Technical Discussions

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REPORT OF THE TECHNICAL DISCUSSIONS ON "THE IMPACT OF DRUGS ON HEALTH COSTS: NATIONAL AND INTERNATIONAL PROBLEMS"

The Technical Discussions were held on 29 and 30 September 1978 in St. George's, Grenada, during the XX Pan American Sanitary Conference, and dealt with the topic "The Impact of Drugs on Health Costs: National and International Problems."

At its session on 27 September 1978, the Conference elected Mr. Wilfred Lee (Guyana) Moderator of the Technical Discussions and Dr. Denise Leclerc-Chevalier (Canada), General Rapporteur. The Director of the Pan American Sanitary Bureau appointed Dr. Pedro N. Acha, Technical Secretary.

At the initial plenary session the Director of the Pan American Sanitary Bureau introduced the topic, emphasizing the concern of the Member Governments over the rising costs of drugs and its effect on the delivery of health services. He pointed out that the high quality of drugs and their proper utilization were essential to the improvement of the health of the peoples of the Americas.

The participants were divided into two working groups, the officers of which were as follows:

Group A

Moderator: Dr. John H. Bryant, United States of America

Rapporteur: Dr. Jorge E. Alfaro U., Costa Rica

Technical Secretary: Dr. Enrique Fefer, PASB

Group B

Moderator: Dr. Mario Gómez U., Colombia

Rapporteur: Mrs. Raquel González Díez, Chile

Technical Secretary: Dr. Harold B. Hubbard, PASB

Group A focused its attention and discussions on the pharmaceutical supply system, including production, procurement, distribution, selection, and utilization of drugs. Group B dealt with national drug policies, including drug costs, legislation and control.

Nature of the Problem[1/]

Throughout the world, in nations of varying degrees of socioeconomic development and with medical systems of varying sophistication, drug consumption is increasing. While a considerable percentage of this increased consumption is due to the appropriate prescribing of potent specific medications for serious illnesses, there is also an element of increased desire on the part of patients for medications for less serious conditions; for example, the stress-related problems leading to the use of "mood" drugs, as well as "fads" or poorly founded beliefs in the efficacy of such drug products as tonics and high-potency vitamins. Also, physicians tend to prescribe unnecessary drugs. One of the serious problems to be addressed by a national drug policy is the disparity between the frequently inadequate provision of drugs essential to the rural population, and the consumption of less important drugs by a relatively affluent urban population with ready access to medical care.

The cost of pharmaceuticals as a part of health care costs is especially important in countries that depend to a great extent on imported pharmaceuticals. Compared to other parts of the health care costs, imported drugs represent an outflow of hard currency which must be balanced against export usually of materials that are not as costly. For this reason, it is important that the imported drugs are carefully matched to the actual needs of the country. There is a growing tendency on the part not only of countries dependent on imports, but on the part of drug-producing nations as well, to address the problem of matching drugs to actual needs through the compiling of lists of essential or basic drugs.

A most important element of a national drug policy is the pharmaceutical supply system which, although varying from country to country, has certain basic components which must be dealt with in any national drug policy. Some of the elements of a pharmaceutical supply system are research, development of new drugs (new chemical entities), the production of the specific drug substance from domestic or imported raw materials, the formulation of

1/ Document CSP20/DT/1, "The Impact of Drugs on Health Costs: National and International Problems"

drug dosage forms, packaging, labeling, procurement, distribution, the development and dissemination of prescribing and dispensing information, and promotion. In a particular country, any or all of these components may be in the hands of private industry, subject to varying degrees of governmental intervention, or a direct function of the Government.

Although the development of a national drug policy is a matter for each nation to approach in light of its governmental and administrative structures, its history and culture, its human and natural resources, and its state of economic development, all of the foregoing elements must be considered.

PHARMACEUTICAL SUPPLY SYSTEM
(Production, Procurement, Distribution, Selection and Utilization of Drugs)

Basic Considerations

Countries should have definite policies regarding their pharmaceutical supply systems. These policies should provide increased coverage of the population with effective and properly utilized drugs at reasonable cost.

Pursuit of these goals needs to be undertaken jointly by government, the health professions and industry. Even where there are different objectives among these parties, resolution of difference should be sought, particularly when the parties agree to the social priorities of serving the populations in need.

Basic Drugs[2/]

The participants recognized the importance of drugs in the protection and restoration of health. Special emphasis should be given to essential or basic drugs which are those most needed for the health care of the majority of the population. These drugs must be readily available to all.

The main purposes of using a list of basic drugs are to assist the government in the pursuit of its priority activities in the health field, improve the utilization of resources, and facilitate the extension of coverage to sectors that do not now enjoy access to appropriate drug therapy.

The lists should correspond to the principal indicators of morbidity and mortality in each country and do not imply the exclusion of other drugs if they are necessary.

Purchasing, Distribution and Utilization

The purchase of basic drugs in large quantity, by non-proprietary (generic) names can reduce substantially the cost of pharmaceuticals. Such

2/ WHO Technical Report Series, 615, "The Selection of Essential Drugs"

purchasing should be based on adequate studies and programs for storage, distribution and utilization. An adequate infrastructure for procurement and distribution is important in making available basic drugs at the various levels of health care. Developing countries may benefit from pooling their pharmaceutical purchases in a joint effort to cover properly their health requirements. Examples of this approach can be found in the Andean Pact and the Caribbean Community.

The importance of responsible decisions by prescribers and consumers was emphasized. In addition, drug advertising and promotion influence drug utilization and expenditures. For these reasons, it is necessary to provide prescribers and consumers with objective and up-to-date information to achieve a more rational use of drugs, including alternative treatment strategies.

Drug Utilization Studies and Surveillance

Studies of drug utilization provide information on local, national, and regional patterns of drug use. These studies permit an analysis of drug expenditures and the detection of inappropriate utilization. If drug utilization is not congruent with predominant disease patterns, these studies will reveal this discrepancy. Further, populations which do not receive adequate drug therapy due to financial barriers or lack of access may be identified. Drug utilization studies can become the basis for an ongoing surveillance system for monitoring drug usage and identifying problems which may be amenable to correction.

Domestic Drug Production

Some developing countries have found the manufacture of pharmaceutical products on a domestic basis to be desirable for the following reasons:

- the expanded availability of drugs and the possible economic savings that can follow from domestic production;
- the gain of technology by manufacturing even simple formulations;
- the utilization of locally trained technical personnel; and
- the possibility of linkages between this industry and other related domestic industry.

PAHO should consider the question of technical cooperation needed to develop production systems, including the role of technical cooperation among developing countries, and other United Nations organizations.

Traditional Medicines

Scientific studies of traditional medicines should be continued to determine their therapeutic safety and efficacy, as a complement to modern medicine. Those with experience in this area should disseminate their information to others interested in this field.

NATIONAL DRUG POLICIES
(Drug Costs, Legislation and Control)

Basic Considerations

The multinational pharmaceutical manufacturers, although relatively few in number, supply a high proportion of the world's medications. They have demonstrated a great capability in research and development of drugs and in ancillary innovation in such areas as packaging and distribution. The principal complaint lodged against these manufacturers has been the cost of their products, especially to the less-developed countries, which has been perceived as often exceeding that required for a fair return.

Many countries have taken steps to control the cost of drugs from these manufacturers and, as a result, an adversarial situation has frequently prevailed. Under these circumstances, opportunities for cooperation in the pursuit of common goals have been lost, and a valuable resource has remained unexploited by those responsible for the provision of drugs to the populations of these countries.

Although many factors affecting drug costs are difficult to control in a satisfactory and equitable manner, there are certain factors under the direct control of governments which might be modified or removed with a beneficial effect on drug costs. As examples, import charges and customs duties, sales taxes, value added taxes and other revenue measures represent, in the case of drugs provided by national health services or reimbursement schemes, simple transfers of funds from one account to another, with the inevitable administrative cost.

The basic purpose of a national drug law and drug regulatory control program is to protect and enhance the health of the population by assuring that drugs and related products, whether imported or domestic, are safe and effective, of high quality, properly packaged and labeled and promoted and distributed in such a way as not to impair safety and efficacy. The national drug law can be an important instrument in implementation of a drug policy, provided it is comprehensive in approach, concise and specific in its requirements, and fairly and firmly enforced. It should clearly define the responsibilities of government, industry, health and allied professions, and other affected parties.

The national legislation should include, among others, provisions relating to:

- registration of drugs based on specific criteria for safety and efficacy;
- licensing of manufacturers and distributors;
- quality assurance, including inspection and analysis;

- packaging and labeling;

- scheduling of drugs with regard to the level of health personnel who might prescribe or dispense the drug, and other restrictions based on potential for abuse, toxicity, and the need for medical supervision in use;

- advertising and other forms of promotion, including prohibition of promotion to the public of certain categories of drugs or of drugs for certain diseases;

- lists of basic drugs and/or drugs to be provided through the health plan or through reimbursement schemes;

- prices of drugs;

- import and export; and

- regulatory action and legal penalties.

RECOMMENDATIONS

The Working Group of the Technical Discussions proposes to the Conference the adoption of the following recommendations:

- THAT each country establish a comprehensive drug control program, including legislation on registration, manufacturing, packaging, labeling, distribution, promotion and advertising.

- THAT registered drugs be submitted to periodic reevaluation regarding their continued marketing.

- THAT the national agency charged with implementing the drug control program be responsible to the Ministry of Health.

- THAT governments provide specifically to the national drug control agency the staff, facilities, and funds adequate to apply properly the drug legislation.

- THAT agencies be established, preferably at the governmental level, with responsibility for providing information on the safety efficacy and quality of drug products, including the use of existing information sources such as PAHO/WHO publications and notices and The Medical Letter.

- THAT PAHO study the feasibility of a PAHO Drug Information Program to collaborate with the above-mentioned national agencies.

- THAT governments encourage at the university and other appropriate levels mechanisms to improve the pharmacological training of all health professionals, including programs of continuing education.

- THAT the role of the pharmacist as a drug information specialist be explored.

- THAT Member Countries conduct simple studies of drug utilization and develop systems for continual surveillance of drug usage.

- THAT PAHO provide technical cooperation and support for country drug utilization studies.

- THAT each Government study and establish, in accordance with its own socioeconomic conditions, mechanisms to reduce the cost of drugs to levels that are equitable to the producer and fair to the consumer.

- THAT governments establish committees to compile lists of basic drugs and/or national formularies, by non-proprietary (generic) names, keep them up-to-date and, for this purpose, secure the participation of health professionals and health sciences faculties.

- THAT a central or national pharmaceutical agency be established with responsibilities for procurement and distribution of basic drugs utilized by the public sector.

- THAT multisource supply systems be used in purchasing to ensure an adequate supply and a competitive price.

- THAT governments establish, when appropriate, national or subregional systems for the production, quality control, and distribution of basic drugs, and that PAHO explore the possibility of arranging for the necessary technical cooperation.

- THAT national authorities maintain close contact with the industry to determine common goals and seek mechanisms for:

  - securing the cooperation of the industry in the conduct of the programs of the governments to extend services to the populations in need;

  - research and development, on a priority basis, of the drugs required to carry out the health programs concerned with the causes of mortality and morbidity in developing countries.

- THAT PAHO organize with the participation of the pharmaceutical industry, a study group to identify areas of cooperation which would be beneficial to Member Countries in their health programs.