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PROGRAM GUIDANCE PAPER
PHARMACEUTICALS IN HEALTH ASSISTANCE

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EXECUTIVE SUMMARY

Achieving health goals within the context of development assistance requires the integration of several components in health care delivery. A key component is the pharmaceutical one for it is essential to the therapeutic, financing and management success of health services. A large portion of the limited health budgets of many developing countries are allocated to the purchase of basic medicines in support of health care programs. Yet, health service projects suffer due to chronic shortages of basic medicines and populations do not have available to them these essential therapeutic tools and information on their use which can prevent and ameliorate disease.

A.I.D.'s health goal is to help developing countries become self-sufficient in providing broad access to cost-effective preventive and curative health services. To assist in achieving this health goal, A.I.D. will address the therapeutic, financing and management problem areas in structuring the pharmaceutical component of health projects when the component has the following objectives:

- increasing the cost-effectiveness and efficiency of drug procurement and use in health programs;
- expanding the supply and appropriate use of essential drugs to the community level through efficient program planning and management;
- indirectly improving the quantity and quality of pharmaceutical sector infrastructure and resources; and
- increasing biomedical research in the pharmaceutical sciences within the context of developing country needs.

In the past, A.I.D. financing of pharmaceuticals under project assistance concentrated largely on procurement of drug commodities as a part of health programming. In future years, A.I.D. will continue to support the procurement of a limited supply of basic pharmaceuticals for project initiation but will couple this with technical assistance and training needed to assure appropriate selection, procurement, distribution and use and where feasible, local formulation of basic drugs. Priority for support will be given to the pharmaceutical component of primary health care projects which focus on preventive measures such as immunizations, family planning and prevention of vitamin deficiencies as well as control of diarrheal disease, malaria, and infectious disease. Priority for support will also be given to programs in countries in which 10% or more of the health budget is used to purchase pharmaceuticals. A.I.D. will assist host countries to achieve a reasonable budget for pharmaceuticals and to target the allocation of drugs purchased more to primary or preventive services than to tertiary services.

The Agency will encourage a pharmaceutical sector-wide approach in the development of a country-specific assistance package. The pharmaceutical sector will be viewed in its totality when there is a broad review of its contribution (including public and private aspects) to health care. However, the focus of action will be aligned with the primary health care activities as outlined in A.I.D.'s Health Strategy. The emphasis for programming will be on using available technologies, developing new ones and strengthening human and institutional resource in developing countries. In so doing, the Agency will promote exploring resources from a variety of sources including the U.S and indigenous private sectors as well as other U.S. federal agencies. A.I.D will collaborate with other donors so that funds applied in improving the pharmaceutical component of health will have maximum effect.

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January, 1985

A.I.D. GUIDANCE PAPER
PHARMACEUTICALS IN HEALTH ASSISTANCE

I. INTRODUCTION

This paper reviews the role of pharmaceuticals in health care delivery and presents guidance for A.I.D. involvement with the provision of drugs within the context of A.I.D. health assistance. The guidance included here supplements the A.I.D. health strategy and suggests implementation elements to ensure the fulfillment of both the A.I.D. health policy and strategy with respect to pharmaceuticals and selected primary health care activities. It is also consonant with A.I.D.'s population policy and strategy.

This guidance draws upon lessons learned from A.I.D.'s wide experience with health care projects, from other donor's experience with programming in the pharmaceutical area and on responses from A.I.D. field officers to a cable (State 240101, 1983) and discussion paper on improving A.I.D. programming in the pharmaceutical sector. The strategy also reflects current public health and pharmaceutical principles. This document is a direct response to the request of the Agency's Director for Health and Population and the Health and Population Sector Councils to provide technical guidance for improved programming in the pharmaceutical sector.

II. BACKGROUND

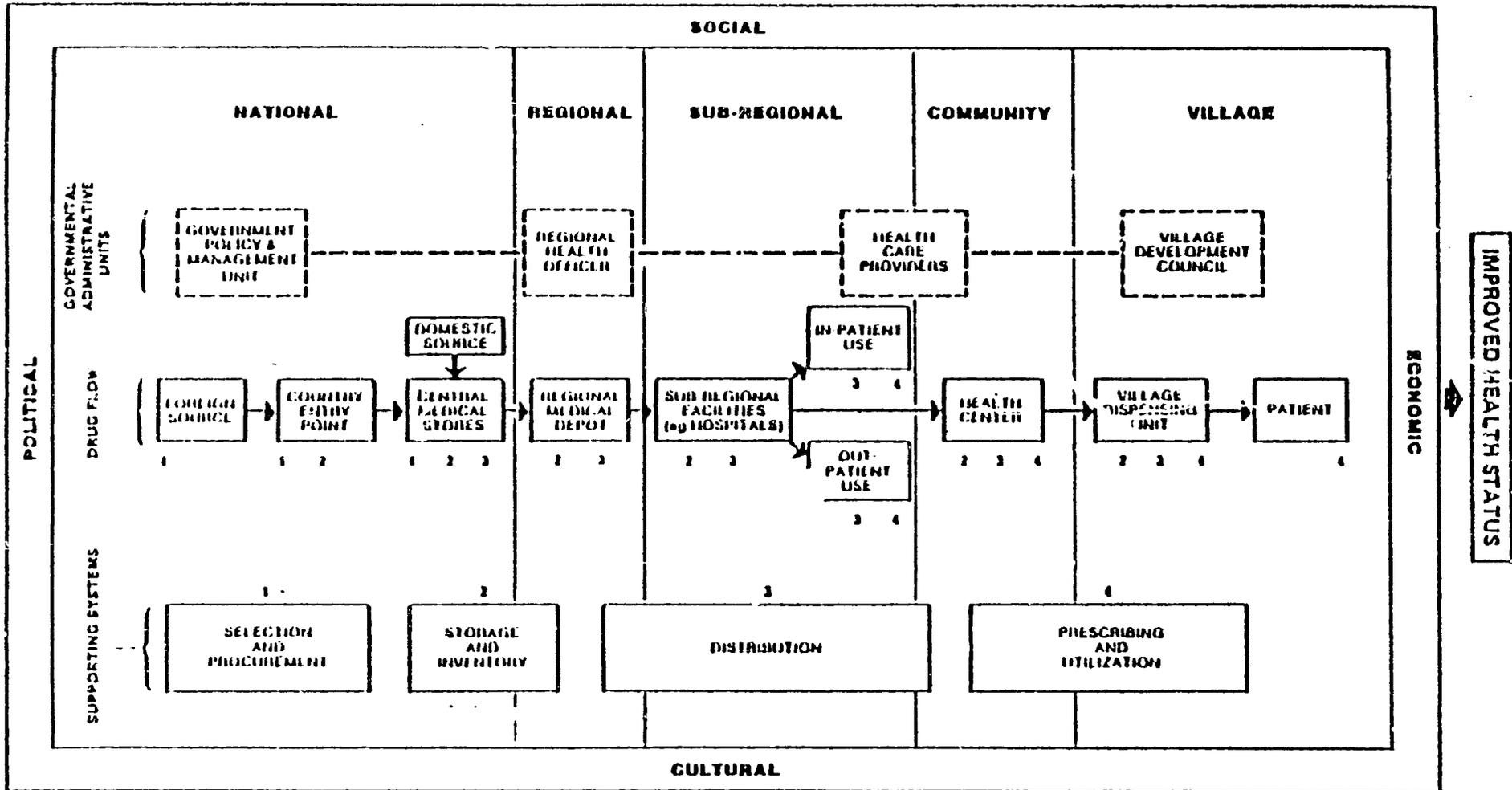
A. The Role of Pharmaceuticals in Health Care

Pharmaceuticals (also termed drugs and basic medicines) are of significance to health care as they are key therapeutic, financing, administrative, and political tools. As therapeutic tools in health care drugs are used to prevent, treat or cure disease. The sale of basic medicines has served as a financing mechanism for primary health care systems. (1) The presence or absence of needed drugs in a clinic or village has been an indicator of administrative soundness of the health care programs. The inclusion of basic medicines in a health care package has been a costly instrument of political good will in those instances when a government has declared health care free for all.

Within the health sector there is a pharmaceutical sub-sector. Drug products, facilities in which they are manufactured and from which they are dispensed, as well as the human and financial resources needed to assure availability and appropriate use all play a role in the pharmaceutical sub-sector. Included also are the indigenous pharmaceutical industry, medical and pharmaceutical training institutions, private pharmacists and pharmacies in addition to government central medical stores (or pharmacies) as well as government ministries of health and finance. This guidance outlines more clearly this sub-sector of health care delivery and promotes more efficient use of this component to achieve improvement in health status. Figure 1 provides a schematic overview of the public portion of pharmaceutical supply for rural primary health care in a developing country (2)

FIGURE 1

THE PUBLIC PHARMACEUTICAL SUPPLY SECTOR FOR RURAL
PRIMARY HEALTH CARE IN A DEVELOPING COUNTRY:
A SCHEMATIC OVERVIEW



B. Critical Ingredients for Providing Basic Medicines In Primary Health Care (PHC) Projects

There are two ingredients critical to the provision of essential drugs in primary health care projects: the drug itself and the supporting systems needed for successful impact on health status. The drug product must be appropriate for the health problem to be treated, safe to use, effective, available and accessible to the target population.

Infrastructure associated with the flow of drugs to the community level, which is essential to effective operation, includes facilities, personnel, financing and source for pharmaceuticals. Pharmaceuticals must be stored or warehoused and dispensed from facilities such as depots, pharmacies, hospitals, health centers and health huts. At these facilities there are usually staff involved in providing pharmaceuticals. This includes physicians, nurses, pharmacists, dispensers, traditional birth attendants and aides. The number, kind of training and experience of personnel present in the country provides relevant information for developing the pharmaceutical component of the project. The source of pharmaceutical preparations for supply may be either foreign or local/domestic.

The supportive systems contribute to successful operation and include the processes for drug product selection, procurement, storage and inventory, distribution, prescribing, drug utilization and information, training for appropriate tasks and overall sector management. The selection of categories of drugs to be used is a primary and key action. The categories and specific drugs are selected based on the health problems to be addressed by the

project. This mechanism, based on sound epidemiological and pharmacological principles and information, should be derived and used to identify the content and source of drugs needed in the project. This selection process will usually produce a formulary for the project which will serve as the basis for the procurement, prescribing, dispensing and training mechanisms which will function throughout the life of the project. Procured drugs must be stored or warehoused when received and the inventory of stock controlled. Techniques for assuring adequate storage and maintenance conditions must be developed. Inventory control procedures such "first in, first out" and the determination of order levels at various points along the distribution line are necessary. Information from these procedures provides program management with data on when and how often to procure additional quantities. The distribution process assures that required drugs travel to selected points and are available for prescribing, dispensing and/or administering. The prescribing process should also be formulary-based and aim to provide appropriate therapy at low cost. This mechanism includes education on the appropriate use of the prescribed drug, even if the drug is self-prescribed. The drug utilization and information process is the mechanism by which the amount and kind of drug prescribed and/or used per dispensing point and patient is tracked. Data generated provide a baseline for clinical and administrative review.

Training for the pharmaceutical component requires a clinical, technical and an administrative perspective. Training for prescribers, pharmacists, and dispensers focuses largely on the clinical use of drugs. Storekeepers must understand why drugs are handled differently from other items. Managers and administrators must be trained in managing their portions of the pharmaceutical component. Overall management includes such tasks as planning

for new activities or expanding existing ones when required, organizing the procedures to be undertaken within the component, directing staff, developing drug policies of the program, and evaluating performance within the project.

All of the above are influenced by government administrative units which relate to health policy and finance. Further, these processes operate within the socio-cultural, political and economic realities of the country. A program to strengthen the pharmaceutical component of health projects in a developing country can be said to be successful if the critical ingredients are determined to be working well and in tandem.

C. Major Issues In Providing Pharmaceuticals

Most countries of the developing world secure the major portion of their pharmaceuticals from outside their borders. In order to import drugs, countries are often required to use scarce foreign, hard currencies which they obtain from their international trade or banking activities. However, drug purchases compete with purchases of other imports for the limited supply of foreign exchange and methods used in purchasing may be inefficient.

Therefore, great importance is given to the questions of available foreign exchange, resource allocation and obtaining maximum value for pharmaceutical purchases. Further, countries may be choosing drugs to be used in health programs in the absence of accurate and adequate technical and scientific information, available in developed countries, on the appropriate use of drugs. This may result in a choice of drugs that do not have therapeutic priority for the health problems of the population to be served. The absence

of comparative price/cost information may result in the choice of costly alternatives.

Existing pharmaceutical infrastructure and resources, if present, are often strained. A sufficient supply of trained personnel, facilities and equipment for assuring quality of pharmaceuticals, imported and/or produced locally, may be close to non-existent. Needed governmental policies, laws and regulations along with methods, staff and funding to enforce them may be present but not functioning at desired levels.

More information is needed on the role the external and indigenous private sector could play in addressing these problems and issues. Representatives of external manufacturers often play a pivotal role in the importation and selling of pharmaceuticals in developing countries. In many countries these representatives work with the private wholesale agents, pharmacies and pharmacists (or dispensers) that can be found in urban and peri-urban areas. They are able to import from external sources and distribute pharmaceuticals using private channels which can include itinerant traders who frequent the countryside and supply villages. It is through this channel that populations of most developing countries obtain a large portion of their supply of basic medicines.

There is some evidence that in some countries the pharmacist in a private store is the first point of contact, outside of the family, when illness strikes. The pharmacist has the potential for serving as a key provider of basic health education and should be incorporated into health programming. This is beginning to occur in countries such as Jordan and Peru (3,4).

In addition to the economic, infrastructure and role of private sector issues there are also the issues related to essential drug availability on the community level. In developing countries, it is not uncommon to find that the drugs purchased for public sector health programs are allocated mainly to tertiary care facilities and not to community health care units. When drugs are provided to primary health care programs, there is the problem of management to assure availability at all dispensing points. The A.I.D.-funded analysis of A.I.D.-assisted primary health care projects indicates that providing essential support services such as drugs has been the major problem of the projects (5). The study goes on to state:

"poor systems to manage and supply drugs in most countries constitute a serious impediment to PHC projects. The credibility of community health workers depends on the availability of drugs; without regular supplies, community use of health services declines. In the pilot project for Afghanistan/BHS, for example, use of health services tripled when drugs were available. To date, progress in improving the availability of drugs has been slow. The lack of trained personnel, inefficient logistics systems and transportation problems continue to impede efforts."

A good supply system should make certain that drugs provided through public, private or voluntary resources reach all health care levels and fulfill defined needs.

D. Relationship of the Pharmaceutical Component to A.I.D. Health Assistance

1. Significance of Pharmaceutical Programming to A.I.D. Health Assistance

Objectives

Of key significance to A.I.D.'s health assistance efforts is the therapeutic, financing and administrative role of pharmaceuticals. A.I.D.'s current health assistance focuses on improving the effectiveness of health programs, and promoting their self-financing. As therapeutic tools, basic medicines are essential to reduction of morbidity and mortality of populations in developing countries. An essential part of preventive measures such as immunizations is the availability of potent vaccines. A diarrheal disease or malaria control program, for example, would certainly have little impact on health status if an appropriate pharmaceutical agent such as oral rehydration salts or chloroquine was not included or was not available for use in the program.

If A.I.D. is to attain its objectives of promoting the self-financing of health programs and encouraging cost-efficiency, it is appropriate to give greater programming attention to an aspect of health care delivery where cost and financing efficiencies can be achieved. The sale of drugs was found to be one of five general types of community-based financing for health care. Of more than 100 health projects studied, 52 used the sale of drugs as a mechanism to defray one-time or recurrent costs. Sixteen of the 52 projects identified were A.I.D. supported. Drug sales supported the purchase of additional drugs and community health worker compensation. This mechanism additionally generated local currency and labor for the projects (6). In many developing countries it is estimated that from 10 to 50% of the health budget is spent on obtaining medicines for health care programs (7,8,9,10,).

Further, it has been shown that by addressing certain problems associated with the pharmaceutical component of health care, selected recurrent costs of health can be reduced and/or cost savings can be channeled into additional health programs (11,12). For example, the Report of the Caribbean Workshop On Supply Management For Essential Drugs indicates that more effective supporting systems and the use of generic nomenclature, instead of brand names, have led to an increased ability to obtain a larger number of drugs when purchased at a similar monetary level and thereby obtain greater value for foreign exchange used. Structuring management systems for efficient selection, procurement, distribution and use permitted an overall cost savings in pharmaceutical purchases of over 20%. This re-structuring also resulted in greater availability of drugs on the country and community levels.

Assessing the role of the external and indigenous private sector can lead to the use of usually untapped resources in the initiation of selected primary health care activities. In Jordan, findings in a study indicated that the pharmacist is a key source of basic medicines and information on their use (13). A project is beginning in Jordan which will use the pharmacist as a promoter of oral rehydration therapy as well as a dispenser of oral rehydration salts which are to be manufactured by a local producer of pharmaceuticals.

2. A.I.D. Programming Experience With Pharmaceuticals.

The Agency has had experience with pharmaceuticals in both health and population programs. There were 75 projects identified in the July, 1983 inventory of A.I.D. health projects with pharmaceutical components. The listing included disaster relief projects and were located in 70 developing

countries (14). The pharmaceutical components most often included the purchase of basic medicines, but contained technical assistance in drug supply management, and education or training as well as construction of dispensing facilities.

Recently, several A.I.D. missions have undertaken pharmaceutical sector assessments in selected countries to determine the role that the sector plays in health programming. The targets of the surveys have been the role of the indigenous pharmaceutical industry, private pharmacists, training institutions for dispensers of medication, the route of drugs from source to patient and the financing of the activities within the pharmaceutical sub-system. For example, surveys have been done in Jordan, Egypt, & Peru; another is planned for Yemen.

To date, the A.I.D. health programming approach has been to view pharmaceuticals primarily as commodities rather than as a key component of health assistance. Drugs were treated simply as supply items and obtained through various procurement mechanisms. Further, not all A.I.D.-assisted purchases were focused on those with priority for primary health care. In order to achieve therapeutic goals in health care there must be a selection of the right drug and assurance that the right amount gets to the right person at the right time in the right place for the right reason.

Population programs have included the development of inventory control systems, use of the pharmacy and pharmacist in the distribution of contraceptives, training of pharmacists and dispensers in the technical aspects of family planning and contraceptive use, point-of-purchase educational material and other strategies designed to assure effective distribution and use of contraceptives and supplies.

However, the issues associated with procurement most often characterize the routine experience of A.I.D. field offices with pharmaceuticals.

A.I.D.-assisted primary health care projects must finance purchases of needed drug products under Agency procurement rules. Except for certain centrally-funded family planning pharmaceuticals, A.I.D. does not buy drugs directly but funds and monitors their procurement under host country contracting systems. These systems may involve host country procurement under their own solicitation documents, the use of a procurement services agent or a request to A.I.D. Washington to arrange purchase by the General Services Administration (GSA), the Veterans Administration or Department of Defense. GSA procurement has been the most important of these mechanisms. The agent acts for A.I.D. and actually buys the drugs. Products are purchased under "Government Schedules" or are competitively solicited (within the prescribed geographic source) and contracts effected. The agent bears the administrative responsibility for insuring and shipping ordered drugs to the requesting country or project.

When difficulties arise, such as a lost shipment or arrival of damaged goods, field officers address them not directly but indirectly through the procurer or, if requested, with the help of the Office of Commodity Management.

Resolving procurement problems is not easy and is time-consuming.

Additionally, field officers have stated, in cables and reports, that the procurement process is difficult to understand and use. This can lead to in-country shortages because field personnel may not have realistic perspectives on the length of time required for the entire process of procurement. When shortages occur, there are attempts to short-cut the process. In some cases there have been efforts to obtain drug supplies under the banner of disaster relief.

The health officers of both the Africa and Latin America and Caribbean Bureaus called for a "simpler" procurement process for pharmaceuticals through A.I.D. mechanisms at recent conferences in the last year. In the second conference of the Africa Bureau health officers in 1981, it was suggested that A.I.D. consider a collaborative arrangement with UNICEF to ease the burden of procuring drugs through normal A.I.D. channels and to reduce the costs of pharmaceuticals to host countries. The Office of Commodity Management is presently regularizing arrangements with UNICEF to permit the purchase of pharmaceuticals from UNICEF using A.I.D. project funds providing, of course, that the project so authorizes under appropriate waivers.

Although A.I.D. plans and monitors host country drug procurement, there is no routine mechanism to capture data on funds spent in this area. A.I.D. is not able to state the full amount of funds spent on the purchase of pharmaceuticals for projects or always state the recipient of those funds, outside of family planning pharmaceuticals. An estimation can be made of the costs of the pharmaceutical component in A.I.D. health projects using the July, 1983 inventory. Twenty-one of the 75 projects in the inventory had a budget line for the pharmaceutical component. (The pharmaceutical component consisted of drug purchases, technical assistance and limited construction.) When the total amount on the budget lines were annualized for FY 83, it was estimated that A.I.D. planned to spend a sizeable amount, \$14 million, for the pharmaceutical components of those 21 projects.

A.I.D.'s basic drug procurement policies incorporate, in addition to the source/origin and competitive rules applicable to all A.I.D.-financed commodities, a number of special considerations. A.I.D. also requires measures to assure: that only safe and efficacious drugs are procured (normally by purchasing from the U.S., products approved by the U.S. Food and

Drug Administration); that drugs are manufactured in accordance with acceptable standards which guarantee content and manufacturing quality; that the prices are appropriate to the U.S. setting and that the procurement is sensitive to the special public interest in this important commodity area. The Office of Commodity Management believes these safeguards have worked reasonably well and program needs have been met. Waiver rules for pharmaceuticals have permitted off-shore procurement when justified. Clearly, however, the rules run contrary to field requests for easier off/shore, or local purchase, tie-ins with existing host country procurement mechanisms and greater acceptance of host country determinations as to acceptable product quality and formulation.

3. A.I.D. Health Policy and Strategy Context

This guidance on pharmaceuticals further defines current A.I.D. health policy and strategy which is documented in the A.I.D. Policy Paper on Health Assistance (December, 1982) and the A.I.D. Sector Strategy on Health (May, 1983). In pursuit of the goal of helping developing countries become self-sufficient in providing broad access to cost-effective preventive and curative health services, A.I.D.'s health program assistance concentrates on:

- increasing the cost-effectiveness of health programs through improved program design, management and implementation;
- promoting self-financing health programs; and
- increasing biomedical research and field testing in developing country settings.

The policy refers to specific deficiencies in health care projects related to the provision of basic medicines:

- poor drug supply management systems; and
- inadequate budgeting for drugs stemming in part from lack of analysis on how countries finance drugs;

The policy clearly states A.I.D. support for:

- basic medicines and supplies needed to support program assistance activities;
- technical assistance to design effective supply management systems;
- involvement of private sector pharmacists, distribution channels and manufacturers of pharmaceuticals;
- research to adapt and test new medicines and vaccines in the developing country context; and
- increased donor coordination at the country level on the codification of basic drug lists.

The health strategy provides guidelines for implementing the policy.

A.I.D. will assist developing countries to reduce mortality among infants and children under 5 years of age and to reduce disease and disability in infants

and children, women of reproductive age and other members of the labor force.

A priority focus is given to:

- a basic package of proven, cost-effective technologies delivered in primary health care programs;
- increased research on methods to identify, prevent, treat and control diseases which affect children and adults in the labor force; and
- development of host country human resource and institutional capability to plan, staff and manage the delivery of at least the basic package of health services to the vast majority of its population.

Guidance on pharmaceutical programming is provided in support of A.I.D.'s health policy and strategy.

III. A.I.D.'s GOALS, CRITERIA FOR AID-ASSISTANCE AND APPROACH IN PHARMACEUTICALS

A. Goals

In order to address the therapeutic, management and financing problem areas, the goals of the pharmaceuticals guidance are:

- to augment developing country programs designed to reduce mortality, morbidity and disability among children and adults in the labor force;
- to improve the access to and effective use of drugs selected as essential at the primary health care level by strengthening the pharmaceutical infrastructure and policies of developing countries; and
- to rationalize the cost of basic medicines within the context of health sector expenditures.

In the past, A.I.D. financing of pharmaceuticals under project assistance concentrated largely on procurement of drug commodities as a part of health programming. In future years, A.I.D. will continue to support the procurement of a limited supply of basic pharmaceuticals for project initiation but will couple this with technical assistance and training needed to assure appropriate selection, procurement, distribution and use and where feasible, local formulation of basic drugs. Priority for support will be given to the pharmaceutical component of primary health care projects which focus on preventive measures such as immunizations, family planning and prevention of vitamin deficiencies as well as control of diarrheal disease, malaria, and infectious disease. Priority for support will also be given to programs in countries in which 10% or more of the health budget is used to purchase pharmaceuticals. A.I.D. will assist host countries to achieve a reasonable budget for pharmaceuticals and to target the allocation of drugs purchased more to primary or preventive services than to tertiary services.

B. Criteria For Assistance

A.I.D. will support the pharmaceutical component of health projects when the component has the following objectives:

- increasing the cost-effectiveness and efficiency of drug procurements and use in health programs;
- expanding the supply and appropriate use of essential drugs to the community level through efficient program planning and management;
- indirectly improving the quantity and quality of pharmaceutical sector infrastructure and resources;
- increasing biomedical research in the pharmaceutical sciences within the context of developing country needs.

Increased effectiveness, efficiency of supply and use of basic medicines can lead to an improvement of the pharmaceutical resources and infrastructure of a country. With an initial focus on preventive measures and selected disease control activities, A.I.D. targets assistance and provides a complement for assistance by other donors and a strengthened pharmaceutical base on which to expand primary health care services. The results of research in the medical and pharmaceutical sciences, especially clinical pharmacology, will also serve as the basis for the expansion of services.

C. Approach

A.I.D. will encourage a pharmaceutical sector-wide approach in the development of a country-specific assistance package. The pharmaceutical sector will be viewed in its totality when there is a review, for example, of essential drug policy, resource allocation, financing, distribution and use of drugs.

However, the focus of action should be tied to the selected primary health activities as listed in the A.I.D. Health Strategy.

This approach permits "packaging" of the pharmaceutical component of health projects to suit requirements of the host country. For example, the package of assistance to a country can include support for one or more of the following elements: development of a cost-efficient procurement strategy or the procurement of a limited amount of essential drugs required for a start-up supply; technical experts to assist a local supplier who wishes to expand pharmaceutical production of essential drugs; assistance to structure access to technical and scientific information needed for the development of a project formulary or treatment protocols which serve as the basis for effective use of drugs; training of health workers in the establishment and maintenance of drug stores throughout a primary health care delivery system; research on dosing to achieve desired therapeutic effects and the development of curricula for the continuing education of prescribers and dispensers.

Procurement of essential drugs will continue to be field-driven. Central procurement of essential drugs, similar to that of the Office of Population's contraceptive commodity program, requires a greater management burden and is not planned at this time. However, in the case of oral rehydration salts, A.I.D. expects in the future to create a central inventory of packets from

which supplies can be obtained by regional bureaus, centrally-funded projects and A.I.D. grantees and contractors. This will be viewed as a pilot activity and lessons learned will serve as the basis for later decision-making on procuring basic pharmaceuticals centrally.

Efforts will continue to streamline administrative aspects of procurement and resolve perceived procurement problems. The Office of Health plans to continue to work with the Commodity Management Staff to devise simpler methods and provide technical information to field personnel which can assist in making the A.I.D. procurement process, with respect to drugs, less complex from a field perspective. The Agency will become a more active partner with host countries in devising more flexible, less cumbersome and efficient strategies for selecting and procuring appropriate basic medicines. This can include the use of tie-ins with existing host-country procurement mechanisms.

IV. A.I.D. EMPHASIS FOR THE PHARMACEUTICAL COMPONENT OF HEALTH PROGRAMS

In order to effectively strengthen the pharmaceutical component so it can assist in achieving health goals, it may be necessary to assess the operation and contribution of the sub-sector as a whole to planned health program objectives and activities. A.I.D. will support assessments designed to detail those activities which may require developing and/or improving. This assessment should describe the sub-sector (including both the public and private aspects) and provide an analysis of how it supports the provision of essential drugs, determine the presence or absence of the critical components,

highlight the degree to which that presence or absence contributes to the attainment of health goals and prescribe the scope of remedies which may be needed.

As in the A.I.D. health strategy, the following program elements will be emphasized :

- Improving and expanding use of technologies which are cost-effective, recognized and available;
- Increased research to develop new and improved technologies; and
- Strengthening Human Resource and Institutional Capability;

This emphasis incorporates A.I.D.'s overall priority emphases: technology transfer, institutional development, host country policies, and private enterprise.

The following sections will describe ways in which these elements can be represented in projects. Programming in pharmaceuticals is increasing in A.I.D. For this reason, additional programming illustrations and suggestions are offered to facilitate the promotion and use of this guidance. Not all of the following areas may appear in pharmaceutical components of health care projects but rather a grouping of rationally selected activities under the elements suggested:

A. Improved and Expanded Use of Available Technologies

Cost-effective technologies exist to assure the appropriate selection, procurement, distribution and use of essential drugs. These are available for adaptation and application in the developing country context. A.I.D. will target support for improvement and/or expansion of such technologies. The following are sample activities which could be implemented under this element:

- Assessing the pharmaceutical sub-sector;

- Developing or revising formularies which aid in the appropriate selection of basic drugs and the preparation of projects as a policy dialogue and project development tool;

- Deriving procurement strategies to explore purchasing options such as bulk purchase, letters of commitment and use of tender systems;

- Supplying accurate drug information for appropriate drug selection and use;

- Structuring education programs for patients and prescribers regarding appropriate drug use;
- Establishing sound management of distribution systems;
- Using private sector resources (eg. pharmacists, distribution systems);
- Conducting operations research on issues associated with distribution and use of drugs;
- Expanding or developing indigenous production where feasible; and
- Encouraging the incorporation of traditional and herbal medicine in PHC efforts where it is rational to do so.

B. Development of New and Improved Technologies

A.I.D. currently supports the development of a vaccine for malaria, the field testing of a new rotavirus vaccine and the adaption of a measles vaccine for immunization of younger children. The Agency will continue to support biomedical research which seeks to develop new, breakthrough drugs or formulations for rapid impact on mortality and morbidity in developing countries.

Examples of research activities in the pharmaceutical sciences which A.I.D.'s assistance will concentrate on include:

- testing the efficiency of dosing and biologic availability of essential drugs at the community level;

- improving the formulation, production, shelf-life and packaging of essential drugs in developing countries;

- devising technologies to monitor chronological use and therapeutic effects in developing countries; and

- augmenting the role of traditional medicine as a technology.

The U.S. government has a vast accumulation of data on new dosage forms, dosing trials etc. A.I.D. will collaborate with other U.S. federal agencies to disseminate research information to requesting host country researchers.

C. Strengthening Human Resource and Institutional Capability

A.I.D. will assist host countries which seek to strengthen the capability of personnel and institutions to train pharmaceutical staff, improve supply management and thereby contribute to a strong pharmaceutical infrastructure. As a precursor, A.I.D. will conduct a dialogue on the direction of the essential drug policies of the host country to aid in pinpointing capability strengthening needs. Illustrative activities which could be included under this element are:

- improving institutions and organizations which have responsibility for overall drug supply management such as the central medical stores or pharmacy of ministries of health;
- training of supply personnel in management aspects of procurement and distribution
- improving financing methods and data gathering techniques on the costs incurred in providing basic medicines

V. STAFFING IMPLICATIONS

The Agency's traditional focus on simply purchasing pharmaceuticals for health care projects was a result of field officers doing the best they could with the information and skills available. The guidance outlined in this paper has implications for the Agency's staffing in health. Currently, A.I.D.'s staffing priorities do not require skills in this technical area. Those who have developed skills and knowledge in this area have obtained it primarily through trial-by-fire problem solving. Implementation of this guidance will require greater familiarity and expertise with the technology associated with the administration and science related to pharmaceuticals. It will be necessary to train health officers to manage the planning, monitoring and evaluating of the pharmaceutical component of health care projects. To this end, the Agency has arranged for the production of aids for component design. Examples are the Primary Health Care Formulary and Managing Drug Supply.

Pharmaceutical Sector Resources is an inventory supported by the Agency to identify non-governmental experts in the U.S. who have expertise in international health and who could be called upon by the Agency. However the pool of persons and organizations available for assignment was small. In collaboration with the International Affairs Staff of the Office of Health Affairs, U.S. Food and Drug Administration (FDA), A.I.D.'s Office of Health is making available to missions a listing of the functions of selected offices and agencies in the U.S. Public Health Service (USPHS) which may relate to development of the pharmaceutical component of health projects. Additionally, the Agency will also explore a relationship with U.S.-based academic institutions to provide technical back-up and training on pharmaceuticals to augment A.I.D.'s staff training process.

VI. DONOR COORDINATION

A.I.D. assistance packages developed should assure coordination and collaboration with other donors at the international and national level. Donors such as WHO, UNICEF, World Bank, UNFPA have programs in the area of essential drugs and there are often opportunities to complement and not risk duplication of efforts.

For example, this strategy permits continued collaboration with the Action Program on Essential Drugs (APED) of the World Health Organization (WHO). Governments which adapt the APED will have four features to their national drug programs:

- the establishment or improvement of national drug policies;
- training of manpower;
- development of pharmaceutical infrastructure; and
- mobilization of national and international financial and technical resources.

VII. RESOURCES FOR PROGRAMMING

A.I.D.'s strategic approach encourages exploring the availability of technical and financial resources from a variety of sources. In addition to A.I.D. this could include U.S. and indigenous private sector resources, collaborating with other U.S. government agencies and with other donors such as regional banks and funds.

A. A.I.D.

Host country governments which request assistance under this strategy have central resources available to them. Under the PRITECH project, resources can be used to purchase a limited supply of start-up commodities in support of oral rehydration therapy (ORT) projects, provide information specifically on oral rehydration salts and the involvement of the private sector. The MEDEX project can be used to train host country personnel in the planning and management of essential drug systems. The resources of the Office of

Commodity Management can assist in procurement planning, particularly in developing information as to sources and availability, prices, procurement options and implementation support.

B. U.S. Private Sector

Additionally, within the private sector of the United States there are professional associations, colleges of pharmacy and a wide range of pharmaceutical manufacturers. For instance, these technical resources, though limited in expertise in international health, can be tapped for experts, collaboration on U.S. based training of pharmaceutical workers and the technology of pharmaceutical production, respectively. A.I.D. will seek to collaborate with these private agencies wherever possible.

C. Indigenous Private Sector

In many countries, there is in the private sector professional associations of pharmacists, pharmaceutical manufacturers and distributors as well as training institutions for pharmaceutical workers and traditional medicine. All of these will be a valuable resource when structuring projects.

D. Collaboration with other US government agencies

Several other U.S. government agencies have a range of technical personnel which may be used for programming. Included are the Food and Drug Administration, the Health Resources and Services Administration (HRSA) and the Center for Disease Control (CDC) of the U.S. Public Health Service (USPHS)

and the Overseas Private Investment Corporation (OPIC). FDA has technical experts in all aspects of drug quality control, plant inspection and post-marketing surveillance. HRSA's supply service center can provide information on the development of the depot system for drug supply management. The CDC has an established track record with A.I.D. population projects in logistics training. OPIC can be used as a technical resource for loan packaging for private sector activities. A.I.D. will collaborate with these agencies to increase the availability of resources to project design and implementation efforts in developing countries.

E. Collaboration with other Donors

In addition to those cited above under donor coordination, there are other donors which may have an interest in projects in the pharmaceutical sector. Bilateral donors, regional banks and private regional funds are examples. A.I.D. will seek to promote collaboration with these donors so that funds applied in developing countries can have the maximum effect.

VIII. CONCLUSION

The economic development and increased productivity of developing countries depends on the strengthening and maintenance of health improvements. The use of basic medicines to reduce morbidity, mortality and disease is a key factor in sustaining health gains achieved. A.I.D. has traditionally provided basic

medicines as a part of its health assistance. This will now be coupled with technical assistance and training to assure the appropriate selection, procurement, distribution and use of pharmaceuticals supplied. A.I.D. will give priority support to the pharmaceutical component of primary health care projects which focus on preventive care. Outlining the pharmaceutical component in health and targeting it for assistance, further attests to A.I.D.'s commitment to improving health in developing countries and to making a lasting contribution to economic progress and individual fulfillment in the developing world.

FOOTNOTES

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