



REPORT OF THE SECOND MEETING
OF INTERESTED PARTIES
Geneva, 22-24 June 1988



ACTION PROGRAMME ON ESSENTIAL DRUGS AND VACCINES

World Health Organization
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SUMMARY

The Second Meeting of Interested Parties (MIP) of the Action Programme on Essential Drugs and Vaccines met in Geneva from 22-24 June 1988 and was attended by 70 representatives from governments and agencies. The meeting undertook the following:

1. It received and discussed a report on the progress and plans of the Action Programme within the context of the WHO Revised Drug Strategy. It praised the Programme's activities and direction and emphasized that essential drugs programmes are long-term endeavours which must be supported on that basis.

2. It reviewed and adopted a proposal for a Management Review Committee as a formal advisory body to the Programme. Terms of reference of the committee were agreed and would be submitted to the Director-General for approval.

3. It reviewed and adopted a proposal for the external evaluation of the Action Programme to be in three parts:

- i) A global assessment of the Programme's activities;
- ii) UNIPAC activities;
- iii) Country programmes.

A Reference Group was established to finalise the draft terms of reference of the evaluation.

4. It agreed to convene its third meeting in Geneva in December 1988: the Agenda to include, inter alia, management and financing of the Programme, research strategy and cost recovery.

This report is based on an edited and shortened version of the transcripts of tapes from the meeting.

1. INTRODUCTION

70 representatives of government agencies and organizations attended the Second Meeting of Interested Parties (MIP), convened by the WHO Action Programme on Essential Drugs and Vaccines from 22-24 June 1988 at the World Health Organization (WHO) Headquarters in Geneva to consider:

- (a) the progress and plans of the Action Programme, including the progress of WHO's revised drug strategy;
- (b) the possible establishment of a Management Review Committee;
- (c) plans for an external evaluation of the Programme;
- (d) technical cooperation among developing countries.

The participants of the meeting are listed in Annex 1.

2. OPENING OF THE MEETING

The meeting was opened by Dr H. Mahler, Director-General¹ WHO, who sketched the history of the essential drugs concept since its emergence in 1977, the initial coolness of its reception and its gradual but still only partial acceptance. Now, however, more than 100 countries have their own national lists of essential drugs, and some 40 are engaged in the process of developing and implementing a more rational drug policy along lines they have collectively approved in the World Health Assembly.

But, despite the progress made, much still remains to be done: a rational selection of drugs; more accurate estimates of drug requirements; better procurement and financing methods; improved warehousing and distribution of drugs; accelerated local production; better diagnosis and therapy; and the introduction of the essential drugs concept into medical education. Countries will have to seek ways and means of recovering the cost of services, as exemplified by the Bamako Initiative in Africa, which aims to use essential drugs to ensure better maternal and child health within the context of primary health care. With commitment and vision on the part of countries, it will be possible to make the essential drugs of today and tomorrow permanently available to the half of the world that most needs them and at present has no real access to them.

The meeting elected as chairperson, Mrs Barbara Kelly (United Kingdom of Great Britain and Northern Ireland) and as Rapporteur, Dr Ali Sallami (Democratic Yemen).

3. ADOPTION OF THE AGENDA

The representative of the Netherlands proposed that an item should be added to the provisional agenda to permit discussion of the possibility of setting up a management review committee or some similar mechanism for the Action Programme. This proposal, which was supported by the representatives of Denmark, Mexico, Pakistan, and Sweden, was accepted.

The provisional agenda, as amended, was approved (see Annex 2).

¹ At the time of the meeting, now Director-General Emeritus.

4. PROGRESS REPORT ON WHO'S REVISED DRUG STRATEGY

4.1 Summary report

Dr E. Lauridsen, Programme Manager, Action Programme on Essential Drugs and Vaccines, described the progress that has taken place. Whereas, in the past the essential drugs concept appealed more to the smaller of the less developed countries, it is now gaining acceptance in such larger countries as Mexico, Nigeria, Pakistan, and Vietnam. Nor has any country reversed any policy it has adopted in relation to that concept. More than 40 countries have progressed from the formulation of an essential drugs policy to its implementation, and some have achieved almost complete coverage of their rural population at a cost they can afford. Evaluations in many countries have shown that, at an annual per capita cost of US\$1.5 or even less, it is possible to provide the essential drugs needed on a regular basis. This has been achieved in some countries by drawing on their own resources, by others with aid from United Nations agencies, bilateral agencies, or nongovernmental organizations, or a utilization of all of them. As is shown by the example of Papua New Guinea, it is possible to formulate a rational drug policy and implement it within a reasonable number of years, and this can be done in countries of very different political, economic, and cultural backgrounds. It is therefore not over optimistic to believe that the rational use and coverage of essential drugs will increase dramatically within the remaining years of this century. Nor has the Action Programme, which aims at promoting such an increase, been a costly one; since its inception the allotment from WHO's regular budget has been approximately US\$4.5 million and the extrabudgetary support approximately US\$25 million.

Within the past year, guidelines for developing national drug policies, for the establishment of a small drug regulatory agency, ethical criteria for the promotion of medicinal drugs, a manual on estimating drug requirements and a report on the world drug situation have been issued. An improved version of the WHO Certification Scheme has also been developed. These complement the technical and training material already produced and furnish countries with much of what they need to launch an essential drugs programme. The Action Programme is also developing a market information system on the prices and sources of supply of pharmaceutical materials, using the experience gained, along with UNICEF, in price information on generic essential drugs. UNICEF is now reporting reference prices every six months and this, it is believed, has had the effect of lowering the prices of common generic drugs in the world market. It is hoped that the new market information system will do the same for raw materials.

There remains the problem of introducing the essential drugs concept into the curriculum of medical and pharmacy students. Only a handful of universities and colleges have done so but the issue is one of priority in the Action Programme, and every effort will be made to persuade more teaching institutions to incorporate the concept in their training.

The Action Programme is not concerned with basic drug research, but with the application of proven scientific and technological results and with operational research. Innovative drugs can be quickly included in the list of essential drugs, an example being ivermectin for onchocerciasis when it was barely out of clinical trial. In operational research a number of studies have been started on such poorly known subjects as the cost of medicine to the individual family, how modern medicine is perceived as compared with traditional medicines, and the interaction between the prescriber or dispenser and the user of medicines.

A social science network is also being created throughout the world to facilitate collaboration in such research and the communication of findings. To ensure that the message reaches all concerned, a comprehensive communication strategy is being developed covering a range of informational and promotional materials, including audiovisual material, position papers, and technical information packs.

Finally, the planning and management system within the Programme has been tightened up, and the recommendations of the internal management survey have been followed.

A number of participants spoke on the Action Programme. Some countries have bilateral projects involving essential drugs, while others use multilateral channels for their contributions. A number provide bilateral aid in accordance with the WHO essential drugs policy and strategy and in conformity with WHO guidelines. It was stressed that the essential drugs policy forms an integral part of primary health care, though one participant wondered just how coordinated they are in fact. The operational research component was held to be important; there is a need to assess the effect of essential drugs on the health of people, to cooperate with professional associations in relation to the rational use of drugs, and to train all the personnel concerned appropriately. For this latter purpose it is desirable that WHO should recommend that the essential drugs concept be added to the medical and pharmacy curricula. But that is not enough. To ensure that essential drugs are used as they should be, proper diagnosis and proper care of disease are needed from the primary health care to the highest level, and there should be training to prescribers, training in management, help in quality control, and local manufacture of pharmaceuticals. All of these need time; essential drugs programmes are long-term endeavours, and they should be supported on that basis.

It was suggested during the discussion that generic names should be used alongside brand names, if the latter are used at all. It was also suggested that the pharmaceutical industry should limit the number of drugs it produces. People in a recipient country, when they discover that developed countries have a great many more drugs available to them than they have, suspect that they are being deprived. It is therefore of vital importance to keep the public informed, to explain this and other aspects of the essential drugs concept and the work of the Action Programme, so that people do not harbour suspicions about the Programme that will prevent it from being effective.

4.2 Action Programme: Progress report and planned activities in major programme areas

4.2.1 Country Support

Mr G.D. Moore, Action Programme, said that the Programme helps countries to select drugs in a rational way, according to their effectiveness, safety, and cost and in the quantities estimated to be required. It stresses quality assurance for the drugs, pre-screening of the manufacturers, establishment of the specifications for tender documents, and testing before and after purchase. The Programme works with UNICEF/UNIPAC for bulk procurement of drugs, the kits it and other agencies supply being very successful; and it encourages cooperation among smaller countries to cut costs by bulk purchase of drugs.

It has succeeded, for example, in bringing down the price of aspirin from about US\$5 per unit to US\$1.25. The Programme tries to ensure that ministries of health have sufficient financial resources to buy and distribute the drugs needed. It is becoming increasingly involved in advising countries on how to recover the costs of drugs prescribed and is working with the World Bank on establishing revolving funds and cost recovery systems.

To ensure that drugs are used rationally, training is required for all health workers, not only in pharmacology but also in prescribing, the management of procurement and supplies, quality control, and other subjects. The Action Programme offers advice on these matters, organizes seminars, and provides training material. Through the Essential Drugs Monitor it attempts to inform all concerned about essential drugs programmes in countries and thereby to promote the essential drugs concept.

For all this support to countries, from situation analysis to establishment and implementation of an essential drugs programme, the Action Programme has since January 1987 put in 200 person-weeks in 72 missions to countries, not including those of consultants recruited by the WHO Regional Offices. In the same period some 25 seminars have been held and a number of manuals on such subjects as training and drug storage produced. The Programme promotes regional cooperation, the local supply and production of drugs, local quality control centres, harmonization of registration requirements, and contact with international organizations. In 1983, 78% of the countries in the world had no essential drugs activity of any importance. Now only 34% are in that position.

4.2.2 Development work

Mrs M. Helling-Borda, Action Programme, said that the aim of development work within the Programme is to provide guidelines, methodologies, and training materials to implement national drug policies and promote rational drug policies and drug use within countries. The Programme has issued a new set of guidelines on the estimation of drug requirements, which includes two methodologies, morbidity/standard treatment methodology and one based on past consumption. These methodologies have been tested in 6-8 countries.

Another development area is educational material for patients, dealing with, for example, how to take drugs. Guidelines and recommendations have also been used for the financing of drug supply and logistics. Manpower development, legislation and regulatory control, monitoring, evaluation, and the promotion and dissemination of information are all included in the Programme's development activities and are reported in the Essential Drugs Monitor. This journal, which began in 1986 with 3000 copies, has grown to 20 000 copies in three languages, English, French and Spanish. WHO helps countries to draft pharmaceutical legislation and holds workshops on all aspects of the essential drugs concept.

It has developed close collaboration with many international organizations and institutions concerned and with national pharmacy associations, but less so with medical associations. The emphasis of future development work will be on training, economics, logistics and, indicators for monitoring and evaluation purposes.

During the discussion on development work the question was asked whether the French-speaking countries of sub-Saharan Africa have been overlooked in essential drugs activities. Dr Lauridsen, Action Programme, said that a pre-requisite of help is that the country should itself ask to be helped; few French-speaking countries in sub-Saharan Africa have requested aid in developing essential drugs policies and trying to bring about a rational use of drugs. The possible reason for this is their close association with France, which means that they do not have the problems with foreign exchange of other countries; with Bamako Initiative requests for assistance may increase.

4.2.3 Training

Dr G. Walker, Action Programme, said that the Programme is continuing with work to promote and facilitate the inclusion of the essential drugs concept in university curricula. On request, it provides consultants to help university departments, medical faculties, and pharmacy schools to reorient their teaching towards the rational use of drugs. It provides consultants to help with seminars in countries on the rational use of drugs. It continues to collaborate with the network of universities established to introduce new curricula into the basic medical and pharmacy training programmes. It intends to develop specific materials to assist the teaching of the rational use of drugs.

It is commissioning a monograph on good prescribing practices and one on clinical pharmacology. It hopes to cooperate with McMaster University, Canada, in a project to establish an international programme in pharmaco-epidemiology.

In 1989 the WHO Regional Office for Europe will convene a meeting of university medical faculty members to review experience in the teaching of rational drug use. The Programme also intends to hold a working group meeting to review manpower development in rational drug use and make recommendations. It hopes to improve information on the subject by helping countries to issue drugs and therapeutics bulletins.

4.2.4 Cost recovery

Ms S.D. Foster, Action Programme, said that a workshop on financing drug supplies held in Harare, Zimbabwe, discussed ways and means of improving efficiency of national essential drugs programmes and eliminating waste. It noted a trend in some countries towards reducing the proportion of their overall budget allotted to health, a trend that required watching.

In discussing cost recovery it considered a number of alternative steps: the reallocation of resources within the health budget; a search for increased external aid; the levy of taxes or an increase in the taxes on, for example, tobacco and alcohol; the creation of lotteries whose profits would go towards payment of drugs. A problem in relation to direct cost recovery is that it will be in local currency, not easily changed into the hard currency usually needed in many countries. Another problem is the administrative costs that will inevitably be involved. Nor is it easy to impose charges when the people are accustomed to receiving drugs free. In any case the imposition of charges is likely to reduce the number of consultations, as in Ghana. There are many problems and many possibilities, all of which must be examined in the light of the situation in each individual country; and the expectations for the option chosen must be realistic.

The Action Programme is issuing in 1989 a special number of the Essential Drugs Monitor dealing in the whole question of financing the supply and distribution of essential drugs.

Some participants preferred the term cost-sharing to cost recovery, the representative of Sudan adding that in his country the term used is self-help, all patients without exception paying for drugs. Because of their weak economic situation, it was observed, many countries cannot afford to supply drugs free of cost; the community must pay its share. In Mexico that share is used to improve clinical and other facilities, roads, schools, and sewage works; the population is supplied with the basic essential drugs.

In Kenya the payments made by patients go to the health system; the community builds its own clinics and the government provides staff and drugs; and patients pay for hospitalization and claim from a hospital insurance scheme.

Elsewhere there is a danger that money paid by patients may be credited to state resources in general and lost to the health services. A problem in many countries is that many people do not live within a cash economy and do not possess the means to pay for drugs.

An answer, it was suggested, is to adapt the method used to meet the diversity of situations in different countries. It was also stressed that cost recovery should be viewed in the light of its effect on primary health care, especially in sub-Saharan Africa.

4.2.5 Operational research

Ms P. Brudon-Jakobowicz, Action Programme, said that, despite the progress achieved, 2000 million people still have no regular access to essential drugs. Among the reasons are the lack of financial resources and especially the lack of hard currency; absence of political will and/or of managerial capacity, so that no attempt is made to assess requirements or select drugs; the existence of conflicting priorities, as between the public and the private sector; and the difficulty of acquiring the technology needed and the supplies of starting materials for local manufacture. These problems, are merely a few of the many that face developing countries.

In developed countries too drugs are used irrationally: prescribing practices follow no rules; self-medication is full of risks; patient compliance is often poor, and people mingle modern and other medicines without thought just as much as in developing countries. Hence the need for operational research.

In 1984 the Programme started operational research with three objectives. The first was to obtain information that would help solve some of the problems described, for example on household expenditure on drugs or on the behaviour of patients and prescribers in relation to drugs. The second was to improve national essential drugs programmes by examining problems and bottlenecks, to see, for example, whether cost recovery leads to fewer attendances at health centres or affects drug consumption. The third objective was to strengthen the capacity of institutions in countries by organizing workshops using research workers from the country, sending consultants, and supplying equipment and other forms of aid.

Research proposals come from countries - but these are not so far very numerous - or from the Programme. A relatively new development that will assuredly increase in scope, is a support network of specialists from countries. Research is being carried out on the effects of temperature and humidity on drugs despatched to Africa and Asia. Other subjects are the assessment of morbidity, the social impact of the Action Programme, community attitudes to drugs, and why some people prefer injections to oral consumption.

In the discussion it was said that training materials and guidelines are needed. An Action Programme staff member pointed out that they are in fact available as general outlines and specific protocols for countries. Among the unanswered questions mentioned are population coverage, non-compliance, and the effect of drugs on health, and these and other questions needed systematic consideration. A participant noted that drug utilization studies are difficult to conduct in developing countries.

It was felt that the Action Programme should consider how to support its research capacity, perhaps envisaging the possibility of twinning arrangements between institutions in developing and developed countries. A staff member of the Action Programme said that the future strategy will be discussed at a meeting in Nairobi in autumn 1988. A project proposal on the effect of essential drugs programmes on health has been approved and the project, which involves the World Bank and a US institution, will be carried out in Tanzania. Other collaboration is with UNHCR, the League of Red Cross Societies, and other non-governmental organizations in revision of the emergency health kit.

4.2.6 Management and administration

Dr E. Lauridsen, Action Programme said that all the of activities of the Programme are aimed at improved availability or the more rational use of drugs. Of the resources at the disposal of the Programme 70% go to country support, some 10% to development work, 3% envisaged to increase to 10% - operational research, and the remainder to administration, including information and communication. Each professional staff member is assigned to a specific country or group of countries for which he or she is specially suited because of his or her language, orientation, and experience. All activities must meet a number of criteria before they are started; they must be based on a request, and they are assessed in terms of the probability of a successful outcome. An internal project management sheet states a clearly defined objective, the justification for the project, the implementation steps, and the cost estimate. Data are collected so that projects can be seen as a whole in individual countries and in regions. The present financial situation of the Programme is satisfactory.

4.3 Pharmaceuticals Unit: Progress Report

Dr J.F. Dunne, Pharmaceuticals, said that his unit has been responsible for International Non-proprietary Names (INN) for the past 40 years. The new challenge in that area relates to generic prescribing. Because of the emphasis on generic prescribing, more and more pharmaceutical manufacturers seek to produce generic products with brand names derived from the INN. This has produced confusion and may cause a breakdown in the systematic development of international nomenclature, because any manufacturer with a trademark similar to or based on an international non-proprietary name is legally entitled to prevent WHO from using any name similar to that of the brand name. WHO itself uses similar names for related groups of drugs and in those circumstances orderly evolution of the system could be disrupted.

The unit is also responsible for the International Pharmacopoeia. No manufacturer produces drugs to the specifications of that pharmacopoeia, but it is very useful to developing countries with small laboratories that wish to check imported materials or materials within the distribution chain.

It has been found that many of the longer established substances in the Essential Drugs List are of uncertain stability. The unit is now sponsoring accelerated stability testing of many of these substances and their dosage forms, which is of vital importance to developing countries. It is also concerned to see more rigorous administrative controls applied to exported substances and products, both branded and generic, through the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce. It perceives the Scheme as the basic administrative mechanism for drug registration in countries largely dependent on imported products, and for stemming growing concerns about trade in counterfeit and spurious products.

The unit is required to produce model prescribing information to complement its work in maintaining and updating the WHO Model List of Essential Drugs. This requires extensive consultation, but the work is well advanced for drugs for parasitic diseases, anaesthesiology and neurological agents and consultations are already in hand for antimicrobial drugs.

The unit collaborates with drug regulatory authorities and the 5th International Conference of Drug Regulatory Authorities will be held in Paris in 1989. The unit also produces a monthly pharmaceutical newsletter, which is issued to all national authorities and a quarterly subscription publication entitled WHO Drug Information. A consolidated list of products that have been withdrawn, banned, or highly restricted is prepared annually in collaboration with the UN Secretariat.

Together with a collaborating centre in Uppsala, Sweden, it produces composite tables of adverse drug reactions reported by doctors in 26 countries. There is also in Sweden an important collaborating centre that produces international reference substances for use in the International Pharmacopeia. The unit also collaborates with the International Council for International Organizations of Medical Sciences (CIOMS).

During the discussion it was stressed that a certification scheme for the quality of starting materials, now endorsed by WHO, is necessary to establish their "pedigree". At present, such importing authorities often have to secure information on where the materials are manufactured, and they have no acceptable guarantee of quality. Dr Dunne said that no exporting countries should be prepared to countenance the export of pharmaceutical products or substances unless their quality, at least, is assured. As yet many developing countries have no effective licensing systems and no pharmaceutical inspectors. Even in developed countries inspectors are in short supply. This operates to the advantage of unscrupulous manufacturers who, in recent years, have become organized internationally to the extent that they escape from the sanction of law within the countries from which they operate, by sending faulty goods abroad.

5. PRESENTATION OF REPORTS BY COUNTRIES

A number of representatives of countries (Bangladesh, Kenya, Mexico, Nigeria, Pakistan, Papua New Guinea, The Philippines, Vietnam, Democratic Yemen and Zimbabwe) described the essential drug policies and programmes in their countries, the problems arising, and the solutions being sought, and the help provided by WHO and other international bilateral agencies. The main problems are financing, the shortage of hard currency, the absence of local manufacture of drugs and of trained staff, the difficulty of assuring quality control, and relationships with the pharmaceutical industry. Other country representatives (Denmark, Federal Republic of Germany, Finland, Italy, Japan, Netherlands, Norway, Sweden, Switzerland, United Kingdom and United States of America) expressed their support for the essential drugs concept and described their bilateral programmes and participation in multilateral programmes in this area.

Bangladesh

The representative of Bangladesh said that the consumption of drugs in his country is among the lowest in the world. In 1982 the Government introduced a national drug policy giving priority to the production of essential drugs and the removal from the market of harmful, useless, and undesirable products. Guidelines were issued to that effect. The number of essential drugs was fixed at 150, of which 45 were for primary health care and the others for the higher health care levels. A Drug (Control) Ordinance was enacted in 1982 to give effect to this policy.

The present position is that the local drug manufacturing industry has adjusted itself well to the new policy, the value of its production having risen from US\$52.55 million in 1981 to US\$122.67 in 1987. The share of the 45 essential drugs for primary health care, which was 30% in 1981, has risen to 75%. Local companies now produce 59% of the drugs manufactured locally, as against 35% in 1981. There has been a significant fall in the prices of many drugs. Nevertheless, 10-12% of the total requirements of drugs are still being imported. But prescribing is more rational and there is no scarcity of generic essential drugs.

In 1985 the Government entered into an agreement with the Governments of Denmark and Sweden on a pilot project for balanced health services delivery through improved drug supply and training to make good quality essential drugs available at minimum cost and in sufficient quantity at the primary health care level. The project started in 1987 and was extended after a year's trial. Priority at present is given to quality assurance, and the facilities of the Drug Testing Laboratory have been improved. Steps are being taken to introduce the essential drugs concept into the medical and pharmaceutical curricula, the dissemination of information about essential drugs is being promoted, and a national formulary for essential drugs is being compiled.

Denmark

The representative of Denmark stated that DANIDA had supported the essential drugs strategy, both multilaterally and bilaterally for a number of years. Support is currently being given to programmes in six countries: Bangladesh, together with SIDA and IDA; Bhutan, together with WHO; Kenya; Uganda, where the project is being executed by the Danish Red Cross; Tanzania, together with UNICEF, and Zimbabwe. Additional bilateral programmes are planned in Sudan, Central America, Ethiopia and Mozambique. WHO has assisted in the planning and implementation stages of all this work. It has also provided valuable technical assistance in the field of selection and quantification of drugs, quality control and training, and information. Even more importantly, WHO's essential drugs policy and strategy, as well as the concrete WHO guidelines, have been used continuously as a frame of reference in negotiations with local authorities. DANIDA is confident that the very useful collaboration with WHO in this area will continue in the years to come. In view of today's many challenges, the economic crisis facing many developing countries and the connected debate about user payment and recurrent cost, it is necessary to realise that ensuring access to essential drugs is a process which must be seen in a long-term perspective, for sustainability and maintenance are very important and integrally linked to the development of the ongoing programmes.

Federal Republic of Germany

The representative of the Federal Republic of Germany stated that his country was a major pharmaceutical producer. It fully adheres to and supports the WHO essential drugs concept as a very helpful and useful instrument to improve the health situation in developing countries. It has some bilateral activities - although not in very close cooperation with WHO - which include aspects of the essential drugs concept, and these are mainly carried out by an organization called Gesellschaft für Technische Zusammenarbeit (GTZ).

The representative of GTZ took the floor to explain that his organization works mainly in the field of quality control, it is also involved in primary health care and medical supply activities. The GTZ has undertaken an inter-regional study on appropriate drug production for primary health care. Its advisory services and cooperation which are on an independent basis and free of commercial bias, focus on: developing national drug strategies, including legislation and corresponding registration procedures; setting-up government drug quality control systems; organizing and administering warehousing and distribution systems in rural areas; standardizing the supply and prescription of drugs; developing cost-sharing systems, including simple forms of insurance; training laboratory, logistic and commercial personnel; setting up hospital pharmacies; and establishing systems to provide independent drug information. For example, in Peru GTZ helped in organizing a quality control institute for basic drugs. In Brazil it is cooperating with a quality control institute. In Indonesia a quality control project has just been completed and a new project on pharmaceutical drug supply of hospitals started. In Cameroon, help has been given in setting up a drug supply system. There are also activities in the field of traditional medical plant research, especially in Thailand and now starting in Sri Lanka.

Finland

The representative of Finland stated that his country recognized the importance of essential drugs to the development of primary health care and in the past years had supported the Drug Action Programme by providing a modest, but steady, amount to help Bhutan. As an indication of continued Finnish interest and support FINNIDA has agreed to finance another essential drugs programme, through the Action Programme, in Burma. The total value will be approximately US\$2.5 million in 1988-91.

Italy

The representative of Italy stated that the Italian Government is highly supportive of all components of the Essential Drugs Programme and actively engaged in supporting the development of the essential drugs programmes in various developing countries. At present through its bilateral programme it contributes to the local production of drugs in Indonesia and Somalia, and of intravenous fluids in Burkina Faso, Kenya and Zaire.

Furthermore, in cooperation with UNICEF and WHO, it supplies essential drugs to Burkina Faso, Guinea Bissau, Mozambique and Somalia and supports activities, also in Ethiopia, covering training, distribution of supplies and management of essential drugs programmes. To date Italy had contributed US\$15 million to such work and an additional contribution of US\$10 is foreseen, starting in 1989, when collaboration will be expanded to two additional countries, Ghana and Guinea Conakry.

Italy will continue to work with WHO in its unceasing efforts to support developing countries in all aspects of the essential drugs programme, including the formulation of national drug policies, national drug formularies and data-sheets, training, operational research and evaluation. Fruitful interaction is also foreseen with WHO and UNICEF in the implementation of the Bamako Initiative, which is particularly relevant to the immunization and child-survival programmes in which Italy collaborates in 26 African countries.

Japan

The representative of Japan described his country's international collaboration scheme which is divided into three categories: bilateral, multi-lateral, and projects directly run by the Ministry of Health and Welfare. In the bilateral scheme there are over 30 health related projects, including pharmaceutical projects. Two involve the establishment or renovation of national institutes of hygienic sciences since the counterpart countries considered the improvement of such facilities to be the crucial factor in the safe and effective use of drugs. Another project covers support of essential drug formulation facilities.

Following a request from counterpart countries, intermediate scale essential drug formulation factories are developed with technical and financial support from Japan. Support is also given to the WHO Action Programme on Essential Drugs. There is also a study programme for national pharmaceutical officials - mainly from South-East Asia, which provides them with an opportunity to deepen knowledge and experience of good manufacturing practice. The pharmaceutical industry has been actively collaborating in this programme.

Kenya

The representative of Kenya said that the essential drugs programme in his country started in 1979-80, and by 1981 the essential drugs list was in line with the WHO model list. Rural health workers were trained, public information began, and drug supplies management units were created. The programme was launched at first in two districts and then extended to cover the entire country between 1980 and 1984; in fact the whole country was covered by 1983. Drugs are delivered to health centres and dispensaries in two kits, one supplied by DANIDA and SIDA, the other by the Kenyan Government and consisting of drugs manufactured and packed locally; each kit supplies the drugs needed to treat 3000 cases in a health centre and 2000 in a dispensary. The composition of the kits is varied according to an analysis of the needs of the district, but a number of drugs are kept as loose stocks and supplied only when specially requested. If stocks of some drugs accumulate in certain districts, they are withdrawn and sent elsewhere. The Government has introduced the essential drugs concept into the curriculum of the training schools.

The essential drugs programme was evaluated in 1985. It was found that 80% of the drugs on the list were available in the peripheral health centres. Because of the success of the programme in health centres and dispensaries, the Government in 1987 launched another one with the aid of the Federal Republic of Germany and the Netherlands to supply hospital out-patient departments with core essential drugs. This programme began in 12 district hospitals with 28 selected drugs in kits and was then extended to 27 districts with 40 drugs. Now it is proposed to cover all the 50 district hospitals of the country, with the advantages of cheap bulk procurement and reduction of pilferage and wastage. The need now is for a quality control laboratory in Kenya.

Mexico

The representative of Mexico said that 75% of the population in his country have access to institutions that provide health care and procure drugs for them. These institutions have decided to adopt an exclusive form of packaging for all drugs included in the National Formulary, using the generic names. A law of 1984 provided for the elimination of unnecessary drugs from the Formulary and for the rationalisation of the national production of starting materials and active intermediates.

The various measures taken increased the national production of pharmaceutical chemicals from 20% in 1982 to 58% in 1987; Mexico now produces 99% of all its pharmaceutical specialities. At the same time the private sector reduced the number of products from 20 000 in 1980 to 7 500 in 1987.

There has also been a greater coverage of primary health care. All these developments have been guided and inspired by the Action Programme, the Alma-Ata Declaration, and the Nairobi Conference. The economic difficulties with which Mexico has had to contend have, however, restricted its efforts. The Government's resources are scarce, and it confronts the problem of the prices of raw materials and finished products. Research on the development and improvement of pharmaceutical technology has suffered. More effort is needed to achieve rational prescribing and better distribution and storage of drugs. Generic drugs need to be promoted in the private sector so as to decrease costs, and the pharmacists need to be trained to play a greater role in dispensing both there and in hospitals.

Netherlands

The representative of the Netherlands stated that his country had throughout the years supported the principle of the Revised Drug Strategy and the WHO Action Programme on Essential Drugs (DAP). In the last few years this support has been expressed in concrete terms through extrabudgetary contributions and the establishment of a very strong collaborative relationship with DAP. The Government of the Netherlands has deliberately not embarked on bilateral programmes in the field of essential drugs, not because of a lack of expertise, but because of its belief that joint efforts under an international umbrella would be of greater efficacy. In addition, a number of UN agencies have an established 'track record' in this field and there was no point in 'reinventing the wheel'. The Netherlands is currently giving support worth 21 million Dutch guilders over 4 years to Essential Drugs Programmes in Gambia, Malawi, Kenya, Sudan and Yemen Arab Republic. The programme components cover, inter alia, drug quality control, technology transfer, management and rational use, training, storage and distribution, and drug procurement.

Activities at the HQ level in Geneva are also supported. The Netherlands is satisfied with the preliminary results of the implementation and progress achieved so far in these programmes. A contribution has also been made to the UNICEF/WHO/UNFPA Revolving Fund for Essential Drugs and Vaccines, and through Dutch NGOs assistance has been given to some sub-Saharan African countries. In this way the grass root and local levels of distribution and use of essential drugs had been reached.

Nigeria

The representative of Nigeria said that the essential drugs programme in his country is at the embryonic stage. In 1985, at the Government's request, the World Bank sent a mission to study the feasibility of such a programme, which it considered from the point of view of logistics; education in the concept of essential drugs; information and communication; domestic production; drug quality assurance; legislation, and the participation of the private sector.

In December 1986 a national workshop was held to promote the essential drugs concept. Studies were carried out between February and July 1987, with help from the World Bank and the Action Programme, and a number of states were chosen to make proposals for an essential drugs programme. Training of personnel for such a programme has been ongoing at the federal and state levels, through seminars, workshops, and short courses.

A World Bank mission has now reviewed this first phase of operations. The ultimate objective is to provide all the states with an essential drugs programme. A major problem which has to be faced is that of cost recovery to meet expenses; some states would like to have total cost recovery, but health care has been free and continues to be so and it is difficult to change course and level charges to meet even a portion of the costs.

Norway

The representative of Norway stated that because drugs and vaccines are an important component of health care, his country has supported the WHO programme from the outset and has played an active role in the establishment of the Drug Action Programme. Like others, Norway noted with satisfaction that the WHO Revised Drug Strategy was now widely implemented and that many countries have developed essential drugs programmes. Expert assistance has been provided to various components of the Programme and also direct financial support.

In addition, substantial support has been given on a bilateral basis, for instance, to Botswana to improve the pharmaceutical supply system, and to Sri Lanka for a revised quality assurance programme. This also included the building of a new quality control laboratory and the training of personnel, which is essential. All bilateral projects have been coordinated with the activities of the Drug Action Programme and this close cooperation of many years is much appreciated.

The Action Programme's approach to all these complex issues has been pragmatic and feasible and the last Progress Report demonstrates the considerable achievements of the last few years. However, the world drug situation is still a matter of concern and many recently implemented national programmes need continued support. For this reason Norway will continue to collaborate with the Drug Action Programme in support of the WHO Revised Strategy.

Pakistan

The representative of Pakistan said that the manufacture, sale, distribution, import and export of drugs in Pakistan are controlled by a Drug Act that provides for the compulsory registration of locally manufactured and imported drugs, the control of pricing, advertising, and labelling of drugs, and action to eliminate counterfeit and sub-standard drugs. No drug manufacturing licence can be granted without government approval, and every drug manufacturing unit is visited by a drug inspector once a year. More than 95% of investment in drugs is in the private sector, and the number of drug formulations on the market is more than 9 700, but has recently been reduced by 603. Another 193 will be removed, but the reduction has led to litigation. The Drug Act also controls the prices of drugs and this too leads to appeals and litigation by dissatisfied manufacturers.

As it is, prices of drugs are higher in Pakistan than in, for example, Bangladesh and India, and this creates discontent among the people. Another problem is that pharmacies sell drugs without prescription. Nor does the Drug Act include traditional medicines in its provisions; consequently, all that is required is to add the word "herbal" to any drug and the drug immediately ceases to be subject to those provisions.

With the help of the Action Programme - of whose usefulness there is no doubt and which has benefited Pakistan considerably - UNICEF and a number of bilateral agencies, the Government hopes to overcome the problems it faces and provide its population with safe and effective drugs at a reasonable price.

One issue which had emerged from the discussion was education. Doctors' knowledge of essential drugs is extremely limited. Although they are taught pharmacology, pharmacodynamics and the generic names of drugs in medical school, when they actually practise they find that the drugs are brought to them under brand names accompanied by forceful promotion.

Whichever drug is the more strongly promoted is the one they learn about and subsequently prescribe. What is needed instead in a developing country, such as Pakistan, is knowledge of the essential drugs and their usefulness. This should be incorporated into the curriculum of schools of pharmacy and medicine throughout the world as Pakistan is now starting to do. The Action Programme can assist by preparing teaching material and promoting the incorporation of teaching on essential drugs into medical and pharmacy curricula.

In connection with the development and research of new drugs by Western countries, it must be borne in mind that while rational use is important, this comes after the rational supply of drugs, which includes their production, manufacture, sales and availability. Pakistan has tried to follow the limited list of essential drugs but this policy is not always understood. People believe that they are being deprived of access to good drugs and medicine.

Their first response when attempts are made to reduce the number of drugs, is to cite the Western countries where the drug production and pharma-formulations run into the tens of thousands. They then try to smuggle into the country drugs which are not permitted but which are available abroad.

The surge in development and production of pharmaceuticals in Western countries no doubt provides an excellent service for developed countries, but cannot be replicated throughout the world, and their attempts to introduce an ever greater number of drugs into the developing countries create conflict both within the governments and countries.

While the generous extrabudgetary support given by Western countries to the Drug Action Programme is appreciated, would it not be possible for these same countries to persuade their manufacturing industry that in the developing countries they should perhaps limit the number of drugs they introduce? The US\$25 million in extrabudgetary support is a sizeable sum but the money wasted in developing countries should not be forgotten nor the potential savings if the number of drugs were restricted.

Papua New Guinea

The representative of Papua New Guinea said that the Medical Stores Catalogue in that country approximates to the WHO essential drugs list. On the whole those who need drugs get them, but difficulties are created by the increase in population, the establishment by the provinces themselves of new health facilities without due attention to the need for adequate drug supplies, an increased demand for drugs for non-communicable diseases, insufficient training of health workers in stock management and inventory control, sporadic access to quality control, no regular review of private sector medicine or pharmaceutical services, no reporting of adverse drug reactions or real system of drug recall, no regular medical check on supplies imported by the private and public sector, no pharmacy degree course so that reliance has to be placed on expatriate pharmacists, and insufficient facilities at area medical stores. There has been little contact with the Action Programme, but in 1986 it evaluated the national programme and it has provided a pharmacist in Western Samoa for some of the smaller islands, which now purchase drugs through UNIPAC.

Philippines

The representative of the Philippines said that his Government launched a national drug policy in April 1987. One of its aims is to strengthen the Bureau of Food and Drugs. With help from Japan, a new building has been constructed and equipped, a manpower development programme is being undertaken, the systems and procedures of the Bureau are being reviewed, and the national drug product registry is being examined so that drugs that are withdrawn, banned, or restricted in other countries are removed. A second aim is promotion of the rational use of drugs. For that purpose a national drug committee has been set up to produce a national formulary using the WHO list of essential drugs as a model.

In 1988 a law was passed that offers incentives to producers of generic products, requires government health agencies to use generic terminology and private practitioners to indicate the generic name of their prescriptions, and obliges manufacturers, importers, distributors, and drug outlets to give prominence to generic names. The government drug procurement system has been improved and is now based on an approved therapeutic list using generic nomenclature; and the question of bulk procurement is being explored. Preparations are being made for a campaign to inform and educate health providers, drug manufacturers and suppliers, policy-makers, and the general public, and guidelines have been issued on the promotion and advertising of pharmaceutical preparations.

At present 90-95% of pharmaceutical raw materials in the Philippines are being imported. To develop greater reliance on local production a feasibility study is being undertaken; three herbal manufacturing plants will shortly start production of five preparations for common ailments; the Department of Health is now manufacturing oral dehydration salts; and a number of vaccines and biologicals are being or will shortly be produced.

A promising start has been made to the rational use of drugs, but much remains to be done in the face of the attitudes of health providers and patients, the resistance of pharmaceutical companies, the pressure of some governments, and the country's dependence on imported raw materials.

Sweden (SIDA/SAREC)

The Swedish representative, speaking for SIDA and SAREC, stated that Sweden has supported the primary health care programmes of WHO for ten years and the Drug Action Programme since its establishment in 1981. The provision and use of essential drugs should be seen as an integrated part of primary health care activities, and training in the use of drugs should possibly be made in connection with training in the treatment of common diseases, such as diarrhoea, respiratory infections and malaria. The aim of the Swedish support is to promote both operational research and the development of implementation methodology. Such support is a very valuable complement to bilateral cooperation in the health sector. Operational research and studies on subjects related to the provision of drugs are very important to elucidate unanswered questions on the rational use of drugs, high non-compliance rates and the number of types of drugs that should be available to the community health worker at the peripheral level. There are still many unresolved problems and obstacles to the implementation of national drug policies in many countries.

The Drug Action Programme has a special responsibility to assess the effect and impact on people's health in general which can only be answered by operational research. How could the Programme mobilize the scientific community in different relevant fields for this, set priorities and further support the research capacities of developing countries?

The Programme should report in a systematic way on indicators proposed to monitor progress in primary health care, and particularly the population coverage with 20 essential drugs, which is an important one. This is a crucial aspect for monitoring health care and also to achieving social equity.

Training is also crucial and ideally should precede and be developed along with the supply of drugs. As the concept of essential drugs is highly appropriate for all countries - not only those which are developing - global efforts are needed to involve schools of medicine and pharmacy throughout the world in the development of the Action Programme.

Switzerland

The representative of Switzerland stated that her country was contributing to the Essential Drugs Action Programme because it believes that WHO, through the Programme, has a very important role to play, not only in improving the supply of drugs but in reinforcing and strengthening their rational use, and in training and the dissemination of information.

Switzerland has drawn up guidelines for its cooperative development activities in the field of drugs. The most important principles of these guidelines are: firstly, while pharmaceuticals constitute an important and often an essential element in health protection and disease treatment they are not the most determinant. Two conditions must be met if drugs are to be properly and safely used: both proper diagnosis and medical care at all levels need to be available under the health system. Hence the importance of training not only specifically in drug use but the general information which is essential to be able to use medications properly and rationally.

Secondly, while the concept of essential drugs is very valuable and the use of generic names alongside brand names essential for their rational use, Swiss policy recognizes other significant aspects such as: the adequate selection of drugs, drug supply and distribution, quality control, prescribing practice, the development of new medications for at present untreatable diseases, particularly those in developing countries, and the cost of medication.

According to Swiss criteria for drug financing in emergency and other situations, only drugs which are on the drug list of the country or - where none exists - on WHO's Model List, can be included. In addition to the financing of drug supplies Swiss support includes activities in the field of information and training manuals. Some bilateral activities - with the exception of Nepal, all in Africa - have also been undertaken. These have covered such areas as drug supply, storage, distribution and management, quality control, training of pharmacologists and prescribers, and - in Madagascar - the production of vaccines.

United Kingdom

The representative of the UK stated that her country's bilateral aid programme had not been very actively involved in the field of essential drugs because it generally acts in response to specific requests from developing countries and few, if any, had been received for support of essential drugs programmes. The UK is ready and willing to take on essential drugs projects in countries where it is operating health assistance programmes. The essential drugs concept is fully compatible with the Overseas Development Administration's refocussed health assistance programme, which is trying to give greater emphasis to the primary health care sector.

There are significant advantages to operating on a multilateral basis in this difficult and sensitive field which is why the UK in the last few years has been a contributor to the Drug Action Programme, increasing its contribution by 50% to £450,000.

The UK is also collaborating with the Programme in funding and research in Nepal on people's perception and use of drugs. The Department of Health and Social Security is willing to provide expertise in given fields and has already provided three people to undertake a review of drug quality assurance, registration and information in Nigeria. In addition to the official public sector activities, UK non-governmental organizations, notably OXFAM and Save the Children Fund, are extremely active in the provision of drugs.

United States of America

The representative of the United States of America stated that it is clear that there are mutual problems, as well as issues unique to each country. No one model could be applied to all countries and sharing diverse solutions to a common problem should enlighten all. The United States Agency for International Development (AID) is very much involved in essential drugs, both bilaterally and multi-laterally. A new cooperative spirit involving consumer groups, health professionals, academia, the pharmaceutical industry, governments and WHO clearly resulted from the WHO Conference of Experts on the Rational Use of Drugs in Nairobi. The USA is working to foster this cooperative spirit as it implements the WHO Revised Drug Strategy and addresses issues concerning the use of pharmaceuticals.

Viet Nam

The representative of Viet Nam said that it is not possible for his country to import all the drugs it needs, and local production is insufficient to meet the needs of the population. The Action Programme on Essential Drugs fitted in with ideas that had already surfaced in Viet Nam and since 1983 steps have been taken to develop an integrated national drug policy.

A network for the supply of drugs down to the peripheral level has been created; a national list of drugs has been established in the light of economic, technical, and cultural possibilities; local production of drugs has been promoted, with special attention to traditional medicines; and the existing drug regulations have been reviewed.

A seminar was held in 1984 to familiarize those concerned with WHO concepts, and others followed in 1986 and 1987. A management committee was set up for the whole country and then for each province and district. A new drug list, which includes traditional medicine, has been drawn up.

A small pharmaceutical kit has been developed, based on the assumption that it was better to use traditional medicine to help meet the needs of the people provided that quality control requirements are observed, than to wait for possibly more effective products which because they needed to be imported might never become available.

Democratic Yemen

The representative of Democratic Yemen said that in 1984 the country was paying about US\$10 per head for drugs, about 75% of which went to the hospitals in big cities. A survey carried out in 1986 showed that very few patients go to those hospitals, most patients being in rural areas. A national drug policy was developed in 1984 and the number of essential drugs was reduced to 270, categorized according to level of care. Legislation is being developed to introduce drug registration. Drug supplies to hospitals and health centres are controlled by estimates of needs prepared by the central medical stores, and a central procurement agency imports drugs by tender.

The concept of essential drugs has been introduced into the curriculum of the teaching institutions, and in-service field training is carried out. These changes have taken place with WHO help.

Dr H. Hogerzeil, Action Programme, said that the Yemen programme has been evaluated in terms of its effect on the rational use of drugs, on their availability, and on the effectiveness of WHO support. The overall result of the evaluation has been positive. Twenty-five health workers were granted WHO fellowships and all are now active in the essential drugs programme of Yemen, including all the senior people in the Ministry of Health Pharmacy Department.

Zimbabwe

The representative of Zimbabwe said that the Zimbabwe Essential Drug Action Programme was launched in November 1986 as a management support programme, with a total allocation of funds of approximately US\$1.2 million for the five-year project. In 1987 a baseline survey was conducted of provincial and district hospitals and health clinics to assess the morbidity patterns, ordering practices, drug supply systems, storage, dispensing, manufacturing facilities, clinical management, training resources, and needs. A national workshop on drug policy and management was held in April 1987, and its recommendations were adopted for the Zimbabwe programme.

In 1981 a national drug and therapeutics committee produced an essential drugs list that was finalized in 1985; in 1988 it was revised to provide for drugs from the rural health clinic up. The national workshop recommended that only generic drugs should be employed, and prescribers in the public sector, and by January 1990 in the private sector, must prescribe generic drugs only. As from 1 January 1989 a special reserve of foreign currency will be available to meet public sector drug procurement requirements. As a result of management restructuration of the drug distribution system with the help of USAID and SIDA, there is a lapse of time of less than four weeks between a requisition from a rural clinic and the arrival of the drugs, as against 12-18 weeks in 1987. A training programme has been developed to promote the rational use of drugs and a manual is being prepared for wide dissemination. The whole programme is being monitored on a monthly basis. Within the next few months a national quality control laboratory will begin functioning, with WHO help, as a part of a regional quality control laboratory for the southern part of Africa.

It is hoped that at the end of the five-year project management systems will have been established that can be taken over by the Government. Shortage of hard currency means that there are still problems with transport and with the local production of drugs.

6. PRESENTATION OF REPORTS BY AGENCIES; UNICEF AND THE WORLD BANK

Ms Karin Lokhaug, Deputy Executive Director, UNICEF, reminded participants of the close ties of UNICEF with WHO. UNICEF supplies selected countries with the drugs needed for their essential drugs programmes, it has at present ten major projects and several smaller projects in essential drugs, some developed jointly with WHO. All new essential drugs projects in sub-Saharan Africa will form elements of the Bamako Initiative, except for emergency programmes.

Existing programmes will be phased into the initiative, which will, it is hoped, impart a renewed impetus to a crisis-ridden region towards which the flow of relief funds has diminished considerably. It is envisaged that 8-10 basic drugs will be provided at community level and 40-50 at district level; and that their sale will generate sufficient funds to replenish stocks and help meet a number of community health needs. The drugs will be supplied for about five years through the Bamako Initiative, by when the funds generated should be usable for improved primary health care and maternal and child health services.

UNICEF estimates that the funds required for the five years will be of the order of US\$380 million. WHO and the World Bank will be close collaborators. As there is a trend in African countries towards self-reliance in health matters and community financing of primary health care using the sale of drugs is one of the possible financing mechanisms, the prospects for the Initiative are good.

Mr D. Halliday, UNICEF, said that, as a result of the Action Programme, UNICEF is purchasing more drugs at a lower price and making essential drugs available where they were not available before. The stocks of drugs held by UNICEF at Copenhagen cover approximately 150 out of the WHO model list of essential drugs and conform with the requirements of the list.

UNICEF invites international tenders for the drugs it distributes, the advantage being that it buys in larger quantities than many countries are able to and therefore at cheaper rates. But it encourages the local manufacture of pharmaceuticals and the creation in countries of an effective purchasing and distribution mechanism. Because of the increase in the volume and distribution of essential drugs, UNICEF is holding discussions with the Danish Board of Health to provide a full quality control service covering all aspects of drug purchase, from a review of the facilities and procedures of manufacturers to quality control at the UNICEF Copenhagen warehouse.

WHO and UNICEF are also jointly undertaking a study to review the stability of drugs during their shipment to countries, a study that will be of value to all concerned with the supply of drugs. UNICEF maintains stocks of drugs for emergencies sufficient to provide immediately approximately 1000 basic and 150 supplementary emergency health kits. It can also ship a substantial proportion of the stocks in Copenhagen within 24-48 hours.

Dr A.R. Measham, World Bank, said that the Bank is a very strong supporter of the Action Programme. Since 1980 it has financed 48 population, health, and nutrition programmes, almost half of which include an essential drugs or pharmaceuticals-strengthening component. The Bank and WHO collaborate closely, especially in sub-Saharan Africa, in which the essential drugs component accounts for the major proportion of the base costs of the many projects instituted.

7. PRESENTATION OF REPORTS BY NON-GOVERNMENTAL ORGANIZATIONS

Reports were presented by the Christian Medical Commission, the International Organization of Consumers Unions, the International Pharmaceutical Federation, Médecins sans Frontières, and the International Federation of Pharmaceutical Manufacturers Associations and a comment was made by Interpharma, not a non-governmental organization. All expressed their support for the Action Programme.

The Christian Medical Commission representative said that the Commission has developed guidelines to help donors of drugs improve the quality and impact of their donations. It is organizing a workshop on essential drugs in primary health care in Nicaragua; and it hopes with WHO help to make drug information available to health workers.

The International Organization of Consumers Unions plays a major role in the network Health Action International, one of the aims of which is to further the safe, rational, and economic use of pharmaceuticals throughout the world. It engages in a constructive dialogue with the pharmaceutical industry to encourage more ethical marketing of drugs, more research on essential drugs, and more cost-conscious pricing. It seeks to improve medical education about essential drugs and to improve information on drugs. The organization has some reservations about cost recovery, since it feels that in the long run it may hit hardest those who most need drugs; a more equitable way of financing the provision of essential drugs might be to tax the promotion and sales of non-essential drugs.

International Pharmaceutical Federation offered help to WHO in spreading the essential drugs concept in developing countries, in the training of health care workers and pharmacists, in providing the public with drug information, and in setting up schools of pharmacy and hospital pharmacy units.

Médecins sans Frontières has published a number of guides on diagnosis and standard treatment schedules, drug lists, and information on drugs; it has developed routine and emergency health kits; and it requires its most important suppliers to standardize drug forms, packaging, and labelling.

International Federation of Pharmaceutical Manufacturers Associations provides training courses in quality control; has coordinated the financial support for a government quality control laboratory in Harare, Zimbabwe, as well as offering on-the-site training on completion of the laboratory. It has published a compendium on the regulation of pharmaceuticals, and continues to monitor and report on the Federation Code of Pharmaceutical Marketing Practices.

Interpharma concentrates its efforts on Burundi, giving priority to improving drug storage and distribution and providing training for all who handle and stock drugs in government pharmacies. It co-sponsored a WHO manual on estimating drug requirements.

8. PROPOSAL FOR A MANAGEMENT REVIEW COMMITTEE

The representative of the Netherlands said that the Action Programme has now become a large organization with complex activities and a large budget, 90% of which comes from sources outside the regular WHO budget. For such an organization a platform is needed for discussion of the policy and managerial issues encountered so as to ensure the continuity and coherence of the Programme. The proposal for a managerial review committee that he put forward was taken from a similar one for the AIDS programme, with the simple substitution of the words "revised drug strategy" for "global strategy on AIDS".

The committee's task would be to review the various aspects of the Programme, its financing, priorities, and relationships with other international organizations such as the World Bank and UNICEF. The present meeting could, with the approval of the Director-General, transform itself into a management review committee as a formal advisory body.

During the discussion of the proposal it was agreed that Meetings of Interested Parties at irregular intervals are not sufficient; a formal mandate is required and, as the Programme has greatly expanded in scope since the Nairobi conference and the promulgation of the revised drug strategy, a new body is necessary to review, analyse, and guide its activities.

It was felt that representatives of developing countries should also be on such a review committee. One representative thought that the review committee should not be too top-heavy; the Programme has done very well so far without such a body and if one is approved it should be small and not too bureaucratic. Another representative, from a developing country, said that officials concerned with essential drugs programmes in developing countries do not attend the World Health Assembly or the Executive Board; the proposed committee will enable them to state their problems and discuss possible solutions. Another view, however, was that the present meeting is adequate for the evaluation of the Programme's activities. The situation should be assessed by governments before a decision is taken on the proposal, especially as business interests in developed countries might be affected. If there is to be a committee, it must be an objective one.

The proposed terms of reference of the management review committee were accepted, with a number of amendments in relation to the membership; and (Annex 3) it was agreed the committee, if approved by the Director-General, should meet in December 1988. It was also agreed that the situation and the utility of the committee should be reviewed after two years.

9. EXTERNAL EVALUATION OF THE ACTION PROGRAMME

The representative of Denmark introduced a proposal for the external evaluation of the Action Programme. The evaluation should be in three parts: the first assessing the Programme's activities from a global perspective, the second the activities of UNIPAC as purchaser, supplier, and distributor of drugs, the third country programmes.

The global overview with WHO and the UNIPAC evaluation should be treated as one 'package' and undertaken by a group of donors. The country programme evaluations should be done in cooperation between the individual donors and recipient countries, with countries which are independently managing drug supply programmes undertaking their own evaluation. The present meeting might wish to appoint a group to examine the proposed terms of reference, work out details of the evaluation, appoint external consultants to do the evaluation, review the results, and present them to the management review committee. DANIDA will finance the global evaluation.

In the discussion of the proposal it was said that ideally evaluations should take place every five years or so, consequently one is now due. Evaluations should be carried out in the light of criteria and objectives that enable both donors and recipients to benefit.

One representative thought that evaluation should be as objective and independent of donors as possible and that donors making bilateral evaluations should make the results available to the reference group. Evaluators should carry out a detailed review of what is happening in the country being evaluated, of the impact of the Action Programme on the country, of the ability of the Programme to help the country and of the country to benefit from the Programme. A problem that might arise is that, if the health profession is not in agreement with the essential drugs concept, it may make it impossible to assess needs and carry out a proper evaluation. A suggestion was made that evaluations should be carried out for each country separately and the results then reviewed. There was general agreement in favour of the proposal and a reference group was set up consisting of the representatives of Denmark, Italy, Mexico, the Netherlands, Nigeria, the Philippines, and Switzerland, other representatives being welcome to join in the discussions or correspond with the members of the group. The group will review the proposed terms of reference and consider the qualifications and composition of the consultants to be chosen for the evaluation, which should include pharmacists. Copies of the final version of the terms of reference (see Annex 4) will be sent to all members of the present meeting.

10. TECHNICAL COOPERATION

Mrs M. Helling-Borda, Action Programme, said that the aim of technical cooperation is to strengthen national and regional essential drugs programmes, make the most of limited resources, avoid duplication in all aspects of programmes, promote good manufacturing practices, attempt to solve the problem of procurement, encourage the establishment of, for example, revolving funds, and help with training and manpower development. She noted that developing countries now exchange personnel with other developing countries, to their mutual benefit.

Mr C. Lissner, Action Programme, described the Market Intelligence System (MIS) that is now being started, the purpose of which is to collect market information from all concerned and disseminate it, including a range of relevant prices. Average prices are not given because they do not exist.

During the discussion it was emphasized that technical cooperation is not limited to developing countries alone but is advantageous to developed countries also. Thus the Nordic countries already cooperate technically in relation to drug evaluation and inspection reports. To a question whether UNICEF provides training, the representative of UNICEF replied that it has done so on a limited number of occasions, but it is not a training centre and cannot offer training on a regular basis. In reply to another question, it was said that it is not financially feasible to provide accurate prices for drugs in terms of quality; nor has WHO a mandate to do so.

Mr T. Kurokawa (Japan) said that the aim of technology transfer is to improve the drug supply system in its totality; it is pointless to have excellent facilities if they do not conduce to that end. Every link in the chain is vital for the appropriate functioning of the system; weakness in any link jeopardizing the whole. Before technology is transferred, therefore, all the weak points must be identified and the entire drug supply system carefully scrutinized.

11. FUTURE ACTIVITIES

Dr E. Lauridsen, Action Programme, said that the proposal for a management review committee would be transmitted to the Director-General and, on the assumption that he would approve its establishment, preparations would be made for the first meeting. Steps would also be taken to implement the Bamako Initiative, the initial aim of which is to provide support for the countries of sub-Saharan Africa; its scope, however, may be extended to other countries in the world. The Programme will continue to be responsive to needs and adopt a responsible approach in its activities.

It was agreed that there should be a further meeting of interested parties in December 1988. The agenda will include, inter alia, management and financing of the programme, research strategy and cost recovery.

ACTION PROGRAMME ON ESSENTIAL DRUGS
SECOND MEETING OF INTERESTED PARTIES
Geneva, 22-24 June 1988

PROGRAMME D'ACTION POUR LES MEDICAMENTS
ESSENTIELS
DEUXIEME REUNION DES PARTIES INTERESSEES
Genève, 22-24 juin 1988

List of participants/Liste des participants
(as at 24 June 1988/au 24 juin 1988)

Representatives of countries/agencies//Représentants des pays/agences
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* Unable to attend/N'a pas pu assister

Secretariat/Secrétariat
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Dr Halfdan Mahler, Director-General/Directeur général*

Dr Joseph Cohen, Advisor on Health Policy**, Director-General's Office/Conseiller en Politique de Santé, Bureau du Directeur général

Dr Nick Drager, External Relations Officer, Health Resources Mobilization/Administrateur chargé des Relations extérieures, Mobilisation des Ressources sanitaires

Dr John F. Dunne, Chief, Pharmaceuticals/Chef, Produits pharmaceutiques

Mr Peter Evans, Expanded Programme on Immunization/Programme élargi de Vaccination

Mr Pat Friel, Global Programme on AIDS/Programme mondial de Lutte contre le SIDA

Mr Jens Jorgensen, Administrative Management/Gestion administrative

Dr Y. Kawaguchi, Office of the Director-General Elect/Bureau du Directeur général élu

Dr Stuart Kingma, Chief, Health Resources Mobilization/Chef, Mobilisation des Ressources sanitaires

Ms Sabine Kopp, Pharmaceuticals/Produits pharmaceutiques

Dr Duane L. Smith, Medical Officer, District Health Systems/Fonctionnaire médical, Systèmes de Santé de District

Dr Martin Ten Ham, Pharmaceuticals/Produits pharmaceutiques

Ms Agathe Wehrli, Pharmaceuticals/Produits pharmaceutiques

Action Programme on Essential Drugs/
Programme d'Action pour les Médicaments essentiels

Dr Ernst Lauridsen, Programme Manager/Directeur du Programme

Mme Pascale Brudon-Jakobowicz, Scientist/Fonctionnaire scientifique

Miss Sandra Doyle, Administrative Assistant/Assistante administrative

Mr Amadeo Fernandez, Technical Assistant/Assistant technique

Miss Susan Foster, Technical Officer/Fonctionnaire des services techniques

Ms Daphne Fresle, Technical Officer/Fonctionnaire des services techniques

Mrs Margaretha Helling-Borda, Senior Scientist/Fonctionnaire scientifique principale

Dr Hans Hogerzeil, Technical Officer/Fonctionnaire des services techniques

Mr Craig Lissner, Technical Officer/Fonctionnaire des services techniques

Mrs Ramona Lunt, Scientist/Fonctionnaire des services techniques

Mr Gerald D. Moore, Technical Officer/Fonctionnaire des services techniques

Miss Anne V. Reeler, Research Assistant/Assistante de recherche

Dr Godfrey Walker, Medical Officer/Fonctionnaire médical

* Until 1 August 1988 - now Director-General Emeritus

** Now retired from WHO

Unable to attend/N'a pas pu assister

Diarrhoeal Diseases Control (CDD)/Lutte contre les Maladies diarrhétiques

Special Programme for Research and Training in Tropical Diseases (TDR)/Programme
spécial de Recherche et de Formation concernant les Maladies tropicales

Countries/agencies unable to attend//Pays/agences ne pouvant pas assister

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BURMA/BIRMANIE

CANADA/CANADA

NEW ZEALAND/NOUVELLE ZELANDE

UNITED NATIONS DEVELOPMENT PROGRAMME (UNDP)/
PROGRAMME DES NATIONS UNIES POUR LE DEVELOPPEMENT (PNUD)

UNITED NATIONS POPULATION FUND (UNFPA)/
FONDS DES NATIONS UNIES POUR LA POPULATION (FNUAP)

Participation invited from following countries/agencies//Participation souhaitée des
=====

pays/agences suivants

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AUSTRIA/AUTRICHE

BELGIUM/BELGIQUE

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION/
ORGANISATION DES NATIONS UNIES POUR LE DEVELOPPEMENT INDUSTRIEL

ACTION PROGRAMME ON ESSENTIAL DRUGS AND VACCINES

Second Meeting of Interested Parties

Geneva, 22 to 24 June 1988

Salle A

AGENDA

afternoon: 14.00-17.00

morning: 09.00-12.30

22 June : afternoon

1. Opening of the meeting and introduction by the Director-General
2. Election of Chairperson and Rapporteur
3. Adoption of the agenda
4. Forty-first World Health Assembly - progress report on WHO's revised drug strategy: summary overview
5. Presentation of reports by agencies
 - 5.1 UNICEF (Bamako initiative; UNIPAC)
 - 5.2 World Bank
 - 5.3 UNDP
 - 5.4 UNIDO
 - 5.5 UNFPA
 - 5.6 Official development assistance agencies

23 June : morning

6. Action Programme on Essential Drugs: progress report and planned activities in major programme areas
 - 6.1 Country support (including reports from selected countries: Bangladesh, Democratic Yemen, Mexico, Nigeria, Papua New Guinea, Viet Nam, Zimbabwe)
 - 6.2 Development work
 - 6.3 Operational research
 - 6.4 Management and administration (including financial resources and projections)

23 June : afternoon

7. Possible establishment of a Management Review Committee or similar mechanism in support of the Programme

8. External evaluation of the Action Programme on Essential Drugs
9. Unit of Pharmaceuticals - progress report: summary overview
10. Presentations of reports by non-governmental organizations
 - 10.1 Christian Medical Commission (CMC)
 - 10.2 International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
 - 10.3 International Organization of Consumers Unions (IOCU)
 - 10.4 International Pharmaceutical Federation
 - 10.5 League of Red Cross and Red Crescent Societies
 - 10.6 Médecins sans Frontières

24 June : morning

11. Review of technical cooperation among developing countries (TCDC) and future trends
12. Opportunities for technology transfer
13. Future activities of the Action Programme on Essential Drugs in collaboration with interested parties

24 June : afternoon

14. Conclusions and recommendations

ACTION PROGRAMME ON ESSENTIAL DRUGS AND VACCINES

Terms of Reference of the Management Review Committee

The Management Review Committee shall represent the views and responsibilities of WHO's partners collaborating with WHO in its Action Programme on Essential Drugs and Vaccines. It shall act as an advisory body to the Director-General of WHO, making recommendations on matters related to the policies, strategies, financing, management, monitoring and evaluation of WHO's Action Programme on Essential Drugs and Vaccines (DAP).

* * *

FUNCTIONS

The Management Review Committee shall have the following functions:

- to review, analyse and guide the programme of activities and related budget submitted by DAP for the forthcoming year and to make appropriate recommendations to the Director-General;
- to review annually the arrangements envisaged by the Director-General of WHO for financing and managing DAP;
- to review the financial statements of DAP submitted by WHO;
- to review periodic reports evaluating the progress of DAP towards the achievement of its objectives and to submit its findings and recommendations to the Director-General for action;
- to recommend ways of improving, as appropriate, coordination between the activities of DAP and of other relevant organizations; and
- to consider any other matters relating to DAP referred to it by the Director-General of WHO or the Director of DAP or any member of the Committee.

In carrying out its functions the Management Review Committee shall ensure it is informed of all policy decisions and recommendations concerning WHO's Revised Drug Strategy (RDS) and DAP made by the World Health Assembly and the Executive Board.

For these purposes, the Management Review Committee shall be assisted in its endeavours by the provision, by WHO, of whatever secretariat and other support services may be considered necessary and reasonable.

COMPOSITION

The Management Review Committee shall be composed as follows:

- governments of those countries which contributed funding in support of DAP's general budget in the previous fiscal year or which provided bilateral support to developing countries for the formulation or implementation of national drug policies in conformity with WHO's policies on essential drugs;
- three governments from each of WHO's six regions, appointed by the Director-General of WHO, after receiving advice from the respective Regional Committees, from among those countries with which DAP is collaborating;
- the four major intergovernmental organizations contributing to the implementation of WHO's RDS, namely: UNDP, UNICEF, UNIDO and the World Bank.

Intergovernmental organizations not included on the Committee as well as non-governmental organizations deeply involved in WHO's RDS will on request be granted observer status.

The identity of those countries contributing funding in support of DAP's general budget and those providing bilateral support in the above manner, and hence their eligibility for membership in the Management Review Committee, shall be ascertained annually. Members selected from WHO's six regions may be reappointed. The four major intergovernmental organizations shall be considered to have permanent seats for as long as they continue to participate with DAP in support of WHO's RDS. The Chairperson of the Committee should in principle be a government representative and shall be elected from and by members of the Committee for a period of two years but while eligible for re-election, may not serve consecutive terms. The Chairperson shall preside over meetings of the Committee and undertake whatever additional duties may be assigned by the Committee, in agreement with the Director-General of WHO.

OPERATION

The Management Review Committee shall meet once a year. The meetings shall be for the purposes of reviewing DAP's programme for that year in light of the financial support that will have been pledged and the past, present, and future coordination of external support for DAP's principal areas of activity (country support, development work and operational research). The meetings shall also review and guide the following year's programme and related budget. The Committee may also meet more often upon the proposal of either its Chairperson or the Director-General of WHO, and with the latter's agreement. The Committee shall decide its method of work, which may include the establishment of a number of functional sub-committees. All such subcommittees will have an advisory role to DAP and the Committee. Each Management Review Committee meeting shall elect a rapporteur from among its members who shall assist in ensuring that the decisions reached by the meeting are adopted and recorded before its conclusion.

REVIEW

At the second meeting of the Management Review Committee its terms of reference as set out above will be reviewed in the light of members' experience.

ACTION PROGRAMME ON ESSENTIAL DRUGS AND VACCINES

Consultative Group Meeting Evaluation
of WHO's Essential Drugs Programme,
Copenhagen 1/2 September 1988

Minutes

1. PRESENT AT THE MEETING

Mr Tatsuo Kurokawa, Japan
 Dr Mario L. Lieberman, Mexico
 Mr Willem Veenstra, The Netherlands
 Dr Tom Segaar, The Netherlands
 Mr Rhais Gamboa, Philippines
 Dr S. Berthoud, Switzerland
 Mr D.J. Halliday, UNICEF/UNIPAC
 Dr Ernst Lauridsen, WHO
 Mr Klaus Winkel, DANIDA
 Mr Ole Frank Nielsen, DANIDA
 Mrs Anne Dorthe Riggelsen, DANIDA
 Mr Niels Dabelstein, DANIDA
 Mr Jens Chr. Wandel, DANIDA

2. AGENDA

1. Discussion of Terms of Reference:
 - a) Part A (WHO)
 - b) Part B (UNIPAC)
2. Discussion of Terms of Reference, Part C (country evaluations).
3. Discussion of time frame.
4. Discussion of possible consultants.
5. Financing.

Mr Winkel opened the meeting giving an introduction to the objectives of the evaluation and a short account of DANIDA'S involvement in international assistance.

Re: 1 a) - TOR to Part A (WHO)

Mr Dabelstein stated that the ultimate objective of the evaluation of EDP was to measure if and how the APED has contributed to a change of policies, a shift of power and a change of attitude which are aimed at:

- improving the position and utilization of drugs;
- ensure equitable access to cost-effective drugs through efficient procurement, distribution and management;

- adequate quality, safety and efficacy of drugs;
- national prescription and consumption.

Dr Lauridsen stated that he expected changes in WHO to be announced at the meeting of IPPMA in October 1988. Mainly the style and focus of WHO activities will change while the basic objectives of EDP will remain as at present.

It was agreed that even if changes come about in WHO the evaluation must assess EDP in its present form and not interfere in the transition of EDP.

It was stressed by Mr Kurokawa that the address of the evaluation should be clear. The group identified possible decision-makers who would be interested i.e., World Health Assembly, WHO & UNICEF management, and the Group of Interested Parties.

Re: 1 b) - TOR for Part B (UNICEF/UNIPAC)

Mr Halliday stressed that EDP was increasing (currently 25% of total activities) in importance but underlined that it is still working within UNICEF rules. These rules might be seen as a constraint by some but it should be borne in mind, that UNIPAC mainly serves UNICEF programmes.

The group found that if UNICEF rules work as constraints then these rules should be identified and maybe the evaluation could help in changing them.

It was agreed only to make changes in the wording of certain paragraphs.

Re: 2 - TOR for Part C (Country-level)

Dr Segaar mentioned that the objectives of the evaluation would determine the extent of Part C arguing that these should be well defined.

Selection criteria and sample size in the evaluation of EDP in the individual countries will be decided upon at the end of the desk study.

The following two parameters will establish a frame for country selection:

Matrix for selection of countries

Stages of EDP implementation:

	<u>NONE</u>	<u>SOME</u>	<u>ALL</u>
Level of development -			
DEVELOPED	%	+	+
NEWLY INDUSTRIALIZED	+	+	+
LEAST DEVELOPED	++	++	++

Re: 3 - Time frame

It was agreed that the evaluation should be completed one year after inception.

Re: 4 - Possible consultants

Mr Dabelstein gave an introductory account of his contacts with The Royal Tropical Institute from Holland (RTI), The London School of Hygiene and Tropical Medicine, UK (LSH) and The Société Générale de Surveillance S.A. (SGS).

RTI and LSH could be a joint venture covering the evaluation of WHO activities and parts of the country evaluation, while SGS could cover the evaluation of UNIPAC.

It was agreed that:

- Mr Dabelstein would continue contacts with RTI, LSH and SGS to work out proposals for the evaluation.
- Consultants should not have been connected to WHO in the past and they should not be dependent on WHO in future activities.
- Mr Dabelstein will inform the group about selection of consultants.
- The evaluation should be carried out in a continuous dialogue between the Consultative Group and the engaged institutes and consultants.
- The report shall be presented in both English and French.

Evaluation methodology

Mr Segaar mentioned that the evaluation methodology should be indicated in the TOR.

Mr Dabelstein stressed that the methodology should be developed jointly with selected consultants and incorporated in the TOR which will form the basis for contracts.

Dr Lauridsen mentioned that an opportunity for gathering information, particularly on policy and coordination, would be the Meeting of the Management Review Committee (WHO) in December 1988.

Mr Gamboa argued that one institution should be identified as leader and stressed that it was important that the teams consisted of consultants covering various languages and cultures and the importance of it involving local expertise. The group agreed to this.

Re: 5 - Financing

The global part of the evaluation is roughly estimated to cost a maximum of US\$600,000. DANIDA is willing to cover this but invites other interested parties to contribute.

The country evaluations were estimated to cost approximately US\$100,000 per country.

When the evaluation is ready to start and the costs have been determined, pledges will be made in the Group of Interested Parties.

Switzerland and Holland expressed a positive attitude towards financing parts of both the global and the country specific evaluations.

DANIDA

16th September 1988

TERMS OF REFERENCE FOR AN EXTERNAL EVALUATION OF WHO'S ACTION
PROGRAMME ON ESSENTIAL DRUGS; SELECTED COUNTRY ESSENTIAL
DRUGS PROGRAMMES AND UNICEF'S DRUG PROCUREMENT AND
DISTRIBUTION SYSTEM

1. INTRODUCTION AND BACKGROUND

Many developing countries spend large sums on the purchase of drugs yet most of their people, particularly those living in the rural areas, do not have continuous access to even the most essential drugs. This not only undermines the morale and credibility of primary health care but also discourages adherence to sound diagnostic and prescribing practices. Adequate supplies of effective drugs to treat the most important and common diseases are crucial if health services are to be effective and credible.

A large number of problems are associated with the provision and utilization of therapeutic drugs in developing countries: inequitable access to cost-effective drugs; inefficient procurement, distribution and management; inadequate quality, safety and efficacy of drugs; and irrational prescription and consumption.

In response to these problems and in an effort to identify safe, cost-effective and affordable drugs, particularly for the developing countries, the essential drugs concept was introduced by the World Health Organization (WHO) in 1977. In 1981, WHO set up the Action Programme on Essential Drugs (APED) with the aim of helping developing countries to procure and use essential drugs and to adopt national drug policies.

Since then, a substantial number of countries have introduced an essential drugs programme (EDP), as recommended by WHO. However, only a few of these countries have managed to include all of the EDP's crucial components.

UNICEF International Procurement and Assembly Centre (UNIPAC) has produced and distributed drugs for developing countries for many years, but its operation has grown considerably since the introduction of essential drugs programmes at the beginning of the 1980's.

It is now proposed to make an external evaluation of WHO's Action Programme on Essential Drugs, of EDP's in selected countries and UNICEF's drug procurement procedures and practices.

2. OVERALL OBJECTIVES OF THE EVALUATION

To evaluate the Essential Drugs Programme in order to:

- a) Determine whether it has achieved its established objectives and targets.
- b) Identify constraints encountered in its activities that hindered the attainment of the established objectives.
- c) Make recommendations on EDP's future thrusts and the required corresponding organizational/operational adjustments needed to respond to such new thrusts.

The evaluation of WHO's Action Programme on Essential Drugs (Part A of the Terms of Reference) should assess the Programme's achievements and effectiveness in order to make recommendations concerning its future activities.

The evaluation of UNICEF's drug procurement procedures and practices (Part B of the Terms of Reference) should assess UNIPAC's ability to procure and distribute drugs of acceptable quality, safety and efficacy in order to make recommendations concerning future activities.

The country evaluations (Part C of the Terms of Reference) should focus on general and policy as well as on operational issues, the latter being already subject to periodic reviews and evaluations. The evaluation should cover the political environment and its implications for EDP; EDP and overall health care delivery; EDP and other PHC components; drug supply systems; drug financing; drug legislation and regulatory control; and local production of pharmaceuticals.

3. OVERALL TERMS OF REFERENCE

Part A - Evaluation of WHO's Action Programme on Essential Drugs

The evaluation will include but not necessarily be limited to the following scope of work:

Issues Related to Activities

- (1) Evaluate the Programme's capacity and capability to assist in the planning, implementation and evaluation of country programmes.
- (2) Assess the development of the operational research of the Programme. What has been achieved? Have the research components been appropriate in meeting the needs of the operative components? Assess the coordination with other WHO research programmes and other action programmes undertaking research.
- (3) Evaluate the Programme's strategic planning and financial forecasting.
- (4) Evaluate the Programme's ability to communicate the concept of essential drugs to a wider audience (general public, consumer groups, professional associations, pharmacies/drug vendors and other NGOs).
- (5) Evaluate the quality and quantity of technical information on drugs and pharmaceuticals as well as materials on the rational use of drugs.

Issues Related to Management and Organization

- (1) Evaluate the Programme's management structure and compare it with other WHO divisions and special programmes like EPI, CDD, HRP, TDR, etc.
- (2) Describe and assess the coordination and collaboration between EDP and other complementary divisions of WHO (e.g. PHA).
- (3) What linkages have been established with other WHO programmes, i.e. CDD, EPI, MCH, SHS, etc., in terms of joint training, review and evaluation activities or the establishment of common PHC management structures?
- (4) Identify policy, organization, financial and other developments within WHO that affect the present thrust of EDP.

Issues Related to Impact

- (1) Evaluate the Programme's ability to provide tools which developing countries can use for their own planning, implementation and evaluation of EDPs with particular attention to the development of methods to improve: the appropriate selection and quantification of drugs, quality control arrangements, training of prescribers and dispensers, legislation and regulatory control, financing drug supplies, monitoring and information to the public.
- (2) Evaluate the impact on the Programme's overall policy and operations of the joint WHO/UNICEF Programme on Essential Drugs and Vaccines in support of the primary health care strategy.
- (3) Identify to which extent the essential drugs concept is adapted in countries, organizations and associations.

Recommendations

The evaluation should formulate recommendations where deemed relevant and possible.

Part B - Evaluation of UNICEF's Drug Procurement Procedures and Practices

(It is not the intention to evaluate the overall operations of UNICEF's procurement division UNIPAC, but only that part of it concerned with drugs).

The evaluation will include but not necessarily be limited to the following scope of work:

- (1) Evaluate the range of drugs procured. Are they in accordance with WHO's model list of essential drugs?
- (2) Evaluate the tender procedure. What determines selection of a supplier? What is being done to include Third-World suppliers?
- (3) Evaluate the quality assurance procedures (technical and managerial).
- (4) Evaluate possible storage and distribution of sensitive drugs. How are sensitive drugs stored and packed? What is done to alert receivers of sensitive drugs? What determines whether a drug is too old to be shipped?
- (5) Establish the total delivery time (from order to receipt) and suggest ways of reducing it.
- (6) From the consumers' (countries) point of view, what are the strengths and weaknesses of UNICEF operations and what is the potential for expansion?
- (7) Evaluate the reimbursable scheme.
- (8) Evaluate the (UNICEF) procedures for price-setting (of essential drugs).
- (9) Describe and assess the development of pricing of essential drugs on the world market and identify the reasons for the identified trends.
- (10) Evaluate UNICEF's ability to supply pharmaceutical raw materials for Third-World local production.

Recommendations

The evaluation should formulate recommendations where deemed relevant and possible.

Part C - Country Evaluations

The evaluation will include but not necessarily be limited to the following scope of work:

Issues related to Policy, Legislation and Organization

- (1) Describe the EDP in the country.
- (2) Evaluate the EDP's integration into the country's overall health policy and strategy. Consider the balance between preventive, promotive and curative health care.
- (3) Evaluate the EDP's links to the effect on other primary health care programmes, CDD, MCH, EPI and ARI, and the extent to which EDP's functional infrastructure (information, management, manpower development, logistics, facilities and research) has been integrated or coordinated with these programmes.
- (4) Describe and assess the existing methods of generating and allocating funds for drugs and indicate alternative financing methods that might be studied.
- (5) Evaluate the pharmaceutical legislation and the role of the EDP in development of legislation which regulates the availability, administrative control and price of drugs in the public and private sectors (e.g. legislation concerning drug registration, import control, local manufacture, patents, price control, prescription, licensing of pharmacies and other retail outlets, control of marketing practices, use of generic names etc.)
- (6) Assess the List of Essential Drugs against the established selection criteria of the country. Assess the process for updating the List by level of service, and, Use of the List in the public, private, and parastatal sectors. Compare it with WHO's Model List.

Issues Related to Operations

- (1) Evaluate the cost-effectiveness of the EDP drug supply and distribution system (e.g. could similar results have been achieved at less cost, or could similar cost have produced better results?). In this respect, consider whether the private sector or other sectors could have carried out some of the tasks more cost-effectively.
- (2) Identify existing local production (raw materials, intermediate, formulation) and identify constraints to the cost-effectiveness of such production of essential drugs. Determine the potential for local drug manufacturers to participate in the supply of drugs.
- (3) Evaluate the public and private drug quality assurance procedures (technical and managerial) involved in enforcing drug control and inspection, and assess the quality assurance procedures set up by the EDP.
- (4) Assess the activities for communicating the Essential Drugs concept and the extent to which the concept has been communicated to the health personnel and general public, and assess the extent to which the list of Essential Drugs is distributed and used.
- (5) Examine the extent to which training in rational drug use has been adopted by professional organizations; included in the curricula of schools of medicine, pharmacy, nursing, health assistants, etc., and whether a continuous in-service training programme has been established for the categories of personnel produced by these schools.

Impact of the National EDP

- (1) Evaluate the impact of the adoption of the EDP on the balance of payments and consider the implications for sustainability of maintaining or expanding the EDP without external funding.
- (2) Examine whether there has been any change in prescribing and use patterns in the private and the public sector after the introduction of the EDP.
- (3) Assess the effect of the EDP on the overall availability of drugs in the country and the distribution between urban and rural health facilities and between primary, secondary and tertiary levels.
- (4) Provide information on the access to essential drugs of the most vulnerable groups, e.g. children and pregnant women. (The EPI simplified households sampling method could be used).

Interaction with WHO's APED Country Activities

- (1) Evaluate the quantity, quality and coordination of the inputs from WHO (national, regional and global offices), development banks, donors and recipient countries.
- (2) Evaluate the input from WHO APED in terms of tools which the country can use for its own planning, implementation and evaluation of EDPs, with particular attention to the development of methods to improve: the appropriate selection and quantification of drugs; efficient supply and procurement systems; quality control arrangements; training of prescribers and dispensers; legislation and regulatory control; financing drug supplies; monitoring and information to the public.

Recommendations

The evaluation should formulate recommendations where deemed relevant and possible.

Phase III Synthesis Report

The synthesis, which will be based on the output of phase II, should provide an overall view of the global status of the essential drugs concept and in particular address the following issues:

1. Has the WHO APED influenced countries to adopt EDPs or to initiate activities toward the development of EDPs?
2. Evaluate the Programme's ability to satisfy the needs of the member countries. Assess why some developing countries have shown no interest in essential drugs and/or support from the WHO Programme.
3. Identify the strengths and weaknesses of the different approaches, procedures and policies adopted by the various countries, WHO, UNICEF/UNIPAC and other organizations in pursuit of the objectives of EDP.
4. Make recommendations for the future direction of the APED.

4. IMPLEMENTATION

The evaluation will be carried out in three phases:

Phase I - Desk Survey

Review of data and documentation already compiled by WHO's Action Programme on Essential Drugs, the country EDP's, UNIPAC and donors. Expected output: A certain amount of information which already exists and therefore will not need to be collected during the evaluations. Timing: December 1988 and January 1989.

Phase II - Evaluations

The three evaluations (Parts A, B and C) are independent of each other and can therefore be carried out simultaneously by different teams, which will speed up the process. Expected output: Parts A and B, separate reports in the second quarter of 1989. Part C separate country reports in the third and fourth quarters of 1989.

Phase III - Synthesis

Comparative analysis of the three evaluations in order to identify strengths and weaknesses in essential drugs programmes (globally and nationally) and to suggest policy and strategy changes at the same levels. Output: Synthesis report. Timing: Fourth quarter of 1989.

5. COMPOSITION OF TEAMS

The teams should comprise senior professionals competent in the disciplines listed below. (The number of disciplines does not necessarily correspond with the number of professionals because some professionals will be qualified in more than one discipline).

Phase I Desk Study

Health policy.
Health planning.

Phase II Evaluations

Part A Health planning.
Social science.
Health policy.
Health management.
Communication.
Pharmaceuticals.

Part B Pharmaceutical production.
Quality control.
Logistics.
Pharmaceutical sales.
International trade.

Part C Health policy.
Health management.
Logistics.
Training and education.
Local production.
Economy.
Communication.
Social science.
Pharmaceuticals.

Phase III Synthesis

Health policy.
Health planning.

6. ORGANIZATION OF THE EVALUATION

DANIDA will be the lead agency supported by a consultative group of 8 members appointed by the Group of Interested Parties.

Phases I, II (part A and B) and phase III will be carried out by independent international teams selected by the lead agency in consultation with the consultative group. Country programme evaluations (phase II, part C) will be carried out by the concerned donors and recipient countries in accordance with their procedures, but in accordance with the TORs described above.

7. FINANCE

Cost of country programme evaluations will be born by the donor(s) concerned.

Phases I, II (A and B) and III will be financed by DANIDA with supplementary contributions from interested donors.

ACTION PROGRAMME ON ESSENTIAL DRUGS
SECOND MEETING OF INTERESTED PARTIES
Geneva, 22-24 June 1988

PROGRAMME D'ACTION POUR LES MEDICAMENTS
ESSENTIELS
DEUXIEME REUNION DES PARTIES INTERESSEES
Genève, 22-24 juin 1988

List of documents/Liste des documents

<u>Reference/Référence</u>	<u>Document Title/Titre du document</u>
DAP/MIP/88.1	List of documents/Liste des documents
DAP/MIP/88.2	Provisional agenda/Ordre du jour provisoire
DAP/MIP/88.3	Provisional list of participants/Liste provisoire des participants
<u>I: Governing body documentation/Documents de l'Assemblée mondiale de la Santé et du Conseil exécutif</u>	
EB81/25	Rational Use of Drugs - Report of the Executive Board Ad Hoc Committee on Drug Policies Usage rationnel des médicaments - Rapport du Comité ad hoc sur les Politiques pharmaceutiques
EB81/25 Annex 1 Annexe 1	WHO's Revised Drug Strategy - Report by the Director-General Stratégie Pharmaceutique Révisée de l'OMS - Rapport du Directeur Général
A41/17	Rational use of drugs (review of implementation of WHO's revised drug strategy) - Report by the Director-General Usage rationnel des médicaments (Examen de la mise en oeuvre de la stratégie pharmaceutique révisée de l'OMS) - Rapport du Directeur général
A41/A/SR/6, 7, 8	Summary Records of the debate on the Rational Use of Drugs, Committee A, World Health Assembly, May 1988 Procès-verbaux provisoires des débats sur l'Usage Rationnel des Médicaments, Commission A, Assemblée mondiale de la santé, mai 1988
WHA41.16	Resolution of the World Health Assembly: Rational Use of Drugs Résolution de l'Assemblée mondiale de la santé: Usage rationnel des médicaments
WHA41.17	Resolution of the World Health Assembly: Ethical criteria for medicinal drug promotion Résolution de l'Assemblée mondiale de la santé: Critères éthiques applicables à la promotion des médicaments

Reference/Référence Document Title/Titre du document

II: Overall programme of work/Plan général de travail

- EDV/MTP/83.1 Global Medium Term Programme, 1984-89
 Programme 12.2 - Essential Drugs and Vaccines
 Programme mondial à moyen terme, 1984-89
 Programme 12.2 - Médicaments et Vaccins Essentiels
- EDV/MTP/88.1 Global Medium Term Programme, 1990-1995
 Programme 12.2 - Essential Drugs and Vaccines
 Programme mondial à moyen terme, 1990-1995
 Programme 12.2 - Médicaments et Vaccins Essentiels

III: DAP operations/Activités du DAP

- DAP/87.4 Summary of WHO's involvement in country support - examples of
 major activities
 Participation de l'OMS à l'appui fourni aux pays - exemples
 des principales activités
- DAP/87.8 Summary of progress in the WHO Action Programme on Essential
 Drugs and Vaccines, December 1987
 Résumé des progrès réalisés par le Programme d'Action pour
 les Médicaments et Vaccins essentiels
- DAP/MIP/88.4* Extract from: Managerial Framework of the Drug Action
 Programme, February 1987 (MSR 191)
- DAP/88.7 Action Programme on Essential Drugs and Vaccines:
 Information, Education and Communication Strategy
 Programme d'Action pour les Médicaments et Vaccins essentiels:
 Stratégie d'information, d'éducation et de communication
- Essential Drugs Monitor, No. 6
 Médicaments Essentiels : Le Point No. 6

IV: Follow-up of revised drug strategy/Suivi de la stratégie pharmaceutique révisée

- World Drug Situation, WHO, Geneva, 1988* I)
- Guidelines for developing national drug policies, WHO,
Geneva, 1988*

V: Cooperation with other organizations/Coopération avec d'autres organisations

- E/ICEF/1988/P/L.40 Recommendation to the [UNICEF] Executive Board for Programme
 Cooperation 1989-1993 - The Bamako Initiative
 Recommandation au Conseil d'Administration pour la Coopération
 au Programme 1989-1993 - L'Initiative de Bamako

* English only/Anglais seulement

I) To be distributed during the meeting/A distribuer pendant la réunion