AN EVALUATION OF WHO'S ACTION PROGRAMME ON ESSENTIAL DRUGS

Submitted to the
Management Advisory Committee,
The Action Programme on Essential Drugs

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PREFACE

After 10 years of existence of the Essential Drugs Programme several countries felt the need to evaluate donor supported national essential drugs programmes. Realizing that such an evaluation would only be comprehensive if they took into account the relationship with the WHO Action Programme on Essential Drugs and UNICEF's drug procurement and supply system the concept of a global evaluation was formulated by several donors in cooperation with WHO and UNICEF. This concept was, in June, 1988, endorsed by the Group of Interested Parties which established a Consultative Group to prepare the terms of reference and follow the progress of the evaluation. The Consultative Group comprised representatives from Denmark, Italy, Mexico, the Netherlands, Nigeria, the Philippines, Switzerland and Sri Lanka. The Group has met three times during the course of the evaluation and has continuously reported to the Group of Interested Parties and its successor, the Management Advisory Committee of WHO's Action Programme on Essential Drugs.

The Royal Tropical Institute, the Netherlands, and the London School of Hygiene and Tropical Medicine, UK were contracted to undertake the evaluation which included a policy study; an analysis of 13 country case studies, reviews of regional co-operation activities in Asia and Latin America, drugs policies in Franco-phone Africa and WHO's regional offices support for the Action Programme on Essential Drugs; and a synthesis into the final report of an evaluation of UNICEF's supply and procurement division which was done by Societe Generale de Surveillance. The 13 country studies and regional studies were carried out by separate consultants contracted by some of the donors.

An evaluation of this nature inevitably depends on the goodwill and support of many. The Consultative Group would like to take this opportunity to express its sincere thanks to the governments, organizations and individuals who willingly participated in interviews and who made extensive documentation available. In particular the financial support provided by the governments of Denmark, the Netherlands, the United Kingdom, Sweden and Switzerland is acknowledged.

This evaluation provides a comprehensive analysis of the development of the WHO Action Programme on Essential drugs over the period 1978-1989. It shows that WHO has been successful in its advocacy and communications role, and has provided important technical support in a number of countries. The evidence shows that the strategies employed by the Drug Action Programme have had a positive impact on the understanding, on the acceptance and on the implementation of the essential drugs concept.

The report concludes that although the essential drugs concept is widely recognized, and many countries are developing national drugs policies, the role of WHO as promoter and advocate of the concept as well as provider of technical support is still crucial. WHO should in the 1990's maintain the momentum established in the 1980's and continue to use its prestige and position as an international specialist agency to promote the essential drugs concept globally and to endorse and support the efforts of member countries to develop policies and implement strategies ensuring the availability, accessibility and rational use of essential drugs in the context of Primary Health Care.

The Consultative Group
EXECUTIVE SUMMARY

In 1978, WHO was requested by the World Health Assembly to establish the Action Programme on Essential Drugs (APED) and in 1981 the Drugs Action Programme (DAP) was established as the main operational unit within WHO responsible for developing policies on essential drugs. The overall objectives for APED shifted over the first few years, but by 1983 had consolidated as ensuring the availability of a regular supply to all people, of a selected number of safe and effective drugs of acceptable quality at lowest cost.

Policy developed slowly in what can be characterized as three periods: the years of developing the concept 1975-1981; defining DAP's work 1981-1983; and action and consolidation 1983-1988. From a global concept articulated in the introduction to the Essential Drugs List in 1977, focus narrowed in the following years to concentrate on the supply of drugs to the least developed countries. However, after the acceptance of the Revised Drug Strategy in 1986, APED increased in scope so that by 1988 it embraced all aspects of national drugs policies. Expansion of activities occurred tentatively at first, accelerating only in the mid 1980s. This was partly because of a lack of clarity about goals and strategies within the Organization, but was largely due to the negative reaction of the pharmaceutical industry which only gradually accepted the essential drugs concept, and used many tactics to limit its application and constrain its influence.

The WHO leadership demonstrated diverse skills in keeping a dialogue with industry open, without losing its resolve. The Organization was pressed in this, sometimes indirectly, by the increasingly professional consumer and non-government organizations which wanted more rapid changes in drug controls. The intense participation and lobbying of both industry and consumer groups in the international policy process was a new experience for WHO which was forced to mediate between a protective industry and an assertive consumer lobby arguing for change.

This participation and experiences with the essential drugs programme in Kenya and a potential for a national drugs programme in Tanzania, provided the impetus for growth in the Action Programme. A new programme manager was appointed to DAP in 1983 and APED entered a vigorous phase of advocacy of the essential drugs concept as well as increasing support to countries.

In this it was greatly assisted by extrabudgetary funds from a number of donor agencies. They facilitated a rapid expansion of DAP's activities. By not demanding a rigid system of accountability for these activities, donors showed confidence in DAP and allowed its programme manager maximum flexibility. Donor aid was a cornerstone of policy implementation.

Expansion was aided by placing DAP within the Director General's office thus removing traditional bureaucratic controls over management and financing. This move also stressed the high priority the WHO leadership gave to APED.

The thirteen country studies undertaken for this evaluation (Bangladesh, Burundi, Colombia, Democratic Yemen, Indonesia, Kenya, Mozambique, Nigeria, Sudan, Tanzania, Vietnam, Yemen Arab Republic and Zimbabwe) suggest that the essential drugs concept has been accepted although definitions vary widely from a narrow
conceptualization of an essential drugs list for the public sector to a broader comprehensive national drugs policy, wholly or partly implemented, including both private and public sectors.

The comprehensiveness of drugs policies undertaken by countries has been primarily conditioned by their political and economic environment. With the exception of Bangladesh and Zimbabwe, centrally planned economies have found it easier to introduce comprehensive policies while mixed economies have implemented some aspects of essential drugs policies, often limited to their public sectors.

Essential drugs lists exist in most of the countries studied and are applied to both public and private sectors in Bangladesh, Democratic Yemen, Mozambique, Sudan, Vietnam and in 1990 in Zimbabwe. Private sectors range from about 19% of the total drugs market in Mozambique to over 90% in the Yemen Arab Republic and are a significant factor in the development of national drugs policies.

None of the countries has developed a fully comprehensive quality assurance system. The number of registered drugs is large and quality control and inspection resources limited. The WHO Certification Scheme seems to be little used.

Few countries have centralised procurement systems and international tendering by generic name is usually limited to the public sector. Seven of the thirteen countries use kits, mainly imported from Europe and often from UNICEF’s Supplies Division. External funding has sometimes been conditional on the purchase of kits. The kit system has been successful in regularly supplying essential drugs to primary level facilities. However, the short-term objective of using a vertical operation of kit distribution during the early 1980s has become a long-term strategy and has been difficult to change. The local packaging of kits does not appear to have been sufficiently promoted by countries or supported by donors and the UN agencies.

Local production capabilities vary widely. The least developed countries produce small quantities of expensive and often non-essential drugs. Many of the countries with greater production capabilities are hampered by the lack of convertible currency to increase production to cost-effective levels. Of the countries that are almost self-sufficient in local production, Bangladesh has increased essential drugs production. Indonesia and Colombia at present produce large quantities of non-essential drugs.

The training of health workers in the rational use of drugs has been unsystematic. Crash training programmes have generally not been followed-up by refresher courses and supervision. The essential drugs concept has been introduced in the curricula of a few medical and pharmaceutical schools.

Apart from the production of educational posters for health units, billboards and public transport vehicles, little has been done to provide information about drugs to the population. In most countries, the marketing of drugs by transnationals is aggressive and often unethical.

Drugs programmes have generally been implemented in a vertical fashion, establishing parallel supply, training and supervision systems which are not usually integrated into the existing health services.
Where multiple drug programmes are being implemented by various donors, coordination with, and between donors has been difficult, resulting in the fragmentation of services and duplication of effort.

Donor funds have been crucial to the development of essential drugs policies. The countries studied are either totally or partially dependent on external funds for their drug programmes. This dependency is likely to continue for the foreseeable future and donors will continue to influence programme development. DAP’s role in attracting extrabudgetary funds for countries, whether as "seed money" to initiate activities in-country, or to support specific country programmes was acknowledged in many of the case studies.

WHO’s advocacy of the essential drugs concept started with the production of the first model list of essential drugs. Inter-regional, regional and country workshops have been organized by DAP to promote the concept. The distribution of a newsletter from 1985, has helped to disseminate information amongst countries about essential drugs programmes.

Technical support provided by DAP includes consultants, guidelines, workshops, evaluations and training. Guidelines are judged as useful within countries and the quality of DAP consultants and staff is generally regarded as high. DAP has facilitated the training of nationals in most aspects of drugs supply management through fellowships as well as country and regional workshops.

DAP’s involvement with WHO regional offices and country representatives varies from region to region and from country to country. However, the links with AFRO in providing country support were particularly weak.

The country case studies demonstrate that WHO can be effective only when governments have the political will to develop national policies. At the same time governments attempting to rationalize their drug systems face enormous political and economic pressure from various interests, national and international, and WHO’s role as a global specialist agency providing political, moral and financial support to countries is critical.

Evidence from these countries suggests that general availability of essential drugs at primary level has increased through regular supply. The accessibility of these drugs to people remains dependent on the health system’s coverage. In comparison to the early 1980s, essential drugs are being preferentially purchased and distributed to primary level services. However, indications are that problems exist in the prescribing of drugs at all levels of the health system.

Where availability of drugs has increased, there appears to have been a corresponding increase in the credibility of the health services and morale of health workers. This has facilitated preventive and promotive health activities.

DAP has been supported in its country work by its relationship with UNICEF. The latter was largely involved in the supply, and in some countries, distribution of essential drugs in the mid 1980s. In 1987 UNICEF’s focus on supply changed to a concern more about policy, and the Bamako Initiative was launched as a way to strengthen primary health care in countries through the provision and sale of essential drugs. The
lack of clarity about the Initiative and limited consultation between WHO and UNICEF initially led to some tension between the two agencies.

In order to assess the Action Programme it was agreed that the evaluation would review and assess policy and its implementation, but for methodological reasons would not measure the impact of implementation below national level. Thus, two questions were posed. The first asked whether the Action Programme had achieved its objectives. It was shown that these objectives shifted, but that by 1983 it was clear that the overall objective was to ensure the availability of a regular supply to all people, of a selected number of safe and effective drugs of acceptable quality at the lowest cost. Many aspects of this objective have been achieved, but not to all people in all countries. There remain a number of unanswered questions about the prices of essential drugs, the accessibility of essential drugs, the role of the private sector in providing essential drugs, the sustainability of programmes, and the rational use of drugs.

The second question asked whether the strategies and activities undertaken by DAP had contributed to the promotion and adoption of essential drugs policies.

One of the most important thrusts of APED was the communication and information activities undertaken by DAP. Many different methods were used by DAP, some more visible than others. For example, a great deal of advocacy took place with policy makers at the World Health Assembly, donor agencies, international meetings, and through the press and scientific journals. The Essential drugs monitor was an important tool in this respect, going to thousands of addresses all over the world. Acceptance of the essential drugs concept is evidenced in the recognition given to it by, and the actions of, many UN agencies, the World Bank, governments, non-government organizations, prescribers and medical associations and even some international industry associations.

Producing technical and information tools was a responsibility shared by the pharmaceuticals unit PHA and DAP. Both units provided a great deal of support to countries and other groups in the period 1983-1988. Some of this material was published as official WHO documents. DAP used its own off-set printing processes to enable it to produce materials quickly and was more productive and distributed much more widely than did PHA. On the whole material reached its target groups, although some lacunae remain. Most of the material produced was appropriate, although again, weaknesses are apparent in the lack and late production of certain sorts of information.

The urgency and energy which went into communications and country support work by DAP was facilitated by DAP's management style of entrepreneurial opportunism. Delegated authority, flexible organization, lack of bureaucratic procedures encouraged a dynamic programme of activities. Extrabudgetary funds which increased from $400,000 in 1980/1 to $20 million in 1987/8 were critical to the expansion of country support work. The existence of discretionary funds allowed DAP to increase its staffing levels from 9 full time staff in 1982/3 to 17 in 1987/8. This management style was instrumental in achieving the rapid expansion of the programme. It created a flexible environment so that the professional and active team selected by the programme manager was able to work with speed and commitment in both advocacy and technical support. However, this approach did not lead to systematic planning or to the institutionalization of the programme.
In general, therefore, DAP has been successful in its advocacy and communications role, and has played an important technical support role in many countries. The evidence shows that the strategies employed by DAP have had a major impact on the understanding, acceptance and implementation of the essential drugs concept. The challenge in the future is to sustain support and interest in the concept.

Table 1: Chronology of major events related to APED

1975  28th World Health Assembly
Director General’s Reprt on drugs. Resolution WHA28.66 requests the Director General "to develop means and advise on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs".

1976  First expert committee on essential drugs list.

UNCTAD IV (4th Session) focus on drug production in LDCs.

Drug Policies and Management Unit (DPM) established.

1977  The Selection of Essential Drugs. First essential drugs list published.

1978  WHO/UNICEF meeting on Primary Health Care at Alma Ata.

DPM regional meetings in Colombo and Manila.

31st World Health Assembly
Technical discussions on Drugs Policies. Resolution WHA31.32 urges Member States to establish essential drugs lists, raises the issue of a WHO marketing code and proposes the establishment of an Action Programme on Essential Drugs. Establishment of Ad hoc committee of the Executive Board on Drugs Policies and Management.

1979  The Selection of Essential Drugs revised.

32nd World Health Assembly
Resolution WHA32.41 calls for the establishment of an administrative structure for the Action Programme on Essential Drugs (APED).

1981  Establishment of an administrative unit for Action Programme on Essential Drugs and Vaccines with the acronym DAP.

34th World Health Assembly
WHA adopts Global Strategy of Health For All by the Year 2000.

IFPMA voluntary marketing code.
Health Action International (HAI) founded.

1982 Third expert committee on Essential Drugs. Published report stresses usage rather than selection as reflected in the title The Use of Essential Drugs.

35th World Health Assembly
Adopts a plan of action for APED: A35/7.

1983 DAP is placed in the office of the Director General.

1984 37th World Health Assembly
Resolution WHA37.33 asks the Director General to call a meeting on the rational use of drugs.

DAP produces five year plan 1984-1989 (EDV/MTP/83.1).

1985 The Use of Essential Drugs revised for the fourth time.

Conference of Experts on Rational Use of Drugs held in Nairobi. Broadens the scope of essential drugs policies.

Essential Drugs Monitor begins.

1986 39th World Health Assembly
Revised Drug Strategy accepted (WHA39.27).

First Meeting of Interested Parties. Donors and recipients invited to discuss progress in DAP.

European Parliament endorses WHO's essential drugs programme.

Pharmaceuticals Unit (PHA) is placed in the office of the Director General.

1987 DAP progress report gives country situation analysis, development activities, operational research and evaluation and monitoring (DAP 87.8).

UNICEF announces the Bamako Initiative.


41st World Health Assembly
Resolution WHA41.17 requests wide dissemination of Ethical Criteria for Medicinal Drug Promotion in all official languages.

WHO leadership changes. Dr H. Mahler leaves and Dr. H Nakajima becomes the Director General.

Second Meeting on Interested Parties.
The Use of Essential Drugs revised for the fifth time.

1989 Meeting of Interested Parties becomes the Management Advisory Committee.
1. INTRODUCTION

In 1978 WHO's executive board and delegates to the World Health Assembly called for the establishment of an Action Programme on Essential Drugs and Vaccines in order to help developing countries select, procure, distribute and use essential drugs, and develop national drugs policies. The Drugs Action Programme (DAP) was established in 1981 to implement this programme. Through its supplies division UNICEF has been involved in drug supply for developing countries for many years, and its operation has expanded considerably since the early 1980's.

As explained in the preface, several donor countries with extensive involvement in bilateral aid to national essential drugs programmes discussed the possibility of coordinating evaluations of a number of country programmes during 1987. Realizing WHO's major role in the development of essential drugs policies and programmes, the concept of the global evaluation emerged. This was supported by DAP which suggested that donors to the Action Programme coordinate their interests to avoid multiple or overlapping evaluations.

The Royal Tropical Institute, the Netherlands and the London School of Hygiene and Tropical Medicine, UK were requested to prepare a joint proposal for carrying out the evaluation, and the Societe Generale de Surveillance of Switzerland (SGS) to evaluate UNICEF's Supplies Division (UNIPAC). Agreements were made with these institutions.

Objectives of the evaluation

According to the Terms of Reference the overall objective was to evaluate WHO's Action Programme on Essential Drugs as established in 1981 by:

a) determining whether the Programme had achieved its established objectives and targets,

b) identifying constraints encountered in its activities that hindered the attainment of the established objectives,

c) giving recommendations for the future, taking into consideration current changes within the Programme.

In line with the objectives of the Action Programme of Essential Drugs the focus of this evaluation was on the Programme's activities in the developing countries.

Definition of Terms

It is important to note that the Action Programme of Essential Drugs and Vaccines is known by several names and acronyms: Essential Drugs and Vaccines (EDV); Action Programme on Essential Drugs (APED); Drugs Action Programme (DAP). These terms are often used interchangeably to describe a policy, a strategy and an operational unit within WHO. For clarity and according to the terms of reference of the evaluation, this document uses APED as WHO's overall policy and strategy relating to essential drugs, and DAP as the operational unit within WHO which has the main responsibility for implementing the policy.
Limitations

It was agreed that the evaluation would review and assess policy and its implementation, but would not measure the impact of implementation. The aim of this approach was to give an overview of a process of change, and provide an analysis of policy which would highlight policy options. It was not considered feasible to undertake a rigorous impact study determining whether inexpensive essential drugs, and of good quality were regularly available to the great majority of any population. This would have demanded measurement at the country level, base-line studies as well as intensive surveys of randomly sampled and stratified areas and health facilities within a country. Furthermore, such an evaluation could give some idea of coverage but not of appropriate or rational use of drugs. Since this evaluation was primarily to obtain a global overview of the extent to which WHO’s concept of essential drugs had been adopted, it was not considered appropriate to give a global view of impact.

In addition, there were limitations concerning the actual undertaking of the evaluation. In spite of holding a workshop to ensure the uniform application of the methodology in the country case studies, not all consultants who undertook the evaluations were identified in time, and therefore did not attend. Difficulties in organising the country visits resulted in some reports arriving late in the synthesis period. It must also be borne in mind that the country visits were organized and funded by the donors. While all attempts were made to review the country programmes objectively, international agencies, including donors, programme managers and ministries of health, all had strong views and interests in the country studies and these did not always coincide. One final limitation was that of the policy study ran concurrently with the country studies. As a result, it was often difficult to link the outcome of the policy review with the investigations being carried out in the countries and vice versa.

Acknowledgement

The team wishes to acknowledge the cooperation received from many people but particularly from the staff and former staff of the Drug Action Programme (DAP); others in WHO headquarters and regional offices, the national governments of the countries visited, DANIDA as donor-coordinator of the evaluation and those donor agencies which organized the country visits. In addition the team would like to gratefully acknowledge the assistance of Mr. Ian Leitch, of LSHTM and Ms. Marja Molenaar of KIT.
2. REVIEWING THE POLICY PROCESS

WHO's policy on essential drugs evolved slowly over a number of years. The first major signal of a policy concern was a report by the Director General of the Organization which was presented to the World Health Assembly in 1975. It called the Director General's attention to problems of high expenditure on drugs, in both developed and developing countries. He then analyzed the myriad of unethical and sometimes illegal practices used in the distribution of drugs in developing countries, concluding that:

There is an urgent need to ensure that the most essential drugs are available at a reasonable price and to stimulate research and development to produce new drugs adapted to the real health requirements of developing countries. This calls for the development of national drugs policies for the whole drug sector, linking drug requirements with health priorities in national health plans formulated within the context of social and economic development (A28/11).

In this chapter the evolution of policy is traced, looking at the different stages in the policy process: problem identification, policy formulation and implementation. Although the boundaries between each stage of this process are not easily distinguishable, it is conceptually useful to describe them separately. In order to understand the way in which issues come on to the policy agenda, and how they fare once there, it is also necessary to look at the context within which policy is discussed, and the influences of the main actors and interests involved. From the analysis three main periods can be distinguished: the first, a period in which the concept was developed 1975 - 1981, the second a period of defining DAP's work 1981-1983 and a third period of action and consolidation, 1983 - 1988.

2.1 1975 - 1981: Developing the concept

The political and economic environment influences the development of policy. In the 1970s critics of past development theories which had emphasised the concept of modernization through investment in the physical elements of national growth - industry, roads, dams - drew attention to the relative neglect of the social aspects of development, and to imbalances in benefits from growth. As a result, focus turned to equity and to redistributive policies as a means of redressing the worst inequalities between groups. The international agencies translated some of this debate into policy. In 1974 the International Labour Office promoted the basic needs approach to development, and at the same time, the new Director General of WHO, Dr Halfdan Mahler, introduced a broad change in policy which emphasized the improvement of basic health services and coverage, especially for neglected rural and peri-urban populations. By the mid to late-1970s WHO's shift in policy was being enunciated through the strong promotion of the idea of Health for all by the year 2000 through the primary health care (PHC) approach. Although the original PHC discussion document did not include essential drugs as one of the components of PHC, debate at the Alma Ata meeting gave essential drugs their place as one of the eight components of PHC in the final declaration.
Economic exigencies paralleled the changing ideas about equity and health. The oil crisis in 1972 put enormous stress on government budgets, and ministries of health in developing countries began to look more closely at their drug costs, which in some cases accounted for up to 40% of the total health budget. There was some exchange of experience between those countries which had reduced drug costs through a number of different limiting and controlling drugs policies. Papua New Guinea, for example, had introduced an essential drugs policy as early as the 1950s. Sri Lanka established an essential drugs list for the public sector in 1959 and extended it to the private sector in 1972. Cuba, Peru and Mozambique all established essential drugs lists in the 1960s and 1970s (Mamdani & Walker 1985).

Not only were the high costs of pharmaceuticals an issue which received increasing attention in the 1970s, particularly from hard-pressed ministries of health, but there was also a crescending public protest at the activities of the pharmaceutical industry. The thalidomide disaster in 1962 and a decade later the Japanese victims of SMON (serious nervous system damage caused by regular intake of cloquinois) were both fully covered in the press and on television. By the 1970s increasing evidence of the mal-practices of the pharmaceutical industry was being reported by consumer organizations and in scientific journals and publications such as The drugging of the Americas (Silverman 1976).

This then was the background against which WHO’s policy on essential drugs developed. Mahler’s 1975 report was the result of many forces: concerns expressed by countries at the rising costs of drugs; experiences of some countries which had introduced controls regarding drugs; a changing world of ideas regarding development in which the focus was on primary health care and equity; significant criticism of some of the activities of the pharmaceutical industry and the iatrogenic effects of some of its products; and last, but not least, a particular interest in drugs by the new Director General of WHO which derived from his own experience in treating tuberculosis in India.

WHO’s structure and policy processes
In order to understand how this background affected policy making within WHO, it is necessary to look more closely at its structure and policy processes. The WHO forms part of the UN system as a specialized agency in health. The organization consists of three constituent bodies: the World Health Assembly (WHA), the Executive Board and the Secretariat. The Assembly meets annually, in May, and is attended by delegations from ministries of health of all member states, representatives from other international bodies and non-government organizations. The main task of the Assembly is to approve the biennial programme and budget and to make major policy decisions.

The Executive Board (EB) consists of 31 people technically qualified in the field of health, each appointed by designated member states and elected by the Assembly. The EB meets twice yearly, normally in January and just after the Assembly. As an executive organ the EB prepares the agenda for the WHA and submits the general programme of work to the WHA, acting on behalf of the membership of the Organization.

The Secretariat, with the Director General as its technical and administrative head, comprises the whole staff, including those in headquarters in Geneva, those in the six regional offices and WHO representatives at country level. The six regional offices are
responsible for formulating policies of a regional character, and have their own planning and biennial budget cycle feeding into the Executive Board meetings in Geneva. The regions are: Africa (AFRO); Eastern Mediterranean (EMRO); European (EURO); Americas (PAHO); South-East Asia (SEARO); and Western Pacific (WPRO).

The Director General's 1975 report to the World Health Assembly arose from requests from delegations for a WHO policy on drugs. The report covered three basic, interrelated issues: the availability, accessibility and efficacy of drugs. The main concern was with making essential drugs available at reasonable cost to those in need. The detailed report advocated the development of national drug policies, describing the components of such policies as including: procurement; research and development, information, production, distribution, legislation, good manufacturing practices, pharmaceutical inspection and control; registration, lists of essential drugs and the monitoring of drugs (A28/11 1975). The WHA endorsed the report and called on the WHO secretariat, to provide assistance to member states to develop national drug policies emphasizing amongst others, the selection and procurement of essential drugs 'at reasonable cost' (WH A 28.66).

Establishing the Drug Policies and Management (DPM) unit
In order to implement the new approach to drugs policy within WHO endorsed by the WHA in 1975, a new unit was created within the Division of Diagnostic, Prophylactic and Therapeutic Substances. Until 1975 there had been only one unit within WHO within the above Division responsible for drugs issues - Pharmaceuticals (PHA). Concerned largely with technical or normative functions, this unit produced the International Pharmacopoeia and the international nomenclature for non-proprietary names in the 1950s. In the 1960s work focused largely on the safety and efficacy of drugs and on quality control.

The first activity of the new unit was to convene an expert committee to produce a model essential drugs list. The official publication of this list in 1977 (WHO 1977) with the WHO imprimatur was a critical tool for furthering a new approach to drugs policy. The introductory section to this document clearly outlined the conceptual and technical bases for the essential drugs concept and specified the complementary policy, legislative, logistic and educational actions that were necessary to ensure the regular supply and the rational use of drugs.

In preparation for the discussions of the expert committee on essential drugs, the DPM unit gathered information and planned the next stage in the development of drugs policy. During 1976 and 1977 staff visited four out of the six WHO regions and 25 countries, talking with ministry officials, doctors, pharmacists and health providers at all levels of the health service. In addition, they prepared three major meetings: a consultation on drugs policy in Geneva which included the other United Nations (UN) agencies involved in drugs issues (UNCTAD and UNIDO), and two regional meetings in Colombo and Manila to discuss activities in developing essential drugs policies. The role of the unit in this period was to search for practical solutions to addressing problems.

The DPM unit also prepared a paper for the 1978 WHO Assembly, where the Technical Discussions were to be on drugs policy (A31/Technical Discussions/1). The paper outlined WHO's approach to the drugs issue and reviewed activities over the past three years, emphasising problems in the less developed countries. The report highlighted
technical and administrative components of drug policies, problems with implementation, and referred to possible solutions. It was reinforced by a recommendation from the WHA (WHA 31.32) to create an action programme on essential drugs. The action programme had the objective of:

strengthening the national capabilities of developing countries in the selection, supply and proper use of essential drugs to meet their real health needs, and in the local production and quality control, wherever feasible, of such drugs. The immediate aim of the action programme is to make essential drugs and vaccines available under favourable conditions to governments of the less developed countries in order to extend essential health care and disease control to the vast majority of the population (EB63/19 p.3).

The focusing of the broad concept into an action programme directed primarily at improving the supply of drugs in support of PHC in the less developed countries was due to various factors. Although the essential drugs concept as originally promoted pertained to all countries, developed or developing, by 1978 stress was being put on the least developed countries. This was partly because of the urgent needs of these countries, but this focus also minimized conflict with industry.

**The Action Programme on Essential Drugs (APED)**
The proposal to launch an action programme was endorsed at the WHA in 1978, and the following year it was recommended that an administrative structure be set up to undertake the activities of the Action Programme. At the same time the Executive Board established an Ad Hoc Committee on Drug Policies and Management, so that policy issues could be debated in detail by a smaller group of members of the Executive Board.

In the two years before a new administrative structure was in place, activities within the DPM unit covered a number of different areas reflecting interests within the unit rather than a clear programme of action. In part this was a result of competing country interests where the more technically advanced developing countries identified the need for local production, a UNIDO initiative, and less advanced developing countries emphasized the need for drugs procurement. Country level activities covered a range of a range of activities including a large study of the national drugs policy in Indonesia focusing largely on local production; missions in conjunction with individual pharmaceutical companies to four African countries to assess the drug supply situation; and support to programmes under the umbrella of Technical Co-operation among the Developing Countries (TCDC).

**The functions of DAP**
In February 1981, the administrative structure which had been requested by the WHA was established. The DPM unit was abolished, and a new unit created. The new unit was called the Action Programme for Essential Drugs, with the acronym DAP (Drugs Action Programme). It was staffed by the same personnel who had made up the DPM unit. The potential for confusion as to whether APED was an administrative or operational unit, a programme, a strategy and/or a policy was exacerbated by the high hopes held by the leadership within WHO which had strongly supported and promoted the development of policy from its initial launching in 1975.
The establishment of DAP formalised the creation of the Action Programme on drugs. However, the WHO delegates and secretariat were by no means the only actors in the development of policy. Significant other groups also influenced its evolution.

**External influences on WHO’s policy**
The most important of the external influences on WHO’s essential drugs policy was the pharmaceutical industry, although the actions of other UN agencies and the non-government agencies also command attention.

**The pharmaceutical industry**
The main representative of the pharmaceutical industry which actively lobbied WHO during the 1970s was the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) based in Zurich. Representing an industry with an annual turnover of roughly US$ 100,000 million in 1986, and with member associations in 47 countries, the IFPMA was an influential force. Relations with WHO were officially established between the IFPMA and the Organization in 1971. Interaction between these two bodies intensified around the issue of national drugs policies and the advocacy of an essential drugs list, industry initially reacting negatively.

WHO tried to deflect antagonism by involving the representatives of industry in the development of the essential drugs list. Five people, including the president, represented the IFPMA at the consultation WHO convened to discuss a model essential drugs list in Geneva in December 1976. Although at times WHO was thanked by the IFPMA for engaging in a dialogue concerning criticisms of the industry their objections to WHO’s advocacy of essential drugs continued to be voiced. They revolted partly around the fear that an essential drugs list would become the model for national drug policies stopping free competition and private enterprise in drugs supplies in developing countries but much more around "the possible repercussions on the thinking of social security authorities in developed countries regarding drug reimbursement" (Scrip 1977 vol. 258, p. 7). The legislation in Norway, Denmark and Holland curtailing the proliferation of "non-essential" products was seen by industry as potentially affecting its profits in the developed countries where the drugs market was worth around $33 billion in 1976 (76% of the total market). It was within this context that the president of the IFPMA stated in 1977 that WHO’s concept was "completely unacceptable to the pharmaceutical industry" (Scrip 1977 vol. 259, p. 23).

The IFPMA was joined in its protests by the US Pharmaceutical Manufacturers Association (between 1977 and 1985, 11 of the 18 drug manufacturers with the largest sales were American). The stakes were high enough for industry to make veiled remarks regarding WHO’s dependence on voluntary contributions for its activities and the source of these contributions being industrialised countries. Some national associations in the other major drug producing countries however took slightly more moderate positions. Gradually industry conceded that least developed countries needed essential drugs policies but tried to limit their application, noting that in exceptional circumstances, in the public sectors of the poorest countries in the world where most drugs were imported

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1 In 1986, the United States did not make its assessed contribution of 25% to WHO and although no formal reasons for this were given, it has been alleged that the failure to make the contribution was due to the US’s dissatisfaction with the Nairobi conference on the rational use of drugs in 1985.
and a serious shortage of foreign exchange existed, a policy based on essential drugs was a "practical, even if regrettable short term decision" (Scrip 1977 vol. 281, p. 16).

From 1977 many pharmaceutical companies wrote to WHO offering to provide one or two specific drugs, which they regarded as "essential" (or which were on the first essential drugs list) at "favourable prices". These unilateral offers were uncoordinated by the IFPMA and the DPM unit was not in a position to take advantage of them. The main action the IFPMA took at this time was to make an offer on behalf of various companies to finance and provide 25 training posts in quality control for nationals of developing countries. As airfares were not part of the offer, fewer places were taken up than were offered. Another activity included some joint missions with WHO partially financed by the pharmaceutical companies to identify the most important health needs and quantify the drug requirements in particular countries. However, this intensive interaction between WHO and the industry resulted in little progress and was to be a source of tension in the following years. The only concrete result was a collaborative effort with the Swiss consortium, Interpharma, and the government of Burundi where a essential drugs programme started to be developed. A joint industry DPM mission took place in 1980, but it was only in 1982 that the programme started. By then the programme in Burundi had changed in emphasis from essential drugs to logistics and local production.

UN agencies

Other external influences on WHO's policy were the UN agencies concerned with different aspects of pharmaceutical production. In the 1960s and 1970s UNICEF was involved in the supply of essential drugs through its Supplies Division (formerly UNIPAC) and UNIDO and UNCTAD had promoted local production of drugs and trade in developing countries. The latter organizations had undertaken several studies of the pharmaceutical industry. By the mid 1970s UNIDO and UNCTAD were concerned about the slow rate of transfer of technology in relation to domestic production of pharmaceutical products, as well as the costs of drugs to less developed countries. In 1975 UNCTAD published a report criticising the excessive profits made by transnational pharmaceutical companies in their trade with the third world (Lall 1975) and a number of international meetings in 1976 specifically focused on problems of obtaining inexpensive drugs and of developing local industry. The debate was a fierce one between unequal, powerful, interests: multi-national industry, governments, national pharmaceutical companies, UN agencies and non-government organizations. In this complex and intense arena, WHO's initial promotion of a broad and radical concept became understandably more cautious.

Consumer Groups

Consumer groups began monitoring the activities of the pharmaceutical industry during the 1970s, and the international organization of consumer unions (IOCU) set up an international network to serve as a countervailing force to the multinational corporations. Increasingly developed country based organizations were joined by consumer groups in developing countries. However it was not until 1982 that they organized public lobbying under the umbrella of Health Action International at the international level. In the early period of WHO's policy development their actors were still off stage.

2.2 1981 - 1983: Defining DAP's work

Although the establishment of DAP with the general objective of strengthening national
capabilities of developing countries in the selection, supply, distribution and proper use of essential drugs appeared clear, many difficulties in interpretation arose in 1981 and 1982. The first years after the establishment of DAP were marked by discussion and debate about the concept of essential drugs and the role of WHO but little concrete action at country level. It was only at the end of 1983 that APED really took off.

Controlling confrontational tactics
From the early 1980s a number of consumer groups began to press actively for changes in multinational marketing practices in the third world. Lively campaigns and considerable media coverage challenged the somewhat remote multi-national companies and a period of sometimes intense confrontation began. This was brought, unusually, to the World Health Assembly in May 1981, just months after DAP had been established. The presence of various groups such as the International Baby Food Action Network which had actively campaigned against the infant formula industry put the pharmaceutical industry on the defensive. Consumer groups successfully lobbied for the introduction of a WHO Code to regulate the promotion of breast milk substitutes in the third world. The Code was passed by all member states except the United States of America in spite of the active opposition of the International Council of Infant Food Industries which represented the producers of infant formula foods.

The pharmaceutical industry knew that a WHO Code on pharmaceuticals had been mooted at the WHA in 1978 (WHA 31.32) and their anticipation of similar tactics being used by consumer groups against the pharmaceutical industry led to a swift response to forestall action. The IFPMA launched its own marketing code in 1981. Events in the year that followed supported their fears. Health Action International (HAI) - a coalition of consumer, professional and development action groups from twenty seven countries - held their inaugural meeting in Geneva, and made a strong impression at the 1982 WHA, launching a pamphlet against GD Searle's drug, Lomotil. At an UNCTAD meeting in 1982 IOCU introduced a draft proposal for an international code of practices prepared by HAI, which was more stringent than the one advised by the IFPMA. Members of the Executive Board in 1982 again raised the possibility of a WHO code, although this was not deemed timely. The introduction of the IFPMA Code, albeit a relatively weak one, had deflected immediate action.

The experience of the intense lobbying tactics employed by consumer groups, non-government organizations and the industry at the 1981 World Health Assembly was a new one for WHO and gave the Organization greater impetus to demonstrate that the Action Programme on Essential Drugs was having an effect in countries. However, even a year after DAP had been established, action appeared to be slow. At the Executive Board meeting in January 1982, some members expressed disappointment at APED’s apparent lack of effect.

The progress report to the 1982 Executive Board suggested that a lack of funds was a problem in implementing APED. The regular budget was restricted - amounting to approximately US$ 1 million in 1980/81 and 1982/83 and the only extrabudgetary allocations had been US $ 400,000 from France.

In 1982, Executive Board members began a lengthy debate on the direction of the Action Programme. Some members appeared to express concern that WHO was exceeding its constitutional mandate. That, while it was able to play its general coordinating role in promoting the essential drugs concept, it was unclear that it was
able to provide technical support in all the complexities of an essential drugs policy such as pricing, procurement, distribution and quality assurance. Instead, it was suggested that emphasis should be placed on motivating and facilitating countries to undertake national essential drugs policies. Some members suggested that industry could handle the more technical aspects. The extent of the discussion implied however, that while the policy on which APED was based was relatively clear, its strategies were open to interpretation.

The relationship with industry was also on the agenda for the meeting. The president of the IFPMA was invited to address the Board, and his criticisms of WHO’s neglect to acknowledge the support industry had made to the essential drugs programme (in the shape of 200 drugs to be offered at favourable prices) was noted. However the Director General noted that it was up to industry to clarify and make such offers practical so that member states could appraise the benefits available to them from the industry. Two other points of discussion were of particular concern to industry: one was a brief observation that APED might be applied to both the private and public sectors, and another that WHO promote a marketing code.

The years 1981 and especially, 1982 were marked by a flurry of meetings between WHO personnel and the various interest groups. Many contacts took place with the pharmaceutical industry to try to define more closely the terms on which the industry was making its offers and to try to reach agreement on practical support for an essential drugs programme in one or two countries. Such meetings took place at the highest level of leadership within the Organization, and included decision makers in UNICEF. The commitment to APED which stemmed from the leadership was evidenced in the many meetings held with industry. The leadership’s impatience with the lack of progress was also expressed in a number of meetings with DAP staff and an external consultant was brought in specifically to recommend ways to give visibility to the programme at country level.

The final impetus for action came from outside the Organization, from the experience of the Danish International Development Agency, DANIDA, in implementing an essential drugs programme in Kenya and the proposal to assist in establishing one in Tanzania. In 1982 meetings were held at WHO to explore the possibility of using both Kenya and Tanzania as proto-types of essential drugs programmes to promote APED. As a result WHO interregional workshops were held so that others could learn from the Kenyan experience of drug supplies through the kit system, and Tanzania became the first country to implement a national drugs programme with financial support from DANIDA and with UNICEF and the Tanzanian Ministry of Health as co-executors of the programme. Soon after this Dr Lauridsen who had experience in essential drugs at country level, was persuaded to join WHO as programme manager of DAP, with responsibility for getting APED operational in countries.

2.3 1983 - 1988: The period of action and consolidation

The new programme manager of DAP moved APED from a fairly conventional programme run along orthodox WHO lines to a much more dynamic global advocacy for essential drugs policies and practical assistance to countries. From mid-1983 DAP channelled assistance to those countries which were among the poorest and demonstrated government political will for an essential drugs programme.
This strategy which included a spirited marketing of the concept was assisted by a flexible management structure and style. The first was made possible because of changes in the organizational and financial accountability of the programme. In 1983 DAP was moved from the Division of Diagnostic Prophylactic and Therapeutic Substances to the Office of the Director General demonstrating the importance with which APED was regarded by the leadership, and giving DAP’s programme manager direct contact with the Director General himself. The programme manager had a great deal of autonomy, recruiting staff of his choice, and rapidly built up a committed and energetic team. By 1988/9 the number of staff in DAP had almost doubled from nine full-time members in 1982/3 to 17.

The increase in staff was made possible because the programme manager concentrated his initial efforts on attracting extrabudgetary resources for DAP and spending the money in such a way as to build and reinforce donor confidence in DAP, resulting in further increases in contributions. By 1984 donor contributions to DAP were significant enough that WHO’s Budgeting Office created a special extrabudgetary account which earned interest for DAP. Thus although the size of the regular budget funds for DAP remained relatively constant in nominal terms at just over US$ 1 million, extrabudgetary sources grew markedly from US$ 400,000 in 1982/3 to over $20 million 1988/89.

The rapid growth of DAP brought into focus the relationship between DAP and PHA, the other WHO unit concerned with drugs issues. PHA focused largely on technical issues related to drugs, taking over the convening of the various expert committees which met to revise the original essential drugs list between 1978 -1988. Among other things PHA also evaluated the Certification Scheme, produced guidelines on quality control, organised international conferences of Drug Regulatory Authorities in Rome (1982) and Stockholm (1984) and managed a training scheme in analytical chemistry for developing country pharmacists/chemists which was paid for by industry (PHA/85.36).

Concern about the differentiation in and complementarity of tasks between DAP and PHA expressed at the Executive Board in 1984 (EB73/1984/REC/1) led to an official publication defining their different roles. (A38/Inf.Doc./3). The Nairobi conference of experts recognised the rational use of drugs as equally important to supply and defined tasks for PHA in support of APED and in April 1986, PHA was also moved to the Director-General’s office. However, PHA did not seek increased funding from extrabudgetary sources arguing that normative functions should not depend upon extrabudgetary funds but should rather be guaranteed through the regular budget.

Operationalizing APED: DAP Activities
In the mid 1980’s the main strategies to promote the essential drugs concept were: technical support to countries (through consultants, workshops and training activities) and advocacy and communications (through the provision of materials and publications) at both the country and global level.

Technical support to countries: making drugs available
In 1982 when the WHA requested a plan of action for APED, there was little national experience on which DAP could draw. Several regional offices had explored the potential for regional drug procurement schemes, none of which had materialised. A great deal of activity in the WPRO region had centred around the potential for local production of drugs, but did not focus on essential drugs policies. In the eastern mediterranean region, EMRO, WHO and UNICEF had been involved in making
situational analyses in several countries but no concrete action had been taken. Only in Africa, in Kenya, had a pilot project been undertaken to supply essential drugs to the national health services based on a kit system. This project supplied 30-40 different essential drugs to peripheral units in ration kits for an average of 3000 patients, thereby reducing losses from breakage, pilferage and wastage. The Kenyan example, as said above, provided the catalyst for renewed efforts for the promotion of APED.

The new Bangladesh Drug (Control) Ordinance of 1982 banned 1700 drugs from production or sale and attempted to restrict drugs sales by foreign firms. WHO had been taken by surprise by this policy and offered no immediate endorsement. By 1983 however, DAP identified the experience as proof of the acceptance for APED and linked its name to this national drugs policy by supporting two quality control consultants to an ongoing donor aided drugs programme.

Tanzania offered another opportunity to promote the essential drugs concept. Faced with an economic crisis, and the increasing inability to provide drugs for its health service, Tanzania asked for donor support to help procure drugs and rationalise the drug supply system. DANIDA agreed to provide $30 million for a project based on the essential drugs supply kits of the Kenyan model. UNICEF became the executing agency in partnership with the ministry of health.

Country support activities formed the basis of DAP’s work in 1983 with the main emphasis on improving supplies and distribution. The new programme manager’s aim was to have DAP involvement in one or two countries in each region to serve as a catalyst for the essential drugs concept. By 1984/5 over 50% of DAP’s resources went on country support. In parallel with country support, DAP put enormous effort into advocacy and communications, providing materials to persuade and inform others. (EB73/18, 1984; DAP 87.8; EB 81/25, 1988).

Advocacy and communications
Development of the concept of essential drugs was fairly narrowly interpreted in the first years of DAP’s existence. Documents produced by DAP between 1983 and 1985 concentrated on the supply side of drugs and the feasibility of regular supply to rural areas in developing countries. Subjects treated in detail were selection, procurement and distribution of drugs. Communications focused on three main areas: a dialogue with the pharmaceutical industry (to ensure the supply of essential drugs), with donors (to guarantee funds) and with third world governments (to advocate the concept). Much of this took place informally at meetings of the Executive Board and the World Health Assembly, although the 1983 Global Medium Term Plan mentions that thirty fact-finding studies had been carried out.

The experience gained largely from the Kenya and Tanzania programmes, highlighted three more areas of need in terms of communications and by 1985 DAP staff were increasingly designing material to help member states train health workers in the use of drugs, writing guidelines for evaluating essential drugs programmes and addressing issues about financing. With the publication of the Essential Drugs Monitor in 1985 the dissemination and promotion of the essential drugs concept became more systematic and widespread with increasing attention being paid to the issues around rational use of drugs. By 1988 the Essential Drugs Monitor had increased its production to over 16,000 copies. The number of papers written by DAP staff for scientific journals increased after 1984 as did audio-visual aids production and presentation.
Research
Although personnel in DAP recognized that more information was required to determine effective ways of reaching its overall goals of coverage and rational use the programme manager saw research as producing results very slowly and therefore a low priority. A grant from SIDA/SAREC in 1984 was an important catalyst in getting research off the ground and led to the inclusion of an operational research component. One member of staff was given the responsibility for developing operational research, and 10 per cent of DAP’s budget was set aside for research as a long term goal.

However operational research was always a small part of DAP’s activities with the first formal publication on research published only in 1989. The budget allowed was also underspent - in 1988 operational research accounted for 5.1% of expenditure against a target of 10%.

1985: Nairobi and the Revised Drug Strategy
In the 1984 World Health Assembly the delegates, led by the Netherlands and the Nordic countries with support from IOCU, asked the Director General to set up a meeting between governments, national regulatory agencies, the pharmaceutical industry, consumer groups, non-government organizations and the medical profession, to discuss the rational use of drugs. These representatives were subsequently referred to as the Group of Interested Parties.

The consequent WHO conference of experts on the Rational Use of Drugs was held in Nairobi in November 1985. Controversial issues - such as WHO’s role as a supranational regulatory body and its implementation of a marketing code - were handled with great discretion, and the disparate groups of experts agreed to support the need for governments to adopt national drugs policies based on the essential drugs concept. Success in establishing the rational distribution, prescription and use of drugs was generally conceded to depend on the political will of governments, as well as having sound policy advice and technical assistance available from WHO.

In spite of considerable disagreement and conflict, particularly between the industry and the consumer groups, a consensus emerged from the Nairobi conference which laid the basis for a broader approach to essential drugs. The Revised Drug Strategy which emerged in 1986 reiterated the need and shifted the emphasis within DAP to greater concentration and information dissemination activities and brought in PHA to deal with normative aspects. The revised strategy on drugs ratified by the WHA in 1986, provided the rationale for a shift in DAP’s communications priorities. Health service providers, their teachers and members of the public became the targets for information, although activities for this last group were slow to develop. In 1987 an information officer was appointed to rationalize the provision and documentation of information, and in 1988 DAP produced its first comprehensive communications strategy.

While not abandoning country support, the revised drug strategy focused on the relevance of the essential drugs concept for both developed and developing countries (a point made in Mahler’s 1975 report), underlining the rational use of drugs, the importance of dissemination, and the universality of concern. By the mid-1980s some developed countries had introduced limited lists and generic prescribing in order to cut drug costs. The essential drugs concept had graduated from being only a developing country concern with a supply focus.
By the mid 1980s DAP’s focus was beginning to move away from supply and distribution issues in poorer countries, to considerations of how to support the larger newly industrializing countries which faced much more complex political and economic situations in their attempts to change the status quo. Increasingly countries such as the Philippines and Mexico were approaching DAP for assistance.

With the change of Director General in 1988, DAP’s status was changed although the framework for activities was retained. Both DAP and PHA were removed from being directly under the Director General’s Office, and returned to the aegis of the Division of Diagnostic, Pharmaceutical and Therapeutic Substances which was reconstituted as the Division of Drugs Management and Policies. In a period of uncertainty following this managerial change, the programme manager resigned, and, after nearly six months with an acting head, Dr Antezana was appointed as programme manager of DAP.

**WHO’s Regional Offices and the dissemination of the essential drugs concept**

Although DAP has been the operational unit at headquarters which has catalysed the Action Programme on Essential Drugs, the concept has been disseminated widely through other parts of WHO in a process in which the Regional Offices have also played their part.

WHO’s six regional offices were established to make the Organization more responsive to regional differences and to country needs. In 1983, regional organization budgets were implemented decentralising much of the headquarters work to regional and country level (EB81/11, 1987 p.3). This action gave regional offices more freedom to operate outside direct control of the headquarters and meant they could adjust priorities according to local situations.

The evolution of policy on essential drugs reflected policy in Geneva. The region with the earliest stated policy was EMRO, which introduced the essential drugs concept in 1978. In WPRO and SEARO, APED was formally adopted as regional policy in 1981 after regional seminars on essential drugs in Colombo and Manila. PAHO had long been involved in aspects of essential drugs but pursued policy with more vigour after a leadership change in 1983 and in 1984 published Policies for the production and marketing of essential drugs. AFRO produced an essential drugs list of 40 products at the end of the 1970s, and spent a great deal of energy pursuing the possibility of bulk purchasing with support from both WHO headquarters and UNICEF. By 1983 after discussions with the African Development Bank and World Bank on the financing of such a scheme, and consideration of some of the complexities of purchase and delivery, the idea of a bulk procurement scheme was abandoned as not viable.

The member states making up each region differ markedly in social, economic and political characteristics, which often also affect the policy process at the regional office. Some countries have formed particular associations: for example, WPRO and SEARO assist in the administration of the pharmaceutical programme of the Association of Southeast Asian Nations (ASEAN), a group established to foster interregional cooperation in economic and social endeavors. Although cultural similarities are cited as unifying the member nations (Brunei, Indonesia, Malaysia, Singapore, the Philippines, and Thailand), ASEAN shares more in terms of open market economic philosophies. Many of the countries have important pharmaceutical manufacturing industries. In terms of essential drugs, this has meant an emphasis on upgrading of technical skills in
quality control and drug evaluation, with essential drugs lists perceived as appropriate largely for the 'poorer' countries of the region. Through the TCDC scheme ASEAN launched a joint UNDP/WHO project in 1981, with the immediate objective of strengthening quality assurance systems, including quality control and good manufacturing practice, drug information and manpower development in drug supply and management. It was only in the third phase of the project, in 1987, that the clear APED objectives of ensuring safe and effective drugs of acceptable quality at the lowest possible cost to all people as well as ensuring their rational use appeared. However, in implementation, the project continued to spend most of the budget on manpower development and training. SEARO also tends to emphasize the need for specialist technical training.

In the PAHO region, the Andean Pact countries (Bolivia, Colombia, Ecuador, Peru and Venezuela) have for long had an agreed policy on various aspects of drug control, but have been constrained in implementation by political instability, weak public health sectors, and substantial pharmaceutical production sectors. Although there are now essential drugs projects in a number of countries in the PAHO region, many suffer the same constraints as do the Andean countries. PAHO's capacity and capability in the region is itself limited, as is its potential for supporting the development of essential drugs programmes in the difficult circumstances many countries face.

This last is an issue common to many of the regional offices, which often have a rather small staff for essential drugs. All have regional pharmaceutical officers responsible for APED but they seldom have more than minimal staff support. Some of the regional offices (EMRO, PAHO and SEARO) have had associate professional officers at various times supported by donor funds with specific duties to promote APED.

AFRO is the region with the largest number of the poorer countries and therefore, the priority for DAP support. However, DAP has recently implied that its priority is now support to countries with a population over 40 million. Thus in Africa only Nigeria and Ethiopia would qualify under this criteria. Francophone Africa has, for the most part, been slow in adopting and implementing essential drugs policies. One major reason appears to be that for many countries the local currency is convertible to the French franc and thus, the drain on foreign exchange is not felt to be critical. Donor support for Francophone African countries has also been more difficult to obtain.

On the whole DAP circumvented the African regional office; the programme manager of DAP paid his first visit to the regional office only in 1986. Donors too, have overruled the regional office. When AFRO identified five countries to receive support in a US$ 15 million project on essential drugs, the regional office's choice was overturned. The regional office, however, is characterized as reactive rather than proactive, playing little direct role in advocacy for APED. This is in stark contrast to the enthusiasm with which it received the Bamako Initiative launched by UNICEF's executive director, Dr James Grant, at AFRO's regional meeting in Mali in 1987.

However, most of the regional offices acknowledge that DAP has been helpful in attracting extrabudgetary finances from bi and multi-lateral sources, for specific country programmes and other support work. In some regions these extra budgetary funds are substantial.
UNICEF and the dissemination of the essential drugs concept

UNICEF has always played a role in the supply of basic drugs and vaccines to organizations such as WHO, as well as directly to country programmes. However it was not otherwise involved in the essential drugs concept until the early 1980s.

The Joint Committee on Health Policy (JCHP) is the official committee that links WHO and UNICEF. It meets every two years with liaison meetings taking place twice annually. At the 1981 meeting, the JCHP’s joint programme on essential drugs was initiated. The catalyst was the establishment of the Action Programme on Essential Drugs in WHO and the development of primary health programmes at the country level.

Although joint action on the essential drugs programme entailed different sorts of collaboration between WHO and UNICEF, including joint country visits to assess the drug situation, the focus of cooperation was, from the beginning, on procurement of drugs. Thus, one of the main aims of the joint programme was to establish a group bulk purchasing scheme. The 1981 JCHP noted that there had been a concrete request from 33 African countries to WHO’s regional office in Africa, for the development of a group bulk purchasing scheme to improve the drug supply situation and this was then given high priority for action.

As has been noted pool procurement by groups of countries (discussions had occurred in the Americas and Western Pacific as well as Africa) was never implemented because of the complexity of the process, difficulties in establishing appropriate legal and commercial agreements among countries and administrative and financial mechanisms. By 1984 it was clear that pool procurement or bulk purchasing as had been originally envisaged was unlikely to succeed and other channels would have to be pursued.

The obvious answer was to increase the capacity of the UNICEF Supplies Division (formerly UNIPAC) in Copenhagen which was already buying large quantities of essential drugs on the world market, had long experience of shipping supplies to developing countries and a new warehouse which allowed the possibility of handling a greatly increased volume. With the establishment of the Tanzanian programme and large-scale bulk purchasing of essential drugs, UNIPAC’s supply operation increased considerably. The volume of drugs handled moved from US$ 17 million in 1982 to $35 million in 1985 to $60 million in 1986. According to UNICEF prices that countries actually paid for essential drugs declined in the order of 50 - 60 per cent - largely through the efficient use of international competitive tendering, bulk purchasing orders and emphasis on generic drugs.

Attempts in the mid 1980s to introduce a revolving fund to be managed by UNICEF which would give developing countries credit in the nine month delay between ordering and receiving drugs, was supported by only one donor, which tied its contribution of US$ 3.0 million to the inclusion of family planning supplies. The fund has been used by a few countries to obtain credit from UNICEF and it has been given a deliberately low profile and is largely inactive.

Having achieved a great deal on the supply and distribution side, UNICEF announced a rather different policy focus in 1987. At the AFRO Regional Meeting of WHO, the Bamako Initiative resolution was presented as a way of revitalizing primary health services in Africa. Essentially this was a proposal that UNICEF provide essential drugs for use in primary level maternal and child health clinics on condition that charges be
made for drugs or services, the resulting income going to health workers’ salaries or other aspects of building up primary health services.

The Initiative met considerable criticism when it was announced and attempts to answer reservations did not wholly allay the range of difficulties envisaged in its operation nor the more fundamental ethical and moral objections raised. Many within WHO in general, and the Action Programme on Essential Drugs in particular, were concerned not only about the feasibility of implementation, but the extent to which the Initiative would undermine the essential drugs policy, by, for example, encouraging irrational prescribing.

In 1989 the JCHP heard that UNICEF’s Executive Board had agreed that UNICEF should proceed with its own support for the Initiative ($2 million from general resources) while seeking supplementary funds (up to $30 million) for specific country support. At UNICEF’s executive board meeting donors showed some reluctance to fund the Initiative as it was presented. A WHO task force was established in WHO specifically to discuss policy development and implementation of the Bamako Initiative but there has been little coordination or discussion of issues related to the Initiative between DAP and UNICEF. However, UNICEF is developing close relations with AFRO in order to assist in implementation. Since the announcement of the policy it seems that the emphasis on cost recovery issues has shifted, and the Bamako Initiative Management Unit at UNICEF’s headquarters in New York is considering broader issues related to the rational use of drugs. UNICEF stipulates that the Bamako Initiative must be seen to be part of a national drugs policy, but this is rarely met. It remains unclear how the Bamako Initiative will develop.

2.4 Summary

This analysis of the policy process highlights a number of trends.

Policy evolved slowly from an initial global and radical concept related to the role of drugs in health care to a more operational programme which focused on the less developed countries in which supply of drugs was a priority. WHO set up an Action Programme in 1978 which by 1988 embraced all aspects of a national drugs policy. This expansion was due to skilful and professional marketing of the essential drugs concept. The role of DAP as the operational arm of the Action Programme was central to this expansion, especially after 1983.

The acceptance of the essential drugs concept, a decade after its introduction is all the more remarkable given its negative reception by the powerful pharmaceutical industry, which employed a number of tactics to limit essential drugs policies. WHO demonstrated diverse skills in keeping a dialogue open without losing its resolve.

In this pursuit, WHO was assisted, although indirectly, by the increasingly professional consumer and non-government organisations which always wanted the Organisation to move faster and more radically than it was doing. The intense participation and lobbying of both industry and consumer groups in the international policy process was a new experience for WHO which mediated between a protective industry and an assertive consumer lobby arguing for change.
WHO legitimized the essential drugs concept in such a way as to force industry to examine its constituent members more closely. In the decade of the 1980s a somewhat more self-critical approach was adopted with some companies undertaking significant reforms in marketing and informational practices mainly in developed countries.

Through their contributions to and their outspoken support for APED, donor agencies in Europe facilitated a rapid expansion of DAP's activities. By not demanding a rigid system of accountability for these programmes donors showed confidence in DAP and allowed its programme manager maximum flexibility. Donor aid was a cornerstone of policy implementation.

In spite of the acceptance of the essential drugs policy, the contention over how far WHO should be involved in the active advocacy and implementation of policy remains a source of tension especially over controversial issues. Many argue that the role of a global, specialist agency such as WHO lies in its skills of co-ordination, facilitation and technical advice, and not in advocacy or action which is the prerogative of national policy makers. The line between these two views is often quite fine, and is strongly influenced by the leadership of the Organisation.
3. SYNTHESIS OF COUNTRY CASE STUDIES

How far has the Action Programme on essential drugs affected national policies on drugs? In this chapter the evidence from 13 case studies is synthesized to give an overview of policy formation and implementation, the influence of DAP and the effectiveness of APED at country level. The selection of countries is described in annex 3.

National drug policies
The economic crises of the 1970s and 1980s had a dramatic effect within the health sectors of the countries studied. The reduction in health budgets together with the limited availability of convertible currency led to drug shortages for most countries. In general, due to the skewed allocation of resources in favour of urban hospitals, these shortages were most acute at primary level services in rural areas. The supply of drugs to the primary level services therefore became a major priority for the countries concerned. In Mozambique, for example, the economic crisis and the increasing dependence on aid threatened the existing rational drug policy and Mozambique's effort was increasingly directed at maintaining its policy. For Vietnam, Zimbabwe and Democratic Yemen there appears to have been an ideological commitment to rationalize their drug systems.

Although it was clear to most countries that drug shortages were the result of economic crisis and internal problems within their drug supply systems, the search for solutions was limited to those feasible within their political and economic ideologies. Thus the question was not whether to rationalize or not, but rather "how much rationalization?" The implementation of essential drugs programmes was therefore determined by the balance of influences exercised by the various interested groups. Thus in some countries the programmes developed into comprehensive national drugs policies involving a total rationalization of the drug system, while in others the programmes remained primarily supply programmes making essential drugs available to public sector primary level facilities and hence rationalization was limited.

External funding of the programmes
All the country programmes included in this evaluation are funded either totally or partially through external funds and these have been critical to their development.

In general, funding for essential drugs has been relatively easy to obtain. Interviews with some of the major donors have revealed that support for drugs is considered favourably for moral and ethical reasons, media interest and easy disbursement.

External funding to countries has been either in the form of grants or loans. Most programmes are multi-lateral. Although incomplete, information on the levels of funding suggests that large sums are involved especially if drug and/or raw materials are part of

2 Case studies were carried out on Bangladesh, Burundi, Colombia, Democratic Yemen, Indonesia, Kenya, Mozambique, Nigeria, Sudan, Tanzania, Vietnam, Yemen Arab Republic and Zimbabwe.
the external support. Nigeria, Democratic Yemen and Bangladesh have all received World Bank loans and Kenya is at present negotiating a loan for the supply of drug kits to the outpatient departments of district hospitals. The EEC has agreed to fund the programme in Colombia. In addition to loans, the programmes in Democratic Yemen, Bangladesh, and Kenya have also benefitted from grants either from bilateral donors or from WHO. Tanzania, Mozambique, Zimbabwe, Indonesia, Vietnam, Yemen Arab Republic and Sudan have all received grants. In addition to assisting countries find donors, WHO, UNICEF, UNDP and UNIDO have all financially supported specific country programmes from their own budgets. Table 2 below shows the different donors involved in the country programmes studied.

Table 2: Donors & external funding for Country Programmes studied

<table>
<thead>
<tr>
<th>Country</th>
<th>Donors involved</th>
<th>Funding provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colombia</td>
<td>E.E.C</td>
<td>1,500,000 ECUs</td>
</tr>
<tr>
<td></td>
<td>WHO</td>
<td>200,000 $US</td>
</tr>
<tr>
<td>Nigeria</td>
<td>World Bank*</td>
<td>65,000,000 $US**</td>
</tr>
<tr>
<td>Tanzania</td>
<td>Denmark</td>
<td>30,000,000 $US</td>
</tr>
<tr>
<td>Kenya</td>
<td>Denmark/Sweden</td>
<td>11,250,000 $US***</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>Denmark</td>
<td>1,000,000 $US</td>
</tr>
<tr>
<td></td>
<td>WHO</td>
<td>250,000 $US</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Italy</td>
<td>23,500,000 $US</td>
</tr>
<tr>
<td></td>
<td>Sweden</td>
<td>n/a</td>
</tr>
<tr>
<td>Burundi</td>
<td>Interpharma/Switzerland</td>
<td>1,000,000 SFr</td>
</tr>
<tr>
<td></td>
<td>WHO</td>
<td>100,000 $US</td>
</tr>
<tr>
<td>Yemen Ar.Rep</td>
<td>Netherlands</td>
<td>2,260,000 $US</td>
</tr>
<tr>
<td>Sudan</td>
<td>Netherlands</td>
<td>2,791,000 $US</td>
</tr>
<tr>
<td>Dem. Yemen</td>
<td>WHO</td>
<td>761,194 $US</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>WHO/UNICEF/UNDP/Sweden/Denmark</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>World Bank/USAID/Asian</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>Development Bank</td>
<td>n/a</td>
</tr>
<tr>
<td>Indonesia</td>
<td>WHO/UNDP/UNICEF/Japan/USAID</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>Italy/West Germany</td>
<td>n/a</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Sweden</td>
<td>85,000,000 SEK~</td>
</tr>
<tr>
<td></td>
<td>WHO</td>
<td>1,369,019 $US~~</td>
</tr>
<tr>
<td></td>
<td>UNICEF</td>
<td>1,411,451 $US~~</td>
</tr>
<tr>
<td></td>
<td>UNDP/UNIDO</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Loans
** Total health sector loan
*** This is the total annual cost of the programme
~ Total assistance from 1984
~~ 1984 - 1989

Source: Country case studies, 1989

Various funding mechanisms have been employed. In Tanzania and Mozambique where UNICEF has been the executing agency, donor funds have been disbursed by UNICEF.
Interest earned on this money is credited to UNICEF. For the Tanzanian programme this interest for the period 1984-86 amounted to $2.2 million. In the case of the World Bank loan to Nigeria, a sum of $1.85 million of a total loan of $65 million, is held in trust by DAP and although Nigeria pays the interest on the total loan to the Bank, the interest earned on the trust fund reverts to DAP. In the case of the grants, money is usually held by the donor and expenditure carried out according to a plan of activities.

3.1 Programme and policy implementation

This section looks at some of the major components of the drug policies being implemented in the countries studied. Rather than describe these in great detail, the country studies are used as examples to highlight certain interesting features and issues. Not all components of programmes are discussed.

Essential drugs lists (EDLs) and their implementation

In the centrally planned economies of Mozambique, Vietnam and Democratic Yemen, comprehensive legislation covering all aspects of drug policy has been introduced. In Mozambique it took two years after independence to achieve this while in Democratic Yemen the problems in the drug supply system only began to be dealt with in 1984, over fifteen years after independence. Four more years were to pass before comprehensive legislation was in place. In Vietnam an essential drugs policy had been followed for years but it was only in 1985 that it was officially adopted as national policy. Relative values of the public and private sectors in the countries studied.

Table 3: Total value of the drugs market in countries studied

<table>
<thead>
<tr>
<th>Country</th>
<th>Total drug market $US *000</th>
<th>Drug ex/cap $US</th>
<th>Public sector</th>
<th>Private sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colombia</td>
<td>285,000 (1986)</td>
<td>10.00</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Nigeria</td>
<td>n/a</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tanzania</td>
<td>30,690 (1987)</td>
<td>1.33</td>
<td>65%</td>
<td>35%</td>
</tr>
<tr>
<td>Kenya</td>
<td>50,000 (1986)</td>
<td>2.36</td>
<td>32%</td>
<td>68%</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>21,500 (1988)</td>
<td>2.47</td>
<td>70%</td>
<td>30%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>6,878 (1985)</td>
<td>0.60</td>
<td>81%</td>
<td>19%</td>
</tr>
<tr>
<td>Burundi</td>
<td>n/a</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Yem. Ar. Rep</td>
<td>65,000 (1988)</td>
<td>7.92</td>
<td>8%</td>
<td>92%</td>
</tr>
<tr>
<td>Sudan</td>
<td>55,000 (1988)</td>
<td>2.43</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dem. Yemen</td>
<td>14,200 (1984)</td>
<td>6.45</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>122,700 (1987)</td>
<td>1.18</td>
<td>13%</td>
<td>87%</td>
</tr>
<tr>
<td>Indonesia</td>
<td>456,000 (1987)</td>
<td>2.74</td>
<td>17%</td>
<td>83%</td>
</tr>
<tr>
<td>Vietnam*</td>
<td>30,000 (1987)</td>
<td>0.47</td>
<td>100%</td>
<td>0%</td>
</tr>
</tbody>
</table>

* An estimated $30 million is said to enter the country annually as "gifts" but has not been included above.

Source: The above figures have been derived from various sources including the country case studies (1989), and should be interpreted with caution.
Bangladesh a mixed economy, enacted its Drugs Ordinance in 1982 under martial law. Zimbabwe’s strategy has been one of creating legislation for the public sector first, expanding to the private sector in 1990.  

Within the mixed economies, programmes and policies have been applied to the public sector only and sometimes are limited to primary level or rural facilities. In Colombia, the essential drugs list applies only to the public sector and then only as being indicative. In Kenya and Tanzania drug programmes were initiated for public sector, rural primary level services and only much later for outpatient services of district hospitals. Indonesia has introduced legislation for the public sector making it mandatory for primary level facilities to follow the essential drugs list but allows hospitals to use drugs not listed and on average, the hospitals are using up to 25% more than the listed drugs. Legislation has also been passed banning the distributing of free drug samples to physicians and requiring all public sector health personnel to prescribe only generic drugs.  

Public sector legislation introduced in Nigeria by the Federal Government, has to be accepted and implemented by the relatively autonomous states and the national list may only be implementable at the tertiary level of health services for which the Federal Government is responsible. However in most mixed economy countries the private sector has been unaffected.  

Quality assurance (QA)  
Reliable QA depends on inter alia, the existence of a strong drug regulatory authority backed by clear legislative powers, the organization of the drugs procurement system and the ability to carry out quality control (QC) tests as and when necessary. QA also requires cooperation and coordination between the ministries of health, trade, industry, justice, and the customs agencies. Because of the complexities, even relatively rich industrialized countries do not have comprehensive QA systems. Of the thirteen countries studied, none has a well developed QA system. Bangladesh, Mozambique and Zimbabwe exercise some control although the security situation in Mozambique has affected this negatively. The drug inspectorates where they exist, are all understaffed, underfunded and often without much executive power. Notwithstanding such constraints, in 1988 the central regulatory law enforcing agency in Bangladesh said it took action in 80 cases against suppliers who were directed to publish warnings against their products in 4 daily newspapers. In another 86 instances, legal proceedings to remove drugs of unacceptable quality were instituted and in one case a drug was de-registered.  

For drug inspectors to play an effective role in ensuring QA, they have to have back-up from well-equipped quality control laboratories capable of carrying out a wide range of QC tests on drugs circulating at all levels of the supply system. Of the countries studied, such government facilities exist only in Indonesia, Bangladesh, Mozambique, Vietnam and Zimbabwe. Even within these countries, the capacities of the laboratories to carry out the number of tests required, are often stretched. Only Indonesia has a national network of laboratories with one national reference laboratory (WHO collaborating centre) and 27 provincial laboratories. In comparison, Bangladesh has 2 laboratories.
The registration of drugs supported by regulation and legislation stipulating stringent criteria for registration, allows a country to exercise control over the efficacy, safety and quality of drugs, at the entry point. Although this does not provide a guarantee of the product's quality for all subsequent shipments, it does allow the country to limit the number of drugs circulating within the country and thereby facilitates the inspection and testing of a limited number of drugs. In practice, the potential benefits of drug registration have been greatly diminished by the number of drugs allowed to be registered. In Kenya, 3,500 drugs are registered, in Colombia the number is 6,250 and in Indonesia it is 12,606 with cases of over a hundred patent products registered for one generic drug. In Nigeria, drug registration is voluntary and this combined with the lack of legislation in the drug sector, inadequate QC facilities and little inspection, has resulted in estimates of 40-60% of drugs on the market being fake or counterfeit. In Burundi, there is no registration of drugs.

The WHO Certification Scheme provides a limited safeguard to countries. Exporting members of this scheme are obliged to provide documentation accompanying the drugs stating that the drugs are manufactured under Good Manufacturing Practices (GMP), and are registered for sale in the exporting country. If not registered (for example, drugs for tropical diseases), an explanation as to why not and a summary of indications and side effects has to be given. Loopholes exist in the scheme however. The certificate is not automatically sent and must be requested by the importing country. GMP does not guarantee that each batch produced is up to standard; and drug information need not be sent if the product is registered in the exporting country. The scheme it appears, is generally not used much by developing countries and benefits the European countries using it regularly between themselves. Of the countries studied, Vietnam does not subscribe to the scheme (mainly because its main trading partners in the drug field do not subscribe to it) and Colombia appears not to be aware of it. The other countries are members.

UNIPAC procured drugs are received by countries on the understanding that the drugs have undergone quality control testing and have been certified as being of good quality. Countries like Mozambique that have carried out quality control tests on the kit drugs have found some to be of inferior quality.

**Procurement and distribution**

The question of what to buy and how to buy it is intimately linked to the existence of a national essential drugs list. In countries where these exist and cover both the private and public sectors, the process of procurement is generally centralised. Democratic Yemen has progressively centralised all procurement under the MOH and Mozambique through its state procurement agency. In most countries, procurement systems for the public and private sectors are distinct. Thus the Central Medical Stores (CMS) or an equivalent body carries out procurement for all public facilities and the private sector buys from private suppliers. Drugs are generally bought from local producers (national and/or foreign) as well as imported. In countries like Kenya, large hospitals often procure their own drugs independently of the CMS.

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3 The registration procedures in Norway include a "need" clause whereby a new drug can only be registered if it is "needed" and by implication, is an improvement over the existing drugs. Using this clause, Norway has managed to effectively maintain a very limited list of drugs registered in the country.
Nigeria, Indonesia and Colombia provide examples of highly decentralised, almost anarchic procurement. In Colombia, even the lowest level of health facility procures its own drugs and in the absence of any mandatory list, what, how and how much to buy follows no rules or patterns. Indonesia has introduced a mandatory drugs list for primary level services, but the drugs budget comes from five different sources, each one requiring complex budgetary and disbursement procedures. Procurement in Nigeria is carried out by the federal, state and local authorities for tertiary, secondary, and primary level facilities, respectively. The system is chaotic with little attention paid to prices when ordering. UNIPAC and other cheap suppliers like the International Dispensary Association, are largely unknown.

The World Bank loan to Nigeria is enforcing a system of international competitive bidding in the country, allowing preference for domestic suppliers within a 15% range of price compared to international suppliers. A Nigerian non-profit organisation CHANFARM, has developed a rational procurement system for buying essential drugs (about 40) by generic name, to supply mission hospitals and clinics. Church run health facilities in Kenya, Tanzania and Zimbabwe use a similar system through a non-profit organisation called "Mission for Essential Drugs and Supplies".

Distribution in most countries tends to follow standard patterns of central to provincial to district stores (if they exist) and finally to health units. It is often affected by factors such as seasonal destruction of roads, inadequate transport capabilities, fuel shortages, inaccessibility to large areas, pilferage and in some cases armed banditry.

The drug ration kit first piloted in Kenya has been an innovative step in reducing the problems encountered in distribution. Supplying rural health centres and dispensaries with a monthly ration kit was tried out in Kenya in 1981 and its success led to national coverage of rural primary units by 1985. The kit is composed of essential drugs necessary for the treatment of the most common ailments and in quantities reflecting the country’s morbidity pattern and using standardised therapeutic schedules. The kits are destined for specific health units and cannot be opened en route. The greatest advantage is that health facilities can rely upon a regular supply of basic drugs. Some problems have arisen with the kit system. Because morbidity and prescribing patterns vary from region to region within the same country, certain drugs tend to accumulate while others run out before the end of the month.

Most of the countries using kits (7 out of the 13 studied), import the major part of their kits from Europe, often from UNIPAC (Tanzania, Mozambique, Democratic Yemen and Bangladesh). The first major international generic name procurement for drug kits was carried out by UNIPAC for the Tanzanian programme and in comparison to the prices paid previously by the government, a drop in prices was achieved. Objections to kits being supplied by UNIPAC were expressed by some countries. Mozambique’s MOH for example, argued that procurement should be carried out by the state company whose capabilities and expertise were well accepted. DAP did not agree and two years after receiving kits through UNIPAC, the Italian funders decided to provide drugs from Italy, for packaging and shipping by UNIPAC, to Mozambique.

Democratic Yemen has always paid for its own drugs and has been buying good quality drugs at good prices through Crown Agents. To test out the feasibility of kits, the first WHO mission recommended they bought from UNIPAC but later advised against this having analyzed the service provided and the prices obtained both by Crown Agents and
by UNIPAC. However, in 1986, the World Bank loan provided to Democratic Yemen came with the condition that kits would have to be bought from UNIPAC and to date, UNIPAC supplies all kits.

**Local production**

In achieving the objective of making available essential drugs to the whole population, one of the intentions is to encourage local manufacturing with the aim of self sufficiency. Local production of pharmaceutical products faces many economic, infrastructural and technical problems. It can also be highly political, threatening the substantial profits made by the transnational drug companies.4

From the country studies, three groupings emerge in terms of local production capacity to meet country needs:

**Group I**, consisting of countries where production is either non-existent or negligible in its impact upon total needs: Yemen Arab Republic, Democratic Yemen, Mozambique, Sudan and Burundi.

**Group II**, composed of countries where there is existing or potential capability for supplying up to 50% of total needs: Kenya, Tanzania, Nigeria and Zimbabwe.

**Group III**, Countries producing from 50% to over 90% of their requirements but still dependent on imported raw materials: Bangladesh, Indonesia, Colombia and Vietnam.

Countries in Groups I and II also import the packaging material for drug production.

**Group I** - Local production capabilities are limited and fragile. The small quantities produced mean higher prices making the products uncompetitive for the public sector but acceptable for the private sector. The costs of locally produced Ampicillin, Aspirin and Tetracyclines in the Yemen Arab Republic for example, are between 200 and 300% of international prices. The employment opportunities do not compensate for the high production costs and bulk procurement by generic names on the international market provides a good alternative. However, the establishment of small production plants for Oral Rehydration Salts (ORS), Intravenous Solutions (IVS) and external ointments and creams is feasible. Mozambique already produces enough ORS for its needs and Democratic Yemen is hoping to develop the ORS and IVS production this year, staff having been trained.

**Group II** - The potential for local production in this group is hampered by underutilization of the local factories due to lack of convertible currency for raw materials, equipment and maintenance (in Kenya about 70% of the capacity is utilised while in Tanzania the figure is about 30%); uncompetitive prices compared to importation; skewed production often geared towards popular profit-making items rather than essential drugs. In Nigeria for example, only a quarter of the drugs produced locally are considered essential.

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4 The value of world drug consumption in 1985 was about $94.1 billion and although the developing world accounted for only 22% of that consumption, this still represents an annual figure of $20 billion.
In addition, many manufacturers in Nigeria and Kenya are small family concerns and do not meet GMP standards. In Tanzania, import and customs legislation favours importation of finished products rather than raw materials. The situation can be further complicated with donor and international agency involvement. Both Tanzania and Kenya could produce the ration kits locally but external support for this has not been sufficient. In Tanzania, the government’s request to donors for local production support has been considerably weakened by the lack of consensus and coordination between the ministries of health, trade/industry, finance and the Central bank. In Nigeria, the World Bank is in favour of 100% importation with the government arguing for 100% local production.

Group III - Within this group, Bangladesh and Vietnam have comprehensive drug policies based upon the essential drugs concept and their experiences are quite different from those of Indonesia and Colombia.

The drug policy in Bangladesh has increased the local manufacturers share in the production of essential drugs. From 1981 to 1987, the share of national companies in drug production rose from 35.4% to 58.6% but for the production of the 45 essential drugs used at district level, the increase was from 30.3% to 74.8%. Fewer than 1% of essential drugs are now imported. The unit prices of raw materials, 90% of which are imported, have been reduced. The government has set up an Essential Drugs Company which supplies 92% of all government purchased drugs.

Vietnam at present produces 50% of its requirements of essential drugs in 7 central level factories and 263 provincial plants. This highly decentralised production is a consequence of the decades of war. Production at provincial plants is inefficient and plans are underway to phase out production of modern drugs at this level in favour of herbal products. Vietnam’s drug policy has been successful in attracting substantial support from Sweden and the UN for local production.

The total drug market in Indonesia is estimated at $456 million annually. The per capita drugs expenditure in 1986 was estimated at $2.70 which is double the amount that WHO assesses is required to provide essential drugs to all. Encouragement of foreign investment in pharmaceuticals in the 1960s and early 1970s combined with the curtailing of finished product importation has resulted in 287 registered manufacturers of which 40 are transnational companies and 4 are government owned. The rest belong to national entrepreneurs. The transnationals control 55% of the market. In terms of value, 95% of all drugs are formulated locally with about 80% of raw materials imported. Legislation requires foreign controlled companies to produce one pharmaceutical raw material locally.

The Indonesian Government has embarked upon a marketing campaign to win over

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5 The kit programme in Kenya provides 2 kits. Kit II used to be fully equipped and packed locally (for about 7 years) but in 1988, the tender was awarded to foreign suppliers. Kit I is imported from abroad and the procurement is handled by SIDA/Stockholm.

6 Typical incentives included: a) Tax exemption; b) Government subsidies for installation of the plants; c) Low customs duty on raw materials/equipment; d) Obligatory importation of intermediate goods from parent companies (facilitated transfer pricing) and e) Profit repatriation facilities.
health professionals to using generic essential drugs. Industry, particularly the foreign companies, argues that locally produced generics may be cheaper but are of low quality and in a country where fake drugs are an increasing problem, this argument is heard. The government strategy is to compete with rather than inhibit, the private sector. Generic drugs are at present being produced by 3 state-owned plants and retail prices are on average, 55% of the patent products.

In Colombia, the incentives for private investment in the country led to a dramatic fall in the production of drugs by national manufacturers from a high of 55% of the market in 1955 to 4% in 1975. The present figure of about 10% is expected to rise to 15% in 1989 but may fall if Congress passes a law protecting foreign patents in the country. Annual drug sales in 1984 amounted to $352 million and per capita expenditure on drugs in 1986 was estimated at $10.0. Almost 97% of the 6,250 drugs in circulation are produced locally by over 200 manufacturers of which 49 are transnational companies controlling 85% of the market. The large foreign debt of $17.0 billion and its rescheduling will certainly demand more incentives for the private sector and deregulation of the economy. Thus, whereas the lack of local production may mean dependence, the capability to produce drugs locally does not necessarily mean independence. A key question to be answered is "what is being produced?"

Research

Drugs related research is a relatively new area in developing countries and apart from the almost annual drug utilization studies in Indonesia since the early 1980s, research activities in this area have progressed slowly. Research projects fall into two main groups:

a) Socio-economic research projects: these projects attempt to answer questions related to the level of household expenditure on drugs, how this varies between rural, urban and peri-urban settings, how the price of drugs affects utilization of drugs as well as health services and whether the drugs being paid for are in fact essential. Such studies are being carried out in Kenya and Zimbabwe. In addition, Bangladesh is looking at the feasibility of cost-recovery on drug prescriptions and Mozambique is monitoring the effect of drug charges on utilization patterns. The studies in Kenya and Zimbabwe have received DAP support in terms of the development of methodologies.

b) Socio-cultural research projects: these projects aim to collect information on people’s perception and use of drugs, to evaluate the impact of educational interventions on the use of drugs and to develop methodologies for assessing the main cultural and contextual factors influencing drug use. Such studies are being carried out in Tanzania, Kenya and Zimbabwe. All these countries have received DAP financial support and technical support on research methodology.

In Democratic Yemen, the review of a large amount of data from morbidity collection forms combined with a survey canvassing the opinions of health workers resulted in estimation of the country’s drug requirements. Zimbabwe has also carried out a similar exercise. Both Democratic Yemen and Zimbabwe have benefitted from DAP financial and technical support.

Education and training
Training on many aspects of the drug supply system has been carried out at various levels. This section focuses upon the education and training of health workers directly involved in the prescribing of drugs.

In all the countries studied, relatively serious problems have been detected in the use of drugs by health professionals. These problems are not restricted to para-medical staff. Irrational use of drugs by doctors may be serious as they have the authority to use a huge selection of sophisticated drugs. The reasons for irrational drug use by health staff are complex and include the lack of technical knowledge, isolation, heavy work loads, lack of career advancement opportunities, patient demand and the potential for economic gain.

All thirteen countries train their own doctors. However, local training of doctors and the training of medical auxiliaries for primary level services often does not include teaching on essential drugs use. Only Zimbabwe, Bangladesh and Tanzania have or are in the process of revising their medical and pharmaceutical curricula. Colombia has managed to introduce the essential drugs concept in some of its schools while Kenya, Vietnam and Democratic Yemen have revised para-medical training materials. For many countries, information on drugs is provided solely by the transnational pharmaceutical industry. Mozambique however, has signed an agreement with the Pan-American Health and Education Foundation whereby copies of the Medical Letter and the Adverse Drug Reactions Bulletin are locally produced and distributed to all doctors in the country. Mandatory formularies with therapeutic guidelines exist only in Mozambique and Zimbabwe although manuals for primary level workers have been produced in Kenya and Tanzania among others.

The implementation of essential drugs programmes in Kenya, Mozambique, Democratic Yemen and Tanzania all revolved around the ration kit and in all these countries, vertically implemented "crash training courses" lasting 5 days were carried out on a large scale. Integration with other PHC programmes was, however, largely absent. The idea behind the courses was to inform and train all health workers about the kit programmes. The courses were successful in beginning to deal with the problems of diagnosis, prescribing and use of drugs, but they have not been complemented by regular refresher courses or supervision. Their benefits have therefore been limited although the numbers of cadres who received the 5-day training is impressive. Tanzania for example trained 4,000 health workers in 138 one week workshops carried out over a period of 6 months.

The programme managers in Tanzania and Mozambique have recognized the importance of supervision and districts in both countries have received substantial support from the essential drugs programme for supervision vehicles or motorcyces. Both countries have initiated more integrated and continuous education programmes.

Zimbabwe has opted for much more integrated training in medical courses. Curricula for both doctors and pharmacists have been revised to reflect the essential drugs concept and the drug programme is providing manuals for nurses' courses. Fifteen training modules for primary level workers have been developed in a participatory manner. Workshops involving district and health centre staff were held to prepare the first drafts of the modules. These drafts were then circulated amongst a larger number of nurses and other workers, comments being integrated to further improve the appropriateness of the modules. The participation of the utilizers of the modules in their preparation should
increase a more rational use of drugs.

WHO support for the production of training materials and manuals as well as financial support for training workshops has been provided in most of the countries studied. However, this support may have had limited impact because regular refresher courses, follow-up workshops and supervision have been irregular.

**Information for the public**

Almost all the countries studied have produced some educational posters for health units. If not actually discouraging the excessive use of drugs, they at least promote the use of ORS for diarrhoea. Kenya, Zimbabwe and to a certain extent Tanzania, have involved schools in disseminating information related to the correct use of drugs. Additionally, these countries have used billboards, radio and television to transmit the rational drug use message. A twice weekly radio programme in Tanzania deals with some of the drug issues. The Indonesian Government’s sophisticated marketing campaign focuses on winning people and health professionals over to generic drugs. There is no provision of information to the public about the use and/or abuse of drugs. This task has been left to consumer organizations which are studying prescribing habits and documenting complaints about drug effects.

Although the government of Bangladesh provides little information for the public, the Gonashasty Kendra (the People’s Health Centre) project, which established a pharmaceutical company producing only generic essential drugs, publishes and circulates a monthly information magazine. Written in simple Bengali it covers many health issues including appropriate non-drug treatments and warns against the damaging effects of existing drugs and over-medication.

With the exception of Mozambique and Vietnam where there is no private sector, drug advertising by transnational as well as local industries is rampant. The WHO Ethical Criteria for Medicinal Promotion are often ignored and double standards relating to what is sold in the industrialized and the third worlds are frequently applied. Marketing is aggressive and both legal and illegal incentives to prescribers and dispensers are common. Advertising costs generally represent 15-20% of turnover figures and if this proportion is applied to the world drug consumption of $94.1 billion in 1985, then $14-18 billion are spent annually on advertising. For Africa, this figure would be between $400-500 million annually.

**Programme management and coordination**

National essential drugs programmes are generally managed by the pharmaceutical departments of the respective ministries of health. As most programmes are funded by external aid agencies, management or steering committees have been created to include all parties concerned. Often the post of programme manager or coordinator exists. Whereas this is an operational function, the steering committees function as overseers and policy making bodies. Tanzania provides an example: policy, strategy and funding decisions are taken by a Programme Management Committee composed of the home and local representatives of DANIDA, UNICEF, DAP and Ministry of Health. In addition, there is an “In-Country Implementation Committee” whose task is to oversee
the daily management of the programme. The programme activities are carried out by the programme manager and his team. A similar framework (with slight differences) is seen in the programmes in Kenya, Mozambique, Zimbabwe and the Yemen Arab Republic.

With the possible exception of Zimbabwe where donor funds are limited, all the above programmes have been implemented in a relatively vertical fashion with little coordination with other PHC programmes. The supply emphasis of the programmes has often overshadowed the training, information and communication aspects of the programmes. In the case of Kenya and Tanzania, parallel distribution systems were created. In Tanzania, the programme was implemented for a time from the UNICEF offices partly because UNICEF was the executing agency, and partly due to the MOH’s stance. It was only in 1986 (the programme began in 1984) after the placement of a full-time Tanzanian programme manager, that this changed. In Mozambique, to minimise the problems of vertical implementation and to ensure local coordination, provincial heads of the Mother/Child Health programmes and the pharmaceutical services were nominated joint supervisors of the essential drugs programme.

In countries where national programmes do not exist, the situation is often characterized by multiple programmes implemented in various parts of the country, often by different donors. Where the essential drugs programme is part of a PHC programme as in Vietnam, the problems of vertical implementation at the project level are minimised. In Sudan, four WHO supported essential drugs projects are coordinated by the same individual who reports to the undersecretary of health and to the local WHO representative. The problem in these countries is more one of coordination with, and between, donors. In Bangladesh there are at least six different programmes related to drugs:

a) UNDP/WHO involved in the intensification of PHC activities; b) UNICEF/SIDA supplying Drug and Dietary Supplement kits (DDS); c) DANIDA/SIDA/WHO Essential Drugs project; d) Asian Development Bank Health and Family Services Project constructing stores for only the DDS and family planning kits; e) World Bank loan to purchase DDS kits from UNICEF; f) USAID construction of warehouses for storing drugs and contraceptives mainly for family planning.

Coordination amongst all these donors and lenders is difficult and often results in the fragmentation of services and in unnecessary duplication of effort.

In the Democratic Yemen the development of the national drug policy has been carried out by the MOH with WHO support and the implementation of the policy is the responsibility of all levels of the health system. No parallel structures for distribution or management have been created. The Nigerian government is making an effort to avoid creating any special structures for the essential drugs programme and is trying to integrate the programme into PHC: federal-state relationships may hinder this process however.

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7 This management structure is at present being reviewed as the original EDP has now been split into two different programmes. See Tanzania Country Study.
3.2 Effects and influences of essential drugs programmes

The two major objectives of the various essential drugs programmes are to assure a regular supply of effective and safe essential drugs of acceptable quality at the lowest cost to the whole population, and promote the rational use of drugs.

Essential drugs programmes have generally been directed at primary level services (often rural) on the basis that it is this level that is the most neglected in terms of drug supply. As the supply of essential drugs is a component of PHC, essential drugs programmes are supposed to be fully integrated into PHC networks and their implementation is a means towards the development of comprehensive national drug policies based upon the essential drugs concept.

Availability and accessibility of essential drugs
Information on the availability and the accessibility of essential drugs to the population has been difficult to collect and an assessment of the achievement of this objective cannot be made. In countries where donor funds are available for drug purchases and where improvements have been made in the logistics side of the drug sector (kits, transport, storage and management), the impression is that essential drugs are generally more available at primary level health facilities than before the essential drugs programmes. According to UNICEF the Tanzania programme reaches 20 million rural Tanzanians. Countries also report reduced queues at hospitals and increased patient loads at health centres and dispensaries or health posts. Many countries mention that morale of health staff is raised because of the availability of drugs, as evidenced in Kenya and Tanzania.

This however, says little about accessibility to these drugs. Targets such as "... at least 20 essential drugs will be available to 80% of the population, within one hours walk or travel, in 20 countries by the end of 1989", specified in DAP's Global Medium Term Plan of 1983, have not been measured. Donor progress reports and evaluations have also not attempted to measure the national availability and accessibility of drugs, possibly because of the time and resources implicated in the collection of such information.

It is likely however, that the preferential and regular distribution of essential drugs to primary level services has had a positive effect on the general availability of drugs at primary level services. Table 4 below shows the distribution of drug kits in five countries.
Table 4: Distribution of essential drugs to primary level services

<table>
<thead>
<tr>
<th>Country</th>
<th>Type/no. of health units supplied by kits</th>
<th>Total no. kits / year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Democratic Yemen</td>
<td>180 Health centres</td>
<td>n/a</td>
</tr>
<tr>
<td>(1988)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kenya</td>
<td>382 Health centres</td>
<td>46,300</td>
</tr>
<tr>
<td>(1988)</td>
<td>982 dispensaries</td>
<td></td>
</tr>
<tr>
<td>Tanzania (1987)</td>
<td>300 Rural health centres</td>
<td>35,880</td>
</tr>
<tr>
<td></td>
<td>2,690 Dispensaries</td>
<td></td>
</tr>
<tr>
<td>Mozambique (1988)</td>
<td>221 Health centres</td>
<td>24,000*</td>
</tr>
<tr>
<td></td>
<td>720 Health posts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>475 Village health workers</td>
<td></td>
</tr>
<tr>
<td>Yemen Ar. Rep. (1988)</td>
<td>368 Health centres</td>
<td>1,391</td>
</tr>
<tr>
<td></td>
<td>273 PHC units</td>
<td></td>
</tr>
<tr>
<td>Sudan (Nile Province</td>
<td>44 Health centres</td>
<td>3,240*</td>
</tr>
<tr>
<td>Project 1987)</td>
<td>78 Dispensaries</td>
<td></td>
</tr>
<tr>
<td></td>
<td>76 Dressing stations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>94 PHC units</td>
<td></td>
</tr>
</tbody>
</table>

* approximate figures

Source: Country case studies, 1989

Rational use of drugs
The assessment of the rational use of drugs has also proved difficult. This is due to the limitations of drawing conclusions from the few countries studied and also to the fact that even within countries, the health facilities visited are not necessarily representative of the national situations. The general picture emerging suggests that many problems exist at all levels of the health systems in the prescribing of drugs. The excessive use of antibiotics, injectables and vitamins appears to be quite serious. Information regarding the use of drugs from the point of view of compliance or self-medication is rarely available. Indications do not provide a positive picture however.

In sum, evidence suggests that essential drugs programmes and policies have increased

* Information on the availability and prescribing of drugs at selected health units is provided in the country studies.
the availability of essential drugs at primary level facilities and in doing this, have
provided these facilities with credibility. The availability of drugs allows health workers
to carry out promotive and preventive activities, and has improved morale in those
facilities. Much remains to be done in the rational use of drugs however.

**Essential drugs programmes and comprehensive national drug policies**
Countries have developed drugs policies which range on a continuum from
comprehensive, national drugs policies wholly or partly implemented, to countries with
essential drugs programmes limited to primary health facilities in rural areas. In some
cases the introduction of an essential drugs programme has led to the development of a
comprehensive national policy. However, as the case of Bangladesh shows, a drugs
policy, comprehensive as it may be, can have little effect on the health of people in the
absence of a clear health policy.

From the countries studied, three groups emerge. The first group consists of countries
where a comprehensive drug policy based upon the essential drugs concept, existed
before the implementation of an essential drugs programme. The countries in the second
group developed comprehensive policies through the implementation of an essential
drugs or a similar programme. The third group is composed of countries where a policy
based upon the essential drugs concept is or will in the future be limited to the public
sector only.

**Table 5 : National drugs policy development**

<table>
<thead>
<tr>
<th>National Drug Policy existed before EDP</th>
<th>National Drug Policy developed through EDP</th>
<th>Drug Policy covers only public sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mozambique</td>
<td>Zimbabwe</td>
<td>Tanzania</td>
</tr>
<tr>
<td>Sudan</td>
<td>Democratic Yemen</td>
<td>Kenya</td>
</tr>
<tr>
<td>Vietnam</td>
<td></td>
<td>Nigeria **</td>
</tr>
<tr>
<td>Bangladesh</td>
<td></td>
<td>Yemen Ar. Rep.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Colombia **</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Indonesia</td>
</tr>
</tbody>
</table>

The situation in Burundi is unclear

* The ED concept existed as a result of political ideology and the war
situation. Involvement with WHO since 1985 has resulted in the
formalisation of the policy.
** Programmes are scheduled to begin in 1989

**Source**: Country case studies, 1989

Thus 2 out of 9 countries where no policy existed have developed comprehensive
policies covering both the public and private sectors. However, 6 of the 9 countries
have opted for limited rationalization avoiding possible conflict with the private sector.

Whereas the size and the power of the private market in Kenya, Yemen Arab Republic,
Nigeria, Colombia and Indonesia is substantial and thus makes total rationalization extremely difficult, the lack of progress towards developing a comprehensive policy in Tanzania is more difficult to comprehend. The profit-making private sector is quite small and private profit making health care was abolished in 1980. The non-profit making private sector, largely mission hospitals and dispensaries, makes up a significant part of the health service and already implements certain aspects of the essential drugs concept, although it is concerned about the loss of its freedom to import duty free drugs from its parent organizations abroad.

The other stumbling block to policy development in Tanzania revolves around the differences in opinion between the ministry of health and the ministry of trade and industry (MTI). The MTI is guided by principles of profit and its parastatal importing body the National Pharmaceutical Company (NAPCO), imports non-essential but profit making items which are distributed to private pharmacies but also through NAPCO's own chain of pharmacies. NAPCO and MTI are therefore against any policy that limits these profits. The amount of money involved however, is small and does not justify the resistance to the development of a national policy.\(^9\)

In Kenya and the Yemen Arab Republic, apart from the resistance to policy development by industry and the private health sector, public service doctors also engage in private practice. In the Yemen Arab Republic, about 90% of pharmacists in the government sector have an interest in the private sector either through running private pharmacies or by being part-time representatives for the drug companies. In most countries, kickbacks to health professionals and government officials can be frequent and substantial and ensure the maintenance of the status quo.

Democratic Yemen and Zimbabwe provide examples of the systematic analysis of the problems within the drug supply systems and the gradual implementation of policies to encourage all concerned sectors to participate in policy development. In both these countries, two factors appear to be of importance: both governments have shown the will to rationalize their drug systems and both countries pay for their own drugs.

The development of comprehensive drug policies based upon the essential drugs concept is the responsibility of national governments. As described above, decisions on whether to rationalize partially or totally are conditioned by factors outside the control of the ministries of health. Within this context, WHO has attempted to use essential drugs programmes as a means of showing governments that rationalization of existing drug systems upon the essential drugs concept can not only make substantial foreign currency savings for the country but can also meet the objective of supplying the most necessary drugs to the majority of the population.

3.3 The role of DAP in promoting the Action Programme.

WHO's involvement in the countries is examined in three parts: management and funding, advocacy and technical support.

\(^9\) Recent information suggests that a draft national drug policy has recently been produced by a team consisting of MOH Tanzania, DANIDA and WHO and is to be presented to the cabinet for approval.
Management and funding: In all regions except AFRO, WHO support to country programmes is generally provided through the regional offices. Sudan and the Yemen Arab Republic have expressed concern about the occasional confusion of roles of the various WHO personnel involved in the programmes. Although in theory the WHO country representative supervises the administration of the programme, WHO/EMRO administers the programmes from a financial point of view and DAP provides technical support.

PAHO has always exercised a certain autonomy from Geneva and until the recent involvement of DAP in Colombia, support to this country in terms of funds, training and technical matters was provided by the regional office. Similarly, Bangladesh and Indonesia have received technical as well as financial support from SEARO.

In the African countries studied the role of AFRO has been almost non-existent. WHO’s involvement is maintained directly by DAP. Similarly, the WHO country representatives’ role is limited to a primarily administrative function, and their participation in the drug programmes seems to depend on personal interest. In Tanzania the WHO representative participates in the “in-country implementation committee” and in Mozambique, the representative has maintained a strong interest in, and contribution to the programme.

Most essential drugs programmes are being implemented with external financial support. DAP’s involvement in the funding of programmes may be one of three kinds: i) DAP funds are used directly to fund country programmes as is the case in Democratic Yemen, Vietnam and Zimbabwe; ii) Donor funds for country programmes are channelled through DAP making it responsible for the management and execution of the programmes as in Sudan and the Yemen Arab Republic where the Netherlands has provided extra-budgetary funds to DAP earmarked for these countries; iii) DAP attempts to find donors to fund specific country programmes. In the case of Colombia, a comprehensive situation analysis and project proposal funded by DAP, was instrumental in attracting EEC funding. DAP often uses its own funds for the preliminary activities of situation analyses and project proposal development and this “seed money” has often resulted in donor funds for the specific programmes.

Direct funding from WHO has certain advantages highlighted by the programme in Democratic Yemen. As the drugs are paid for by the country itself and no direct donor is involved, the programme has all the characteristics of a bilateral programme, the major funding support being provided through WHO/EMRO. The Director General’s Development Fund contribution in 1985 of $350,000, was crucial in allowing the programme to develop without donor constraints and influences. A significant proportion of the funds were spent on training and on the development of the management and transport infrastructures, which have a long term benefit for the country. Similarly, the Director-General’s contribution to Zimbabwe was used to initiate the training of health workers. This contribution appears to have influenced DANIDA to support the Zimbabwe programme.

Advocacy: Perhaps the most critical aspect of WHO’s role in promoting the acceptance and the implementation of essential drugs programmes and policies has been the production of the model lists of essential drugs. These lists have provided the scientific justification for what are basically political decisions. The introduction to the
first Essential Drugs List produced in 1977, outlined the conceptual and technical bases for an EDL and specified the complementary policy, legislative, logistic and educational actions that were necessary to ensure the regular supply and rational use of essential drugs.

This list was distributed to all member states and was the first advocacy tool produced by WHO. For the Bangladesh government, this list with the WHO imprimatur provided not only the technical but also the inspirational and moral support for its new policy. In Kenya, this list became the basis for thinking about drugs policies and for Mozambique it provided an important validation of the policies it was already pursuing.

The implementation of the ration kit programme for rural health facilities in Kenya provided WHO with a "model-case" which could be publicized and serve as an encouraging example for other countries. Thus, as part of its advocacy campaign, WHO organised an inter-regional Workshop on Essential Drugs in Nairobi in 1982. Participants to the workshop were taken on field trips to see the functioning of the programme. Documents from this workshop were widely disseminated. A similar workshop was again organised in 1983, this time directed at both Francophone as well as Anglophone countries. It is difficult to assess the effect of these workshops but in 1983, neighbouring Tanzania embarked upon an essential drugs programme conceptually similar to the Kenyan programme. The first WHO mission to Democratic Yemen in 1983, resulted from the participation of the present country programme manager, in an inter-country workshop on essential drugs in Amman.

Within countries, WHO's usual work method has been to first carry out a situation analysis at the request of the country and then hold a workshop where the problems within the drug supply system and solutions based upon the essential drugs concept can be discussed. These workshops therefore have an advocacy objective and often the first practical action is the production of a draft essential drugs list. Such workshops have been held in Nigeria, Vietnam, Tanzania, Democratic Yemen, Yemen Arab Republic and Zimbabwe.

Although the "national drug policy development" workshop in Tanzania in 1985 resulted in little progress on the policy side, other countries have benefited from such advocacy workshops. In Nigeria, WHO helped to ensure that the drug programmes in various states would be integrated into PHC. In Vietnam where the essential drugs concept was already being implemented, workshops helped in the analysis of problems within the context of a national programme and also helped to formalize and add new elements to the policy. DAP's conceptual contribution to the programme in Democratic Yemen was significant and resulted in shifting the focus from supply to policy development. A WHO-supported workshop in the Yemen Arab Republic in 1986, produced a draft of the country's first essential drugs list. The 1987 "rational drug policy" workshop in Zimbabwe resulted in the adoption of a comprehensive national drug policy. Surprisingly a comprehensive national workshop on the essential drugs concept has never been held in Kenya.

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10 The Kenya programme was initiated in 1981, through Danish and later Swedish support. WHO was not initially involved. The publicity value together with the recruitment to WHO/DAP of one of the key individuals in the programme, brought it under WHO's fold and from 1982-1985, extensive contact was maintained between WHO/DAP and the Kenyan programme.
In 1985, WHO started the Essential Drugs Monitor with a view to disseminate information about essential drugs programmes and policies by highlighting existing programmes. All programme managers receive copies of it. Its role in communicating information to those not involved in essential drugs programmes at the country level is thought to be limited.

Technical support: This has generally been provided through consultants for specific areas, through the provision of generic guidelines covering all the important aspects of drug policy and supplies, through inter-country as well as in-country workshops, through the facilitation of training for national staff and through participation in evaluations. In addition, DAP staff through their regular visits to country programmes, provide technical support on management, programming, selection and quantification. Consultants have been provided by DAP on request from country programmes as well as through DAP initiatives, on almost all aspects of drug supply management. The country studies have not assessed the effectiveness of the consultants in detail but generally the opinions from the countries suggest that the quality of the consultants has been high and their reports and recommendations useful for programme development.

The Democratic Yemen study provides the only quantified assessment of the effectiveness of WHO consultants to the programme. It shows that between 1984-88, a total of 21 technical reports were produced by 20 consultants (including DAP staff), at an average cost of $5,250 per consultation. Of the 216 recommendations made by the various consultants, 156 (72%) had been implemented at the time of the evaluation and an additional 21 (10%) were implemented later. Although the implementation of recommendations is largely dependent on government will and capability, the above data suggest that care is exercised in selecting consultants. As the group of regular DAP consultants is relatively small and as DAP staff themselves often provide the technical support, it seems that technical support to countries has been of a high quality.

Information on the availability of various guidelines and technical documents produced by WHO, at ministries of health, pharmaceutical departments, medical faculties and so on, is limited. Country reports make general statements such as "the guidelines and materials produced by WHO have been useful". No complaints were expressed in the country studies and the generic nature of most of the guidelines make them adaptable to many different situations.

Support has also been provided through the organization of workshops on operational technical issues. In 1987, DAP organised a 5-day workshop on "operating essential drugs programmes", in Addis Ababa. Nine countries participated and seven of the countries studied in this evaluation were present: Bangladesh, Democratic Yemen, Kenya, Mozambique, Tanzania, Vietnam and Zimbabwe. The agenda allowed the countries to share their experiences in the fields of logistics, procurement, management, financing/cost recovery, training and drug use. The final communiqué from the workshop stated "... the workshop had been useful, particularly to exchange and share experiences, and the open discussion between representatives from different programmes were inspiring, interesting and a morale booster".

DAP often participates in the joint evaluations of countries essential drugs programmes. Evaluations have been carried out in Tanzania, Democratic Yemen, Kenya and Zimbabwe. It should be noted that the situation analysis carried out in Nigeria, Vietnam, Burundi and Colombia are in fact evaluations of existing drug situations. The reports
that stem from such analyses are technical in nature as they recommend policies and actions likely to improve the drug supply systems. Situation analyses and evaluations have therefore been considered a form of technical support. The evaluation teams often represent all interested parties within a specific programme and a joint evaluation helps resolve different points of view. These evaluations and situation analyses are also important in convincing donors either to initiate or to continue funding specific programmes.

Training has taken the form of in-country sessions facilitated by consultants, fellowships, visits to other country programmes and technical and/or financial support in the production of manuals. Responding to identified training needs in country programmes, DAP has provided training support in all the countries studied. Country reports consistently refer to WHO support for the training of key policy makers, managers and staff working in all aspects of the drug supply system including prescribers. In Democratic Yemen, between 1984-88, 34 fellowships were awarded to 24 fellows and all but 4 of these professionals are working at the jobs they were trained for. In Zimbabwe, an innovative training programme was possible with WHO’s financial contribution of $250,000.

An area where WHO has devoted much attention is the introduction of the essential drugs concept into the curricula of medical and pharmacy schools. Over the last few years, limited success has been achieved in this area. The essential drugs concept is being taught in medical schools or is to be introduced in the next academic year, in Zimbabwe, Nigeria, Sudan, Democratic Yemen, Bangladesh, Tanzania and in some universities in Colombia.

3.4 Summary

The comprehensiveness of drugs policies undertaken by countries has been primarily conditioned by their political and economic environment. Centrally planned economies have found it easier to introduce comprehensive policies while mixed economies have implemented some aspects of essential drugs policies, often limited to their public sectors.

Essential drugs lists exist in most countries and are applied to both public and private sectors in Sudan, Mozambique, Democratic Yemen, Bangladesh, Vietnam and in 1990 in Zimbabwe. Private sectors range from about 19% of the total drugs market in Mozambique to over 90% in the Yemen Arab Republic.

The countries studied are either totally or partially dependent on external funds for their drug programmes. This dependency is likely to continue for the foreseeable future and donors will continue to influence programme development.

None of the countries has developed a fully comprehensive quality assurance system. The number of registered drugs is large and quality control and inspection resources limited. The WHO Certification Scheme seems to be little used.

Few countries have centralised procurement systems and international tendering by generic name is usually limited to the public sector. Seven of the thirteen countries use kits, mainly imported from Europe and often from UNIPAC. External funding has often
been conditional on the purchase of kits. The kit system has been successful in regularly supplying essential drugs to primary level facilities. The short-term objective of using a vertical operation of kit distribution during the early 1980s has become a long-term strategy and has been difficult to change. The local packaging of kits does not appear to have been sufficiently promoted by countries or supported by donors and the UN agencies.

Local production capabilities vary widely. The least developed countries produce small quantities of expensive and often non-essential drugs. Countries with greater production capabilities are hampered by the lack of convertible currency to increase production to cost-effective levels. Of the countries that are almost self-sufficient in local production, Bangladesh has increased essential drugs production. Indonesia and Colombia at present produce large quantities of non-essential drugs.

The training of health workers in the rational use of drugs has been unsystematic. Crash training programmes have generally not been followed up by refresher courses and supervision. The essential drugs concept has been introduced in the curricula of medical and pharmaceutical schools in a few countries.

Apart from the production of educational posters for health units, billboards and public transport vehicles, little has been done to provide information about drugs to the population. In most countries, the marketing of drugs by transnationals is aggressive and often unethical.

Drugs programmes have generally been implemented in a vertical fashion, establishing parallel supply, training and supervision systems. Where multiple drug programmes are being implemented by various donors, coordination with, and between donors has been difficult, resulting in the fragmentation of services and duplication of effort.

Donor funds have been crucial to the development of essential drugs policies in these countries. DAP's role in attracting extrabudgetary funds for countries, whether as "seed money" to initiate activities in-country, or to support specific country programmes was acknowledged in many of the country studies.

Advocacy of the essential drugs concept started with the production of the first WHO model list of essential drugs. Inter-regional, regional and country workshops have been organized by DAP to promote the concept. The distribution of a newsletter from 1985, has helped to disseminate information about essential drugs programmes.

Technical support provided by DAP includes consultants, guidelines, workshops, evaluations and training. Guidelines are judged as useful in-country and the quality of DAP consultants and staff is regarded as high. DAP has facilitated the training of nationals in all aspects of drugs supply management through fellowships as well as country and regional workshops.

The country case studies demonstrate that WHO can be wholly effective only when governments have the political will to develop and implement national policies. At the same time governments attempting to rationalize their drug systems face enormous political and economic pressure from various interests, national and international, and WHO's role as a global specialist agency providing political, moral and financial support to these countries is critical.
Finally, evidence from these countries suggests that general availability of essential drugs at primary level has been increased through regular supply. The accessibility of these drugs to people remains dependent on the health system’s coverage. In comparison to the early 1980s, essential drugs are being purchased and distributed preferentially to primary level services. However, indications are that problems exist in the prescribing of drugs at all levels of the health system. Excessive use of antibiotics, injectable and vitamins is common. Where availability of essential drugs has increased, there appears to have been a corresponding increase in the credibility of the health services and morale of health workers. This has facilitated preventive and promotive health activities.
4. ASSESSMENT OF THE ACTION PROGRAMME ON ESSENTIAL DRUGS

The last two chapters analysed the formulation and implementation of essential drugs policies first at the international level and then at the national level, drawing on thirteen case studies. The main question addressed in this chapter is how successful was the Action Programme on Essential Drugs? This is answered by considering:

the overall objectives of APED and how far these were met
the extent to which strategies and activities undertaken by DAP contributed to the promotion of essential drugs policies

Some of the main findings from the evaluation of UNICEF's Supplies Division (formerly UNIPAC) by the Societe Generale de Surveillance S.A. (SGS) are included in this chapter. The summary of the SGS report is given in Annex 6.

4.1 1975 - 1981: developing the concept

Objectives
In this period WHO searched to formalize objectives for an essential drugs programme. As a result the documents of the period suggested different objectives at different times.

The first written statement of intent appeared in the Director General's report to the World Health Assembly in 1975 in which he concluded that

There is an urgent need to ensure that the most essential drugs are available at a reasonable price and to stimulate research and development to produce new drugs adapted to the real health requirements of developing countries. This calls for the development of national drugs policies for the whole drug sector, linking drug requirements with health priorities in national health plans formulated within the context of social and economic development (A28/11).

The Action Programme on Essential Drugs, as conceptualized in 1978 had the following objectives:

To strengthen national capabilities of developing countries in the selection, procurement and distribution and the proper use of essential drugs to meet the health needs of the majority of the population;

To strengthen, whenever feasible, the local production and the quality control of such drugs;

To make essential drugs, including vaccines, available under favourable conditions to governments of the least developed countries in order to extend primary health care and disease control. (A32/10)

These objectives shifted the original statement of intent in four ways.

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First, by emphasising support to developing countries in the areas of selection, supply, distribution and proper use of essential drugs rather than in research and development.

Second, by adding support to local production and quality control which was not singled out in the 1975 resolution.

Third, by focusing on the extension of health care coverage through the availability of essential drugs.

Fourth, by changing the term at reasonable cost to the term under favourable conditions.

The subtle change in objectives between 1975 and 1978 reflected shifting priorities and interests. Countries’ problems related largely to supply and distribution of drugs; local production was seen as a way of increasing supply; the central role of drugs in building confidence in expanded primary health coverage had been discussed at the Alma Ata Meeting, and had led to the inclusion of essential drugs as one of the eight components of primary health care; and the provision of drugs under favourable conditions replaced the term reasonable cost because these were the terms under which industry was offering to support essential drugs policies, although it was not clear what favourable conditions meant.

**Strategies and activities**

The main activities undertaken in this period included the publication of an essential drugs list which became the basis of the essential drugs programme. It was first revised in 1979. Unit staff travelled extensively to investigate the problems and priorities of the member states and to promote the essential drugs concept. Workshops were held in Colombo and Manila to discuss issues related to essential drugs. In Geneva unit staff prepared papers for the technical discussions on drugs policies presented at the World Health Assembly in 1978 and held numerous meetings with representatives from industry. Efforts were also made to incorporate the essential drugs approach into PHC and the Global Strategy for Health for All by the Year 2000. Consultant visits to Indonesia resulted in a report to the Indonesian government in 1981. The same year DAP was established to operationalize the Action Programme at the country level.

**Did these strategies work?**

In the first three years up to 1978 there was a clearly focused effort to define an Action Programme. WHO established a lead and took clear responsibility for the promotion of the essential drugs concept. In particular the publication of the first Essential Drugs List legitimized the concept, while WHO’s imprimatur gave it prestige and scientific respectability. The revision of the original model list only two years later was testament to the wide interest with which it was regarded and the practical contribution it made. After 1978 as it became clearer what countries’ problems were in the area of drugs, the essential drugs concept broadened and WHO’s attention began to shift from local production to the problems of supply and distribution in the poorer countries. With the establishment of DAP the years of cautious advocacy gave way to defining more precisely what the new unit’s role should be in the dissemination of the essential drugs concept.
4.2 1981 - 1983: defining DAP's work

Objectives
By the World Health Assembly in 1982, the objectives for the Action Programme had been simplified: APED was to promote the regular supply of drugs which are safe and effective to all people at the lowest possible cost within the context of PHC and Health for All. The term under favourable conditions was replaced with at the lowest possible cost. The Action Programme was for all countries which desired to participate but priority was placed on developing countries (A35/7).

Strategies and activities
The attempts to operationalize the Action Programme were evidenced in a series of activities in 1981 and 1982 when numerous meetings, workshops and consultancies were undertaken. Experiences exploring bulk procurement in the South Pacific, Africa and the Americas and consultant advice for local production to Indonesia consumed enormous effort and energy. In spite of this, at the end of 1982 there was little evidence of concrete outcomes of activities. There was no national essential drugs programme which could be directly attributed to WHO support in spite of numerous workshops and meetings on the subject.

In addition, discussions with the pharmaceutical industry about support and cooperation had faltered. Although industry moved from a negative position to an expressed support for APED in the late 1970s this was seldom translated into action. In spite of offers of drugs from individual companies, 25 training posts in quality control, and some joint visits to African countries, industry’s support for the programme remained elusive. The joint industry-WHO mission to Burundi had taken two years to be developed and the objectives had changed in favour of local production rather than improving essential drugs supply.

Why did these strategies not work?
Although a policy had been established for the Action Programme, it was more difficult to define how this should be enacted. This was partly because of the lack of a clear direction which was apparent in the debates within the Organization. There was confusion over means and ends: in 1982 members of the Executive Board questioned the role of WHO in advocacy, arguing the Organization’s strength lay in its role as a technical and advisory agency. There was disagreement about the extent to which essential drugs should refer to the public sector only, or include the private sector; whether essential drugs were relevant only for developing countries. Decisions over what essential drugs should cost were camouflaged in discussions with industry about 'reasonable' versus 'favourable' versus 'lowest' costs. And finally there was considerable uncertainty as to whether the supply of essential drugs should be through local production or through procurement.

There were several reasons for this confusion. While the creation of the Action Programme asserted WHO’s commitment to the essential drugs concept, WHO had traditionally used its expertise to promote relatively uncontentious technical programmes. The Action Programme on Essential Drugs attracted controversy, was perceived as a threat by both the pharmaceutical industry and, to some extent, health professionals and depended on advocacy and promotion at all levels of the health service. The entry of the consumer groups as lobbyists in the international arena in 1981 and 1982 polarized
positions and led to periods of stalemate.

The ambivalent political climate was reflected in the changing objectives for the Action Programme during these years. Even though the WHO leadership was firmly committed to the essential drugs concept, unit staff were more ambivalent about the sorts of strategies they could pursue, an uncertainty engendered all the more tenuous by the initial hostility and the continuing constraining influence of the industry.

4.3 1983 - 1988: the years of action and consolidation

Objectives
After mid 1983 the Action Programme grew. Its overall objective was consolidated as:

   ensuring the availability of a regular supply to all people, of a selected
   number of safe and effective drugs of acceptable quality at the lowest
   cost. (EDV/MTP/83.1)

Specific objectives and actions taken to meet this main objective are described in annex 5. In the analysis below the extent to which these actions were successful is assessed, using the framework of the terms of reference: management and organization, linkages, communication and information and effect.

Management and organization
The terms of reference asked for answers to the following questions:

   1. How far did DAP's management structure allow it to assist in the
      planning, implementation and evaluation of national essential drugs
      programmes?

   2. What financial resources were available to implement this process?

   3. How did the management structure of DAP compare with other units
      in WHO?

   4. What developments within WHO affected the thrust of the Action
      Programme?

Each will be treated separately.

1. How far did DAP's management structure allow it to assist in the planning,
   implementation and evaluation of national essential drugs programmes?

No standard managerial process exists in WHO. Each unit designs its own internal
system of management, although there are uniform administrative procedures for the
Organization.

DAP was given a great deal of autonomy after the appointment of a new programme
manager in 1983. This was partly to revitalize the programme to give it high visibility
and partly because of the new programme manager, whose appointment was based on
his known commitment to the idea of essential drugs, a strong record of projects implemented and working, and whose management style was, in his own words, one of "entrepreneurial opportunism". Making DAP directly responsible to the Director-General's office, facilitated the new style of management. Not only did the programme manager have a routine and immediate link to the WHO leadership, it also meant that he had direct control over DAP's budget and was given great freedom to develop initiatives.

How did this management style affect DAP's operations?
The sense of urgency and activity that prevailed under DAP's new direction and the selection by the programme manager of a group of equally committed, energetic professionals established a strong team approach. The programme manager encouraged a flexible response to country requests, to proposals of the staff and to the commitment of funds to carry out activities at the country level. Few formal procedures of planning, monitoring and communication existed. Operational meetings were held every Monday morning, without minutes, where important issues were discussed. The programme manager rapidly developed a loyal and hard-working team with delegated responsibilities.

In the period 1983-84 DAP undertook activities which included formulating project proposals, travelling to various donors to raise extrabudgetary resources, discussing potential programmes and speaking to the delegates from member states during visits to WHO. Whenever possible, opportunities were sought to expand technical assistance and spread the essential drugs concept. The urgency given to promote, advocate and fundraise, meant that little systematic long term planning occurred. Objectives for achieving the programme's aims were not translated into clear work plans, although the 1983 Global Medium Term Programme did contain general targets to be met over the following five years and most individuals on the staff had a clear programme of work. Technical assistance was organized haphazardly; as long as a problem existed and a request for assistance was made DAP staff responded without consideration of longer term goals. There was no record of how well consultants performed their tasks and while a review of curricula vitae suggest high competency, they also show a lack of third world representation. Reticence to keep information on consultant performance might have been due to the fact that files were open and generally available.

At the request of the programme manager WHO's Management Unit conducted a study of the managerial framework of DAP in 1986. The report was comprehensive and although it recommended no change in the existing organizational structure, it pointed to the need for a more systematic approach to management processes. It was suggested for example, that a management plan be drafted for the next year, and an improved approach to the budgeting and control of DAP's resources be implemented. A more systematic classification of DAP work in terms of country support, operational research, development work and managerial functions was also suggested. Other technical and managerial responsibilities and tasks were to be updated (Management Survey, 1987).

Although the majority of recommendations were acted upon a few were not. In spite of considerable weight put on the value of appointing an officer or manager to deal specifically with administrative and managerial functions in DAP this was not implemented. The results were that some technical staff continued to be more involved with administration than was efficient. A DAP management plan appeared only in outline and a clear policy with regard to regional relationships was never developed.
Overall this management style and its supporting structure resulted in the creation of a
dynamic group able to respond to a promotional task. However, the unit sacrificed long
term planning in order to achieve immediate advocacy objectives. The lack of clearly
mapped plans and of a management system which demanded clear lines of
accountability in terms of money and manpower was a weakness which was not
decisive while the programme manager was in control, but once he had gone, it left
DAP vulnerable.

2. What financial resources were available to implement this process?

DAP has three major sources of funding: regular budget, extrabudgetary pledges by
donors, and discretionary funds. The amount from the regular budget remained
relatively constant in nominal terms from 1982/83 at just over $1 million, implying a
fall in real terms.

Table 6: Donor Contributions for DAP (in '000 US$)

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<td>Denmark</td>
<td>595</td>
<td>1,165</td>
<td>2,171</td>
<td>703</td>
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<td>595</td>
<td>3,929</td>
<td>11,012</td>
<td>1,462</td>
<td>6,307</td>
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</table>

- a Unspecified in so far as they are reported in Financial Reports.
- b DANIDA 1988 pledge includes $500,000 tied for Bhutan.
- c FINIDA money in fact tied for Burma and Bhutan.
- d Money from Italy and the Netherlands for use in five specified countries.

Source: Up to 1986/87 data from Financial Reports, various years; data for 1988/89 are
unofficial and taken from DAP printout and reflect the status as of 30 April 1988.
However, the predominant source of funds is from bilateral donors. By 1989 donor funds amounted to over $20 million, roughly 90% of the available budget. Mobilizing donor support was initiated by the programme manager. In the first six months he travelled extensively to visit potential donors. His personal promotion of the programme, backed by project proposals, resulted in a flow of extra budgetary funds beginning in 1984/5 as is seen in the table 6. Most donor funds were untied although some Italian, Netherlands and Finnish money was intended for use in selected countries. The SIDA/SAREC money was tied to operational research. Other tied funds included the Nigerian Trust Fund from the World Bank, and a recent Danida pledge for Bhutan. Most donors continued and increased their support over the years. The Canadian donation however was explicitly a once-off contribution; and while the French continued to give some money after 1981, the level dropped markedly.

Discretionary sources have also been useful for DAP. The Director General gave considerable support to promoting APED by allocating funds from his Development Programme: both Zimbabwe and Democratic Yemen received funds from this source. A second source of discretionary funds was the interest that accrued on extrabudgetary funds. Initially all interest earned was kept by WHO, but in the mid 1980s, interest including that on the 13% charge made on extrabudgetary funds, was transferred to programme managers, as an incentive for raising extra resources. For DAP these funds were substantial and went primarily to funding additional posts. These funds made an important impact on DAP's ability to operate and expand at a time when the UN and WHO were under increasing monetary constraints. The predominance of these funds over the WHO regular budget allotments provided insulation from broader financial issues which confronted most other parts of the Organisation.

How were funds used?
Before 1983 DAP carried out very little country operational work. By 1984/85 over 50% of DAP's resources went for country support work and currently it accounts for approximately 70% of an ever-growing budget. (See Table 7 below) Most funds for country support were channelled through Regional Offices, with the exception of the Africa Region where DAP was involved directly at the country level.

Table 7: Use of DAP funds as % of total budget

<table>
<thead>
<tr>
<th>Activity Type</th>
<th>PPB 1988/89 RB</th>
<th>OS</th>
<th>PPB 1990/91 RB</th>
<th>OS</th>
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<tbody>
<tr>
<td>Country Support</td>
<td>68.8</td>
<td>69.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development work</td>
<td>10.2</td>
<td>10.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operational research</td>
<td>5.1</td>
<td>6.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management</td>
<td>1.0</td>
<td>1.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salaries</td>
<td>4.7</td>
<td>4.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5.7</td>
<td>94.3</td>
<td></td>
<td>5.0</td>
</tr>
<tr>
<td>Total Budget</td>
<td>$22.3 Million</td>
<td></td>
<td>$26.4 Million</td>
<td></td>
</tr>
</tbody>
</table>

Note: RB -- Regular Budget; OS -- Other Sources. (last two PPBs only)  
Source: Armstrong 1989
Increasing country work and increasing extrabudgetary funds coming to DAP were mutually reinforcing trends. Donors in general liked to see a larger share of funds spent at country levels and this could well be an explanation of continued and increasing support. Both the country case studies and some regional offices testified to an appreciation of DAP’s ability to draw in extrabudgetary funds.

3. How did the management structure of DAP compare with other units in WHO?

DAP differed in both style and lines of authority from most other WHO programmes. The environment within which it worked was much more contentious than other more technically oriented programmes making comparisons between units less relevant.

Several other WHO units receive extrabudgetary funds: in the case of the special programmes this is often much higher than those received by DAP. In 1988/9 for example, the Global Programme on Aids received $62 million; Tropical Diseases Research $61 million; Human Reproduction Programme $46 million. Other programmes such as the Control of Diarrhoeal Diseases attracted less external funding ($12 million) and PHA procured no extrabudgetary funds.

In management terms the above units all had more formalized advisory structures with a variety of committees, steering groups or task forces than did DAP. For example, the Control of Diarrhoeal Diseases unit was monitored by a technical advisory group, a management review committee and a meeting of interested parties. The larger special programmes had even more complex co-ordinating and monitoring bodies. Most of these units employed a manager, and followed a more traditional, structured managerial process than did DAP. All required relatively elaborate reporting arrangements to donors, structures which were rejected by DAP as time consuming and were probably not important in this phase of DAP’s activities. At later stages however, such bodies may have helped legitimate some of DAP’s activities.

4. What developments within WHO affected the present thrust of the Action Programme?

In July 1988 Dr Mahler’s term of office as Director General came to an end, and Dr Nakajima took over. As the first head of the Drugs Policies and Management Unit in 1976, Dr Nakajima had helped to establish the essential drugs programme. One of his first actions when he took office in 1988 was to remove DAP and PHA from their position in the Director General’s office, and to put them into a new Division of Drug Management and Policies. Dr. Fattorusso, a former director of the Division of Prophylactic, Diagnostic and Therapeutic Substances until 1979, was appointed acting director of this division. Dr Lauridsen resigned as DAP programme manager and in mid 1989 Dr Antezana replaced him. He had been been a member of the original DPM unit.

The managerial changes introduced in 1988 and 1989 were accompanied by an increased number of bureaucratic procedures. Although DAP staff were accustomed to seeking permission for attending conferences, giving speeches, visiting countries this was
relatively easily decided by the programme manager. In 1988 lines of management were more bureaucratic, so that permission for visits, even for the programme manager, had to be obtained first from the Acting Director of the Division. On at least two occasions permission was refused. Planned visits to the Philippines and Mexico were at first not authorised although the visit to Mexico did eventually take place. Papers and letters were no longer sent first to the programme manager. Amidst considerable speculation about the extent to which the leadership would or would not continue to support the essential drugs concept and the revised drug strategy rumours abounded.

Meetings of the Interested Parties took place in 1986, 1988 and 1989. At the meeting in May 1989 Dr Nakajima announced that the group would be restructured into a Management Advisory Committee, formalizing the position of the Interested Parties, and giving its members the role of advising the Director General on various aspects of the Action Programme, as proposed by some of the donors in 1988. This restructuring also created the potential for the Management Advisory Committee to monitor more closely not only DAP’s activities but also the adherence of DAP to policy defined at the World Health Assemblies. Dr. Nakajima also outlined the reasons for the changes in organizational structure affecting DAP and added

I should like to emphasize that for the Action Programme on Essential Drugs this change is one of administration and not of policy. As you are aware, the Programme’s goals and objectives are clearly stated in WHO’s revised drug strategy, and also by the thirty-ninth World Health Assembly, and these, of course, remain unaltered (Nakajima 1989).

In spite of considerable pressure from the Interested Parties, focusing on questions of staffing and operations, the head of the new Division of Drug Management and Policies merely reiterated the Organization’s support for the Action Programme. The Interested Parties concern arose in part from an earlier speech by the Director General when he drew the distinction between the responsibilities of WHO and its member states.

Under the terms of its constitution, the World Health Organization is required to cooperate with governments, upon request, in strengthening health services and also to provide information, counsel and cooperation in the field of health. It is expected to furnish technical support and services, to promote research, to provide a forum for informed debate, even to examine the available options for strengthening health services. Determination of national policy, however, is the prerogative of national governments (Nakajima 1988).

While this was not new, some suggested that this could be interpreted as a shift of balance in essential drugs policy for the future towards national government action, with WHO doing less advocacy and more technical advice.

Linkages

The terms of reference asked the following questions:

1. What level of coordination and collaboration existed between DAP and PHA?
2. What linkages were established with other WHO programmes?

1. What level of coordination and collaboration existed between DAP and PHA?

Both DAP and PHA were responsible for the Action Programme, the former for general operational strategies, the latter for collaboration and support. PHA was responsible for the technical problems of quality control, safety and efficacy of drugs and DAP for the planning and development of drug policies. Until 1983 the division of work between DPM (later DAP) and PHA resulted in a reasonable level of collaboration. After the appointment of a new programme manager, moving DAP to the Director-General's office, and the influx of funds to DAP, relations between the two units became more strained even though PHA was later also moved to the Director General's office.

The regular budget for PHA was estimated to be about $1 million per biennium. With the adoption of the revised drug strategy in 1986 the proposed budget for 1988/89 called for an additional $1.1 million per biennium, $300 000 to be provided from the regular budget and the shortfall to be made up through extrabudgetary funds. It is not clear whether these funds have materialized but generally extrabudgetary funds have played an insignificant role in PHA's funding. Although PHA has the responsibility for all normative functions as well as for the production and dissemination of scientific information, in 1988 it had only six staff members while DAP had 17. The differences between resources available to DAP and PHA are striking.

As DAP expanded its work, and especially after the Revised Drug Strategy was introduced, new demands were made on PHA for guidelines on technical issues. While PHA produced the materials requested, PHA's remit was more related to quality control than accessibility of drugs. Criticisms for not producing and divulging information more openly, related to regulatory guidelines on drugs in circulation, and delays in publication of drug data sheets, for example, were explained in interviews with PHA staff who revealed a certain reticence to produce material on issues where incorrect or controversial information might be sent out under the WHO logo. Staff in PHA worked closely with industry and felt strongly that antagonising industry was counterproductive.

Differences in resources, in attitudes to industry, in interests that focused on quality control all led to an uncomfortable relationship between the two units. Although this did not particularly appear to affect developing countries, opportunities were probably lost. For example, DAP's contacts with countries could have provided PHA with valuable feedback, and distribution of PHA material could have been increased with DAP's financial and logistic support.

2. What linkages were established with other WHO programmes?

There is little evidence to show that the 'integrated approach' promoted by the introduction of PHC affected management between DAP and other units within WHO. Most links were sporadic and based on personal contact rather than specific structures. A few joint activities took place in the mid 1980s. Examples were the mission to Lesotho sponsored by both DAP and the Epidemiological Unit to investigate the quantification of drug usage and the joint visit with the Division of Strengthening of Health Services to Thailand as part of support to the district management programme in
that country. Considering the priority given to strengthening primary health care at the
district level, there was very little evidence to show that there had been much
discussion of how essential drugs programmes could be integrated at district level and
below.

More intense action has taken place with the Global Programme on Aids in looking at
the impact of AIDS on drug costs and utilization. In addition, there have been joint
country visits to look at condom distribution in which DAP provided experience on the
logistical side of distribution.

Reasons for this lack of systematic linkages reflect the history of interactions between
units and divisions within WHO more than the management style in DAP. Where
linkages did take place, they were often where the programme managers had specific
issues to pursue and therefore made efforts to work together.

How did DAP link with the regional offices?
There exist no clear lines of accountability in an operational sense between
headquarters, regional offices and countries. Personal relationships and goodwill
determine the extent of cooperation starting at the country level where the WHO
representatives are dependant on the cooperative inclinations of their host ministries of
health. The regional offices vary in degrees of capability and internal organisation as
well as in the type and amount of support that they give member states. DAP was able
to help regional offices by initiating the programme of associate professional officers
and selecting them. In addition, DAP paid for consultants requested by the regional
office and provided programme support to targetted countries.

The relationship between the regional offices and DAP was sometimes uneasy. Visits to
regional offices by DAP staff were more frequent in some regions than in others. For
example, relationships between SEARO and DAP were close in the mid 1980s.
However, the largest number of essential drugs programmes was in Africa, and DAP
bypassed the regional office because they felt it could not support so many activities.
As a result, contact between the regional office and DAP was minimal. Both EMRO
and AFRO staff felt that the interest on the 13% charge on donor financed programmes
which DAP was able to use could have been used to support and strengthen the
regional offices, instead of being used in headquarters.

Communication and information

The terms of reference asked the following questions:

1. How far did the Action Programme communicate the concept of
   essential drugs to a wider audience?

2. What was the quality and quantity of technical information on drugs
   and of material on the rational use of drugs?

3. Was DAP able to provide countries with tools to develop their own
   essential drugs programmes?
4. What operational research was developed?

1. How far did the Action Programme communicate the concept of essential drugs to a wider audience?

DAP used a number of means to communicate the essential drugs concept at the global level, some more visible than others. A great deal of advocacy at a one-to-one level took place regularly with policy makers at the World Health Assembly, donor agencies, international meetings and through the press and scientific journals. DAP staff members gave numerous speeches at international meetings. In 1985 DAP initiated the bi-annual, free, Essential drugs monitor, which was distributed widely to both developed and developing countries. By 1988 DAP had professionalized its communications approach and had formulated a communications plan. A documentation centre and bibliographic service distributed DAP materials. An overview of the first two months of 1989 showed that an average of five requests for information were received per working day, and a total of 3000 documents despatched. An additional 750 were distributed to visitors. A special set of slides was prepared for Teaching Aids at Low Cost (TALC) which has a wide distribution network. DAP also made materials available to many other interest groups.

How far has this information resulted in an acceptance of the essential drugs concept at the global level? It is not possible to give a comprehensive overview here, but by the mid- to late- 1980s various interested parties other than WHO had accepted and were advocating the essential drugs concept.

Within the United Nations, the World Bank, the UN High Commission on Human Rights has adopted an essential drugs policy and the UN High Commission on Refugees has introduced essential drugs into refugee camps. UNICEF also promoted essential drugs as part of the Bamako Initiative. Both donor governments and governments of developing countries have advocated essential drugs. The European Parliament adopted a resolution saying pharmaceutical exports should focus on essential drugs in 1986. The UK introduced a limited list of drugs for general practice in 1986, and the Overseas Development Administration adopted an essential drugs policy for pharmaceutical aid in 1989. The Nordic countries and the Netherlands have always been strong supporters of essential drugs programmes. Among developing countries Bangladesh, Mozambique and Sri Lanka have been pioneers of essential drugs policies.

By the mid 1980s some international pharmaceutical industry associations actively supported the concept of essential drugs. The IFPMA initiated a journal Health Horizon (similar in format to the Essential Drugs Monitor) that often carried articles on essential drugs and generics. Although the IFPMA continued to insist on limiting the scope of implementation of essential drug policies, the fact that they addressed the issue in their journal can be considered a form of advocacy. At the country level industry associations rarely support the essential drugs concept.

Medical associations often endorsed the essential drugs concept during international symposia of pharmacology, public health and pharmacy associations. The British Medical Association, the Commonwealth Pharmaceutical Association and the International Federation of Pharmacists, among others, are examples of national and
international level advocates of the essential drugs concept. A number of other organizations have adopted the essential drugs concept, although putting it into practice is often slow. In seven of the thirteen country case studies essential drugs are being, or are planning to be incorporated into medical curricula. Non government organizations such as the Christian Medical Commission strongly advocated the essential drugs concept, and others such as Oxfam, Medecins Sans Frontieres and Freres des Hommes campaigned specifically on the issue. The country case studies confirmed that many non-government organizations implement essential drugs programmes in countries. Patients and consumers groups particularly those linked internationally in Health Action International and the International Organization of Consumers Unions have played a strong role in advocating essential drugs, often arguing for more stringent regulations on drug distribution and promotion and extension of the scope to the private sector.

2. What was the quality and quantity of technical information and materials?

Production of information tools to disseminate the essential drugs concept - technical publications, guidelines, standards, reports of workshops, training materials and market intelligence information - was a responsibility shared by DAP and PHA. DAP's materials fell into three categories as shown in the table below.

Table 8: Major DAP materials 1983 - 1988

<table>
<thead>
<tr>
<th>guidelines for:</th>
<th>(DAP/83.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>the development of national drug policies</td>
<td></td>
</tr>
<tr>
<td>evaluating an essential drugs programme</td>
<td>(DAP/85.8)</td>
</tr>
<tr>
<td>drug procurement and distribution</td>
<td>(DAP/88.11)</td>
</tr>
<tr>
<td>estimating drug requirements</td>
<td>(DAP/88.2)</td>
</tr>
<tr>
<td>ethical criteria for medicinal drug promotion</td>
<td>(WHO 1988)</td>
</tr>
<tr>
<td>for developing national drug policies</td>
<td>(WHO 1989)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>training manuals on:</th>
<th>(DAP/85.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>policies for essential drugs in PHC - a course module</td>
<td></td>
</tr>
<tr>
<td>policies for essential drugs in PHC - a teachers manual</td>
<td>(DAP/85.4)</td>
</tr>
<tr>
<td>national drugs policies (guides)</td>
<td>(DAP/86.2)</td>
</tr>
<tr>
<td>national drugs policies (sessions)</td>
<td>(DAP/86.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>international workshop reports on:</th>
<th>(DAP/84.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>procurement</td>
<td></td>
</tr>
<tr>
<td>introducing the essential drugs concept into curricula</td>
<td>(DAP/85.5)</td>
</tr>
<tr>
<td>educational material for patients</td>
<td>(DAP/85.10)</td>
</tr>
<tr>
<td>operating essential drugs programmes</td>
<td>(DAP/88.3)</td>
</tr>
<tr>
<td>drug financing</td>
<td>(DAP/88.3)</td>
</tr>
<tr>
<td>social science research</td>
<td>(DAP/89.2)</td>
</tr>
</tbody>
</table>

Source: Bannenberg & Kanji 1989

Table 8 represents only DAP's main documents. Most material was produced by DAP itself, in offset, rather than as official WHO publications. This was done deliberately, in order to avoid the lengthy printing and bureaucratic processes of WHO publications.
The exceptions were the Ethical Criteria for Medicinal Drug Promotion and the Guidelines for Developing National Drug Policies which were official WHO publications. The table also underestimates the number of workshop reports and training materials produced in country: the Kenyan manual on the use of essential drugs by health workers has been used as a prototype in a number of countries, and Zimbabwe developed its own manuals in a creative programme of participatory workshops.

Two other important DAP publications are the Essential Drugs Monitor and The World Drug Situation. The former is an an information bulletin, distributed widely. Over 16,000 copies were printed of the sixth issue (April 1988) and it was sent to over 8,000 addresses all over the world, half of which were in developing countries. Most other WHO newsletters have much smaller coverage. The World Drug Situation was requested at the Nairobi conference and produced in 1988 as an overview of progress in essential drugs policies the world over.

PHA has also produced materials of relevance to the essential drugs concept, although usually of a more technical nature. The table below gives some of the more important examples that have some relevance to the Action Programme.

Table 9 : Major PHA materials of relevance to APED 1983 - 1988

| Cost estimate on equipment for QC laboratories | (PHA/84.2) |
| Good laboratory practice | (PHA/84.512) |
| Good practices in manufacturing QC drugs | (PHA/84.6) |
| Training in drug QC | (PHA/85.36) |
| Updated list publications by DRAs | (PHA/86.1/LPB) |
| Administrative planning and budgetting small labs | (PHA/86.43) |
| List of material for a first step lab | (PHA/86.44) |
| Instructions for drug inspectors | (PHA/86.45) |
| Scope and implementation of Certification Scheme | (PHA/88.104) |
| Principles for small scale regulatory authorities | (PHA/88.18) |
| Dissolution testing for international pharmacopeia | (PHA/88.4) |
| Dissolution tests | (PHA/88.5) |
| Basic tests for pharmaceutical dosage forms | (PHA/88.528) |
| Stability of drug dosage forms | (PHA/88.6) |
| Introduction to WHO-GMP guidelines | (PHA/88.78) |
| Some sources of information on GMP | (PHA/88.90) |

Source: Adapted from Bannenberg & Kanji (1989)

The material above forms only a part of what PHA produced. From 1982 it took over the revision of the essential drugs list. The Pharmaceutical Newsletter is sent as a restricted document to 132 drug information officers; and the quarterly WHO Drug Information bulletin costs $50 per annum and goes to just under 4000 individuals or institutes.

Did material produced reach its target groups?
Languages influence the availability of information. In the materials catalogue produced by DAP, 100 different English language publications including PHA and non-WHO sources were listed. Only the document Ethical Criteria for Drug Promotion (WHO,
1988) was published in the six official WHO languages. Of the remaining, 44 are available in French, 23 in Spanish and 2 in Arabic. Apart from the WHO Drug Information and the Pharmaceutical newsletters, which were available in French, all PHA publications were in English.

Advocacy and informational materials such as the Essential Drugs Monitor aim widely and are used largely by country programme managers, ministries of health, consumer, industry, university and other groups. A postal survey of the Essential Drugs Monitor, carried out in 1988, with a response rate of 25% revealed that the readership exceeded 100,000 (an average of 8.4 readers per copy) and that 57% of the respondents lived in developing countries. Of the respondents, 47% stated that the newsletter influenced their decision making. In 1988 about ten new requests for the Monitor were received per day.

Other documents produced have been aimed at those involved in implementing essential drugs programmes. The extent to which these have reached their targets is difficult to quantify. While workshops themselves may have important effects in exchanging information about essential drugs, their ability to communicate such issues is limited. Workshop reports were often produced quickly, but not very attractively and were relevant only to those at the workshop or a few with a particular interest in the subject. The country case studies say they have found DAP materials useful, but a systematic look at the availability of documents at country level was not possible.

What is striking is the difference between DAP and PHA materials and their coverage levels. DAP has made particular efforts to disseminate broadly and distributes its own material. Much of the material produced by PHA is available on request only and because documents defined for wider circulation go through official WHO channels they often take considerable time to produce.

In general then, both DAP and PHA responded to the needs identified in providing materials to support APED. DAP’s response was faster partly because of the dynamic nature of its activities and management structure but also because it had sufficient human and financial resources. However, questions do arise about why certain publications produced years ago still remain drafts. For example the revised curricula for medical faculties has not been published. Material on patent rights exercised by industry, rational prescribing, compliance and public education as well as the question of the private sector and national drugs policies is either little developed or absent. In addition requests for provision of information for prescribers and consumers appears to have been dropped. No developing countries have well-developed systems for objective drug information for health workers - although some send irregular and unsystematic information. It is a general weakness that DAP has not emphasized material for the general public nor facilitated its production. These topics would almost certainly have aggravated tensions with industry and were perhaps left alone for that reason.

If the quantity of material produced was reasonable, what can be said about its quality? The technical quality of documents produced is not assessed: what is of concern is how appropriate the materials were.

Were the materials produced appropriate?
In that tools have been produced in response to needs identified either by DAP or by member states, they have been appropriate in choice. On the other hand, the great
diversity amongst member states and between different essential drugs policies has meant that tools have often attempted to include aspects relevant to all countries. The result has sometimes been a large and extremely detailed document. However, evidence suggests that countries still find such documents useful even if only to provide direction, priorities and categories. An example of this is the Guidelines for Evaluating Essential Drugs Programmes.

Some materials have had little impact. An example is the Marketing Intelligence System which was initiated to provide developing country manufacturers with international prices of pharmaceutical raw materials. This is partly because it is new but mainly because very little information is fed into the system; prices of raw materials are influenced by many factors; WHO cannot release the names of the cheap suppliers so the information is of little value to countries; and the time lag in getting information out often invalidates the information. It is surprising that although PAHO has been running a similar scheme for some time, DAP had no knowledge of it.

A review of the Certification Scheme in 1983 showed that the system was little used although it has 124 members. Industry has accepted the system but consumer organizations have argued that the Scheme has no teeth. However, a more detailed users’ guide has been written and in 1988 the World Health Assembly increased the scope of the Scheme.

Some potentially appropriate materials have not been produced. For example guidelines on communications with patients, which were requested by the Revised Drug Strategy, have not yet appeared; the involvement of DAP in the preparation of popular information on health care and the proper place of drugs is limited. The development of training manuals for the use of essential drugs by health workers, and for introducing the concept of essential drugs into medical curricula has been slow. Although there was some discussion within DAP on the need for these types of manuals few were produced in countries. The Kenyan manual has been copied and translated with only minor adaptations made in a few cases, often with the assistance of foreign consultants. An exception to this was Zimbabwe, which developed its own manuals with DAP financial assistance.

3. Was DAP able to provide countries with the tools to develop their own essential drugs programmes?

Within countries, WHO’s usual work method was to carry out a situation analysis at the request of the country and then hold a workshop where the problems within the drug supply system and solutions based upon the essential drugs concept could be discussed. These workshops therefore had an advocacy objective and often the first practical action was the production of a draft essential drugs list.

Most essential drugs programmes were implemented with external financial support. DAP’s involvement in the funding of essential drugs programmes was through direct funding to country programmes; donor funds channelled through DAP for specific country programmes; and attempts by DAP to find donors to fund specific country programmes. In some cases DAP used its own funds for the preliminary activities of situation analysis and project proposal development, and this “seed money” often resulted in donor funds for specific programmes. Evidence suggests that direct DAP funding had advantages of flexibility and rapid response to areas of need when other
funds were either unavailable or earmarked.

Technical support was also provided by DAP through the running of workshops for policy makers, managers or health workers, which ranged from general discussions on essential drugs policies to specific training on stock-taking. The country studies did not assess the effectiveness of consultants in detail but generally opinions suggested that the quality of the consultants had been high and their reports and recommendations useful. DAP staff themselves took responsibility for particular countries, and continuity of support was stressed. In 1987/88 DAP staff made 72 country visits, with a total of 200 person weeks. Countries stated that workshops were useful for training, to exchange experiences and as a morale boost for their work. DAP also carried out joint evaluations with national staff - in Kenya, Papua New Guinea, Thailand, Democratic Yemen, and Nigeria - testing the guidelines on evaluation.

In sum, the materials produced by DAP (and to some extent, by PHA) were useful to countries as generic guides to be adapted to local circumstances. However they were largely oriented to Anglophone Africa and were less used in other parts of the world. After 1987 however, more materials were translated into French and Spanish. DAP also provided support through workshops, technical support as consultants, and, importantly, through funding. The country case studies show that various of these means were useful in developing national policies on essential drugs but that economic and political circumstances were often strong constraining influences on implementation of national policies.

4. What operational research was developed?

Up to 1986 limited research had been done on the development and field-testing of the manual on quantification of essential drugs requirements. Research on a collaborative epidemiological study for improved morbidity information for estimating drug requirements and for a multi-country socio-economic and socio-cultural studies were in a preparatory stage. There were hardly any requests for research from developing countries.

From 1986 the research activities fell into two categories: two multi-country studies, and other research oriented more towards concrete operational problems in the implementation of essential drugs programmes. Examples included research into the stability of essential drugs during international transport, the feasibility of including contraceptives into the essential drugs programmes, and the effectiveness of the drug kit distribution system.

Has the research been useful in supporting essential drugs programmes?

Given the funds allocated, more research could have been done. Nevertheless, despite lack of time DAP staff managed to initiate and coordinate research projects in a number of important areas. This required major inputs from DAP as researchers in developing countries largely followed the proposals made by DAP in order to get the funds. With the limited time available to staff subsequent follow-up could not always be ensured.

It is unclear how many of the country projects will be completed with a publication. Relatively little research has been published in scientific journals, although this may be due to the fact that many studies are not yet completed. To what extent the results of what research has been done has benefited the essential drugs programme is unclear
partly because the practical relevance of the research results varied. Preliminary results from research studies in Benin on drug expenditure by households and morbidity related drug requirements in Sri-Lanka seem promising. In Thailand an interesting methodology has been developed whereby school children are collecting data in their own homes on expenditure on drugs.

Effect

The two questions asked by the terms of reference were:

1. How did joint WHO/UNICEF cooperation in the Action Programme on Essential Drugs support primary health care?

2. To what extent has the essential drugs concept been adopted in countries, organizations or associations?

1. How did joint WHO/UNICEF cooperation in the Action Programme support PHC?

Much of the interaction between WHO and UNICEF in the 1980s centred around the implementation of the primary health care approach. Support to the Action Programme focused on UNICEF’s role in making essential drugs available to primary health facilities, especially in rural areas, and in the implementation of essential drugs programmes within PHC where UNICEF was involved in programme implementation, as in Tanzania. After the announcement of the Bamako Initiative in Mali in 1987 which was seen as a way of supporting primary health care efforts in deteriorating economic conditions in Africa, UNICEF’s focus shifted somewhat from supply and distribution questions to policy issues.

DAP’s programme manager was aware of the potential of using UNICEF’s supply division for the provision of essential drugs to Tanzania. This was one of the first issues that was explored: the extent to which drugs could be provided for the first and largest national programme on essential drugs. The usefulness of UNICEF’s supply division in procuring essential drugs for countries (not only Tanzania) was assessed by SGS (1989). Below are just a few of the main findings relevant to the question. The full conclusions are in Annex 6.

i) What was UNICEF’s role in the procurement of essential drugs?

Drugs represent a steadily increasing proportion of UNICEF’S Procurement Unit in Copenhagen. The Unit procures different supplies for all of UNICEF’s programmes, including education, water, EPI) as well as essential drugs. It also procures supplies and essential drugs on behalf of governments, non-government or international agencies on a reimbursable basis. Purchases of drugs in 1988 were 30 % ( $US 36.6 million) compared with a total procurement of $248.5 million. Reimbursable procurement of drugs was valued at $11.6 million, out of a total of reimbursable procurement of $49.2 million (24%). The trend in drug procurement has been unsteady, but there was a 50% increase from 1987 to 1988.

The items listed in the UNICEF catalogue accord with the most recent WHO essential
drugs list. Out of 284 on the WHO list, only 102 active substances are listed in the UNICEF catalogue. The reasons for this are that UNICEF responds to demand in the decision to stock drugs, that some of the drugs on WHO's list are substitutes for one another, and that there are other specific reasons why drugs from certain therapeutic groups are not stocked.

No clear policies exist on how to accomplish an increased use of third-world suppliers, which would further one of DAP's objectives - self-reliance. UNICEF's procurement section has commissioned appraisals of manufacturers in five developing countries, but concerns remain over their ability to supply in the needed quantity, quality, and price. None of the firms responded to the most recent UNIPAC general tender, and none has been contracted for direct shipment or for kit-packing, although Third World companies have been used for local procurement for the same country.

Evidence suggests that reasonable steps are taken to ensure procurement of drugs of an acceptable quality. It should be noted however, that there is room for improvement. As a matter of policy UNICEF does not assume any responsibility for purchased drugs. Despite this disclaimer, SGS believes that improvements in the technical side of the quality assurance programme are advisable and possible. They suggest a significant rate of non-conformance detected by UNICEF's own inspection and confirmed by third party testing, indicating a continuing need for re-inspection of purchased drugs, and a need for more studies to be done on stability of drugs during sea shipment.

Notwithstanding the fact that a genuine and representative comparison between price levels resulting from open commercial transactions and UNICEF's list prices proved impossible, UNICEF's pricing compared favourably in all instances. This finding remains valid when handling charges and contingency factors are added to the list price to calculate the end-user level. It can be concluded that generally UNICEF's price trends are slightly better than world market trends.

ii) To what extent did the joint WHO-UNICEF support for the Action Programme support PHC at the country level?

It is clear from the review of the policy process that DANIDA's financial support and UNICEF's operational input into the Tanzanian programme was critical, and provided an important impetus to APED at a time it needed revitalizing.

From the country case study on Tanzania and other reports it seems that after the introduction of the essential drugs programme in 1984 rural health facilities which had previously suffered from shortages of drugs, in general have regular stocks. The essential drugs programme provides about one-third of the total drug needs of the country - with 90% of donor funds going on the purchase of drugs. This raises questions of long-term sustainability, although it should be noted that about 50% of the cost of the kits should be recovered in local currency from local government.

How far did the programme support PHC?
The main criticism of the essential drugs programme is that in many countries it was set up as a parallel system. In Tanzania internal UNICEF systems are employed to import the kits from Copenhagen and deliver them directly to the six zonal medical stores, bypassing normal procurement and distribution channels. The kits are only opened at the zonal stores in the presence of a customs official. The programme's trucks then deliver the kits to the districts within the zone, and from that point, the
district medical officer is responsible for getting the kits to health facilities. Although a number of workshops have been held to train health workers in the use of essential drugs, the lack of refresher courses and supervision have been a concern. UNICEF's support to the Mozambique programme has not suffered the same criticism because Mozambique has largely used its own infrastructure for distribution.

The extent to which the essential drugs programme in Tanzania has been integrated into primary health care has been questioned because of its parallel structures. Criticisms of this sort have been made about other programmes such as the expanded programme on immunization, and are certainly not peculiar to Tanzania. Vertical implementation, an initial concentration on supply and distribution rather than training and education, limited transfer of skills to Tanzanian counterparts, and various differences among the donors, led to adjustments in the programme after the first couple of years. In 1988 the Ministry of Health reorganized the structure of the Ministry in support of primary health care. The essential drugs programme, as with all other programmes excepting AIDS are now co-ordinated under a PHC manager.

In summary, since essential drugs play an important role in the extension and utilization of primary health care facilities, the joint actions of WHO and UNICEF have supported PHC. Weaknesses have been where this support has relied on parallel structures of implementation rather than being integrated into, and thereby strengthening, existing structures.

iii) The role of the Bamako Initiative in support of PHC

Relations between WHO - not only DAP - and UNICEF became somewhat strained with the announcement of the Bamako Initiative in Mali. There had been no prior joint discussion of the ideas of the Bamako Initiative, so a great deal of confusion existed as to the exact meaning and shape of the Bamako Initiative.

After the announcement of the Initiative, UNICEF set up a special management unit at their headquarters in New York to develop and refine the Bamako Initiative, and WHO set up a task force in Geneva, to pursue the implications of the Initiative. A number of countries have introduced some of the ideas of the Bamako Initiative at the district level sometimes with support from non-government organizations.

AFRO is highly supportive of the Initiative and sees the potential opportunity it affords not only as strengthening primary health care in many countries, but also leading to greater collaboration between AFRO and UNICEF. Although it has been suggested that DAP give advice and technical guidance on essential drugs and UNICEF use its social mobilization and communication skills to implement the Initiative at district levels and below, the roles of DAP and AFRO have not been defined clearly, and coordination at country level is weak. The extent to which DAP may or may not be marginalized is unclear, but given its resources and experience, its cooperation and input could only reinforce the Initiative.

2. How far has the essential drugs concept been adopted in countries?

Essential drugs policies may be defined narrowly, as the existence of an essential drugs list or may be defined broadly, as a developed national essential drugs policy. In the Director-General's 1986 progress report on the Action Programme, it was said that 80
countries had developed essential drugs lists, and 40 national essential drugs policies.

In the World Drug Situation of 1988 a distinction is made between national essential drugs policies in the initial phase and those that are fully developed. While 41 countries were defined as being in the initial stage, only 25 were said to have a fully developed national policy. Similar distinctions are made between those countries which have an essential drugs list which is being used in drug management (45 countries) and those countries in which an essential drugs list exists but is not always used (45 countries).

Table 10 below demonstrates drugs policy development in the country case studies.

Table 10: Drug situation in countries studied 1989

<table>
<thead>
<tr>
<th>Country</th>
<th>Policy</th>
<th>Legisl.</th>
<th>Essent dr.list</th>
<th>Inform</th>
<th>Manpower develop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Colombia</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Dem.Yemen</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Indonesia</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Kenya</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Mozambique</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Nigeria</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sudan</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Tanzania</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Vietnam</td>
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<td>1</td>
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<td>2</td>
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</tr>
<tr>
<td>Zimbabwe</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Policy: 1= Public sector policy marginal or beginning  
2= National policy exists for public sector  
3= National policy exists for public sector and private sectors

Legislation: 1= Drug regulatory administration at an early stage  
2= Drug regulatory administration exists but not fully functioning

Ess. drug list: 1= An essential drugs list exists for the public sector  
2= An essential drugs list covers public and private sectors

Information: 1= No organised provision of information to health workers and patients  
2= Provision of information for health workers is semi-organized  
3= Systematic information available

Manpower Dev. : 1= Continuing education is not systematic  
2= Systematic continuing education for drug systems staff

Source: Country case studies, 1989
Although there are limitations to the table above, its value lies in the picture it gives of the progress made in the development of a broad range of policies largely since the establishment of the Action Programme on Essential Drugs.

As was shown in the country case studies, countries are constrained in a number of ways as to the extent to which they are able to introduce national essential drugs policies. The size of pharmaceutical production, whether locally- or largely foreign-dominated, the size of the private sector, the ideology of the government, are all factors which affect the extent to which governments feel they can legitimately act on this issue and receive sufficient support to counteract objections from the various interest groups. Some of these are extremely powerful and can form formidable barriers to the implementation of essential drugs policies, however strong their moral and ethical imperative. However, DAP's experience through the 1980s has been invaluable in indicating what options are possible under what conditions, and it is noteworthy that by the end of the decade some of the larger, complex newly industrializing countries such as Mexico and Colombia were approaching DAP for advice on action in developing policies on essential drugs.

Two questions were posed at the beginning of this chapter. The first asked whether the Action Programme had achieved its objectives. It was shown that these objectives shifted, but that by 1983 it was clear that the overall objective was to ensure the availability of a regular supply to all people, of a selected number of safe and effective drugs of acceptable quality at the lowest cost.

Many aspects of this objective have been achieved, but not to all people in all countries. However, whether the increased availability of essential drugs at primary level services has had any effect upon the accessibility of these drugs to those most in need, cannot be answered without carrying out in-depth studies. The same is true for assessing whether essential drugs programmes and policies have affected the rational use of drugs. In addition to these, there remain a number of unanswered questions about the prices of essential drugs, the role of the private sector in providing essential drugs, and the sustainability of programmes.

The second question asked whether the strategies and activities undertaken by DAP had contributed to the promotion of essential drugs policies. From the foregoing analysis it is clear that the answer is affirmative. Although there have been some weaknesses and gaps have been identified DAP has been extremely successful in its advocacy and communications role, and has played an important technical support role in some countries. The evidence shows that the strategies employed by DAP have had a major impact on understanding, on acceptance and on implementation of essential drugs.

In the next chapter the major conclusions from this evaluation are followed by recommendations.
5. CONCLUSIONS AND RECOMMENDATIONS

Conclusions

1. The essential drugs concept articulated in the introduction to the first model Essential Drugs List in 1977 defined the role of drugs in health care. The need to avoid major conflict with industry, operationalise the concept at the country level and prioritise the supply of drugs to the least developed countries in support of PHC, focused the global concept on the supply of essential drugs in developing countries. However, programmes at country level have generally not been integrated with other PHC programmes and policies have tended to cover mainly primary level services in the public sector. An essential drugs policy isolated from a wider PHC policy is potentially damaging to both.

2. Expansion of the Action Programme accelerated in the mid 1980s and by the late 1980s it embraced all aspects of national drugs policies. This expansion can be attributed to three major influences. Firstly, the moral and ethical dedication of the WHO leadership combined with the energy and commitment of DAP staff. Second, a limited number of smaller donor countries made available extrabudgetary funds to WHO from 1983 onwards. Third, these donors, a number of recipient countries and other organizations demonstrated their support for the programme in the World Health Assembly and Meetings of Interested Parties.

3. The now wide acceptance of the essential drugs concept was initially hindered by its negative reception by the powerful pharmaceutical industry which employed a number of tactics in the early years to limit its application and constrain its influence. It is a sign of the legitimisation of the essential drugs concept that the IFPMA was forced to examine its constituent members more critically. In the 1980s some international drug companies accepted many of the ideas underlying the essential drugs concept and introduced some reforms in marketing and informational approaches. This is less true of their subsidiaries and other companies in developing countries.

4. If the pharmaceutical industry was a constraining influence on WHO's promotion of essential drugs, the international network of consumer groups was the opposite. It was rare in WHO's history to be lobbied so actively by assertive consumer groups and non-government organizations arguing for radical change. Few other WHO programmes had suffered this intensity of lobbying and in this sense the Action Programme was qualitatively different from most others within the Organization.

5. The confrontational tactics and participation in the policy process pursued by both the pharmaceutical industry and the consumer groups exacerbated an underlying tension within the Organization. Many regard the constitutional role of a global, specialist agency such as WHO to be to coordinate and offer technical advice, and not to actively promote and advocate contentious issues. Given the controversy surrounding the essential drugs issue, those adhering to this view felt it was even more imperative that WHO restrict its role to uncontroversial technical issues.

6. The move by the Director General in 1983 to put DAP directly under his own office was a strategic action to give visibility, support and protection to the Programme. This move contributed to the the growth of both advocacy and technical support.
provided by DAP under the dynamic direction of its new programme manager from 1983 onwards. However less priority was given to the institutionalization of the Programme, the development of sustainability through a process of decentralization and the development of planning, monitoring and evaluation procedures. The limited role played by the regional offices and the country representatives in the drugs programme has resulted in country support carried out mainly by DAP. This centralised approach is not considered to be conducive to providing sustainable country support.

7. The action of the new Director General in 1988 to remove DAP from under his aegis, and place it within a new Division of Drug Management and Policies can be seen as a rational decision on managerial grounds. Given that the Action Programme was well established, and had demonstrated its success in promoting the essential drugs concept it no longer needed high visibility and routine access to the Director General’s office. However the controversy surrounding the essential drugs concept has not disappeared, and although it was managerially correct to incorporate DAP within the WHO bureaucracy, it suggested that in political terms DAP would no longer receive the support and protection previously afforded by the Director General’s office.

8. The Revised Drug Strategy resulting from the Nairobi Conference in 1985, stressed the importance of the rational use of drugs and the need to provide objective information on drugs to both health workers and the public. It also called for the promotion of operational research. Although work on these aspects is developing, more emphasis is necessary.

9. In 1988, a decade after its introduction, APED had matured into a programme in which the problems of implementing essential drugs policies were better understood, where technical support to countries addressed operational issues and dissemination of information was a major activity. DAP’s focus had begun to shift from the poorer countries, many of which had by now introduced essential drugs programmes at national level, to the needs of more industrialized countries. It may be a sign of DAP’s acceptability that by the end of the 1980s some of these countries were increasingly approaching DAP for advice and support.

10. There are signs that the present leadership will focus more on a technical than an advocacy approach to APED. In these circumstances the promotion of the concept may rest on other organisations and institutions already engaged in this area.

11. Support has been given to countries by DAP, donors and the UN agencies particularly UNICEF. However, the coordination of this support has been erratic and in cases has led to the duplication of effort and fragmentation of health services.

12. The Action Programme on Essential Drugs has been successful both in promoting the essential drugs concept and providing support to those countries concerned with formulating and implementing essential drugs policies. It must be stressed, however, that the acceptability and the implementation of essential drugs policies at the national level is the responsibility of national governments who in turn face many political, infrastructural and economic constraints. In this context, the influence and practice of the private sector is often inimical to the concept.

13. There are strong indications that the availability of essential drugs of good quality and low cost has increased in many countries. There is, however insufficient evidence
for drawing conclusions on the extent of the availability at various levels of the health care system, or on the degree to which changes in availability are directly related to APED.

**Recommendations**

1. WHO should place greater emphasis on essential drugs as a global concept that is applicable in all countries, developed and developing.

   Specifically it is recommended that:
   * experiences of developed countries such as Norway and Sweden be publicised to show the global application of the essential drugs concept.

2. There is a need to improve the integration of essential drugs programmes with primary health care.

   Specifically it is recommended that:
   * an integrated approach be promoted at all levels of the health care system.
   * DAP establish formal linkages with other units and programmes within WHO.

3. DAP should seek ways of coordinating with other UN agencies and donors which promote the essential drugs concept.

   Specifically it is recommended that:
   * more effective mechanisms for coordination between WHO, UNICEF and donors be developed at the country level, to ensure effective support of national primary health care programmes. This is particularly important in relation to the Bamako Initiative.

4. The Action Programme on Essential Drugs continues to need support and assistance. In the uncertainty following the removal of DAP from the Director General’s Office it was suggested that donors establish an alternative organization to DAP to ensure the continuing promotion of the essential drugs concept. The team does not recommend this, believing that the legitimacy bestowed on the concept by the World Health Organization is critical. If present donors withdraw their financial and moral support from WHO others may take their place, and even if the stated objectives of the Programme do not change, strategies may.

   Specifically it is recommended that:
   * Donors continue to support DAP activities.
   * DAP seeks medium to long term funding commitments from donors and donors look favorably on this approach.

5. DAP should place greater emphasis on supporting the conditions that lead to sustainable and comprehensive national drug policies based on the essential drugs concept. It is necessary to create a critical mass of people within countries, who can sustain the development of the concept. To facilitate this, it is recommended that the Revised Drug Strategy be further promoted, by focusing on the rational use of drugs.
Specifically it is recommended that DAP:

- pursue as priority those strategies requested in the Revised Drug Strategy including promoting intensified training on rational drug use; providing learning materials for medical students, health workers and doctors; launching initiatives for the preparation of popular information materials on health care for public use, including the proper place and use of drugs; and preparing guidelines on communicating with patients.
- develop prototype educational material for changing the habits of prescribers and users.
- develop methods to adapt these materials for specific situations.
- provide opportunities for exchange of experience within and between countries
- stimulate countries to develop communications plans for information and training in essential drugs
- encourage training on the rational use of drugs at all levels of health care.
- stimulate and support initiatives that enhance the systematic provision of objective drug information to the general public and health workers at the country level.
- develop a monitoring system to ensure that the ethical criteria guidelines are followed particularly in developing countries.

6. DAP should further develop its work in the promotion and advocacy of the essential drugs concept at the global level.

Specifically it is recommended that:

- the Essential Drugs Monitor be produced regularly and its distribution continue to be extended.
- new documents and publications continue to be produced in a relatively short time span, but their lay-out and appearance are made more attractive.
- the documents and publications be translated into major languages, and their distribution expanded.
- requests for information continue to be responded to in an efficient manner.
- national, regional and international workshops on national drug policies and their components continue to be held.

7. DAP and the concerned parties (as identified in the Revised Drug Strategy) should coordinate with and support organizations which have a professional and competent record, in order to keep up the momentum for change.

Specifically it is recommended that:

- a support-advocacy network among these organizations be built systematically.
- long term relations with institutions involved in the training of health workers, including medical and pharmaceutical workers be developed.

8. Research should be recognized as a fundamental element in achieving APED’s objectives. DAP should continue to expand its research capacity, concentrating on the
four areas (policy, supply, socio-economic, and socio-cultural) that have been identified. However mechanisms need to be established to improve selection and support of research projects.

Specifically it is recommended that:
* a systematic review be made of other WHO units who are undertaking research to learn from their experiences.
* using health economics, epidemiological and anthropological methods, research be undertaken into (1) the impact of essential drugs programmes in terms of accessibility, availability and rational use of drugs; (2) issues concerning the cost of drugs, including those related to the distribution and production of drugs; (3) cost recovery based on the sales of drugs and (4) methods for monitoring and evaluating the effectiveness of essential drugs programmes at different levels of the health service for the use of national policy makers.

9. Weaknesses in the management and organization of DAP should be systematically approached in order to further strengthen the programme.

Specifically it is recommended that:
* overall work plans and target be set for all areas of DAP’s activities, including those activities that are recommended above.
* DAP’s relationships with WHO regional and country offices should be re-assessed with a view to creating greater sustainability and support for country programmes. Other WHO units should be consulted in order to use their experiences.
* indicators be developed to monitor the progress of these plans and progress reviewed every two years.
* DAP stimulate countries to monitor the effectiveness of the implementation of essential drugs programmes at various levels of the health service.
* the World Drug Situation be revised and updated every two years based on an improved methodology as one means of monitoring progress.
* the monitoring system, and this evaluation report be used as a baseline for future evaluations.
ANNEX 1

List of TOR’s for APED policy review

The following list contains the main TOR’s for the policy review of APED as agreed between DANIDA and the core team. For a full text, please refer to "Methodologies for the evaluation of WHO’s Action Programme on Essential Drugs", KIT/LSHTM, December 1988.

Organization and Management

1. Evaluate the Programme’s capacity and capability to assist in the planning, implementation and evaluation of country programmes by examining DAP’ manpower, infrastructure and ability to respond to country requests

2. Evaluate planning and financial aspects of APED by reviewing WHO’s global and programme plans, looking at fundraising, budgeting and resource planning, and procurement strategies

3. Analyse the management structure of DAP and compare it briefly with the PHA, EPI, CDD, HRP and TDR programmes by reviewing the management reports and management style, through reports, publications, papers and interviews with key people

4. Identify policy, organization, financial and other developments within WHO that affect the present thrust of APED by assessing the historical developments identified and reviewing present policy statements and activities within this context

Linkages

5. Describe and assess the co-ordination of and the collaboration between DAP and Pharmaceutical Unit by reviewing documents identifying the tasks of each unit, and interviewing key staff

6. Assess the linkages which have been established with other WHO programmes including CDD, EPI, MCH and SHS by looking as joint training schemes, PHC reviews and evaluations, training programmes for district management

Communication and information

7. Evaluate APED’s ability to communicate the concept of essential drugs to a wider audience which includes governments, the general public, consumer groups, professional associations, pharmacists, drugs vendors, NGO’s and drug producers by looking at DAP’s output in terms of publications, audiovisuals, meetings and workshops, discussions and speeches, use of media and allocations of time and finance for these activities

8. Evaluate the quality and quantity of technical information on drugs as well as materials on the rational use of drugs. by examining publications, guidelines, standards, staff capability, papers from the Rational Use of Drugs conference

9. Evaluate APED’s ability to provide countries with tools to develop their own
essential drugs programmes by looking at guidelines and norms provided by DAP and PHA regarding the appropriate selection and quantification of drugs, quality control arrangements, training of prescribers and dispensers, legislation and regulatory control, financing, monitoring and general information

**Operational Research**

10. Assess the development of operational research of APED through DAP’s research achievements, the extent to which these have contributed to the operation of the programme and the co-ordination with other WHO research and action programmes (including TDR, EPI, HRP, CDD, GPA) by reviewing WHO’s global programme plans, looking at fundraising, budgeting and resource planning, and procurement strategies

**Impact**

11. Evaluate the impact of the joint WHO/UNICEF’s APED in support of the primary health care strategy by looking at the history of the joint WHO/UNICEF programme and the development of the Bamako initiative and assessing its possible impact on APED

12. Identify to what extent the essential drugs concept has been adopted in countries, organizations or associations by analysis of existing documentation, and interviews with key people in relevant organizations to ascertain action or resistance to the pursuit and/or dissemination of the essential drugs concept
ANNEX 2

Methodology

The evaluation looked at the evolution of policy, analyzing how the essential drugs concept was incorporated into WHO’s policy agenda, and how it fared once there. Each stage in the policy process was studied, from policy formulation to implementation, with a focus on the main actors involved, and their possible influences on policy. This was carried out at international as well as at national level.

The methodology used relied on published and unpublished documents and reports, access to relevant files and interviews with key personnel. As with all such studies, contradictory or opposite views, often representing particular interests, had to be incorporated into the mass of information and evidence collected. Many of the key actors were interviewed several times by several members of the evaluation team. All attempts were made to corroborate views and actions in order to reach objective conclusions.

Following the terms of reference (Annex 1) the evaluation is divided into three parts:

a) The Policy Review: evaluation of WHO’s Action Programme on Essential Drugs and vaccines, focusing largely on essential drugs

b) The Country Studies: evaluation of a number of country essential drugs programmes/policies and APED’s influence on the country programmes

c) The study of UNICEF’s Supplies Division: evaluation of UNICEF’s drug procurement procedures and practices. This was done by SGS and produced as a separate report. The recommendations are in annex 6

The policy review focused on the development and implementation of APED’s policies through WHO’s operational unit DAP, while the country evaluations assessed the effect of APED’s policies within selected countries, thus complementing the policy review.

Policy review

The principle objective of the policy review was to examine how the World Health Organization promoted the essential drugs concept among its member countries through its Action Programme on Essential Drugs (APED) with the support of the operational unit responsible for this policy and strategy, the Drug Action Programme (DAP). This analysis focused on:

a) the formulation and implementation of policies related to the essential drugs concept, by examining the organization and management of APED and DAP.

b) DAP’s country support activities and the information and technical tools provided.

c) the communications of the essential drugs concept on both a global and a national country level.
Framework of the policy review
The terms of reference suggested twelve sets of questions for investigation of the policy review. These were grouped into four major areas: management and organization; linkages; communication and information; and effect. The framework for the policy review explored the different phases of policy formulation, from the appearance of essential drugs on WHO's policy agenda onwards, followed by an analysis of the strategies and activities used to implement the Action Programme. In this analysis attention was paid to the different interests involved and how they influenced policy development.

Country case studies
The principle objective of the country studies was to evaluate APED's influence through DAP, on the development of national drug policies. The country evaluations also sought to assess the effects in-country of implementing an essential drugs programme. While the country evaluation teams collected, wherever possible, existing information on the extent to which the countries' drug programme or policy had made essential drugs regularly available to the population, it is critical to emphasise that the objective of the country case studies was not to evaluate the impact of the essential drugs programmes. The country teams had neither the time nor the resources to do so. Where this information existed, in previous evaluations or progress reports, it was used.

In addition, one of the evaluation questions was to assess why some developing countries had apparently shown no interest in the essential drugs concept and/or support from WHO. To investigate this situation, visits were made to several of the countries who were members of the ASEAN (Association of Southeast Asian Nations) pharmaceutical programme and desk studies were undertaken to review the situation in the Francophone countries of Africa and the Andean countries of Latin America. All WHO's Regional Offices, with the exception of the European Office in Copenhagen, were visited in order to assess their role in supporting APED at the country level.

Framework of the country assessments
The overall framework of the country case studies was to look at the development of policy regarding essential drugs, focusing on DAP's influence on that process, and to assess the effects on policy development and implementation, following the framework developed for the policy review.

The criteria for selection of countries for evaluation can be found in Annex 3.

Organization
A co-ordinator was appointed in each Institute with overall responsibility for the evaluation. A Secretariat was set up in the London School of Hygiene and Tropical Medicine, with a team leader and a full-time manager. Together with selected consultants they formed the core-team of the evaluation.

From the London School of Hygiene and Tropical Medicine:

Core-team members: N.Kanji; S.Rifkin (teamleader); G.Walt (LSHTM coordinator) supported by the following consultants: J.Armstrong; S.Fabricant
From the Royal Tropical Institute:

Core-team members: J.W.Harmmeijer (KIT coordinator); P.Streefland
supported by the following consultants: A.Hardon; W.Bannenberg

A reference group was suggested to follow the process of the evaluation and to comment on its findings. Members of the group are recognised academics linked to reputable institutions:

Professor B. Abel-Smith, London School of Economics and Political Science, U.K.
Professor I. Darmanisjah, University of Indonesia
Professor C. Kunin, Ohio State University, USA
Professor L.A. Salako, University of Ibadan, Nigeria
Professor G. Tognoni, Mario Negri Institute, Milan, Italy
Dr S. Van der Geest, University of Amsterdam, The Netherlands

In operational terms the evaluation was divided into three phases:

Phase I: Planning and general desk study
This comprised of the following activities:

1. Review of existing literature,
2. Development of the methodological approach to the policy study
3. Development of the methodological approach and guidelines for country case studies
4. Proposal and plans for implementation of the evaluation: objectives, methodology, timing, consultants, budget.

Guidelines were developed to obtain maximum uniformity in approach by evaluators in the country case studies, and a 2-day workshop was held in order to discuss the guidelines and methodology to be used in the case studies.

Phase II:
During this phase the actual execution of the evaluation took place.

Policy review through visits to WHO Geneva, donors, pharmaceutical industry, consumer groups, NGO’s, UNICEF and other key informants. The policy review mainly took place in Geneva and was conducted by core-team members and associated consultants to obtain maximum uniformity in approach and enable continuous mutual exchange of information.

Furthermore visits by members of the core team and/or consultants were made to:

ASEAN countries (Malaysia, Indonesia, Philippines) to investigate the influence of APED on a regional cooperation initiative under the auspices of Technical Cooperation between Developing Countries (TCDC)

WHO Regional Offices (AFRO/Brazzaville, EMRO/Alexandria, SEARO/Delhi, WPRO/Manila, PAHO/Washington) for information on country programmes and for the
policy review.

All these visits resulted in reports which were used in the final synthesis. The executive summary of these reports appear in Annex 9.

Evaluations were carried out in the following countries, by a team of three members in most cases, a national, a member of the core evaluation team (or a consultant selected by the evaluation team) and a member selected by the major donor to the specific country. This donor-selected member was usually the team leader. The country case studies were done by the following people. The donor which supported the visit is in brackets.

Bangladesh (DANIDA)
K. Islam; J. Martinussen; S. Rifkin

Colombia (DANIDA)
J. Hansen; J. Ramírez-Hernandez; V. Ruiz

Indonesia (DANIDA)
P. Ascobat; N. Dabelstein; B. Hausman

Kenya (SIDA)
P.K. Lunde; C. Matai; M. Mamdani

Nigeria (DGIS)
D. Bol; P. Polderman

Sudan (DGIS)
Z. Ali Nur; S. Postma; K. de Wilde

Tanzania (DANIDA)
N. Kanji; G Munishi; G. Sterky

Vietnam (SIDA)
I. Darmansjah; S. Fabricant

Yemen Arab Republic (DGIS)
F. von Massow; K. de Wilde

ASEAN TCDC (DANIDA)
J. Martinussen; M. Tan

The desk studies were undertaken by:

Francophone Africa J. Maritoux
Andean Pact Countries P. de Vos
Mozambique N. Kanji
Democratic Yemen N. Kanji
Burundi W. Bannenberg
Zimbabwe W. Bannenberg
UNICEF
During phase II the evaluation of UNICEF's Supplies Division located in Copenhagen took place. The overall objective of this evaluation was to assess UNICEF's ability to procure and distribute drugs of acceptable quality, safety and efficacy. Some of the most relevant findings of this evaluation have been included in this report in Chapter 4, while the full conclusions are in Annex 6.

The study was undertaken by the Belgian branch of Societe Generale de Surveillance (SGS), Antwerp. The team consisted of:

D. Hellmans; W. Lambaerts (team leader); J. Moreau; C. Somers.

Phase III
In this last phase the analysis of information took place, and was synthesised for this draft final report. A final report will be prepared once the team has received the comments of the reference group and other interested parties.
ANNEX 3

Selection of Case Study Countries for DAP Evaluation

I. Introduction

As part of the Desk Study in Phase I of the evaluation, investigations for criteria by which to select countries for field studies were undertaken. These investigations resulted in two outcomes. The first was the definition of DAP involvement in a range of countries. The second was a list of suggested criteria by which to choose countries for the evaluation.

Sources of information

1. DAP progress reports on country activities
2. DAP budget submission dated November 1988
3. Reviews and evaluation reports on country programmes
4. Interviews with DAP staff

II. Definition of DAP Involvement

Based on the above sources, an outline of activities which can be described as DAP inputs was compiled. By using the list of countries from the 1989 DAP budget submission, it was possible to describe DAP involvement in these countries.

DAP inputs were defined as:

1. Situation analysis: sending of DAP staff or DAP recruited consultants to identify areas of support.
2. Plan of operations: support from DAP staff to countries to assist in drawing up project proposals.
3. Obtaining donor funds: coordinating DAP extra-budgetary funds from donors in order to fund country programmes. DAP may also approach donors for funding programmes in specific countries.
4. DAP/WHO funding: non-committed DAP extra-budgetary funds used to fund country programmes. These funds may derive from interest accrued and/or from special WHO funds (eg. DG’s development fund).
5. Executing agency: where DAP/WHO funds a country programme (Democratic Yemen), or where it holds the funds for the programme (Nigeria), its role becomes one of executing the programme albeit with national counterparts.
6. Selection: DAP staff or consultant support to countries in developing essential drug lists.
7. Quantification: consultant support in quantifying national drug requirements.
8. Therapeutic guidelines: consultant support in developing therapeutic guidelines. May also include financial support for the production of the guidelines.
9. Procurement: DAP staff and/or consultant support in setting up a centralize procurement agency, developing tendering documents, creating a database of reliable suppliers.
10. Local production: consultant support in carrying out situation analyses with recommendations, recruitment of suitable technical staff.
11. Storage: consultant support in identifying problems with storage facilities.
12. Inventory control: consultant support in developing systems for stock control.
13. Distribution: consultant support in making situation analyses of transport needs, vehicle maintenance, regional and local storage depots, fuel requirements etc.
14. Quality control: consultant support in setting-up of laboratories, recruitment of qualified international staff.
15. Legislation: DAP staff and/or consultant support in drawing-up comprehensive drug legislation.
16. Registration: consultant support in setting-up drug registration procedures.
17. Assessing training needs: DAP staff and/or consultant support in identifying types and numbers of people required to manage the country programme.
18. Workshops: national workshops supported financially and/or technically by DAP staff and/or consultants.
19. Fellowships: funding of national staff to take specific courses aimed at improving management of the country programme.
20. Exchange visits: financial support for work visits to other countries.
21. Training material: financial support in producing training material.
22. Collaborative studies: funding of collaborative studies in-country often to test out new methodologies.
23. Evaluations/reviews: participation in or carrying out an evaluation/review of country programmes.
24. Information for doctors: financial support for production of material.
25. International/regional meetings: funding of and preparing the documentation for such meetings aimed at discussing policy or at publicizing the EDP concept/programme. This activity may be used to promote the programme in the host country.
26. In-country staffing: recruitment and placement of a project manager in-country.
27. Collaborating centre: financial and/or technical support in setting-up or in upgrading specific units in-country to be WHO collaborating centres.
28. Regional centre: financial and/or technical support in setting-up or in upgrading existing units in-country to regional centres.

III. Selection of Countries with DAP involvement

Country selection was based on the list of DAP inputs identified through the 1988-89 budget submission. Although the list of inputs was useful as a basis for country selection it has certain limitations. It gave no indication of the depth or intensity of DAP involvement and it was not always possible to get a compete picture of DAP's inputs to every country with an essential drugs programme. It was therefore decided to use additional criteria to help select countries to be evaluated.

The first criterion was the division of countries listed in DAP's budget submission for 1989-90, by WHO regions. This was done so as to reflect WHO's management structure of decentralised regional offices. This classification also reflects to a certain extent the historical development of DAP's policy and involvement. For example, in the AFRO region, sub-groups on the basis of cultural/colonial legacy were created (Anglophone, Francophone & Others) so as to compensate for DAP's more extensive involvement in Anglophone countries in relation to Francophone and Lusophone countries.

The second criterion was DAP involvement. Countries in each region were listed by the various types of DAP supported activities, technical as well as monetary input. Certain
countries without any DAP involvement were excluded at this stage.

The third criterion was the division of countries by DAP's own criteria. DAP's first criterion is that of need (the poorest countries). GDP/capita was considered an important criterion because it is one of the criteria that DAP itself identified as a pre-requisite for its initial involvement. In relation to population size, preference was given to selecting countries with relatively high populations as the theoretical benefits of DAP activities in such countries would reach more people. DAP's other two criteria are government will and possibility of success. These two criteria could not be considered at this stage because of lack of information. However, they are to be part of the overall evaluation.

The fourth criterion was which donors were involved in which country in order to have a range of donor experiences in the country evaluations.

The final criterion was the type of information available on DAP involvement in each country.

As a result of this process the following countries were selected for country case studies for country visits: Bangladesh, Indonesia, Viet Nam, Sudan, Yemen Arab Republic, Burkino Faso, Kenya, Nigeria, Tanzania, Colombia. Burkino Faso was not visited due to lack of time to complete arrangements.

In addition, it was decided that four countries with quite a bit of documentation about the development of national essential drugs programmes would be reviewed and the findings incorporated in the report. These countries were: Burundi, Mozambique, Democratic Yemen and Zimbabwe.

IV. Selection of Countries with little or no DAP involvement

The case for using the same criteria for selecting countries with little or no DAP was not so strong. It was seen that each had individual characteristics which could tell about essential drugs programmes in that country alone but would not contribute to a more general picture of essential drug policies. In addition, it was clear that many of the criteria identified for countries with DAP involvement were not relevant. Thirdly, the information collected about these countries during the desk study phase was not sufficient to allow the criteria to be of use in selection.

Thus, given the time and resources an alternative to obtain information in these groups of countries was chosen. It was seen that this would be a two stage process.

The first stage was to visit to all WHO's regional headquarters with the exception of EURO. It was seen that people at the regional level could provide information and point to important areas of concern in the essential drugs programmes in their areas. To offest the bias of this source, the team talked to other groups easily accessible during the visit who have been involved in essential drugs programme. These groups included NGOs, consumer groups, pharmaceutical associations, etc.

After reviewing and analysing the information obtained during these visits, it was decided that two approaches would be undertaken to assess APED's influence. The first would be field site visits of some of the countries within a regional co-operative
network supported through TCDC. ASEAN was selected and Malaysia, Indonesia and the Philippines were visited. The second approach was to undertake desk study of the Franco-phone African countries and Andean Pact countries in Latin America to assess the influence of APED in these regions. The information from the visits and desk studies was analysed and incorporation into the final report.
ANNEX 4  Overview of DAP country support and activities

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### ANNEX 5

**DAP objectives and major action taken**

These objectives are taken from a report by the Executive Board Ad hoc Committee on Drugs Policy, 1982 (A35/7)

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Major Actions</th>
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<tr>
<td><em>make available objective information on the world drug situation.</em></td>
<td><strong>World Drug Situation</strong> produced in 1988</td>
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<tr>
<td><em>develop international policies for WHO’s governing bodies.</em></td>
<td>WHA resolutions</td>
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<tr>
<td><em>formulate international programmes and plans of action.</em></td>
<td>Global Medium Term Programme, 1983; WHO’s Revised Drug Strategy; Rational Use of Drugs; Ethical Criteria for Medicinal Drug Promotion.</td>
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<tr>
<td><em>bring together in various combinations as necessary all concerned parties.</em></td>
<td>Nairobi meeting, 1985; MIP meetings</td>
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<tr>
<td><em>provide information on therapeutic indications and side-effects of drugs.</em></td>
<td>Draft in 1982; published in <strong>WHO Drug Information Bulletin</strong> in 1988</td>
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<td><em>provide guidelines for making national drugs policies; estimating and quantifying needs for various drugs; planning and operating procurement systems, drug storage and distribution systems.</em></td>
<td>NDP guidelines; Manuals on drug requirements; manuals on distribution and procurement; workshop on procurement; workshop on operating ED programmes; estimating drug requirements; Kenya workshop reports.</td>
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<td><em>foster collaboration with UN and NGOs</em></td>
<td>Approval for pool procurement in 1984 with UNICEF and attempt to establish a revolving fund in same year; provide information for visitors and upon written request for groups such as CMC.</td>
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<td><em>facilitate negotiation between LDCs and industry</em></td>
<td>little progress during this time period</td>
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<td><em>promote international collaborative research</em></td>
<td>1986-88 DAP initiated two multi-country studies focusing on economics of drugs and socio-economic aspects of drug use</td>
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<tr>
<td><em>developing and implementing national drugs policies</em></td>
<td>see appendix for country support activities</td>
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<td><em>support manpower development</em></td>
<td>development of curricula</td>
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</table>
*facilitating inter-country cooperation

*provide information on drug legislation and models on legislation and regulation

*promote research of global significance on development and proper use of drugs including quantities needed by countries

*develop communications plans for promotion of APED in WHO, UN system, NGOs and other potential partners

*develop active collaboration with industry

*ensure close collaboration with EPI, TDR, CDD, MAP and other disease control programmes

*identify expertise and use it to support APED and advise regions of its availability

*mobilise global resources for country support activities including financing of drug supply

*evaluate efficiency and effectiveness of APED

*support regional offices on request

*encourage member states to support the Certification Scheme

*inform EB and WHA of extrabudgetary requests

assistance with pool procurement (see country studies); sending of consultants; publication of *Essential Drugs Monitor*, 1985

publications on drugs legislation and on drug regulation in LDCs; *International Digest of Health Legislation*

*Estimating Drug Requirements* produced in 1988

developed communications plan in 1988

present at Nairobi meeting, invited to attend MIP/MAC meetings

ad hoc and limited collaboration; joint support for Burundi EDP

provided consultants for country support

donor aid and WB funding to country programmes (see country studies and policy review)


see policy review and country studies

as of 1987, 124 countries participating

progress reports regularly prepared; presentations to and reports of MIP

Objectives from the Global Medium Term Programme (EDV/MTP/85.1)
* all countries fully informed about the ED concept by end of 1989

* NDPs based on the ED concept launched in 12 countries by 1986; 28 countries by 1989

* by 1986 6 countries to have 20 essential drugs available to 80% of the population; by 1989 20 countries

* WHO with UNICEF make expertise available for procurement

Objectives from WHO's Revised Drug Strategy (A39/13)

* accelerate national essential drugs programmes by country missions; seminars; dissemination of information; preparation of material in local languages

* undertake technology transfer through training activities including 20 national seminars; 5 inter-regional workshops; inter-country training through collaborating centres

* publish guidelines on national drugs policies

* strengthen market intelligence

* make available learning material to health workers on rational drug use

* intensify normative activities including promotion of Certification Scheme, quality control, use of INNs preparation of model drug formularies, guidelines for drug regulatory authorities, expansion of ICDRA work, consolidation of UN banned products list

* convene meeting of experts to update ethical criteria for drug promotion

* more systematic dissemination of WHAs; essential drugs lists and Essential Drugs Monitor

40 countries have ED policies (WHA 39.14); 25 countries have fully developed NDPs (World Drug Situation, 1988)

no evidence to support achievement of this objective

see above actions concerning UN collaboration

Jan-June 1988, 25 seminars held; 200 person weeks in 72 missions (MIP, 1988); of 100 DAP catalogue publications 45 available in French, 23 in Spanish and 2 in Arabic

see above but unable to tell type of seminar

guidelines published 1988

MIS initiated in 1988; producers from 44 countries participate

DAP personnel helped PATH in Bangladesh and Kenya

Certification Scheme now has 124 members; other normative activities intensified (see PHA publications) ICDRAs being regular organised; guidelines for small drug regulatory agencies not published

Ethical Criteria for Drug Promotion published in 1988

World Drug Situation, 1988; drug
drug information
*intensify training of health personnel on rational drug use
*collaborative research on new drugs
information sheets
see country studies
no evidence of activities up to 1988
ANNEX 6


1. Overall assessment

The issue dealt with in this evaluation were approached with the overall aim of allowing for the assessment of UNICEF’s ability to procure and distribute drugs of acceptable quality, safety and efficacy.

It should be noted that we were favourably impressed with the personnel’s motivation and attitude backed up by the particular company culture of dedication resulting from the development aid environment within which UNICEF operates.

The organisational set-up of the Supply Division Copenhagen, supported by the appropriate equipment and skilled personnel is sound, allowing for adequate storage and distribution of drugs, in as far as the drug range ascertained remains unchanged.

When evaluating our findings on Copenhagen’s Supply Division’s operations, in respect of its tendering procedures and practices, we would conclude that these are, notwithstanding the room for improvement, both effective and efficient.

We believe UNICEF could also play an important role in the study, selection and procurement of raw active substances for Third-World drug manufacturers to allow local production.

Notwithstanding the fact that a genuine and representative comparison between price levels resulting from open commercial transactions and UNICEF’s list prices prices revealed impossible, UNICEF’s pricing compared favourably in all instances. This finding remains valid when adding handling charges and contingency factor to the list price to calculate the end-user level.

It can as a whole be concluded that on the overall UNICEF’s price trends do slightly better than the world market level, meaning that UNICEF’s procurement is getting more and more efficient.

The accountancy of UNICEF Copenhagen was experienced to be far from transparent and complete, due to a split-up of the expenses over the Copenhagen and New York accounts, in function of the funding resources.

As an external observer we believe that, under the present circumstances and considering the continuous growth of the activities, incorporation of budgeting and accounting of all aspects related to the supply function in the Copenhagen organisation, would contribute to the efficiency and possibilities of Supply Division. This would also improve the transparency of price-setting.
When comparing UNICEF’s approach to Quality Assurance with the applicable ISO 9002 Standard (*), we would emphasize that, although the requirements of the Standard cannot be fully documented in all instance, the greater part of the operations follows the spirit contained in this Standard.

As a result, one can state that reasonable steps are taken to ensure procurement of drugs of an acceptable quality. It should, however, be clear that UNICEF should not be complacent about this situation in view of the mid- and long-term.

In this respect we can across recent tangible actions aiming at improvement in this area and it is our firm belief that it is UNICEF’s intention to reach full compliance.

In this instance it is appropriate to remind all parties concerned that a full-fledged QA set-up requires defined and documented objectives and regular checking of compliance at all levels.

Further we emphasize the clear distinction one should observe between QA policy and Quality control related measurements, particularly where drugs are concerned.

Full compliance with the pharmacopea should be a minimumm requirement. We noted appropriate measure were taken and work is in progress to reach this objective.

For good order’s sake, it could be considered whether UNICEF should or should not go beyond the requirements of the pharmacopea of the countries of origin, mainly when stability and efficacy of drugs come about.

Finally, the present report contains a number of suggestions aiming at improvement of the already well managed operations and which could, in our opinion, be implemented easily.

2. Comments and Recommendations

In the following pages we summarize a selection of the comments and recommendations with regard to UNICEF’s drug procurement procedures and practices resulting from the study of Items 1 to 5, 7, 8 and 10 of the Terms of Reference.

Advice is grouped under three main headings:

- policy matters, involving global and/or external rethinking;
- organisational matters related to the operations and the functioning of the Procurement Section and the Warehouse;
- product-related matters requiring mainly practical measures.

Each group of recommendations is sorted in a suggested rank-order of priorities chosen in function of the scope and the objectives of the study.

(*) "Quality Systems Model for Quality Assurance in Production and Installation" and, as stated in this standard, appropriate to service activities.
2.1. Policy-Related Matters

1. Management should document its corporate quality policy and objectives. Appropriate levels of management should define specific quality objectives consistent with this corporate quality policy and other corporate objectives.

The Quality Management System should be defined more explicitly.

2. The selection of suppliers should be governed by strict adherence to a Quality Assurance oriented approach with more frequently performed audits of selected manufacturers and scrutinised updated documentary evidence of approved companies and products.

3. The reimbursable scheme would benefit substantially from review of the following aspects:
   - length of the communication channel
   - importance of the handling charge
   - necessity of the contingency factor and, when charged, the refunding delay.

4. A global cost accountancy of all Copenhagen operations would allow for better monitoring of efficiency, as well as for a more precise calculation of the Supply Division Overhead Factor.

2.2. Organisational Matters

1. The Supply Division Manual should be reviewed to include a global chapter covering, as a whole, the basics and fundamental rules of tendering/bidders’ selection/market information gathering/quality-related matters. Screening of some present sections is required in order to evaluate deviating practices and bring the content in compliance with daily operations when acceptable.

2. The preparation of a Warehouse Operations Manual is recommended to replace the verbal instructions to the warehouse manpower. This will serve as tool for training and follow-up sessions.

3. Frequent internal checks should be carried out at all levels in order to determine whether objectives are met and operations comply with rules and procedures.

4. The tendering methods and issuance of purchase orders could be reconsidered on some issues, e.g.:
   - published tenders are advisable in the case of long-term and global tenders instead of a mailing list;
   - careful monitoring of the market evolution and contract conditions should allow for corrective action in case of long-terms orders.

5. Improvement on the data recording and filing system on bidders, suppliers’ performance, capabilities, product range, appraisal result and commercial market information is recommended.

6. Expediting of direct shipments should be improved and computer-assisted warning/monitoring is strongly advised.

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7. The job current of the Drug Procurement Officer should be restricted to quality and price matters. Expediting should not be part of his daily task.

8. The Shipping Department should become an integrated part of the organisation with common computer programmes and files.

2.3. Product-Related Matters

1. A more stringent check of the incoming analytical certificates against a check list should be considered.

2. More care should go into data on the results of stability studies and, where appropriate, proper action for testing under tropical conditions is required.

3. Written procedures of the required inspections on incoming pharmaceuticals are to be drafted.

4. All performed tests and results should be recorded and all related documents centralised per purchase order or per batch.

5. The outer cardboards of packed kits have to bear appropriate printed storage instructions.

6. It is considered convenient to require on the labels an indication of the maximum temperature at which products remain stable during the quoted shelf-life.
ANNEX 7

List of people interviewed during policy review

WHO-HQ

Dr. Hu, Assistant Director General
Dr. V. Fattorusso, acting director, Drug Management and Policies
Dr. Tor Godal, Director, Special Programme for Research and Training in Tropical Diseases
Dr. E. Tarimo, Director, Division of Strengthening Health Services
Dr. John Martin, District Health Systems, Division of Strengthening Health Services
Dr. R. Henderson, Director, Expanded Programme for Immunizations
Dr. Widdus, Unit Chief, Programme, Co-ordination and Development, Global Programme on AIDS
Dr. J. Barzelatto, Director, Human Reproduction Research
Dr. M. Belsey, Chief, Maternal and Child Care
Dr. S. Litsios, Malaria Action Programme

Dr. Halfdan Mahler, former Director General, WHO

PHA

Dr. John Dunne, head
Mr. Martijn ten Ham, pharmacist
Ms. Agathe Wehrli, pharmacist

DAP

Ms. Margarethia Helling-Borda, Senior Scientist
Mr. Gerald Moore, Technical Officer
Ms. Pascale Brudon-Jakobwicz, Scientist
Dr. Hans Hogerzeil, Technical Officer
Dr. German Velasquez, Consultant
Ms. Ramona Lunt, Short term Professional
Ms. Daphne Fresle, Technical Officer
Mr. A. Fernandez, Technical Assistant
Ms. Sandra Doyle, Administrative Assistant

Ms. Susan Foster, former Economist, DAP
Mr. Jens Hasfeldt, former DAP staff member
Dr. Ernst Lauridsen, former Programme Manager, DAP
Dr. Godfrey Walker, former Scientist, DAP

Representatives of the Pharmaceutical Industry

Dr. Richard Arnold, IFMPA
Mrs. Sylvie Ayyoubi, Hoffman La Roche
Dr. Hassan Nour Eldin, Hoechst
Mr. Derek Illey, ABPI
Dr. Albert Itschner, Ciba Geigy
Dr. Rudi Stuessi, Sandoz
Mrs. Wiesia Wroblewska, IFMPA

NGOs

Ms. Christel Albert, Pharmaceutical Adviser, Christian Medical Commission
Ms. Phillipa Saunders, OXFAM

Representatives from Donor Agencies

SIDA/SAREC

Mr. Nils Ostrom, Head of Health Division
Ms. Anna-Kari Bill, Health Division
Dr. Harald Heijbel, Medical Adviser, Health Division
Ms. Ingrid Cornell, Desk Officer, UN and WHO Collaboration
Dr. Lennart Freji, Research Officer, SAREC
Ms. Helen Ohlin, Research Associate, SAREC

DANIDA

Mr. Flemming Bjork Pedersen, Head of Division, DBJ
Mr. IB John Kelland, Deputy Head, UN Collaboration
Mr. Johannes Dahl-Hansen, Deputy Head,
Ms. Susanne Esbjorn, Head of Bangladesh Section
Mr. Kaj Andersen, Bangladesh Section
Mr. Carsten Laage-Petersen, Officer responsible for Kenya, Uganda
Dr. Ole Frank Nielsen, Medical Adviser
Dr. Ernst Lauridsen, Medical Adviser

Italian Development Cooperation

Dr. G. Bertolaso, Head, Health Sector
Dr. G. Riva, in charge of Essential Drugs
Mrs. R. Pasqualini, Evaluation
Dr. V. Luchetti

Overseas Development Administration (ODA)

Ms. Barbara Kelly, Head, Health and Population Division

Netherlands Government Directorate for Development Cooperation (DGIS)

Dr. K. Wit

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List of used abbreviations in country studies and evaluation report

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<th>Abbreviation</th>
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<tr>
<td>AFRO</td>
<td>African Regional Office (of WHO)</td>
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<td>Action Programme on Essential Drugs and Vaccines</td>
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<tr>
<td>APO</td>
<td>Associate Professional Officer</td>
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<tr>
<td>ASEAN</td>
<td>Association of South East Asian Nations</td>
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<tr>
<td>CDD</td>
<td>Control of Diarrhoeal Disease (WHO unit)</td>
</tr>
<tr>
<td>CFA</td>
<td>Francs CFA</td>
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<tr>
<td>CHANFARM</td>
<td>Nigerian non-govermental organization</td>
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<tr>
<td>CIOMS</td>
<td>Council for International Organizations of Medical Sciences</td>
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<tr>
<td>CMC</td>
<td>Christian Medical Commission</td>
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<tr>
<td>CMS</td>
<td>Central Medical Store</td>
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<tr>
<td>CDP</td>
<td>Consultants for Development Programmes</td>
</tr>
<tr>
<td>DANIDA</td>
<td>Danish International Development Agency</td>
</tr>
<tr>
<td>DAP</td>
<td>Drugs Action Programme (operational unit of APED)</td>
</tr>
<tr>
<td>DGIS</td>
<td>Netherlands Government Directorate for Development Cooperation</td>
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<tr>
<td>DMP</td>
<td>Drug Management &amp; Policies (WHO division)</td>
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<td>DPM</td>
<td>Drugs, Policies and Management</td>
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<tr>
<td>DPT</td>
<td>Diagnostic, Prophylactics &amp; Therapeutics (former WHO division)</td>
</tr>
<tr>
<td>EB</td>
<td>Executive Board</td>
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<tr>
<td>EDL</td>
<td>Essential Drugs List</td>
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<tr>
<td>EVD</td>
<td>Essential Drugs and Vaccines</td>
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<tr>
<td>EEC</td>
<td>European Economic Community</td>
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<tr>
<td>EMRO</td>
<td>Eastern Mediterranean Regional Office (of WHO)</td>
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<tr>
<td>EPI</td>
<td>Expanded Programme of Immunization (WHO unit)</td>
</tr>
<tr>
<td>EURO</td>
<td>European Regional Office (of WHO)</td>
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<td>FINIDA</td>
<td>Finnish International Development Agency</td>
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<tr>
<td>GDP</td>
<td>Gross domestic product</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<td>GMTP</td>
<td>Global Medium Term Programme</td>
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<td>GNP</td>
<td>Gross National Product</td>
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<tr>
<td>GPA</td>
<td>Global Programme on AIDS</td>
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<tr>
<td>HAI</td>
<td>Health Action International</td>
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<td>HRP</td>
<td>Human Reproduction (WHO unit)</td>
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<tr>
<td>IBFAN</td>
<td>International Baby Food Action Network</td>
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<tr>
<td>ICDRA</td>
<td>International Conference of Drug Regulatory Authorities</td>
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<tr>
<td>IDA</td>
<td>International Dispensary Association</td>
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<tr>
<td>IFPMA</td>
<td>International Federation of Pharmaceutical Manufacturers Associations</td>
</tr>
<tr>
<td>IOCU</td>
<td>International Organization of Consumers Unions</td>
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<tr>
<td>IVS</td>
<td>Intravenous Solutions</td>
</tr>
<tr>
<td>JCHP</td>
<td>Joint Committee on Health Policy (WHO-UNICEF)</td>
</tr>
<tr>
<td>KIT</td>
<td>Koninklijk Instituut voor de Tropen (Royal Tropical Institute)</td>
</tr>
<tr>
<td>LDC</td>
<td>Less Developed Country</td>
</tr>
<tr>
<td>LSHTM</td>
<td>London School of Hygiene and Tropical Medicine</td>
</tr>
<tr>
<td>MAC</td>
<td>Management Advisory Committee (former: MIP)</td>
</tr>
<tr>
<td>MAP</td>
<td>Malaria Action programme (WHO unit)</td>
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<tr>
<td>MCH</td>
<td>Mother and Child Health (WHO unit)</td>
</tr>
<tr>
<td>MEDS</td>
<td>Mission for Essential Drugs and Supplies</td>
</tr>
<tr>
<td>MGT</td>
<td>Management (WHO unit)</td>
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</tbody>
</table>
MIP  Meeting of Interested Parties (around WHO/DAP)
MIS  Management Information System
MOH  Ministry of Health
MTI  Ministry of Trade and Industry
MTP  Medium Term Programme
NAPCO  National Pharmaceutical Company
NDF  National Drug Formulary
NDP  National Drug Policy
NGO  Non Governmental Organisation
ORS  Oral Rehydration Salts/Oral Rehydration Solution
OXFAM  Oxford Famine Relief (NGO)
PA  Pharmaceutical Advisor
PAHO  Pan American Health Organization
PHA  Pharmaceutical Unit (WHO unit)
PHC  Primary Health Care
PPB  Proposed Programme Budget
QA  Quality Assurance
QC  Quality Control
RDS  Revised Drug Strategy
SAREC  Swedish Agency for Research Cooperation with Developing Countries
SEARO  South East Asia Regional Office (of WHO)
SGS  Société Generale de Surveillance
SHS  Strengthening Health Services (WHO unit)
SIDA  Swedish International Development Authority
TALC  Teaching Aids at Low Cost (Tropical Child Health Unit, London)
TCDC  Technical Cooperation Amongst Developing Countries
TDR  Tropical Disease Research (WHO unit)
TOR  Terms of Reference
UNCHR  United Nations Commission for Human Rights
UNHCR  United Nations High Commission for Refugees
UNCTAD  United Nations Conference on Trade and Development
UNDP  United Nations Development Programme
UNFPA  United Nations Family Planning Association
UNICEF  United Nations Children’s Fund
UNIDO  United Nations Industrial Development Organization
UNIPAC  UNICEF’s Supply Division, Copenhagen
UNRWA  United Nations Relief Work Agency
USAID  United States Agency for International Development
WB  World Bank
WFPM  World Federation of Proprietary Manufacturers
WHA  World Health Assembly
WHO  World Health Organization
WPRO  Western Pacific Regional Office (of WHO)
ANNEX 9  SUMMARIES OF COUNTRY CASE STUDIES

BANGLADESH

The purpose of this paper is to review the essential drugs policy of Bangladesh by analyzing the development, implementation and impact of this policy and to examine the role of WHO in supporting this policy. This summary reviews the major findings of the country study team.

The essential drugs policy adopted by Bangladesh in 1982 aimed at ensuring that the common people get the necessary drugs easily at a reasonable price and that such drugs are of good quality.

The policy has eliminated within a few years, useless, non-essential and harmful drugs from the market. The overall supply of essential drugs has increased significantly since 1982. Considerably more drugs are now made available free of charge through the public health care delivery system. A strategy has been pursued whereby the number and types of essential drugs prescribed and dispensed at the various administrative levels tend to reflect to the morbidity patterns and health personnel qualifications. There are in principal 12 drugs available at the Union level, 45 at the upazila level, and 150 at the district level.

In practice, there is an overall shortage of a number of drugs, especially in some rural areas, as compared to the demand. In terms of meeting the needs of the common people, Bangladesh is far from achieving the policy objectives.

But remarkable progress has been made in that direction, not only in the public sector. The private sector has also contributed and as unit prices of drugs have declined quite considerably in the wake of the policy, medicines are now available at lower prices in the market throughout the country.

The most vulnerable groups and those with least information and awareness about public health services are yet to be covered by the policy. The health extension service in the unions is insufficiently developed and remains separated from the family planning domiciliary services.

The present level of procurement and supply of essential drugs can be maintained without increasing external funding. An extended coverage of EDP, on the other hand, requires a proportionate increase in external funding or adoption of cost recovery schemes, or a combination of the two.

Quality assurance and control procedures in Bangladesh are inadequate. Most small-scale manufacturers have no quality assurance procedures at all. The public sector agencies entrusted with carrying out drug quality control are understaffed and overstretched. The Government laboratories in Dhaka and Chittagong, have reached the limit of their capacity and capability. The number of samples tested and rejected as substandard by the laboratories is still alarmingly high. There is thus considerable scope and need for improvement in this area.

Available information does not indicate that the present drug supply and distribution system suffers from any serious shortcomings in terms of cost effectiveness. Opportunities for improvement do exist in the public as well as the private sector but mostly in the form of
better management, including better inventory control and indenting. As suggested some adjustments in the budgeting procedures may also help ameliorate identified problems.

WHO/DAP's support has been mainly inspirational providing the scientific justification for taking action on essential drugs. It also has provided technical consultants, funds for training workshops and fellowships for advanced academic studies. It also has included an essential drug component in its support for "district" (upazila) level intensification of PHC programmes. It efforts have however not been systematic and its capacity for more support particularly in terms of the provision of information has not fully been tapped by the government.

In terms of economic impact, apart from reducing unit prices on essential drugs the policy has induced local production. Bangladesh is now close to being self-reliant with respect to the formulation and supply of finished medicines. The country is still highly dependent on import of pharmaceutical raw materials, but at least these are obtained at lower unit prices as a consequence of government regulations.

Looking at the supply side of essential drugs, although there are lower unit prices there is still far to go before drugs are available in sufficient quantities to meet the needs. There is also far to go in terms of quality assurance and control.

Looking at the demand side, demand created by rational use of drugs depends on how the country can move on to the next phase where prescribing practices and the use of drugs become more rational and where a significantly larger proportion of the population comes to benefit from access from a more rationally administered dispensing of drugs.

Improvement has taken place in these areas simply because useless, non-essential and harmful drugs are no longer available. But within the range of drugs supplied at the various levels there appears to be widespread overprescribing and irrational use of drugs. There is a dire need for training of health personnel and for target group adjusted information to medical and other health staff as well as dispensers in general. In addition, much more need to be done by way of informing and educating the consumers on rational use of drugs.

EDP contributes to PHC program in Bangladesh. It is not closely integrated however into a comprehensive health care delivery strategy nor is it linked up very carefully with other components of a PHC strategy. It is doubtful whether the essential drugs policy can attain a significantly higher goal achievement in respect to the rational use of drugs and coverage without being effectively integrated into a more comprehensive approach to PHC and considerable strengthening of health management and infrastructure support. As one prominent person said "This country has an essential drug policy; what it needs now is a health policy."
COLOMBIA

Since the programme is only going to start in this country, we can not answer whether it has achieved its objectives. But we can asked what has been its impact, that is to say, strengths and weaknesses so far, and explore its linkages with the internal and external conditions of the country.

The concept of essential drugs has been on the agenda of Colombia before the idea reached world wide acceptance with the Alma-Ata Declaration in the late seventies. And yet, the combination of the forces that would make the programme possible would only happen in the mid eighties national individuals from different institutions and PAHO consultants started to interact. Later on, a negotiation between the government of Colombia (by means of the Vice Minister at that time) and DAP Geneva Office, set the basis to obtain funding from the EEC for this specific programme. The result of these negotiations helped the MOH to obtain additional funds from the Exchequer to develop the programme of "Boticas Comunales" (Community Drugstores). This programme attempts to integrate drugs provision with other primary health care activities in which community participation is a central issue. Everything within the context of the government’s National Programme Against Absolute Poverty.

A well defined tendency to "institutionalize" activities was detected. That's to say, to create rules, decrees etc. that could stand the changes of peoples and governments. This was done in order to overcome the brief and uncertain period that top functionaries tend to stay in power. e.g. the last three ministers of health had been in charge on average each, less than a year.

EDP has therefore been given the same treatment of "institutionalizing" in order to make it resistent the ongoing political unrest. It is important to mention that the human technical team of the programme tend to be more stable.

There are however gaps to be considered some of which the MOH is already trying to fill: the legislation in relation with the so called "natural products" and the connections with EDP; the actual policy towards the national and transnational pharmaceutical industry is being revised, and the actual coordination with other parts of the health system is also expected to be reinforced.

Some other problems that have been considered by MOH but remain to be solved are: to state clearly a policy on prices which could consider more accurate and up dated information on Latin American and world prices on raw and manufactured drugs, specially now that a major danger lies ahead. This danger is the possibility which can modify patent laws making it compulsory to accept the patents in Latin American countries with the negative effect on the local industries. This fact would threaten EDP in the country.

Other elements to consider are: there are still a relative dispersion of efforts among health institutions to purchase drugs, although there is more technical co-operation than before. Public as well as health personnel education are still an activity to develop by the MOH including availability of information (e.g. Some PAHO's publications are difficult to find). The relationship between PAHO's Office and the MOH has to be redefined. A strong effort to strengthen the first level of supply of drugs has to be made as well as on the inspection side.
Among the effects that have already occurred as a consequence of the programme are: The MOH has strengthened its role by implementing its own EDP linking it to other PHC activities. The research carried out by the MOH assessed the supply of drugs. Different consultancies sponsored by DAP Office have widened the discussion on different important issues about how to operate the programme considering the experience from other countries. The MOH was in a stronger position to negotiate with other Ministries additional funds for its Community drugstores.

Since there are several important programmes on ED running in the country (like El Quindio, "PIMA" in Antioquia and Popayan), there is a good opportunity to compare and eventually evaluate them rigorously in order to obtain the basic components worth applying.

Finally the research side could offer the unique opportunity to study this programme from the beginning in a nearly controlled experiment that could provide much insight of this Latin American experience.
INDONESIA

This study is a part of the Global Evaluation of WHO Action Programme on Essential Drugs. The purpose of the study is to review the essential drugs policy of Indonesia by analyzing the development, implementation and results of this policy and to examine the role of WHO in supporting it. The study was carried out by Dr. P. Ascobat, University of Indonesia, Dr. B.A. Hausman, Consultant, and Mr. Niels Dabelstein, Danida. This summary presents the main findings of the study.

Policy formulation

Until 1979 the drugs policy of Indonesia was mainly aimed at establishing self-reliance in drug production through domestic and foreign investment and at drugs control. The Third Five Year Plan, Repelita III (1979-84), emphasized rationalization of drugs supply and use through implementing the essential drugs concept. A National Essential Drugs List was promulgated in 1980 followed by a comprehensive National Drugs Policy in 1983.

The development of the essential drugs policy dates back to the mid-seventies when the large number of proprietary drugs and high prices became an issue of concern. This coincided with the emergence of the essential drugs concept in WHO. It should be noted that the Indonesian member of the Executive Board chaired the 1978 World Health Assembly where Essential Drugs was subject to technical discussions at which the Indonesian Minister of Health made a presentation.

The WHO Drugs Policies and Management Unit was at that time developing strategies and approaches to support countries in implementing the essential drugs policy. There is no doubt that this parallel development of policy was mutually reinforcing and beneficial and partly the result of both formal contacts and informal personal relations between Indonesia and WHO.

WHO staff carried out a situation analysis in 1979 which identified the major problems as proliferation of drugs, inefficient procurement, storage and distribution and weak legislation and control. On this basis several WHO consultants and staff carried out a number of studies in 1979-80 which assisted the government in formulating the comprehensive national drugs policy. These studies were also major inputs to the formulation of the ASEAN TCDC on Pharmaceuticals.

Parallel with the shifting of WHO/DAP focus towards LDC's, WPRO assumed the leading role in the further development of the ASEAN TCDC project which during the period 1982-89 has been the focal point for WHO involvement in the implementation of drugs policies in Indonesia.

Implementation

The 1983 National Drugs Policy which is in conformity with WHO principles has as its objectives:
- to ensure the availability and equitable distribution of drugs in compliance with actual needs.
- to ensure quality, efficacy and safety of drugs.
- to promote rational use of drugs and protect the public from misuse and abuse.
- to develop the national pharmaceutical potential.
The strategy employed has focused on the development of efficient public sector production, procurement and distribution of essential drugs, that is, the supply side, while, until recently, the demand side and the private sector has largely been left unattended.

Interventions have to some extent been designed on the basis of the 1979 WHO situation analysis and the subsequent studies. WHO consultants have on several occasions been employed to assist in the design phase and several fellowships and workshops have been financed through the WHO country programme. Most of these activities have been managed by the country office and by SEARO, only on few occasions has WHO/DAP been involved. There has been little WHO involvement in the implementation of interventions other than Quality Control and the UNDP financed WHO executed ASEAN TCDC Project. Several bilateral donors have provided substantial support to implementation, notably Japan and The Federal Republic of Germany (quality control), Italy (production) and USA (planning and management).

It is, of course, difficult to assess the effects of WHO/DAP global activities like technical papers, guidelines, policy statements and general publications. However, at central level in Indonesia these sources are well known and used.

**Institutional Framework.** Drugs legislation in Indonesia cover most if not all the elements in drug legislation and regulatory control as described in WHO guidelines. The Regulatory agency, the Directorate General for Drug and Food Control (POM) is responsible for The Essential Drugs List with supporting formulary and therapeutic guidelines, drugs registration, quality control and production at government owned facilities.

**Essential Drugs List.** While there has been little attempt to restrict the number of drugs other than those considered dangerous in the private sector the essential drugs list concept has been implemented in the public sector with the aid of promoting rational use of drugs and of optimising the use of the limited funds available. The first list was issued in 1980 and has been revised twice since.

WHO consultants were requested to participate in the preparation and first revision. The list, which contains a limited number of drugs outside the WHO list, proscribes the drugs for use at the various levels of public health facilities. Informatoria and therapeutic guidelines have been issued and Pharmaceutical & Therapeutical Committees established at referral and teaching hospitals.

In 1986 the concept of generic essential drugs was introduced for use in both the public and private sector. In July 1989 a ministerial decree requires public health physicians to prescribe generics only, for the 133 items now available.

**Production.** The total value of drugs marketed in Indonesia is estimated at more than US$ 470 mill. (US$ 2.75 per capita) showing an annual increase of 17% since 1973. Since 1979 approx. 95% has been formulated locally; approx. 80% of raw materials are imported. The government now produces approx. 15% of domestic production, 52% is produced by 40 foreign controlled companies (down from 66% in 1980) while the remaining 33% is shared among some 240 national companies. Production is generally only 50-60% of capacity. Marketing is extremely aggressive including discrediting of other products and kickbacks to prescribers and dispensers. Free samples to prescribers were banned in 1987. Government production is increasingly generic and now supplies some 80% of government purchases.
The retail price of generics is app. 55% of proprietary drugs. So far generic drugs have been primarily distributed though public sector health facilities. When a new large plant (financed by Italy) for generic essential drugs starts production in late 1989 generics may constitute serious competition to proprietary drugs hopefully bringing prices down. This strategy will be supported by a planned rigorous implementation of GMP both in the public and the private sector. This should have the effect that a large number of very small producers will have to merge or close down allowing better capacity utilization in the surviving plants.

**Quality Control.** The responsibility for quality of drugs rests with the producer. POM exercises control through sampling from retailers and inspection for GMP. Sampling at 75,000 per year appears inadequate in light of the generally acknowledged low compliance with GMP. The physicians' and consumers' general lack of confidence in domestic products including those from the government is being capitalized on by the foreign companies.

The National QC Laboratory as well as the 27 provincial laboratories have been developed with extensive technical assistance and fellowships from WHO and capital support from Japan and FRG. In 1986 The National QC Lab was designated a WHO Collaborating Centre for Quality Assurance of Essential Drugs. In order to ensure the quality of the newly introduced generic products each batch is tested at the national or one of the provincial POM laboratories.

**Drugs Procurement.** The public sector drugs procurement and distribution system is a highly complex matter. There are 6 different budget sources for drugs with sometimes different budgeting and disbursement schedules and procurement committees. The quantification of drugs is still primarily based on past consumption.

WHO/SEARO has provided technical assistance to the design of a computerized drugs information system which is currently being implemented with support from USAID. The distribution of centrally procured drugs to regency level is being managed efficiently by one of the government owned manufacturers. A programme to improve the storage and distribution system at regency level and below is also being implemented.

**Manpower Development.** Changing the prescribing habits of health personnel in both the public and private sector is perhaps the biggest challenge facing the Ministry of Health in its efforts to promote rational and effective drug use and to reduce the expenditure on pharmaceuticals. Unnecessary prescribing of antibiotics and non-therapeutic drugs is pervasive and sub-therapeutic prescribing is common. Although this has been acknowledged for some time the lack of systematic education and training is only now being seriously addressed. Hitherto the information activities have primarily consisted of the issuance of drugs lists and the national informatorium. With the introduction of Generic Essential Drugs (GED) in 1989 the MOH has initiated an active promotion campaign directed towards the prescribers and the dispensers as well as the public. Little or no inputs have been available from WHO on this approach.

**Information for the public.** With the increased availability of the Generic Essential Drugs (GED) a concerted effort is being undertaken to inform the public about the availability and quality of low cost generic drugs. This is a professional communications campaign using a logo, printed material and TV announcements. Affordability and quality of the generic drugs are the messages being conveyed.
**Evaluation and research.** The major subject for research in relation to essential drugs has been drug use. Several studies have been carried out documenting the irrational use of drugs. Most of this research has been financed from national or bilateral sources with two small studies being financed by WHO. The research in drugs use has been instrumental in providing information on ways and means to promote the rational use of drugs. No comprehensive evaluation of Indonesia's essential drugs programme has been carried out. A DAP country programme review is scheduled for October, 1989.

**Effects**

It is difficult to assess the result of the drugs policy in terms of availability of affordable essential drugs at public health facilities. In general the most commonly used drugs are available to meet 50-60% of demand. Two major factors have to be considered. One is that public per capita expenditure on drugs has remained constant while prices have not been reduced until 1989. The other is the irrational use of drugs which distorts the picture. The first factor will be remedied through the increased production of Generic Essential Drugs (GED). The other is yet to be tackled. In the private sector little impact can be observed. The number of drugs registered has increased from 7,200 to 12,600 and prices are among the highest in developing countries. However, as has been discussed above, the infrastructure has improved considerably and recent initiatives are likely to increase the availability of affordable drugs substantially.

**The Role of WHO**

It is obvious from the information contained in this report that much progress has been made in the area of drugs policy in Indonesia. Before 1983 one could not speak of a comprehensive National Drugs Policy. Since the late 1970's WHO has played a significant role in assisting Indonesia develop such a policy.

WHO has throughout the years also provided assistance in many technical aspects through the country and regional offices and through the UNDP funded TCDC on Pharmaceuticals Project. These aspects, however, have almost entirely focused on what has been called the "pharmaceutical supply" side of the essential drugs concept, i.e., importation, production, quality control, GMP, distribution, management, etc. with little attention being paid to the "medical demand" side of the picture, i.e., education and information for prescribers and consumers. This last aspect includes not only education and information on types of drugs and their price but also on the rational use of drugs.

This is, of course, in line with WHO's initial mandate to emphasize procurement, quality control, distribution, etc. Quality of essential drugs remains an important issue in Indonesia and deserves continuing serious attention. Ensuring good quality will be a key factor in determining the success of the 1989 Generic Essential Drugs (GED) initiative. However, in a free market economy such as to be found in Indonesia it is obvious that supply and demand go hand-in-hand. In fact, with the aggressive and sometimes unethical marketing techniques used by the pharmaceutical industry to create demand for any pharmaceutical product, it is not surprising to find the essential drugs concept embodied in policy but not functioning in the free market.

The importance of the "medical" aspect of the essential drugs concept in addition to the "pharmaceutical" aspect has been stressed for several years - also in Indonesia. It could reasonably be asked if it was wise for WHO to focus on procurement, quality control,
management and distribution, etc. without sufficient emphasis on the other aspect, at least for Indonesia. The country is now forced to create demand for low cost generic drugs by ministerial decree instead of having demand created through professional understanding and public awareness. One can only speculate as to how many domestic pharmaceutical manufacturers would now be producing such low cost quality products if such a demand had arisen from prescribers and consumers.

Was this a missed opportunity for WHO to assist Indonesia? Or should we rather say that its time has come?
KENYA

This evaluation study was performed during a 2 week visit to Kenya during August/September 1989. The team consisted of three members. Of those, two external consultants were recruited by the evaluation programme coordinators, the remaining being a Kenyan representative proposed by the team leader upon arrival and subsequently approved by the Ministry of Health of Kenya.

The objective of this evaluation was to look at the development of a National Drugs Policy in Kenya with major emphasis on the EDAP implemented, and WHO's influence on these processes. Whenever relevant, other parties involved were also considered.

Upon consultation with various local parties, including MOH, DANIDA and SIDA, the team decided on a working procedure as follows:

1. A 3-4 days site visit to Districts and Rural Health Facilities (RHF). Hence the coastal province (Mombasa zone) was selected and approached by the two external consultants, as guided by health officers from that zone. About 10 sites were visited at relevant levels of the EDAP-related health care system.

2. The remaining time was spent by visits to and quite extensive discussions with key persons among the parties involved (MOH/EDAP, DANIDA, SIDA, UNICEF, African Medical Research Foundation (AMREF), MEDS, various teaching and training institutions etc.) In broad, the three team members acted together, often with panels of counterparts from various relevant areas and professions. Thus a wide range of information and qualified opinions were obtained, as often revalidated through discussions with several other parties. In addition, relevant previous documents (basic WHO documents on EDAP, evaluation and progress reports, developmental plans etc) were consulted.

The following observations and analyses were made:

At the time when Kenya got its independence (1963), the country was in a relatively good position (resources, infrastructure, political stability) as compared to many other LDCs. This situation is basically unchanged, but has been sought further improved through a wide range of ambitious initiatives and developmental programmes. The most relevant of these included the establishment of a public health care system (broad coverage, free of charge), strong emphasis on education and training (health workers at all levels, as well as the public), improvement in drug procurement and accessability also being a priority objective. Within a mixed economy and "open doors’ policy" setting, various contributions from other parties were invited and welcomed and sought coordinated with local strategies, in order to expand financial and other resource limits, all the time also having cost-effectiveness in mind.

In the 1970s, rapid expansion, rocketing growth in population (still at a rate of 4% per year), set-backs and fluctuations in economy, failures due to mis-management and sometimes corruption, among others, made Kenya face a crisis with subsequent risk for a collapse of what had been obtained within the public sector of health care. One prominent indicator was a desperate shortage of drugs and diversion of the stream of patients, away from RHFs towards hospitals. Hence Kenyan authorities immediately welcomed the ED concept, subsequently adopting the EDAP as well as the Alma Ata Declaration, both being launched through WHO, in 1977 and 1978, respectively. Advice, financial and technical
assistance were sought through WHO, other organizations (UNICEF, World Bank etc) and via bi- or multilateral agreements with MDCs, various institutions (including academic) etc.

The EDAP of Kenya was officially started in January 1981, mainly based on external advice (WHO in particular) and financial assistance (DANIDA, later SIDA), but utilizing and gradually improving the pre-existing physical facilities and networks, all with main emphasis on CHC. In fact, although some efforts were paid to develop a comprehensive and unitarian health and drug policy (ED concept/ EDAP-based), no whole-hearted steps towards such an implementation were ever taken. Thus the private health and drug sector is still flourishing, despite some regulatory actions taken on with regards to the latter. Within the public sector at higher levels of the health care system, "mixed practices" go along. These problems are presently being re-emphasized by Kenyan authorities, and to an increasing extent also by the great number of involved partners (e.g. UNICEF, AMREF, SIDA, DANIDA, among others), the plurality of approaches by which having caused severe coordination problems, but presently better solved in terms of harmonization.

The RHC/EDAP has mainly focused on drug procurement, management and distribution aspects along with related training and re-training of relevant personnel at the middle/lower level, e.g. clinical officers, nurses, pharmacy technicians etc. The Ration Kit system adopted is virtually unchanged since the outset of EDAP which has been quite successful in meeting its objectives since 1985, ensuring quite a regular provision of drugs to RHPs in broad, although with fluctuating deficiencies due to financial, managerial and transport constraints etc. Hence the EDAP seems well appreciated by the health workers as well as the clients at the level of RHC, though somewhat less at the district hospital level. However, too little emphasis has, hitherto, been paid to how the drugs are really prescribed and used. Problems related to EDAP - oriented training and continuous education of health workers tend to increase with the increasing number of these categories now qualifying within the general training system. Research specifically related to EDAP and its more fundamental consequences also remain inadequate, although the need for it is widely recognised.

WHO, mainly through DAP/Geneva has played quite a crucial role, especially during the period of planning and implementation (1979-85), in terms of catalyzation, advice, direct initiatives for training and evaluation, as well as by facilitating contact with other key contributors to the EDAP, i.e. DANIDA and SIDA. Kenya's example as a successful implementor has also probably had some positive spreading effects to a number of other African countries. During recent years, the contact with WHO has been limited to a number of contact visits and consultations. The role of the WHO Regional Office for Africa has been hard to trace, and the local WHO Representative is presently focusing on other activities within the health sector.

The successful implementation, although incomplete, of the EDAP in Kenya, coupled with rapid expansion in various related areas, calls for a more permanent solution to financing (a revolving fund/ patient cost -sharing system is presently under adoption). Also the fact that DANIDA and SIDA may withdraw their direct support to EDAP by the fiscal year 1990/91, has put Kenya onto a crossroad in this context. As a consequence, the need for a broader and more unitarian ED concept-based implementation is emerging.

As the number of qualified personnel at the upper level (physicians or pharmacists) presently has become substantial, these categories will be having a much stronger and broader role in the Kenyan health system than hitherto, i.e. beyond institutional/hospital
level. Consequently, more coordinated programmes will have to be developed within the setting of the overall health system. Among others, this calls for a reinforced dialogue between the Health Authorities and the whole chain of the health network, with subsequent constructive and critical professional involvement.
1. Due to a number of constraints, the conclusions of the evaluation mission on Nigeria's Essential Drugs (ED) Policy and Programme and the contribution by WHO's Action Programme on ED through WHO/DAP, have to be considered mainly as impressions. The absence of two Nigerian members in the evaluation team, who's presence had been requested before, proved to be a major drawback, and the team was unable to reach to the level of Local Government Authorities (LGA), the third tier of public affairs (see annex1).

2. The concept of ED was endorsed by the Federal Government of Nigeria in 1984 in its National Health Policy and Strategy, and a National Drugs Formulary and ED List were approved in 1986, followed by a national ED Policy in 1988. A national drugs policy is presently being formulated.

3. These policies were adopted in a period of serious economic crisis, which weighed heavily on the health sector as well, leading among others to an extreme shortage of drugs in 1985-86.

4. The Structural Adjustment Programme, subsequently adopted to overcome the economic crisis, again had a major influence on the health sector, most noticeably through a deregulation of the foreign exchange market and a continuous depreciation of the Naira, which in its turn contributed to drastic price increases of the (mainly imported) drugs in the country.

5. Partly related to these developments, a vast amount of fake drugs started to enter the market, with estimates ranging from 40 to 60% of the total supply, causing a further deterioration of the drugs situation in Nigeria.

6. One important reaction to the crisis was the introduction of Drugs Revolving Funds at federal and (some) state levels, which improved the supply of drugs to some extent, and the serious implementation of a national PHC Policy (including federal funds) to increase drugs supplies at the level of LGAs.

7. The design of an ED Programme (EDP) from 1986 onwards is another important step in the process of rehabilitation of the health sector that may contribute to restore confidence in the Public Health System.

8. A careful process of planning for this EDP in all its aspects is still going on, with the participation of a great number of people at all levels, through a sizeable amount of interesting workshops and with an impressive production of in depth studies on the main elements of an EDP.

9. So far, only a limited number of recommendations of the workshops and studies have been implemented, with the result that there is little impact to measure from an EDP as yet. This slow implementation is partly the result of a deliberate decision to erect the correct structures before supplying the drugs.

10. Although it was impossible for the evaluation team to verify detailed progress in all aspects, the overall impression points to a continuous existence of many of the problems and constraints identified in December 1986, and listed in the proceedings of the National
Workshops on ED in Lagos.

11. The main factors responsible for the continuation of an absolutely inadequate access to affordable drugs of a reasonable quality still are: the limited allocation of public funds to the health sector; the high amount of recurrent costs absorbed by wages and salaries; the inefficient procurement mechanisms with a continued dominance of non-essential and branded drugs; very limited facilities for quality control; irresponsible attitudes in parts of the private sector with regard to quality assurance and insufficient enforcement of legal sanctions; lack of support by the private sector (as yet) for the new drugs policy.

12. Careful introduction of an EDP is commendable, including the efforts to integrate this as much as possible into the PHC structure set up recently. But the slow progress in its implementation also suggests the presence of the following constraints: inadequate facilities, staffing, organization and management within the Ministries of Health at federal and state level, difficulties to get clear agreement on the responsibilities of all public bodies involved, and the inability to overcome resistance from vested interests (groups).

13. The ED project, to be funded by the World Bank and designed with the assistance of WHO/DAP, is to become a cornerstone of the National EDP. Starting in 1990 in four states, it will allow for a verification of the feasibility of many aspects of the EDP, particularly the efforts to increase the drugs supply at state level and to rationalize procurement procedures.

14. Its chances for success are limited by the great number of conditions that need to be met prior to the supply of drugs, the resistance to International Competitive Bidding felt everywhere, the serious under-staffing of the ED Unit of the PHC Department in the Federal Ministry of Health, the insufficient participation of LGAs in the design of the project in a number of states, and a rather vertical approach in general.

15. WHO/DAP has undoubtedly been instrumental in contributing to the elaboration of a comprehensive EDP, particularly in spreading awareness of the full implications of all aspects involved, enabling key personnel to receive further training, and commissioning a number of valuable studies. However, insufficient funds and manpower in WHO/DAP set limits to this support.

16. Future WHO/DAP assistance should focus more on the aspects of quality control and local production, the design of a feasible and simple framework for implementation of the EDP, strengthening a more "horizontal" approach and stimulating (other) donors to work through local structures as much as possible, and mobilization of funds from other (bilateral) donors. The number of consultants involved in DAP's services should be expanded to benefit more from different experiences, and DAP should at least be enabled to fully finance its own services directly from WHO funds.

17. Well designed information campaigns targeted at the general public seem to be urgently warranted, in view of the massive pressure exercised by drugs suppliers through the media inviting consumers to indiscriminate drugs use.
SUDAN

1. The possibilities of implementing an essential drugs policy in Sudan are to a great extent limited by the macro political, social and economic situation in the country. The scarcity of foreign currency considerably hampers the import of drugs and of raw material for local drug manufacturing. The political situation (recent military coup, conflicts in the south) might lead to an increasing reluctance of creditors and donors to provide loans and grants. The workings of the bureaucratic system are impeded by frequent changes at top policy level.

2. The present National Drug Policy was established in 1981 and is essential drugs oriented. In the process of identification that was the first step towards the new policy, three interrelated developments have played a role: experiences in health programmes in Sudan itself, a growing awareness among government officials regarding an increasingly unequal distribution pattern of drugs, and an international exchange of information and ideas.

3. The formulation of the new drug policy was a completely Sudanese affair, with only marginal WHO involvement in the form of some technical advice. The committee appointed to formulate the policy was broad based, including representation of the private and public sector. The resulting policy bears traces of compromise between the opinions and interests of the two sectors. WHO/DAP did not play a role in this phase, simply because it did not exist then.

4. Present drug legislation (Pharmacy and Poisons Act) dates back to 1963, a period when a minimal interventional role for the government prevailed. The act introduced mandatory registration of drugs and licenses of pharmacies. In the policy of 1981 a new Medicine Act was announced. This act is still not adopted. Organizational issues, especially the possible establishment of a national corporation, seem to stand in the way. WHO/DAP is not involved in the process of bringing about new legislation, nor in giving advice on the institutional set-up of the drugs sector.

5. WHO/DAP did not participate in creating the present structure, since that had been done prior to DAP's existence. The basic feature is that regulatory authority rests with the Central Board of Public Health, while the Directorate General of Pharmacy of the Ministry of health is the administrative arm of the Board. DAP is assisting in strengthening some functions of the Directorate General, especially with regard to drug information, registration and quality control. This support was given through programmes funded out of the regular WHO-budget.

6. With regard to the system of procurement of drugs, WHO/DAP had no involvement. The many sources of drugs and the lack of exact data makes the system not very transparent. The greatest constraint is the lack of foreign currency to fulfil the public tender and to meet the requirements of the private producers and importers. Local production takes care of about 10% of the consumption. WHO/DAP extended no support to the manufacturing sector.

7. The improvement of the distribution system is the main objective of the Dutch-funded Central Medical Stores project. The main achievements are the contribution of a new store in Khartoum and the introduction of a distribution system based on the health area system. The WHO-supported (with extrabudgetary Dutch funds) Nile Province Essential Drugs
Programme can generate valuable experience on the distribution from the rural hospitals, the hub of the health area system, to the periphery. Other notable achievements of the NPEDP are the assistance in the latest version of the NLED and the elaboration of the morbidity method in the quantification of drug needs.

8. The relation between the Essential Drug Project and the WHO-bureaucracy has caused some confusion in the past, especially in the case of the NPEDP. In order to assess the required clarity, it is advised to prepare a new Plan of Action for the next two years (1990-1991). The Plan should include the feature of the management structure, the distribution of tasks and responsibilities among the different parts of the WHO-organization and job descriptions for all members of the project staff. The Plan should highlight the innovative activities that can have a demonstrational effect on other projects. The Joint Programme Review Mission (Sudan/WHO) should also review the NPEDP, although this programme is not financed out of the regular budget.

9. The brief survey carried out at a limited number of health facilities revealed that availability of drugs is still far from what would be adequate. On average only 50% of the list of drugs that had to be checked according to the Terms of Reference was available. Drugs are not distributed according to need, but according to what is in stock in CMS. In the prescription behaviour of health staff the essential drugs policy is not yet reflected. Training seems an urgent necessity.

10. It can be concluded that the essential drugs policy has not been very effective as yet in terms of reaching its goal of a "regular supply to all people of safe and effective drugs of acceptable quality at lowest possible costs". The economic situation prohibits adequate import of drugs and raw materials. The distribution system is still in its initial phase of development. What happens with the distribution after the rural hospital is completely dependent on the quality of the yet underdeveloped PHC-system. WHO has not given much support in formulating the policy, but has assisted the implementation, through targeted project assistance. The weak points of this support were found in the management side (no proper monitoring, delays in activities causing delay of project progress).

11. In future WHO should endeavour to give attention, apart from the existing activities, to the legislative aspects and the institutional set-up of the drugs sector, as well as to local manufacturing of drugs. Since the (macro)economic and financial situation has such a direct and substantial impact on the availability of an essential commodity as drugs, WHO should consider to transcend its traditional role of being a "technical" agency by using its influence in moving the Sudanese Government and organizations such as IMF and World Bank towards a policy that would safeguard adequate supplies. If strict adjustment programmes are being implemented, import of drugs and raw materials for local drug production should be secured.
TANZANIA

This study which is part of a global evaluation of drug programmes, reviews the development of the Essential Drugs Programme in Tanzania, its integration within a Primary Health Care strategy and its influence in developing a National Drug Policy. The study also examines WHO’s influence in these processes.

The health policy in Tanzania has emphasised the principles of equity and accessibility. From 1967, the main thrust of the health policy was to extend health facilities to rural areas. The Alma-Ata declaration in 1978 embodied the principles that Tanzania was trying to implement and the government embarked on a major programme to train village health workers. Per capita expenditure adjusted for inflation and devaluation, has remained fairly stable from 1975 to 1988, possibly as a result of increased donor support. At present 70% of the population lives within 5 Km. from a health facility and 93 % lives within 10 Km. The average number of visits/person/year to a health facility is given as 5. Although preventive services have greatly improved since independence, the extension of curative services has been the focus of policy concerns.

The main reason for the adoption of the Essential Drugs concept in the late 1970s was economic. Severe foreign currency shortage and the lack of drugs in rural areas led to a move towards rationalization and the first drug list in 1978. The crisis provided an opportunity for the overhauling of the drug supply system and DANIDA agreed to fund an EDP through UNICEF. The main objectives of the EDP were to ensure availability of essential drugs to rural facilities and to cut down wages by improvements in procurement, distribution, use and stock control. $30 million was available for the first phase, 1984-86.

As drug supply was identified as the main problem and UNICEF identified as co-executor of the programme with MOH, the focus of activities was procurement of drug kits from UNIPAC and distribution to zonal medical stores. The need to prove the viability of the procurement system overshadowed many other considerations and as a result, EDP was implemented mainly by UNICEF from its own offices with the help of a programme manager and four experts. This vertical implementation meant that although an improved supply of drugs was achieved, all other activities lagged behind and no transfer of skills and responsibilities to nationals was made.

MOH and DANIDA’s dissatisfaction with the vertical nature of EDP was frequently expressed at management meetings. For UNICEF and WHO, a "success" was considered crucial; for MOH more integration and control of resources by government was the issue and for DANIDA it was important to use its money rationally and to be able to answer to the Danish taxpayers. After much discussion, some conflict and compromise, the second phase of EDP (1988-90), was split into two parts. MOH/UNICEF through multilateral DANIDA funds would be responsible for drug procurement, distribution, local production, packaging and social mobilization while MOH/DANIDA through bilateral funds, would work to integrate EDP into a PHC support programme.

The development of a National Drug Policy faces many problems, not only financial but also conceptual, political and structural. A non-mandatory essential drugs list exists but only Central Medical Stores adheres to it while the National Pharmaceutical Company, the voluntary agencies and indeed all other private importers purchase what they like. Local pharmaceutical manufacturers as well as the National Pharmaceutical Company come under the ministry of Trade and Industry and inter ministry cooperation and coordination is sadly
lacking. Quality assurance leaves a lot to be desired. The legal framework for registration and inspection is not comprehensive and the units responsible to carry out these functions are poorly staffed. In addition, there are structural problems whereby the budget meant to operationalize MOH activities falls partly under the Ministry of Local Government and partly under the Prime Minister's Office. This is one of the reasons for CMS having fallen into debt. Possibly the greatest obstacle to a national drug policy is the lack of understanding about or the will to accept the essential drugs concept. The EDP as a means of providing drugs is seen as an end in itself.

Training programmes have finally been integrated within the MOH and prospects for comprehensive continuous education are promising. Information to the public has been focussed on the logistic side rather than on the use of drugs. Research areas have been identified and studies are being carried out.

Whereas the EDP has certainly succeeded in supplying drugs to rural health facilities, there is evidence that not all these drugs are getting to patients. Pilferage and leakage to the private market seem still to be the main problem. Although EDP was a vertical programme, it offered unexpected benefits to MOH by providing a detailed picture of the practical skills and knowledge of health workers. It also posed pertinent questions relating to the structures of the programme, the PHC strategy and indeed the structure of MOH.

WHO's essential drugs list produced in 1977, provided the scientific basis for MOH to draw up its own list. It also provided the opportunity for a few individuals to discuss the ED concept. In the quest to provide an example of a successful drug supply system however, the kit and the list have received much more attention than aspects related to the conceptual basis of EDP and a National Drug Policy. WHO did support a workshop in Tanzania, on National Drug Policy in 1985 but little practical good seems to have come out of it. Programme Management Committee minutes show that WHO did not play a significant role in the discussions to integrate EDP into a PHC system until much later. This concern was more actively pursued by MOH and DANIDA. WHO did however participate in the evaluation that pointed to the "integration" problem. The AFRO was not involved as much as it could have been. Similarly there was no role for the WHO-representative. Technical consultants have been provided from time to time and the guidelines from WHO on various subjects are appreciated by many. WHO is also supporting a study on the socio-cultural aspects of drug use.

EDP is 100% donor financed and supplies 30% of the country's drug needs for use in the rural areas. This raises the question about the sustainability of the programme and whether the kit and the list sacrosanct as the have become, should be radically revised to supply a minimum number of drugs to cover a larger population for the same or less cost.
VIETNAM

The MOH invited the DAP Evaluation team to present its impressions of their Essential Drug Programme and make recommendations about how the programme should proceed to develop. The Team met with Vice-Minister Dan on 1 September to discuss the following points:

Overall Impressions:

Excellent progress has been made on nearly all fronts. It is obvious that the MOH is highly committed to the programme, and there has been effective use and coordination of external assistance.

The ultimate objective of self-reliance and good basic health care for the population is very much in harmony with the essential drugs concept, and it comes as no surprise to the team that these are primary motivations for Government action in essential drugs.

Many major sub-components of the programme have been evaluated in detail already, and others need only a further step. It will be very advantageous for the Ministry of Health to use this information to prepare operational plans for remaining activities requiring external assistance from international cooperation organizations. These new projects must be rational from a health and economic point of view, and consistent with APED and PHC objectives.

Legislation and Regulation

Recent profound changes in Vietnam's economic policies call for new regulations which will foresee a greatly expanded role for private drug production and importation, including the sale of drugs by clinicians in private practice. Recent legislation is a good start, but no time should be lost in establishing drug registration and licensing mechanisms. An advisory committee should be established which uses expertise from universities and medical specialists as well as the MOH. Counterfeit drugs have in the open market been recognised as a serious problem, and this can be brought under control only with a strong regulatory and enforcement mechanism.

Drug Supply

The present situation of a large but mostly outdated and underutilised production capacity - and an undersupply of essential drugs - demands an economic analysis and development of a comprehensive master plan for drug production in Vietnam. The objective of this effort is to reform the production and importation in order to make best use of existing and future investments. This will entail examining the cost-effectiveness of manufacturing each drug and raw material under consideration, and especially the advantages and disadvantages of the extremely decentralised production found today. While this was appropriate for a country at war, it may be found to be inefficient under current conditions. The ultimate decision about producing a particular formulation in Vietnam should take into account its world market price, its cost of production locally including the hard currency component, quantity required, and the strategic importance of being self-sufficient in that particular item.

Satisfactory guidelines and recommendations for this analysis have already been made by
SIDA and UNDP/UNIDO consultants, and now the actual analysis should be done and the plan developed so that the international cooperation organizations which might be interested in assisting the essential drug programme in the future can be approached. A team of Vietnamese consisting of a procurement specialist from VINAPHIA, an industrial economist, and an industrial pharmacist, should be complemented by foreign experts in pharmaceutical industry planning on a national level and perhaps an industrial economist. A survey of the Central Pharmaceutical factories has already been made by UNDP/UNIDO, but the MOH should commence a detailed survey of the provincial and district production facilities to determine what role they should play in drug production in the future. These results should be available before the team of experts begins work. The need to make reasonably accurate estimates of drug requirements should also be noted, and work accelerated in this area.

**Drug Storage and Distribution**

The evaluation team had no chance to assess the situation, but a comprehensive analysis has been made by Battersby and Mohlin for DAP. It is possible that international or bilateral cooperation organizations such as the World Bank will be interested in undertaking this project, as it represents a way to get involved quickly in the health field in Vietnam when new assistance starts to flow to Vietnam. The MOH should examine their report carefully and decide on priorities within the total package recommended, since the total amount of funds required is quite large (over 2 million dollars). In the meantime, the MOH should keep DAP/Geneva reminded of the need to find a donor to support this activity.

**Rational Use of Drugs**

There should be some concern over the overuse and incorrect use of antibiotics, and the overuse of vitamins. This was observed during the field visit, and the MOH is already aware of these problems. The irrational use of antibiotics can lead to serious problems of resistance and the need for more expensive substitutes for basic antibiotics, while the overuse of vitamins is more of a purely economic concern.

Priority in applying the Essential Drugs concept has been given to the lower levels of the health system. This has been a sound decision since most drug treatment will occur at the grassroots level. Additional attention should be given to strengthening the APED at the secondary and tertiary levels of the health system, to provide information to influential clinicians at these levels, and to limit and guide the procurement of drugs from outside VINAPHIA. In addition, some more attention should be given to the rational use of traditional medicines, considering their importance at the grassroots level.

**Expansion of Primary Health Care/Integration of Essential Drugs**

The Team has made some observations regarding their visit to the rural areas in Binh Luc district. The most significant results of the pilot project are the changes in the amount of curative activities at the different levels of the health system, and the potential for self-sufficiency in drugs at the village level. There has been a great reduction in patient visits to the intercommunal polyclinic in Binh Luc district, and also a decrease at the district level in Quang Ninh since the strengthening of primary health care at the commune and village levels. Whether this is due to the increased availability of drugs is not certain, but it hints at the need for changes in manpower and resource allocations in the future, with
fewer practitioners needed at the higher district levels but more personnel who can supervise the lower-level workers. Also notable was what appeared to be a low rate of visits even at the village level, suggesting that preventive and sanitation measures could have an important effect on drug requirements even at this level. These phenomena should be studied through field investigations.

These effects, even if they may be only inaccurate random observations, indicate a need to carefully evaluate the various PHC pilot projects under way. We have learned of at least three different PHC essential drugs schemes, including the one we saw in Binh Luc, a UNICEF project using kits from UNIPAC, and the SIDA Quang Ninh Province pilot, where a different range of drugs is supplied. These should be evaluated and compared, in terms not only of cost and their effect on health status at the grassroots level, but also their manpower implications and requirements for training village health workers on a large scale.

Programme Management

The APED currently enjoys strong leadership and excellent planning at the top levels, but may be seriously understaffed at lower management levels as the programme expands. The approach of using Working Groups has been appropriate for the planning stages of the programme, and good use has been made of short-term consultants, but more project management staff will be needed. Given the overall limitations on adding new personnel to government ministries, a strategy could be adopted of including the retraining of one or more present MOH employees in each new project submitted to international cooperation organizations for assistance, thereby gradually building up a team of people who can manage these components.

Drug Quality Control

The capabilities of the MOH in Drug Quality Control are being improved rapidly through the efforts of the MOH and with the assistance of WHO and SIDA. The functions of the Institute for Drug Quality Control (IDCQ) have a specific role in the implementation of the essential drugs programme, but should not be regarded as a substitute for quality control at the level of drug production. The Institute, however, will be an excellent training facility for graduate pharmacists and technicians in the specialised field of industrial drug quality control. In addition, quality control must be extended to the domain of traditional medicines.

Drug Selection

The capacity to carry out clinical trials of drugs in Vietnam is very limited. This capability is critical for selecting drugs and determining the indications and administration for their rational use. In addition, the further development of traditional medicines will require the strengthening of pre-clinical research capabilities. Training in clinical pharmacology may be possible through the support of WHO/DAP.
YEMEN ARAB REPUBLIC

1. While assessing development policies and programmes in the Yemen Arab Republic, one always has to bear in mind that relations with the outside world did not begin until after the overthrow of the imamate in 1962. The present state exists since 1970. About 90% of the population of 9.8 million live in rural areas, often in small dispersed villages in rather inaccessible territory.

Real GNP shows an annual growth of 5% over the last year. The negative trade balance is compensated by financial assistance, mainly from the Gulf States and through remittances from migrant workers. The external dependence of the country will be lessened by exports of oil and, probably, natural gas.

2. The health budget is 4.5% of the overall Government budget. The country couples a relatively high per capita income (US$ 500.--) with unfavorable health indicators. The development of a modern health care system did not start until the seventies. The introduction of the PHC approach began in 1978. The development of the health system is only in its initial phase, though the system is gradually expanding, both in the urban and rural areas. The Government faces the problem of a continuous increase in running costs, whereas the health budget is more or less constant.

3. It is estimated that the size of the drugs market is about US$ 65 million per year (excluding smuggle). Private imports amount to US$ 49 million; public sector imports amounts to US$ 5 million. The value of local production (one company, with the Government as major shareholder) is US$ 11 million (all 1988 figures). The Government distributes the drugs free of charge. The number of pharmacists is rapidly increasing (30 in 1980; 180 now). About 90% of the pharmacists working for the Government have an interest in the private sector, either through running a pharmacy or through an agency representing a foreign firm. This seems to be a complicating factor when designing and implementing essential drugs policies.

4. The present Pharmacy Law was enacted in 1975. Based on that law the Supreme Board for Drugs and Medical Appliances was established, the regulatory agency in the drugs sector. The law is mainly a matter of registration and licensing. The essential drugs concept was not an issue yet in that period. In the phase of problem identification (late '70s, early '80s), WHO provided valuable information on essential drugs policy. But the introduction of the PHC approach and of standard drugs packages was implemented by the Ministry of Health and UNICEF. At a later stage WHO began its participation in the PHC programme.

5. There is no comprehensive policy document on the subject of essential drugs. There was, and is, not so much a process of formulating a policy, but rather of giving it shape during implementation. The Plan of Operations (1987-89) for the WHO-supported programme "Essential Drugs for the Yemen Arab Republic" comes closest to a formal policy document. The programme, with extra-budgetary funding from the Dutch Government, started early 1987. It is a comprehensive plan covering both policy and management aspects. WHO played a crucial role in designing the programme and getting it underway.

6. An important achievement has been the formulation of the National List of Essential Drugs. WHO/DAP stimulated and sponsored the organization of National Workshops (1986

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and 1988) where the first draft and the first version were discussed. The latest version of the list has been issued in the course of 1989. The list has had its influence on the 1988-89 public tender. In the private sector, however, relatively expensive patent drugs in retail packaging still prevail.

7. A more prominent place should be assigned to local manufacturing (now nearly 17% of total consumption). The Government should make more use of the experience, knowledge and facilities of the single manufacturing company.

8. Central Medical Stores, the centre of the national distribution system, now has a proper base in its new well equipped building. The management capability of the CMS staff still has to be improved considerably; procedures have to be further developed. There is as yet no established system of distributing the drugs to the Governorates and further to the rural periphery.

9. The managerial links between the Programme and WHO/EMRO have not been all that clear. The core of the confusion probably lies in the uncertainty about who is in charge of what within the WHO organization. It is recommended to provide the required clarity by putting the division of tasks and responsibilities of parties involved on paper. The topics for which short term WHO consultants have been sent were in general highly relevant. Good reports have been produced. More attention should be given to the follow-up of the findings and recommendations of such missions.

10. One cannot conclude that the central goal of the essential drugs policy ("regular supply to all people of safe and effective drugs of acceptable quality at the lowest possible cost") has been reached in North Yemen. The development of the PHC system is still in its initial phase. The effects of the essential drugs concept are by and large limited to the private sector (under 10% of all consumption). There is no established system of distribution. In view of the short period of actual WHO involvement with the essential drugs policy (Essential Drugs Programme did not start until the beginning of 1987), it is much to early to assess the impact. In future, WHO should give attention to the management aspects, especially to the role of the different levels of the WHO organization, and to the function of the National Programme Coordinator. The main issues that have to be addressed seem to be the introduction of the essential drugs concept in the private sector, and the development of a system of health information and education geared towards professionals and the general public.
MOZAMBIQUE DESK STUDY

1. The development and the implementation of the health policy in Mozambique after independence, was largely inspired by the Front for the Liberation of Mozambique (FRELIMO’s) experiences of "health with the people" in the liberated zones during the armed struggle for independence. Social equity was the foundation of this policy and the Primary Health Care strategy was adopted as policy a year before the Alma Ata Conference. Health facilities were extended to the rural areas and priority was given to preventive medicine.

2. The development of the National Drug Policy was a logical consequence of the health policy. The drug policy was seen as an essential tool for meeting the health objectives and the legislative and executive organs for this policy were set-up within two years after independence.

3. The period 1977 to 1982 was characterized by major advances in the implementation of the health and drug policies. There was a rapid extension of services to the rural areas and preventive programmes gained ground. The centralised procurement by generic names on the international market brought economic benefits and the use of the National Formulary and the Therapeutics Guide helped to improve health workers’ attitudes to the use of drugs.

4. With increased South African backed destabilization from 1982 onwards, the agricultural, industrial and social infrastructures began to be systematically destroyed. Droughts and floods aggravated the situation and combined with the international economic crisis, brought about an internal economic crisis of dramatic proportions. Per capita expenditure on health began to decline and drug expenditure in 1984/85 was half the value in 1980. Mozambique became increasingly dependent on foreign aid for its drugs.

5. The strategy adopted by the ministry of health, to maintain its drug and health policies revolved around convincing donors about the importance of the drug policy and that coordination between the donors and the government was absolutely crucial. In general, Mozambique was successful in this and managed to convince the donors that the whole health system could not function on 30 basic drugs and that procurement of drugs was best carried out by the state procurement company. In addition, the distribution system was reorganised upon more rational lines and the Essential Drugs Programme was agreed upon with Italy, UNICEF and WHO. Thus a minimum but regular functioning of the health system was maintained.

6. In that a comprehensive drug policy existed, the Essential Drugs Programme from Mozambique's point of view, was a means to guarantee the supply of drugs to the primary level. The programme required a vertical management structure for implementation and also excluded the state from the procurement process which was to be carried out by UNIPAC. The resources available through the programme did however allow investment and improvements to be made in the storage and transport facilities of the health sector. More importantly, the assessment of the programme raised relevant questions regarding the ministry's training and supervision strategies. The vertical nature of the programme allowed an analysis of the structure of the ministry and this contributed to the ongoing review of the health sector.

7. WHO’s role in the development of the drug policy was non-existent. WHO/DAP first appeared on the scene around the discussions related to the Essential Drugs Programme.
The local WHO representative was actively involved in the programme management meetings and his contribution was appreciated by the ministry. Good relations between the local WHO office, the local UNICEF office and the ministry facilitated the smooth running of the programme.

8. Currently, the country is in the throes of rampant armed banditry on one side and the International Monetary Fund (IMF) stabilization programme on the other. Production is extremely low due to the security situation and the country is almost totally dependent on foreign aid and loans. Although Mozambique has managed to maintain the drug policy through great effort and heavy costs, it is the geopolitical situation in the Southern African region and western interests in South Africa that will determine whether the drug and health policies of Mozambique survive.
DEMOCRATIC YEMEN DESK STUDY

1. The government's commitment to extend health services to under-served areas and to supply them with basic drugs appears to be the main reason for embarking upon the rationalization of the drug supply system. The participation of an Assistant Deputy-Minister in the WHO sponsored intercountry workshop on drug policy in Amman and his subsequent interest in the Essential Drugs Concept led to the request to WHO for support to the country's Medical Supplies Programme.

2. For WHO, the request provided an opportunity to begin a drug programme in EMRO. As a result, the Programme Manager of the Drug Action Programme, the Director General of WHO as well as the EMRO Regional Director have visited the project areas. The Director General also made a substantial financial contribution to the programme. The major source of funding has been the EMRO regular budget. The country's socialist policies, its centralised structure and its small population were positive factors for implementing a drug programme and the active regional office was an added advantage.

3. The first WHO mission made a crucial change to the proposal elaborated by the government. Emphasis was placed on the development of a National Drug Policy as opposed to essential drug lists and this conceptual change has allowed for the development of a comprehensive drug policy.

4. The absence of donors has allowed the programme to develop in a direction and at a speed defined by the government. "Aid conditionality" only came about with a World Bank loan which obliged the country to buy more expensive drug kits from UNIPAC. In this context, the Director-General's contribution was crucial in allowing the space and the time for the programme to develop unhindered by donor interests. Incidental financial support from the Drug Action Programme allowed for a rapid and flexible response to an evolving situation.

5. WHO funds have been used to provide infrastructural support to management and transport areas, to provide technical assistance through consultants and to provide fellowships. Indications are that this money has been well spent in developing local expertise for all aspects of drug policy implementation and is of long-term benefit to the country.

6. Although WHO support has been essential to the success of the programme, this success appears to be due to a greater extent to the active interest and commitment of the government and to the never failing efforts of the country Programme Manager.

7. The government has never asked for financial support to purchase drugs and has thus avoided getting into a dependency situation. From 1989, it has taken over responsibility for all running costs previously supported by WHO. With trained cadres in all components of drug policy implementation, the potential degree of self reliance is perhaps the most impressive aspect of the programme.
BURUNDI DESK STUDY

WHO, jointly with the pharmaceutical industry, did a situation analysis of the drug policy in Burundi in 1980. The mission report concentrated on storage and logistic problems. WHO, not having funds in 1980 and rating the project with a lower priority under new DAP management in 1983, left the initiative to the industry.

Interpharma appointed a consultant who visited Burundi 14 times between 1981 and 1989. Objectives were vaguely defined and plans were changed from year to year. Four reports were circulated to the World Health Assembly during 1982-1985. A negligible amount of money had been invested by Interpharma until the Swiss government (DCA) agreed to co-finance the project with 450,000 Swiss Francs in 1985.

The project upgraded and renovated central and peripheral storage facilities, provided 5 trucks, and organised 4 one-week training courses. Little was achieved outside the scope of storage and distribution.

Plans to build new or to renovate existing local production capacity were also made by SK&F, France and the CEPLAN (Economic Community of the Great Lakes), but these plans did not materialize. Only an UNICEF sponsored oral rehydration solutions production unit has been built in addition to ONAPHA.

As agreed with DCA, the Interpharma project was evaluated in 1987 by an independent consultant. His report was frank: a clear National Drugs Policy is absent, and the Interpharma project is working on an isolated aspect of the drug policy (storage and logistics). Although an essential drugs list exists, it does not follow WHO recommendations as it uses brandnames and contains unessential drugs. There is no quality control or drug registration for imported drugs.

Drug management and distribution of essential drugs has, however, been improved thanks to the efforts of the Interpharma consultant.

The evaluation report recommended Interpharma to continue with a revised project, in collaboration with DCA, WHO and the Ministry of Health. WHO had done an essential drug quantification exercise in 1986, and had noted several weaknesses in the national drug policy and the essential drug list. In 1988 a WHO short-term consultant helped to reorganize the central warehouse and drug distribution procedures.

Joint WHO/Interpharma missions in 1988 and 1989 developed a new project proposal currently awaiting approval. It consists of the construction of a new warehouse by the MOH, continued improvement of drug storage and logistics, more vehicles and fellowships for further training. An unclear national Bamako Initiative plan is being integrated into the project and might provide extra drugs.

The 1981-1987 Interpharma project cannot be described as an essential drugs programme, as it does not touch essential components such as appropriate selection, information, control and training. The project has, however, improved the drug storage capacity and distribution chain of Burundi. The success of the new WHO/Interpharma/DCA/UNICEF 1989-1991 project will depend on the outcome of a National Drug Policy Workshop, planned for early 1990.
ZIMBABWE DESK STUDY

Zimbabwe introduced drug registration in 1971. Local drug production and distribution in the private sector were protected by the government during the international blockade of the Ian Smith regime.

At independence in 1980, the PHC approach adopted as official government policy, included the essential drugs concept. A proposed essential drugs list (PEDLIZ) was published in 1981.

The Government policy led to a 3-fold increased demand for drugs in the health care system. The centrally organized Government Medical Stores could not cope with this demand, and a lack of foreign exchange led to acute drug shortages. A new provincial Medical Store in Bulawayo was opened in 1983, with donor support (USA), and 4 other regional stores were planned.

WHO’s assistance was requested, and a joint WHO/DANIDA mission drafted an Essential Drugs Programme in 1985, known as the Zimbabwe Essential Drug Action Programme (ZEDAP). Its objectives were to ensure a regular supply of low-cost good quality essential drugs in the government and non-profit private health services and to ensure optimal and rational use of drugs

ZEDAP started with some delay in November 1986. WHO supported ZEDAP with US$250,000 from its own budget. DANIDA gave US$1m in addition. Drug costs were not covered by this: Zimbabwe’s national policy was to finance its own drug procurement.

A national workshop to establish a National Drugs Policy was organized by ZEDAP and Ministry of Health in April 1987. Nearly all professionals who were involved in drug matters in Zimbabwe attended the conference, and the National Drug Policy was consequently adopted by the Ministry of Health.

The ZEDAP team developed excellent rational drug use training material, using innovative bottom-up and low-cost techniques. Numerous workshops were held at provincial and district level. Drug distribution management was improved: the response time in Government Medical Stores dropped from 4 months to 3 weeks. However, these activities were endangered by continuing drug shortages, caused by a lack of foreign exchange allocation by the government.

The ZEDAP team responded quickly by executing a drug availability study, and presented the data in a clear report to the government. The necessary foreign exchange was finally allocated, and it is hoped that drug shortages will decrease.

ZEDAP also changed the content of the Essential Drug List of Zimbabwe (EDLIZ), and - through bottom-up consultation - adapted the stepwise essential drugs list more to needs. After the publication of the 1988 edition of the EDLIZ the private sector agreed to cooperate, and EDLIZ is to be applied to both public and private sectors.

It is the aim of the Ministry of Health that from 1st January 1990 all drugs in Zimbabwe in both public and private sectors, will be prescribed under generic name only.
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