tool to better link the activities of PTD to the ones of CPD.

3.5 Measuring the indirect impact of DAP work

The final objective of DAP's work is the improvement of the pharmaceutical situation in the world, mainly in developing countries. This means that people in need should have access to essential drugs and that drugs should be of acceptable quality and well used. DAP, through the development of policies/guidelines/methods, advocacy and information activities, capacity-building, etc. contributes to the fulfillment of this objective.

A measure of the progress achieved in countries will provide an indirect measure of the effects of DAP work.

Three methods will be used to monitor the world drug situation:

- *A regular update of the data on access to essential drugs in the countries throughout the world.* These data will be collected through a questionnaire to key informants every four years. The questionnaire and the selection of key informants will be prepared in close collaboration with the regional offices. The latter will be responsible for the collection of data. The analysis of the data will be carried out jointly with DAP and will be used to reassess global policies and strategies.
- *The collection of selected indicators in all developing countries (see Annex) on a regular basis.* The indicators measure some of the most important intermediate objectives of a NDP and the four final goals (availability of and accessibility to essential drugs, quality and rational use of drugs). This information will be collected by DAP every two years, stored in the DAP database, used on an ad hoc basis and analysed at regular intervals for publication in the world drug situation report. In view of the difficulties linked to the collection of accurate data in most of the developing countries, this exercise will begin with a rather limited number of countries already committed to monitoring. In order to use the indicators listed in the Annex with quantitative scores in multinational comparison, DAP will set notional targets which countries should meet. For example, process indicator N°5 of the Annex "Number of drug outlets inspected per year" will be converted to: "Proportion of countries surveyed in which "x" number of drugs outlets are inspected per year".
- *Creation of a network of a limited number of countries in different stages of development where more information will be collected regularly by DAP on key reforms in the pharmaceutical sector.* This will allow the Programme to document new ways of solving problems, other countries will then be able to learn from these sentinel countries what works, how it works and under what circumstances. Sentinel countries will be selected among countries which participated in the comparative analysis of NDPs and countries with innovative reforms of the pharmaceutical sector. Specific strategies such as decentralization of the drug supply or the establishment of an independent drug regulatory authority will be monitored over a number of years through quantitative methods (indicators) which will assess the content of the reforms and qualitative methods (policy analysis, political mapping, etc.) which will focus on the processes and the actors.

3.6 Implementing DAP monitoring and evaluation approaches

In order for DAP to monitor and evaluate more systematically the effects of its work, there is a need to reinforce at each level — country, region and headquarters — a culture of monitoring within the staff. It is argued in this paper that evaluation begins with a good monitoring system which carefully specifies targets and indicators. DAP is already quite far ahead compared to most WHO programmes in setting realistic and achievable targets. The work performed in the Organization as a whole in streamlining monitoring and evaluation could certainly be an opportunity for DAP to continue improving its monitoring and evaluation activities. A special effort will however be necessary to sensitize staff at all levels of the necessity to better assess and analyse the effects of the work done. It will be the task of the coordinator of "National drug policy methods and monitoring" to raise awareness and train staff in close collaboration with the coordinator of CPD.

It is expected that these combined approaches, summarized in Table 4, and an increased awareness of the staff at all levels will allow the Programme to better assess its effects on countries and its contribution to national action. This in turn should assist DAP in further developing its specific role on the drug scene and in adjusting basic programme strategies to achieve maximum impact with available human and financial resources.

Table 4: DAP monitoring and evaluation approaches			
Objectives/questions	Type of information collected	Frequency of collection	Sources of information
Measuring the effectiveness of CPD and PTD			
To what extent does DAP achieve its targets?	Quantitative data on targets.	Each year.	DAP monitoring system/Proposed plan and budget.
What are the factors which explain the extent to which DAP is able to achieve its targets?	Qualitative information (critical analysis).	Biennial.	DAP staff, regional advisers, eventually experienced individuals.
Have the activities been executed efficiently?	Qualitative assessment linked to financial data.	Biennial.	Country evaluation, DAP documents, DAP monitoring system.
Measuring the direct effects of CPD			
Has the country made a gain from cooperation with DAP?	(d) Review of intermediate and final objectives in type 1, 2, 3 countries.	Biennial.	Country plans of action. Country reviews.
	(e) In-depth evaluations.	Three per biennium.	Country reports + interviews.
	(f) Surveys.	Every four years.	20 people at country level/20 people at global level.
Measuring the direct effects of PTD			
Is the material known? Has it been developed with extensive participation of future users? How far have the concepts/policies advocated by the Programme been adopted by countries and other agencies?	Quantitative and qualitative.	Biennial.	DAP monitoring and information system.
Is it used? By whom is it used? Is it relevant to the most pressing needs of countries?	Quantitative and qualitative.	Every four years.	Evaluations. Surveys.
For materials related to training or applications of methodologies: • Have they been followed by training and/or any implementation activity by DAP? • Has there been uptake by others for training and/or research?	Quantitative and qualitative.	Every four years.	Evaluations. Surveys.
Measuring the indirect effects of DAP's work			
Global access to essential drugs.	Quantitative data.	Every four years.	Questionnaire.
Collection of selected indicators.	Quantitative data.	Biennial.	Questionnaire.
Creation of a network of countries.	Quantitative + qualitative methods.	Ongoing.	

4. Operational implications

The suggestions made in this paper include:

- (1) Increased national action in monitoring more closely the various aspects of the national drug policy and evaluating the effects of the changes introduced in the system.
- (2) Systematic evaluation of DAP's work and of its contribution to NDPs' objectives.
- (3) Improved follow-up of the pharmaceutical situation in countries.
- (4) Development of research, guidelines and training materials.

These suggestions have important implications for DAP in terms of financial and human resources. All the activities will not be carried out by DAP; however, the coordination, the advocacy, and the implementation of the activities will create additional workload for the staff of the Programme.

Some activities have already been planned for 1998-1999. It is suggested that as soon as the MAC has reviewed the proposals and agreed on them, a detailed workplan be prepared which will outline how activities will be organized and propose collaboration with different organizations in carrying out the plan. It is expected that monitoring and evaluation activities in countries supported by specified funds will be covered by these funds; for other activities, unspecified and regular budget funds will be used. A preliminary estimate suggests that the total amount spent on all these activities, including staff, should not exceed 3% of the total DAP budget. This amount does not cover activities such as the network of sentinel countries whose mandate goes far beyond the sole monitoring and evaluation role.

5. Conclusions

This paper has presented approaches and methods to evaluate pharmaceutical reforms at country level and to better assess the role of DAP and its contribution to national action. It has tried to keep a balance between the need to better know the effects of the actions of the various players on the final objectives of a NDP with the costs in human resources and time taken by evaluation activities. This can be done as proposed in the paper by being more careful at the planning stage of a policy or of DAP support in developing approaches and indicators which will then be useful when assessing the effects of the policy or of DAP support. It is also suggested in this paper that descriptive analysis of the actions taken and of their effects is a cost-effective way to identify strengths and drawbacks of actions taken at national level and by DAP and can lead to recommendations for policy changes. This has been done successfully in the past by DAP and others. It works as long as people carrying out these evaluations understand the critical issues and ask the right questions. The same applies to questionnaires proposed in the paper. It is therefore important to prepare simple guidelines that will orient people to better use some of the approaches described in this paper.

There will always be a need for hard data which are often difficult to collect and analyse; in view of this the paper advocated that more importance be given by governments, international agencies and others to training of staff at all levels in monitoring and evaluation and in the use of the results of these activities.

In conclusion, it should be remembered that even when using valid methods and asking good questions it is often very difficult to be sure that the changes observed are due to the interventions or to the reforms; changes do not take place in a laboratory. The pharmaceutical sector is complex, with many external and confounding factors such as the macroeconomic situation and the international treaties, influencing the final outcome. Therefore, even if progress is evident over a certain period, it is often difficult to relate cause and effect. Operational research is needed to identify more precise tools to assess causality links and to ensure that the evaluation efforts contribute by their accuracy to more equitable access to essential drugs, mainly for the poorer people.

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Annex

Draft selected indicators for monitoring the world drug situation

COMPONENT 1: POLICY, LEGISLATION AND QUALITY ASSURANCE
1. (a) Is there an official national drug policy document updated in the past ten years? ^{* a} (b) Is there a current implementation plan? (ST1) ^{b*}
2. Have regulations based on the drug legislation been issued in the past five years? (ST3) [*]
3. Are there controls on drug promotion based on regulations and consistent with the WHO ethical criteria for medicinal drug promotion? (ST11)
4. Total number of registered drugs (active and formulations). (BG30)
5. Number of drug outlets inspected per year. (PR1)
6. Number of samples tested per year. (PR5)
COMPONENT 2: ESSENTIAL DRUGS SELECTION
7. (a) Is there a national essential drugs list/formulary using INN officially adopted and distributed countrywide? (ST12) [*] (b) Has the national essential drugs list/formulary been updated and distributed countrywide in the past five years? (ST14) [*]
8. Total number of drugs on the national essential drugs list (INN). (BG31)
9. Percent of essential drugs prescribed in the public and private sectors. (PR9)
COMPONENT 3: PROCUREMENT AND DISTRIBUTION
10. Is procurement in the public sector limited to drugs on the national EDL? (ST28)
11. Is there a system for monitoring supplier performance in the public sector? (ST25)
12. CIF/ex-factory value of a basket of drugs, out of "reference" value on the international market of the same basket in the public sector. (PR22)
13. Number of drugs beyond the expiry date, out of the total number of drugs surveyed. (OT6) (To be reformulated)
COMPONENT 4: DRUG FINANCING AND PRICING
14. Total public drug expenditure per capita. (BG17)
15. Total drug expenditure (public+households+international aid) per capita. (BG19)
16. Are drug prices regulated in the private sector? If not, are they monitored? (ST37)
17. New indicator to be developed on generic prescribing and dispensing.

^a The asterisks refer to the indicators which will be collected for review of countries (see Table 2).

^b The number in brackets refers to indicators in the WHO Manual for Monitoring National Drug Policies

COMPONENT 5: RUD STRATEGIES
18. Is there a national therapeutic guide with standardized treatments? Has it been updated in the past five years? (ST43)
19. Is the concept of essential drugs part of the curricula (min. 10 hours) in the basic training of: a. pharmacists; b. doctors; c. nurses? (ST44)
20. Are there therapeutic committees in the major hospitals which have met in the last six months? (ST48)
21. Are there public education campaigns on drug use? (ST49) (To be reformulated)
AVAILABILITY
22. Number of drugs from a basket of drugs available in a sample of remote health facilities, out of total number of drugs in the same basket. (OT1)
AFFORDABILITY
23. Average retail price of standard treatment of pneumonia, out of the average retail price of a basket of food. (OT3)
QUALITY
24. Number of drugs/batches that failed quality control testing, out of the total number of drugs/batches tested, per year. (OT5) ^c
RATIONAL DRUG USE
25. Average number of drugs per prescription. (OT7)
26. (a) Number of prescriptions with at least one injection, out of the total number of prescriptions surveyed. (b) Number of prescriptions with at least one antibiotic, out of the total number of prescriptions surveyed. (OT8)
27. Number of drugs from the national EDL, out of the 50 best-selling drugs in the private sector. (OT10)
OTHER DATA
Total number of pharmacists. (BG23) ^d
Total number of pharmacy technicians or other aides/assistants. (BG24)
Total number of drug manufacturing units in the country. (BG25)
Total number of wholesalers in the country. (BG26)
Total number of pharmacies and drug outlets in the public sector (including health facilities and hospitals that dispense drugs). (BG27)
Total number of pharmacies and drug outlets in the private sector. (BG28)

^c In many countries sampling of drugs is based on past quality problems or because one expects quality problems connected with particular products. Therefore the number of samples failing testing may be high and does not reflect the average failure rate of drugs on the market. For this indicator to be useful the criteria for sampling must be known.

^d Can be disaggregated further by specific categories – public/private.