Latin America: Essential Drugs

This issue examines the development of essential drugs programmes in Latin America in a national and regional perspective. The region's experience is particularly interesting because some countries' essential drugs programmes predate the elaboration of the WHO concept.

A study of Latin American and Caribbean experience is valuable for another reason and that is the diversity of the region. It encompasses every aspect of the political, social, economic and health care spectrum. Latin American countries range from among the lower on the global scale of economic development to those with a sophisticated technological capacity and highly skilled workforce. They include those whose population health indicators reflect acute social and health care deprivation and others which are comparable to the most highly developed countries. The political heterogeneity of the region demonstrates that a healthy population is not the prerogative of any particular political or social system.

As early as the 1950s Colombia had established a system of prescribing pharmaceutical products under generic names (INN), which later led to the systematic use of generics throughout the entire country. Peru followed with its "social medicines" initiative, which later in 1968 became the "basic drugs programme", a designation which was the precursor of "essential drugs". At the same time, Chile was already promoting the establishment of a national formulary of essential drugs.

By the mid-seventies Brazil had established a system of centralized procurement of drugs within a federal administrative structure. In 1972 the Andean Group (Bolivia, Colombia, Ecuador, Peru and Venezuela) pioneered a major collaborative project to improve drug supply and rational use, creating a first multicountry list of essential drugs and developing mechanisms for integrated operations and normative standards.

Joint drug-related activities initiated by the Latin American Economic System (SELA) in 1981 showed that interest was spreading beyond the health field to become multilateral. The 1984 technical discussions of the WHO Regional Office for the Americas/Pan American Health Organization included the production and marketing of essential drugs, leading to a proposal for coordinated regional action later taken up at various sub-regional meetings.

This spirit of regional cooperation became a recurring theme at the first Latin American Conference on Pharmaceutical Policy and Essential Drugs in Mexico City, organized by the Ministry of Health of Mexico in collaboration with WHO, PAHO, and the Action Programme on Essential Drugs.

The effect of the economic crisis on health care delivery and the availability of essential drugs underlay many of the discussions. Participants expressed concern about the apparent conflict that sometimes existed between the goals of industrial development and public health needs. The economic crisis had led to a situation in which competing demands for hard currency meant that ministries of health - often the weakest government departments in terms of political strength and access to national financial resources - suffered disproportionately.

This was a particularly serious situation in countries with little national pharmaceutical productive capacity.

In most Latin American countries per capita drug expenditure averages US$15 per year, which is a relatively high figure compared to other developing areas (Asia US$4.2, Africa US$3.9 in 1985), although coverage is often only moderate. Many participants made the point that much could be done to improve coverage and self-reliance with a better use of available resources. A rationalization of drug supply would greatly improve the access of the whole population to essential drugs. But in most cases drug needs could not be accurately estimated because of lack of data on morbidity and past consumption, while coordination between public sectors was often weak. A lack of access to good objective information for both health professionals and the general public was another major contrast, while education was still deficient in communicating essential drugs concepts and the use of generic names.

It is clear from the discussions in Mexico, and from the number and variety of essential drugs programmes which have been developed and are evolving in Latin America, that governments recognize access to necessary medicines for all of their populations to be a vital element in health care delivery and social equity. There is also an increasing awareness that developing a national formulary, or encouraging national production, or focusing on any one component of rational drug use in isolation is not enough. Each component of the essential drugs concept forms an indispensable link in the chain without which the system cannot be viable, much as the Latin American countries themselves are developing strength through collaboration and recognition of their interdependence.
RATIONAL USE

A model system for drug supply

Ivan Osterblad*

One of the many problems of drug supply in developing countries is transportation over difficult terrain. This truck negotiates a difficult bridge in Tanzania's Moruga District.

A state collective

Swedish pharmacists had already developed a system of mutual support in the twenties and thirties which particularly aided those situated in remote and sparsely populated areas. When in the 1950s and 60s the Government took over responsibility for the expanding health care services, it seemed a logical step to also include the pharmacies in this "state collective". It was argued that effective modern pharmaceutical management required a strong system which could adapt easily to medical, technical and economic developments, while improving drug information to health professionals and the general public. Some initial resistance soon disappeared as the potential advantages of the new system became apparent. Under 1970 legislation all pharmacies were purchased by the State and all pharmacy owners and other personnel were guaranteed employment.

Apoteksbolaget not only has the sole right to retail drugs in Sweden, but through a subsidiary, also covers 80% of the wholesale market. It operates under the same rules as any other Swedish incorporated company and is committed to providing a good pharmaceutical service and objective information about drugs, in close cooperation with the medical services. A first evaluation of the system in 1983-84 showed it to be highly successful.

A flexible system

The core of the concept is to achieve an organization that can cover the whole chain of drug supply: from purchase to quality control, storage, sales and information dissemination.

Following the example of Apoteksbolaget the different sections of the organization - i.e. stores, wholesale, warehouses and pharmacies, are arranged in an association and administered from a common head office, with the latter responsible for such aspects as purchase, financing, information, external contacts and other common activities.

The model is designed so that it can be easily adapted to fit a variety of circumstances. Different modules can be combined to meet the given conditions, infrastructure, desired capacity and existing markets. Flexibility is the keyword.

What could be gained?

The advantages would probably prove different for individual countries depending on circumstances. But some generally attainable advantages could be:

- improved control, supervision and long-term planning;
- easier inclusion of the pharmaceutical service into social security programmes and health insurance schemes to the benefit of the population;
- regular drug supply, even to remote rural areas where an independent private pharmacy would not be economically viable;
- more rational drug logistics and ability to meet personnel requirements.

But there may also be problems...

Most of the problems of drug supply in developing countries are well known and do not need repeating. However, some are especially relevant to this particular project.

One considerable difficulty will presumably be the relationship to existing systems for drug supply, not least to private pharmacies. If the integration of these is not feasible it will be desirable - and in most cases probably also possible - to find solutions based on coexistence and cooperation.

Another major area of concern will be to establish a sound financial basis for the association. Drug care must be paid both to the initial funding and to long-term financing, to structure the organization in accordance with economic realities.

Among the many decisions to be taken must be how goods and services are to be paid for by consumers. Will drugs be entirely or partially subsidized or will consumers pay the full price? Whatever choice is made the income flow must be secured to enable long-term development.

While organizations for drug supply in industrial countries can normally profit from the existence of a well functioning infrastructure this will not always be the case in the Third World.

The association will need pharmacists, economists, technologists and other specialists who are often in short supply in developing countries. Staff support, possibly from abroad, may be needed and staff training and development should be a major aspect of the association's development.

No miraculous cure

Organizational change is not, of course, in itself a miraculous cure. But the very process of change implies the possibility of improved methods, more rational use of resources, and the chance to tackle the ubiquitous problems of unequal access to pharmaceuticals. Apoteksbolaget now has a proven "track record", embodying the principle of coordination, rationalization and consistency. It has integrated drug supply into a wider health care and economic perspective. In so doing, a community concept whose value is surely not restricted to Sweden's borders, has been tried, tested and found effective.

* Mr Osterblad is a pharmacist who works for the Apoteksbolaget and who has recently conducted a study of its potential applicability to developing countries. Further information can be obtained from Apoteksbolaget, National Corporation of Swedish Pharmacists, 5-1814 Stockholm, Sweden.
RATIONAL USE

Caribbean countries pool resources to lower drug costs

Concerned by irrational use and rising prices of pharmaceuticals, members of the Organization of Eastern Caribbean States (OECS) established in 1986 the Eastern Caribbean Drug Service. The new agency provides pharmaceutical services to the participating countries of Dominica, Grenada, Montserrat, St. Kitts, Nevis, St. Lucia, St. Vincent and the Grenadines. The British Virgin Islands are in the process of joining and Antigua is expected to join in the course of the year.

Centralized purchasing...

As a new public enterprise ECDS's most crucial service is a centralized public tendering for pharmaceuticals. The first ECDS contracts with suppliers were effective 1 June 1987. 100 suppliers had been invited to tender, 66 responded, and 32 were awarded regional contracts. Products are shipped directly from the suppliers to the central medical stores in each country. ECDS is responsible for regional coordination, administration and paperwork.

Each country had established a special account with the Eastern Caribbean Central Bank (ECCB) to fund its purchases from ECDS pharmaceutical suppliers promptly. Because of the stimulation of private sector competition through the public tendering process, and the assurance of prompt payment to suppliers, the ECDS has reduced the unit prices of pharmaceuticals in the Region by a weighted average of 44%. Price reductions for the largest country, St. Lucia, were over 60%. The graph printed here illustrates price reductions obtained on a market based on the top 25 products in each of the participating countries. Price reductions obtained on the second cycle contracts (1988-89) matched or exceeded those of the first cycle.

In addition to the procurement service, the ECDS assists with quality assurance, especially through selection and monitoring of suppliers who are invited to tender and awarded ECDS contracts.

Meeting members' needs...

In order to ensure that this new public enterprise is responsive to the needs of the ministries it serves, all policy or strategic decisions are made by the country representatives who serve on the ECDS Policy Board or one of its two sub-committees. The six ministers of health comprise the Policy Board. The chief pharmacists or supply officers for each country comprise the Tenders Sub-committee. This sub-committee selects the products required, chooses the suppliers from whom tenders will be invited and adjudicates the award of ECDS contracts.

The Tenders Sub-committee also assists the Formulary and Therapeutics Sub-committee, comprised of senior physicians from each island, who have been appointed by their respective ministries. The Formulary and Therapeutics Sub-committee is responsible for both the regional and country formulary process, including the development and publication of a regional formulary and therapeutics manuals that can be used as a reference tool by physicians, pharmacists and other health care workers.

Drug Supply for PHC: courses for managers

MANAGEMENT Sciences for Health, a non-profit technical assistance, educational and scientific institute involved in the management aspects of international health development, holds regular courses on managing drug supply for primary health care. Participants are typically physicians, pharmacists, senior health system managers and technical assistance professionals from donor agencies who are actively concerned with the provision of drugs and medical supplies for primary health care programmes in developing countries.

The courses - which last approximately four weeks - are small and highly participatory and cover the selection, procurement, distribution and use functions of drug supply management.

Further details are available from: Management Sciences for Health, 165 Allendale Road, Boston, Mass., 02130, USA.

A regional drug list...

Beginning in mid-1987, strong emphasis has been given to regional formulary development with the goal of adopting one regional list of drugs for all participating countries. The regional formulary list is based on drugs common to most national formularies of participating countries, the WHO List of Essential Drugs, and other reference sources. The list now contains 238 drugs with a total of 348 different dosage forms.

The ECDS published the first edition of the ECDS Regional Formulary and Therapeutics Manual in July 1988. The 320 page pocket-sized manual contains concise drug information for doctors, pharmacists and nurses. The drug monographs include the usual headings for indications, adverse reactions and dosages, as well as information on clinically significant drug interactions. Prescribing guidelines are included for specific patient types, such as pregnancy, lactating mothers, renal and hepatic impairment, pediatrics and the elderly. Suggestions for patient counselling are also listed for each drug. Prescribers are encouraged to consider relative costs of therapy. The manual also provides comparative daily costs for each drug within a therapeutic class.
Estimating Malawi's drug needs

A high-powered group of 11 Malawian pharmacists and health professionals was assembled to work with WHO staff and advisers to carry out the quantification of Malawi's drug needs. Despite difficulties linked to the highly aggregated nature of the data available, the group managed to carry out its assignment and to generate drug needs for hospital and health centre outpatients on the basis of available morbidity data and draft treatment schedules.

In addition, the group performed various types of data analysis such as ABC analysis and Defined Daily Dosage (DDD) calculation, and compared past drug consumption with the estimates made on the basis of morbidity data for several key drugs. The group concluded by recommending modifications of the data collection form to make future data more useful.

Quantification of outpatient drugs

On the basis of available morbidity data, the group proceeded to de-aggregate the conditions and to assign frequency percentages for each disease group, based on participants' extensive clinical experience. Some 100 diseases or conditions, for which treatment at either hospital outpatient or health centre level would be necessary, were selected. Draft treatment schedules had been prepared and were reviewed and modified before being expanded where necessary. The quantities required of various drugs in 1987 were totalled and, then to estimate needs in 1989 the figures were multiplied by a factor of 1.08 for the expected 4% annual increase in consultations.

Discussion with teaching staff of health training schools on possible additions to curricula, to cover rational prescribing, economic aspects, and the importance of good data collection.

Malawi hopes to repeat the exercise in about a year's time with improved data, but with the same invaluable base of experience and input from all levels of the health system which was of such importance to the success of this exercise.

When a clinic cannot provide medicines patients stay at home. This clinic's empty shelves are reflected in the lack of people seeking care.

Preliminary findings of OTA drug labelling study

AFTER concern expressed about the adequacy of information provided with products sold in developed countries during the debate on the 1986 Drug Export Act - the US Office of Technology Assessment was set up by Congressional and Senate committees dealing with health, the environment and human resources to investigate the situation. Its interim report on the first phase of the resulting study gives basic information on health and pharmaceuticals for Panama, Brazil and Kenya; presents obstacles to improvements, and offers suggestions for further improvements.

Further information about the study can be obtained from the Health Programme, Office of Technology Assessment, US Congress, Washington DC 20510-6025.

Malawi: National Drug Policy Seminar

A seminar bringing together some 60 persons from all over Malawi was held in Lilongwe, from 5-6 September 1988. Both the pharmaceutical public and private sectors were represented, including mission hospitals, local industry, as well as ministries and government organisations. Topics included the new drug control legislation, procurement and distribution by Central Medical Stores, local production, quantification methodology, financing and cost recovery, self-medication and drug resistance, drug information and traditional medicine.

Participants agreed on five broad recommendations to the Government:

1. The protection and preferences accorded to the local pharmaceutical industry should be reviewed with the aim of improving the position of local manufacturers in CMS international tenders.

2. Commodity aid (tied aid) should be considered to be complementary to the regular recurrent budget for drugs (i.e. the value of drugs obtained through commodity aid would not be subtracted from the overall drugs budget, as has been the case in the past).

3. Training of pharmacists and pharmacy assistants should be accelerated to ensure adequate personnel, especially prior to implementation of the new Medicines and Poisons Act.

4. Measures should be taken against unethical prescribers and suppliers of medicines, and to this end, the establishment of an Inspectorate of pharmacy should receive high priority.

5. Dispensing physicians should no longer be permitted to purchase low-priced drugs from the CMS for resale at commercial prices.

Sterilization Slideset

TEAM sterilization of reusable syringes and needles has been adopted as the preferred global policy of the Expanded Programme on Immunization and over 100,000 portable sterilizers have been distributed to the field in the last two years. More recent addition to the range of training materials available from the EPI unit in Geneva is the "Sterilization Slideset." The set of 8 slides, packed in an A5 size plastic folder with an English and French commentary, is intended to be used during the practical training of health workers in the use of steam sterilizers and reusable plastic syringes. The first 26 slides are focused on the basics of loading the sterilizer and conducting a sterilization cycle. The remainder of the slides show the steps of using the sterilizer to be followed when assembling syringes for use and the mechanical cleaning of the syringes and needles.

The slideset was prepared by the EPI using funds and facilities provided by Prestige Medical, United Kingdom.
RATIONAL USE

Argentina: a new agreement with industry

Companies which adhere to the Agreement are required to contribute 3% of their domestic sales to supply essential drugs for the needy.

In 1984 Argentina developed a national centralized drug purchase scheme (SIM - Fondo Asistencia al Medicamento), which incorporated the free distribution of a kit of 60 essential drugs funded by taxes on tobacco and the sale of pharmaceuticals in the private sector. This initiative ran into difficulties due to the economic impact of the taxes and the general development of the economy and was halted for evaluation in 1987.

Opposition to new agreement

A new General Agreement for the Development of the Pharmaceutical Industry in Argentina has now come into being on a voluntary basis. The Agreement sets out new procedures for fast-track products and puts limits on the number of approvals per company; and standardizes procedures for awarding pharmaceutical price increases. Companies which adhere to the Agreement are required to contribute 3% of their domestic sales and these funds will be used to supply essential drugs for the needy. They will also have to reinvest no less than 3% of their revenues in research and development. SCRP reports that there has been considerable opposition to the Agreement from multinational companies, whose Association CAEEM has described as irrational, discriminatory and contravening current pharmaceutical legislation. Companies which do not adhere to the agreement, states CAEEM, will be unable to benefit from the new fast registration system, obtain additional price increases or secure adequate prices for their new products.

Support from local industry

The national pharmaceutical industry association, CILFA, on the other hand, has given its full support to the Agreement, and Cooperalia - the cooperative which represents about 60 national pharmaceutical companies - says that one of the main benefits of the Agreement is the way in which it will promote growth of the local industry through the production of pharmaceutical raw materials for domestic consumption. This in turn will lead to import substitution, create new jobs and improve the balance of trade.

Feedback on prescribing for UK GPs

The cost of drugs for family practitioner services in England is over £1.5 billion each year, and the Department of Health has announced a new scheme to promote more economical and effective prescribing.

Three levels of information are provided, and level one will be sent out automatically. This will tell general practitioners the prescribing costs for their practice and give the averages for the local family practitioner committee and nationally. The figures for the practice are also broken down into the five most important treatment groups in terms of cost (cardiovascular, musculoskeletal, gastrointestinal, central nervous system, infections, and respiratory system). The percentage of prescriptions for generic drugs will be stated.

Level two information highlights particularly expensive aspects of the prescribing and will be sent automatically to doctors in practices where total prescribing costs exceed the family practitioner committee's average by at least a quarter, or costs in the six major groups exceed the average by at least three quarters.

Any other doctor can receive level two information on request. General practitioners can identify their major costs in terms of groups of drugs or individual preparations. When information is given about an individual doctor the figures for the practice are given for comparison. Information about the practice (for a single-handed general practitioner) is compared with the figures for the local family practitioner committee.

The third level is a complete list of all prescriptions written and is supplied on request. This allows general practitioners to perform a detailed audit of their prescribing patterns and could form the basis for developing a practice-specific formulary. The information is available for individual doctors or for the whole practice.

A continuing review of the system will consider further developments, including the possibility of generating information about repeat prescriptions.
New Publications from the Americas


A preliminary first edition, intended mainly for national drug registration departments, drug supply systems and drug information centres, and aimed at facilitating the regional adoption of a common system of drug identification. It contains a list of 378 active ingredients under generic name and 1642 presented in the form of salts, esters and derivatives. The active ingredient nomenclature follows WHO's international nonproprietary names (INN). For those not included in the INN a nonproprietary name (not trade name) proposed by the country where the drug is registered is used.

The structure of the book is similar to that used for the International Classification of Diseases (ICD). It is composed of a tabular list and an alphanumerical index with a six digit relevant code. This allows the classification to be used as a therapeutic reference to the first four digits and if more details are required, the two remaining digits will indicate the active agent and its salt.

Available to institutions free of charge from: Regional Programme on Essential Drugs, WHO Regional Office for the Americas/Pan American Health Organization, 533 Twenty-third Street, N.W., Washington, D.C., USA.


(The development and health benefits of a hospital pharmacy)

This brief guide gives practical advice on most aspects of establishing and running a hospital pharmacy. Topics examined include the structure and functions of a pharmacy service, its personnel, physical infrastructure and reserve activities. The specific functions of a hospital pharmacy, such as drug selection, procurement, quality control, storage, and inventory control, are detailed, as are the distribution and use of drugs, and provision of drug information.

Another section on clinical activities provides suggestions on drug utilization and cooperation with nutritionists and dietitians; patient education on the use of drugs; participation of hospital pharmacists in drawing up treatment protocols; pharmacovigilance in the hospital setting; clinical pharmacokinetics; and cooperation with quality care monitoring programmes. Special emphasis is placed on the rational use of hospital drugs, and on the crucial role of hospital pharmacists in the provision of quality health care. For this reason it is a welcome addition to the literature on the management and use of essential drugs.

Available in Spanish only from: WHO Regional Office for the Americas/Pan American Health Organization, 533 23rd Street N.W., Washington D.C., USA.


A very useful, pocket-sized manual divided into five sections. Section 1 describes the organisation, activities and structure of the Eastern Caribbean Drug Service. A guide to rational prescribing follows in section 2, which leads the practitioner through prescription writing and dispensing; variations in dose selection; prescribing for children and the elderly, in hepatic and renal disease, and during pregnancy and lactation. It also covers the emergency treatment of poisoning and snakebite. Section 3 contains drug monographs, organised by pharmacological/therapeutic classification. Each pharmacological classification heading contains a general statement which provides an orientation to the diseases commonly treated by the drugs within the group, guidelines for treatment approaches, and in some cases cost and therapeutic comparisons. The individual drug monographs follow and cover generic names; indications and contra-indications; special information to be communicated to the patient during the consultation; dosage and administration; available preparations, and common brand names. A glossary of words and terms, plus conversion tables, is given in section 4, and an index to generic and brand names, diseases and symptoms appears in section 5. Each section is colour coded for ease of use.


Report of the First Meeting of Acción Internacional por la Salud - AIS (HAI) for Latin America and the Caribbean, Montevideo, 14 December 1987. Gives an outline of discussions and conclusions from three main agenda items: current situation and prospects of essential drugs programmes; irrational combination products available on the regional market; drug marketing and advertising, with proposals for areas of priority action.

Available in Spanish only from: Acción Internacional por la Salud, Casilla 10993, Sue 2, Montevideo, Uruguay.

Pahef Drug Bulletin Service

Camera ready Spanish translations of the Adverse Drug Bulletin, Drugs and Therapeutics Bulletin and selections from the Medical Letter and other related material are available free of charge for reproduction and distribution throughout Latin America. This material is produced by the Pan American Health and Education Foundation in collaboration with WHO/PAHO. For further information contact PAHES, 125 23rd Street N.W., Washington D.C. 20037.

British National Formulary Scholarship

The British Medical Association and the Royal Pharmaceutical Society, joint publishers of the British National Formulary, are again offering for the first time a scholarship for editorial work experience in the production of a national formulary.

The scholarship will provide six months' work experience as an integrated member of the editorial staff of the British National Formulary, commencing in February 1990 (preferably) or in August 1990. It will include a grant of £4,500 to meet subsistence and travel costs.

Applicants should possess a registrable medical or pharmaceutical qualification and have had at least five years' post-registration experience. They should be fluent in written and spoken English, and have the support of their home institution. A government commitment will also be required that the applicant will be employed by the formulary production on completion of the scholarship.

Application forms can be obtained from: The Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN. Completed applications, with supporting documentation, must be received no later than 31 August 1989.
Clinical Guidelines: Diagnostic and Treatment Manual, Médecins sans Frontieres, 1988, 256p. A therapeutic guide for nurses, medical assistants and doctors in hospitals, health centres, dispensaries and refugee camps. It summarizes epidemiology, prevention, diagnosis and treatment of approximately 200 common diseases and complaints and is based on many years of practical field work. The book is very successful in combining recommendations by technical organizations, such as WHO, and standard specialist handbooks with the practical experience of organizations, such as Médecins sans Frontières, UNICEF and UNHCR. The result is a highly practical manual that can serve as a reference. Its size and price make it as essential as the drugs it is intended to accompany. Available in French only from: Groupe d’Etudes EpidemioLogiques et Prophylactiques, Laboratory de Controle, Pharmacie Centrale, Centre Hospitalier Regional et Universitaire d’Angers, 49033 Angers Cedex, France.

The International Pharmacopoeia, 3rd Edition, Volume 3: Quality Specifications, WHO, Geneva, 1988, 407p. Presents quality specifications for 157 widely used pharmaceutical substances. The volume, which is a continuation of Volume 2 of the International Pharmacopoeia, provides monographs for most substances contained in the WHO Model List of Essential Drugs. Quality specifications were established in consultation with numerous specialists, several Pharmacopoeia Commissions, and a number of national institutes for drug quality control. In keeping with the overall purpose of the International Pharmacopoeia, the monographs are based on sound, classical chemical methods appropriate for use in small and medium-sized laboratories. Searching techniques, such as high performance liquid chromatography, have been included only when necessary for the adequate control of certain complex materials. The monographs for substances are arranged in alphabetical order by Latin name. Each monograph gives clear and concise information on nomenclature, formula, chemical name, description, solubility data, storage conditions, category, identity tests, purity requirements and assays. Presentation of objective tests, requiring less sophisticated equipment and yet capable of yielding reliable information on quality, helps enhance the applicability of the Pharmacopoeia to a large range of laboratory settings. The volume also includes a list of reagents, test solutions, and volumetric solutions followed by expanded information on some general methods, and amendments to the previous volumes. Use of the Pharmacopoeia is further facilitated by inclusion of an extended index, including references to the reagents, test solutions, and volumetric solutions described in previous volumes. Clear, concise, and easy to follow, the volume will be a useful laboratory aid in any country wishing to establish a quality control system for pharmaceuticals.


Radical Community Medicine: Pills, Potions, Profits, No.5, Autumn 1988, 56p. A quarterly journal covering the politics of public health, aimed at providing a forum for critical debate among those involved in public health and health policy, and promoting information exchange. This issue covers the politics of pharmaceuticals, including distortions of distribution and use, campaigns for rational drug use, benzodiazepine dependence, industry and the National Health Service, and the role of clinical trials. Available from: Radical Community Medicine, 55 Fairhbridge Road, London NW3 6EW, UK. Price: £2 per issue, or annual subscription: £8, £11 UK and £13, £18 Europe and world surface mail; £16 world airmail.

Analytical Guidelines, Victorian Drug Usage Advisory Committee, 1988 An excellent guide to analytical therapy, which is a model of clarity and borrows heavily from the highly successful Antibiotic Guidelines, produced by the same Committee. The guide opens with a description of the pathophysiology of pain and the clinical pharmacology of drugs used in analgesia. A number of general prescribing points follow, and the reader is alerted to special precautions to be taken for particular disease conditions or groups. The different routes of drug administration are described. The major part of the manual covers analgesia for defined conditions, symptoms and anatomical areas. Available from: Victorian Medical Postgraduate Foundation Inc., "Travalla", 22 Lascalles Avenue, Toorak, Victoria 3142, Australia.
**Breaking down the walls of the pharmacy**

MEDICINES are an important element in today’s health care yet their use is far from ideal, stressed participants at a meeting on the role and functions of community and hospital pharmacists in Europe, held in Madrid from 29 November to 1 December. Studies in European and other industrialized countries repeatedly identify problem areas such as the overuse of medicines and the excessive use of ineffective or obsolete products, it was reported. This created unnecessary risk to the patient and additional cost both individually and the public health care system as a whole. Improved prescribing and use of medicines can be achieved by cooperation and participation which are not only between professional groups, such as doctors, pharmacists, manufacturers and government authorities, but also patients and the public as a whole.

Current shifts in health policy towards the community and self-care make it necessary for the pharmacist to function fully in the community and not only within the walls of the pharmacy. Pharmacists have wide-ranging contacts in the health care and lay communities and, with training which gives them a broad knowledge of drugs, their properties and uses, in addition to providing services traditionally associated with their profession, they are well placed to play a central role in the multidisciplinary process of ensuring the rational use of drugs. Participants emphasized the need for provision of advice and information on the use of medicines and their side effects to patients and the public, the promotion of health, education in research and drug monitoring.

**Industry - Move towards generics**

FORCES are building that could make the 1990s the decade of the generics. In 15 months, patents will have expired on more than 80 percent of the 100 top-selling US prescription drugs. It will then become legal to make low-priced generic versions of these products. In 1991, generics will get another boost from the Federal Government, when the Medicare Catastrophic Coverage Act of 1988 will expire thereby requiring all US pharmacies to dispense generic drugs to Medicare unless a physician insists otherwise.

A consultant to McKesson Corp., one of the largest US drug wholesalers, thinks the world market for generics could reach US$15 billion in 1991, nearly double what it was in 1986. Some of that surge may come from West Germany, where Parliament is on the verge of passing a health reform bill that caps insurance reimbursements for most prescription drugs, pricing the price of the lowest-cost generic that’s available. The idea is to cut US$1.1 billion off West Germany’s drug bills in 1991.

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**Pakistan: “Let’s dispense treatment not drugs”**

At the end of the workshop participants formulated a set of practical recommendations which covered: rational prescribing; education of both the professionals and the general public; the essential drugs list and the need for its adoption by both federal and provincial governments; the drug distribution system; and drug policies and management through legislation, registration and regulation. The support of WHO and other international agencies had been invaluable in making the Essential Drugs Programme more effective and visible at both the country level, concluded the workshop, and called for the continuation and expansion of such support.

In a closing address, the Special Advisor to the Ministry of Health, reiterated the Government’s special interest in health care and the essential drugs concept, and endorsed the workshop’s recommendations.

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**Africa: Organizing for health**

AFRICAN consumers are getting ready for changes. At the 1st IOCU conference in the continent, some 120 participants from 19 countries met in Nairobi, Kenya from 14-18 June 1988 to discuss urgent problems that face their people. At the end, they adopted the “Nairobi Declaration” which expresses the commitment of the consumer movement in Africa to a common mission and identifies specific actions needed. On health, the participants urged governments to:

- to provide safe, effective and affordable medical products to all consumers who need them, in compliance with the WHO’s essential drugs policy;
- to support, encourage and disseminate research into traditional medicinal products and practices;
- to adopt the WHO Guidelines on Ethical Media for Medicinal Drug Promotion.

The Declaration encouraged the strengthening of the existing network of groups involved in drug-related issues in Africa.

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“A herbalist selling his wares in a Sudanese market. The “Nairobi Declaration” encourages research into traditional medicine.”

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“Cost recovery not a goal in itself” concludes French conference

CAN health systems in developing countries be self-financing or is this nothing more than the latest trendy idea to development circles? What is feasible? Where? What action should be taken? By whom? These and other questions were tackled by some 40 health professionals, researchers, students and representatives of international development agencies at a two-day Montpellier seminar organized in February by Medicus Mundi France.

Given the differing economic and geographic circumstances it was not possible to come up with standard solutions, participants concluded. It was essential that new approaches be carefully considered in a local context which took into account socio-cultural, economic and other issues. Nor could pharmaceutical cost recovery be regarded as a goal in itself but only in relation to the quality of health services and their accessibility.
LETTERS TO THE EDITOR

MaLAM calls for better drug information

At the 1988 WHA, Dr Arnold of the International Federation of Pharmaceutical Manufacturers Associations (IFMAPA) said that “the industry had a key role to play in the provision of information and a responsibility that it should be accurate and reliable and should not mislead”. (Essential Drug Monitor 1988; 7:4). We write to express support for his statement.

The Medical Lobby for Appropriate Marketing (MaLAM) is an international organisation for health professionals concerned about misleading advertising. Our aim is to encourage drug companies to provide sufficient, consistent and accurate information to enable appropriate prescribing, dispensing and administration of drugs. We support the development within drug companies of International Marketing Quality Control Systems (IMQUCS) as a key factor in the improvement of advertising. All IMQUCS need a set of standards to implement. The IFMAPA Code is important because many companies have used it as a starting point for developing their own marketing standards documents.

We have supported the IFMAPA’s work by recommending over 500 violations of their Voluntary Code of Marketing Practice. Our experience has enabled us to identify two priority areas for improvement of the IFMAPA Code. We have suggestions for upgrading the requirements for disclosure of warnings and provision of evidence to support claims.

Disclosure of warnings

The IFMAPA Code appears to require that printed promotional material concerning drug products must be in the form of a statement of side effects, precautions and contra-indications. However, the Code does not require that this information need not necessarily contain all the above information. ‘Reminders’ need only be offered to the readers. Consequently, less responsible drug companies can claim that all their advertisements are reminders and thus avoid the disclosure requirements except for the generic names. Allowing such interpretations of the Code makes its requirements trivial. We conclude that Section IV of the IFMAPA Code should be improved by replacing the current wording with Sections 1010-13 inclusive of the WHO Ethical Criteria for Medicinal Drug Promotion. Section 13 of the Ethical Criteria defines “reminders” as advertisements without claims.

Provision of evidence to support claims

The IFMAPA Code states that companies have an obligation to “use complete candour in dealings with public authorities, industry, health professionals and the public”. It also requires that “information should be based on evidence which is accepted by all the available scientific evidence and should reflect this evidence clearly”.

MaLAM frequently requests drug companies to provide information to support their advertising claims. We regularly request advertisements to become appropriate. However, some less responsible companies have refused to provide information about their drugs. We suspect that failure to provide information indicates an awareness that the evidence supporting their advertising claims is inadequate or non-existent. However, certain companies maintain that they have no responsibility to inform health professionals about drugs. We have reported a number of these companies to the IFMAPA.

The IFMAPA’s response has been that “the principle which is followed by IFMAPA, in evaluating complaints which refer to the need for scientific evidence, is as follows: Account is taken of the regulatory status of the product and where the product has been evaluated and registered by an established regulatory authority, this will be accepted as evidence of adequate scientific data”. (3) The IFMAPA has also refused to provide the evidence or to direct companies to provide us with the opportunity to do so.

MaLAM takes a very different position from the IFMAPA on this issue. We believe that all health professionals have a responsibility to demand the advancement of scientific medicine. Self-regulation should mean that the industry takes some responsibility for evaluating disputed advertising.

Government regulatory authorities have the key role in evaluating drugs promotion. However, to place the full onus for the evaluation of claims on government regulatory authorities is an unacceptable and unacceptable burden. Arthur Yellin of the United States Food and Drug Administration wrote in February 1989 that “the vast majority of promotional material submitted for consideration by the US FDA is false and/or misleading (but) the agency is able to take regulatory action in only about 5% of the cases, primarily because of a lack of resources”.

Improving the IFMAPA Code

The IFMAPA Code could be improved by the adoption of Sections 6 to 9 inclusive of the Ethical Criteria, which includes the following statements. All promotional-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, consistent, capable of substantiation and in good taste. Scientific data in the public domain should be made available to prescribers and any other person entitled to receive it, on request as appropriate to their requirements. A key step in implementing these criteria will be to ensure that all promotional claims are accompanied by references to scientific data in the public domain which provide substantiation for every claim.

Upgrading the requirements for disclosure of warnings and provision of evidence to support claims are priority areas for improving the IFMAPA Code. However, the IFMAPA could do better by putting their support behind the entire WHO Ethical Criteria. If they fail to adopt the entire Ethical Criteria we must ask them to justify their lower standards.

Innovations in the availability and quality of drug information will obviously benefit health professionals and patients and also benefit from having better informed health professionals because effective prescription and greater value for money. It is also likely to release the more responsible sections of the pharmaceutical industry to narrow the gap by tightening the IFMAPA Code so that scientists are not disadvantaged by unfair competition.

Dr Peter Mansfield

MaLAM Secretary

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Extract From Ethical Criteria For Medicinal Drug Promotion, WHO, Geneva, 1988

PROMOTION

6. In this context, “promotion” refers to all informational and persuasive activities performed by manufacturers, their agents, the effect of which is to induce the prescriber, supply, purchase or use of medicinal drugs.

7. Active promotion within a country should take place only with respect to drugs legally available in the country. Promotion should be in keeping with national health policies and in compliance with national regulations, as well as with voluntary standards where they exist. All promotional-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, consistent, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable use of the drug or to give the wrong risks. The word “side” should only be used if care is properly qualified. Comparison of products should be factual, fair and capable of substantiation. Promotional material should not be designed to disguise its real nature.

8. Scientific data in the public domain should be made available to prescribers and any other person entitled to receive it, on request, as appropriate to their requirements. Promotion in the form of financial or material benefits should not be offered or sought by health care practitioners to influence them in the prescription of drugs.

9. Scientific and educational activities should not be deliberately used for promotional purposes.

ADVERTISING

(a) ADVERTISMENTS IN ALL FORMS TO PHYSICIANS AND HEALTH-RELATED PROFESSIONALS

10. The wording and illustrations in advertisements to physicians and health-related professionals should be fully consistent with the approved scientific data sheet for the drugs concerned or other source of information with similar content. The text should be fully legible.

11. Some countries require that advertisements should contain certain product information, as defined by the approved scientific data sheet or similar documents. For a given period from the date of first promotion or for the full product life. Advertisements that make a promotional claim should at least contain summary scientific information.

12. The following list, based on the sample drug information sheet contained in the second report of the WHO Expert Committee on Essential Drugs (1) and appended by expert review, contains an illustration of the type of information that such advertisements should contain, among others:

- the name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug
- the brand name
- content of active ingredient(s) per dosage form or regimen
- name of other ingredients known to cause problems
- approved therapeutic uses
- dosage form or regimen
- side-effects and major adverse drug reactions
- precautions, contra-indications and major interactions
- name and address of manufacturer or distributor
- reference to scientific literature as appropriate.
Mexican conference on essential drugs

The economic crisis in Latin America has created grave problems for health care. At a time when resources are diminishing, health needs are increasing. 15-30% of the population have no regular access to essential medicines and even where drugs are available their rational use is no means the norm. In this context, concluded participants at the First Latin American Conference on Pharmaceutical Policies and Essential Drugs, new approaches to the production, supply and use of drugs are indispensable.

The Conference - organized by the Ministry of Health, and the Mexican National Institute for Public Health, in collaboration with WHO and the Pan American Health Organization - was held in Mexico City from 10-14 October 1988. More than 120 experts from 21 Latin American countries shared experiences, problems and possible solutions in the complex area of formulating and implementing national drug policies. The wide range of disciplines represented - which included medicine, pharmacy, economics, anthropology and sociology - ensured lively and far-ranging discussions. Despite the diversity of the countries involved, the common objective of identifying strategies that would ensure the accessibility and rational use of drugs throughout the region, acted as a catalyst for the meeting.

The meeting focused on five themes: pharmaceutical policies; production; supply; rational use; and regional cooperation, to which a sixth - drug financing - was added during the course of the discussions because of the degree of interest expressed in this topic.

Reorientation of drug production

Production should be geared towards meeting therapeutic needs, and essential drug lists should act as a guide for investment and production, the goal being the development of a sound national essential drugs industry.

Role of the state

The state should play an important role in drug production. It could help meet the needs of the priority sectors - such as vaccines - and of people not covered by the private sector. It should also regulate the sector, establish pharmacological norms and lists of agreed drugs. Production by the public sector could positively influence supply and demand.

Local production

Participants noted the predominance of multinational companies in Latin America and stressed the need to strengthen local industry. They generally considered that health needs could be better met by supporting national industry, but views differed on the desirable extent of local production in each country. Some recommended its increase so that few imports would be necessary, although this could result in high prices. Others emphasized the need for combined efforts at the regional level rather than seeking self-sufficiency for each country at any cost. Whatever the level chosen, it should go hand-in-hand with quality, good manufacturing practice and the full exploitation of natural resources.

Patents

Patents were the subject of extended debate. Some participants favoured patents, arguing that they are essential for the promotion of research and development. Others maintained that patents impede the development of national industry. The group concluded that it should be possible to arrive at a common regional position which took into account the need to provide a financial basis for innovation while avoiding a situation in which patents would be an obstacle to national development.
REGIONAL COOPERATION

It was clear from the discussions that regional cooperation already exists in many areas. Even so, this can be strengthened and participation in regional drug supply, research and development, technology transfer, clinical pharmacology and joint procurement. Other models of cooperation—such as those dealing with the field of oil and the Central American Common Market—could also provide valuable insights and guidance. The development of a Latin American Pharmaceutical and the harmonization of pharmaceutical and health legislation at the sub-regional level would also facilitate regional cooperation.

The groundwork was laid for a Latin American Information Network covering every aspect of the drug sector: legislation, technology, programs, experts, lists of essential drugs, suppliers, quality control, systems, pharmacological information on drugs and new products. Drug information centers to provide more specific data on drugs should be considered a priority, the group concluded.

A GOOD CONFERENCE

So what were the achievements of this first Latin American Conference on Pharmaceutical Policy and Essential Drugs? Perhaps the principal aim was an increased understanding of the interactive nature of the various components comprising a drug policy, and the wide range of disciplines involved in efficient planning and implementation. It was also helpful to share problems and learn how they had been tackled, sometimes successfully, in different countries. The meeting publicized existing regional initiatives and paved the way for other coordinated activities that can use pooled resources and strengths. Perhaps the conference itself exemplified one theme which reverberated through the discussions, namely the need for easily accessible and objective information. Information that would provide the basis for appropriate education, legislation, drug selection, distribution and purchase, and rational use of medicines by both professionals and consumers.

Finally, this multicultural and multidisciplinary exchange made a very real contribution to developing a common understanding of how a rational drug policy incorporates objectives and components in line with the WHO Revised Drug Strategy. Participants requested WHO's Regional Office for the Americas to approve the conference conclusions and to support countries in the formulation and implementation of national drug policies.

(The Proceedings of the conference are available in Spanish from: Dr. Noél Raccah, Instituto Nacional de Salud Pública, Fac. de P. Médica & Real, 173 1pito, Col. Plateros, Mexico D.F., 04400.)


drug supply

Supply problems can jeopardize the success of any health policy, warned participants, adding that there was frequently a lack of planning and coordination of the whole process. Frequent problems included:
- no information on past drug consumption or morbidity so that accurate estimates of need cannot be made;
- commercial interests which may conflict with health priorities;
- administrative difficulties, such as changes in personnel, lack of resources, late payment by the state, and scarce market intelligence;
- poor storage, distribution and quality control.

Although a drug supply system seems to involve separate activities, these are all interlinked. Careful planning and coordination by a multidisciplinary team is necessary to ensure the selection of products based on safety, accessibility and therapeutic efficacy.

The efficacy and transparency of administrative procedures—particularly those related to acquisition—should be increased, and procurement procedures should be clearly specified and closely followed. A suitable organizational structure, trained personnel and adequate funds, facilities and equipment, are the necessary structural components. Centralized state pharmaceutical buying has proved successful in Latin American countries which have implemented such a system (e.g., Mexico), although it was acknowledged that improvements can still be made in this area. But while state pharmaceutical vendors should be centralized, distribution should be decentralized, participants stressed. Unifying the drug supply systems of the various government bodies maximizes efficiency and facilitates integration at the intersectoral level. An adequate quality control system, a legal framework, and an information system covering inventories, suppliers and prices are also useful tools.

RATIONAL DRUG USE

Rational drug use can also play a major role in health policies, particularly in the containment of pharmaceutical spending.

Poor prescribing practice was cited as the major problem area. The reasons are multiple and complex, but include inadequate training in clinical pharmacology, the promotional activities of the drug companies, pressure from patients and paucity of information. Participants expressed concern about the lack of knowledge of essential drugs and of generic names.

Measures to improve prescribing and to influence self-medication need to be part of a comprehensive policy which includes legislation, information, drug monitoring, training and education at all levels of the system.

The participants recommended that pharmacists be integrated into health teams, since they are often the most reliable source of information on the indications, interactions and side effects of medicines. To achieve this integration and to improve prescribing patterns, drug therapeutic committees and medical audits should be established or reinforced. The development of information centers is a priority task in each country since they provide the best channel to disseminate information on medicines to health professionals and the general public.

The rational use of drugs also depends on the knowledge and attitudes of the population, the consumers, and public information campaigns which show the risks of uninformated self-medication, and the properties and role of drugs in health care should be intensified. The use of generic drugs should be encouraged among the population as a means of rationalizing use and decreasing family expenses. Similarly, the participants agreed that the rational use of drugs should be backed-up by strong legislation, which, among other aspects, would regulate the promotional activities of company representatives.

DRUG FINANCING

The frequent emphasis on problems related to drug financing in the early days of the conference led to the establishment of a small group to examine the issues involved. The international situation, the debt crisis and the internal recession in most countries have caused a reduction in public expenditure on health and drugs. Various international agencies have proposed as a solution the decentralization of services and the transfer of public spending to consumers. But the group expressed concern about these alternatives and alerted the conference to the danger they might pose for the most vulnerable groups of society.

An exclusively economic approach to the drug sector is not adequate to its myriad aspects, participants argued. Rather, an interdisciplinary perspective is necessary in order to
LATIN AMERICA

Colombia: Major programme to tackle inequality of drug supply

Colombia, like many countries in the latter half of this century, has experienced major social and demographic change. Its population has doubled in 30 years, rising from 15 million in 1959 to around 30 million in 1989. While scarcely 25 years ago 70% of the population lived in rural areas, now 66% of the population is concentrated in the cities. And these changes are reflected in patterns of death and disease. Twenty years ago the leading causes of mortality in the country were enteritis, diarrhoea and malnutrition, whereas by 1985 myocardial infarction, cerebrovascular diseases, other heart diseases, homicide and cancer head the list.

Despite an economic growth rate of about 5% in recent years - the highest in Latin America - the Government estimates that 22% of Colombians are living in absolute poverty. The average working family's monthly expenditure has been assessed at US$130, but economic analysis in Colombia is complicated by a parallel illegal economy. The value of illegal exports of marijuana, coffee between US$15 000 and US$3 000 000 per annum.

The social and economic complexities and contrasts which characterize life in Colombia are not without their repercussions on the health sector, and on the pharmaceutical sector in particular.

The country has one doctor per 1150 population, 7 000 pharmacies, more than 200 drug manufacturers (Colombian and foreign) and there are some 6 000 pharmaceutical specialties in circulation. It is estimated that one third of the population does not have access to health services and that about 30% of households cannot afford the drugs they need, although the average annual per capita expenditure on drugs is estimated at US$10 - more than enough to supply the entire population with essential drugs. Drug utilization studies in Colombia have shown that there are marked inequalities in consumption, which is concentrated in the urban areas among the wealthiest classes of the population.

Ensuring compliance with good manufacturing practice is one important measure of the Colombian Essential Drugs Programme.

What is happening today...

At present there is no overall pharmaceutical policy to frame, guide and control the selection, procurement, production, distribution and utilization of drugs.

Although certain elements of an essential drugs policy are in place, such as the national essential drugs list and pharmacological forms for the registration of products, they exist in isolation and are not integrated into a cohesive structure. As a consequence these measures have not produced the desired results.

For example, the procurement and supply of drugs by institutions in the public sector are decentralized. Even the most remote rural health centres deal directly with a wholesaler or pharmaceutical laboratory to obtain the small quantities it needs in order to function. This "decentralization" gives rise to high and uneven levels of drug prices, and makes it almost impossible for the Ministry of Health to exercise due surveillance and control.

Most institutions make purchases by direct negotiation - sometimes more than 20 times a year - and frequently without any methodology to determine the type and quality of drugs they should obtain. Ordering is based on past consumption rather than real needs.

What is it hoped to do...

Faced with this situation, the Colombian Government, with the assistance of WHO and the Pan American Health Organization, carried out a large investigative study of the pharmaceutical situation in the country in the second half of 1988. This led to the development of a national essential drugs strategy and programme whose initial cost is estimated at US$200 000. The European Economic Community and WHO/PAHO will participate in its funding and ensure international technical assistance for three years.

The programme will support the Government in the implementation of activities covering the selection, procurement, production, marketing and utilization of the drugs, which are all included in the action plan on essential drugs, a component of the national health plan.

People in Colombia spend more than US$10 annually on drugs but use is far from rational.

The technical structure of the Ministry of Health in Colombia will also be strengthened under the programme in order to enhance multi-disciplinary coordination for the implementation of the essential drugs policy.

Programme objectives...

The national health plan underscores the necessity for the Government to ensure that essential drugs are available when and where needed and at accessible prices. In practical terms this will necessitate policy formulation and, if necessary, rationalization of production to respond to health needs, a restructuring of the drug marketing sector and the strengthening of the public sector supply system.

Some very specific measures and mechanisms...

The Ministry of Health recognizes that local industry is a vital partner in the restructuring and rationalization of drug supply and demand under the essential drugs policy. But the pharmaceutical sector cannot be successfully restructured by economic means alone. Other important measures which the Government plans to introduce in its national essential drugs programme include:

- strengthening the drug monitoring system to ensure quality control;
- ensuring compliance with good manufacturing practices;
- re-evaluating the safety, efficacy and quality of the many products on the market;
- facilitating correct use through standardization of doses, presentation and packaging;
- promoting the essential drugs policy in the universities, scientific associations and professional associations, through the provision of independent and objective information on the drugs;
- introducing a national therapeutic formulary for the public sector;
- strengthening and enforcement of the regulations controlling the sale of drugs on medical prescription;
- mass public education campaigns to promote the proper use of drugs and especially to stress the advantages of essential drugs;
- inclusion of the concept of essential drugs in the training of health professionals;
- promotion and support of continuing education to improve prescribing and dispensing practices.

The Colombian programme is one of vision, which it is hoped will have far-reaching consequences at every level of health care. The country is fortunate in that - unlike others in the Third World - it has the human resources and technology to take up this challenge. Long term success will depend on maintaining today's political will, enthusiasm and determination that the equitable access to rational drug therapy is an achievable national goal.
Quality control: a network of laboratories

WHILE no quality control programme can be complete without a laboratory service, the mere fact that laboratories exist does not mean that there is effective and efficient quality control. This is borne out by conditions in Latin America where dozens of laboratories for drug analysis in the health sector, the universities and the industry itself co-exist with an alarming lack of control over the quality of drugs marketed, nor guarantee - within acceptable limits - the quality, safety and therapeutic efficacy of the drugs supplied to the consumer.

The cause of this seeming anomaly is, that efforts and resources are often directed to the analysis of samples taken under varying conditions which do not meet standards for statistical validity. Testing is also frequently undertaken within the framework of programmes that have no visible effect on health. In many cases this type of activity enables the laboratory to pay its own way, an objective to which many ministries and governments are pledged as a partial response to the economic crisis that is having repercussions on the health sector. In their efforts to survive what is becoming a chronic economic situation, the original goal of such laboratories can be lost from sight, and an academic exercise substituted which is unrelated to the real health viewpoint. Even in situations where the laboratories work to improve public health, lack of the legal machinery to back up corrective measures and delays in putting such measures into effect result in wasted investment.

After a study of the problem was made in 1984 by WHO's Regional Office for the Americas, it was decided to establish operational units at national centres with similar functions and activities. This would facilitate the updating and sharing of knowledge, and permit the mobilization of national and international resources.

In the four years since the Network's establishment much has been achieved. Standards for good laboratory practice have been prepared and agreed. These define, briefly and systematically, the general principles that should guide the conception and administration (management and operation) of the official control laboratories in the health sector, in order to guarantee the quality, integrity and reliability of the results of analyses. A regional programme for external quality control has been established initially with the support of the official laboratory of the University of Buenos Aires and now with the cooperation of the United States Food and Drug Administration (FDA). Other programmes cover the preparation of reference material and methodology for collaborative studies.

A hoped for spin-off of this work will be the acceptance and mutual recognition of the analytical results and research by the institutions of countries participating in the system, and the effective establishment of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce. Library updating has also figured as a prominent part of the strategy. With financial support from CIBAGEGY, Switzerland and the United States Agency for International Development (USAID), network members were provided with sets of key literature, each worth several thousand dollars. This sum, although not apparently large, was considerably beyond the reach of most of the institutions concerned, due to hard currency restrictions resulting from the economic crisis. With no possibility of updating material, the libraries were rapidly becoming obsolete.

From its inception, the importance of training senior and middle-level staff in laboratory management was recognized and a series of training workshops has formed part of the network strategy. A training programme and teaching materials - developed and tested by the School of Public Health of Mexico and the National Laboratory - are now being distributed to members to facilitate the organization of national courses. The Network has also been very successful in developing closer relations between participating institutes, reflected by the number of staff exchanges - a rare practice in the past.

Despite many positive results, there are still obstacles to overcome if the strategy of setting up a laboratory network is to prove as successful as in other fields. These include a certain inertia that still affects many of the institutions in the Network and appears difficult to dispel. This may stem from a failure to define the role which the laboratories should play in a local public health context, causing them to function in isolation without the opportunity to integrate or participate in specific programmes. Poor communication between technical and political levels is another problem and has hampered systematic staff training and career development. The combined result of these factors has been a sustained frustration which can sap individual and collective enthusiasm.

Despite these very real difficulties, it seems probable that the rationale of the Network, combined with the stimulus of its activities, will enable it to develop and face such challenges. A joint venture to optimize the use of separate resources clearly makes economic and scientific sense. This is reflected in the growing awareness of the value of such interchange and collaboration in helping quality assurance laboratories meet the demands of the public health role they should play - as shown by the increase from 10 to 21 in the Network's membership during the four years of its existence. No one would dispute that quality assurance is a pre-requisite of effective and rational drug therapy. Equally, the laboratories' essential contribution to this goal cannot be overstated.

Cooperative Programme on Pharmaceuticals

THE Pan American Health Organization and the US Food and Drug Administration (FDA), began a cooperative programme in January 1984. The objective is to help strengthen national drug regulatory agencies and improve pharmaceutical manufacturing practices in order to ensure the availability of safe and effective drugs in Central and South America.

Under this agreement, the FDA has provided a drug specialist to serve as a PAHO consultant for up to two years to assist in organizing and presenting formal training programmes.

Earlier collaboration resulted in the development of training materials in Spanish that were successfully used in a pilot training course held in Chile in June 1986 and a second course held in Mexico City during November-December 1987. Since the cooperative programme began, courses have been held in Colombia, Costa Rica and Guatemala, and preparations have been completed for a 1989 course in Brazil.

The updated course material, consisting of 16 training modules, about 500 slides, 19 audiovisual programmes, reference material, and a bibliography, will be used to train 400 to 500 Latin American industry and government professionals during a three-year period. PAHO will donate a duplicate set of these training materials to each participating country so that they can repeat the course or parts of it in accordance with their needs (Figures 1, 2, 3 and 4 are illustrations from course material).

In addition to the one-month sub-regional training courses, the programme provides for on-the-job training through direct technical assistance to participating countries and advanced training opportunities at US pharmaceutical plants or FDA field offices.

For further information contact: Dr Enrique Fefer, WHO Regional Office for the Americas/Pan American Sanitary Bureau, 525 23rd Street N.W., Washington D.C., USA.
Rationalizing drug use in Costa Rica

The essential drugs concept has contributed to Costa Rica's remarkable progress in maximising health resources.

Selecting essential drugs

A national formulary, containing 362 drugs in 522 dosage forms, using generic names only, was established in 1982 in order to rationalize drug use. Each health care institution selects from this list, written by the Ministry of Health, whereas the CCSS uses almost the whole formulary.

The lists are updated by multidisciplinary committees which basically use the WHO selection criteria of efficacy, security, cost/benefit, and combinations only in certain conditions. Responsibility for maintaining and updating the ED list within the CCSS lies with the Committee of Pharmacotherapy, composed of physicians, specialists and pharmacists.

Equal importance are the functions of the Department of Pharmacotherapy, which analyses every drug purchased, in its quality control laboratory, collaborates on purchase programming and actively promotes rational drug use. The work of the Department is backed up by some 90 hospital and clinic pharmacotherapy committees which manage drug supply and use at the local level.

A broad range of strategies has been developed to encourage rational drug use:

Education

There is continuing education for doctors and pharmacists during which they identify and analyse problems in their own working environment and jointly develop a series of objectives to bring about better prescribing practice and drug use. These lead, in turn, to the development of optimal standardized drug treatment plans. 35 trainers have been trained and some 200 doctors and pharmacists have so far participated. The impact of the course is evaluated by measuring drug consumption at the local level before and after participation, using defined daily dosage (DDD) methodology. With help from WHO/PAHO's Regional Essential Drugs Programme the course methodology is being polished so that its use can be extended to other countries in the region.

Information

In order to provide objective, unbiased and up-to-date information on drugs, the Department distributes a monthly "Medical Letter" every three months to all doctors and pharmacists. This contains articles translated into Spanish and taken from the Medical Letter (USA) and the Drugs and Therapeutic Bulletin (UK). A bulletin containing decisions of the pharmacotherapy committee and new information or directions concerning the Essential Drugs List is also distributed at regular intervals. In addition, the Department produces a journal called "Farmacós" (Drugs), with reports on clinical drug investigations, utilization studies and literature reviews.

Brazil: rationalizing procurement

In 1975 Brazil created a state-owned enterprise, Central de Medicamentos (CEME), to rationalize the procurement of medicines for public hospitals and clinics and to provide free prescription drugs to the poorest in the population.

The first essential drugs list was issued in 1972. The present list contains 231 products, after reduction in 1987 to counteract the effects of pharmaceutical shortages that arose during 1986 and to ensure adequate supplies. The criteria used for the revision included cost of manufacture, extent of use, and the proportion of locally produced raw materials. A further measure to improve supply was the setting up of 19 basic pharmacies operating in public service outlets. Each pharmacy is supplied with 30 essential drugs in 44 presentations.

CEME, which currently serves about six million people, hopes to extend pharmaceutical supplies to the entire needy population, estimated at 50 million people. This will be done by supplying a basic list of some 40 drugs. The second field of CEME activities covers the promotion, research and production of essential drugs. Of the total consumption of drugs in the country, the government health services account for 15%, supplied by publicly owned manufacturing companies.
LATIN AMERICA

64% savings by essential drugs revolving fund: the FORMED experience

THE availability and use of drugs in Central American countries is limited by numerous socio-economic, technical, and administrative factors, as well as by the structure of the drug industry and the international and national pharmaceutical market. Formed, a project of the WHO/PAHO, provided a one of these factors: government procurement of drugs, confirmed that the prices paid by governments not only varied greatly from country to country but were also considerably higher than those obtained through PAHO or UNICEF.

Start-up funding...

In an effort to make the most efficient use of economic resources, particularly scarce foreign exchange, and faced with reduced purchasing power, an essential drugs revolving fund (FORMED) was established in 1986 to facilitate drug procurement at substantial savings. The Fund permits prompt payment of suppliers and allows countries a period of grace in which to make reimbursements. The Government of the Netherlands, which contributed US$400,000 to finance the Joint purchase of a selected number of drugs, while a contribution of US$277,000 from the Government of Sweden funded the technical cooperation necessary to implement the programme.

Additional Swedish contributions of US$300,000 in 1988 and 1989 have been used to improve the infrastructure at provincial and local levels in order to provide better storage capacity and controlled distribution.

Economical large-scale purchases make it possible to acquire a greater quantity of drugs and, consequently, extend coverage to groups in need while keeping costs low. However, the objectives of this initiative go beyond reducing cost. It also seeks to enhance regional collaboration, improve information flow, and strengthen management of the purchase process, and promote participation by local industry in the purchase made.

Selecting 16 essential drugs...

In the initial phase of the project, 16 essential drugs were selected on the basis of the following criteria:

- the small number of basic drugs required to treat the most prevalent diseases should be included;
- the drugs should be part of specific health care programmes for the control of priority health problems;
- they should be single drugs of good quality and recognized effectiveness although FORMED accepts combinations if therapeutically justified;
- their price should represent a sizable public sector expenditure and/or consumption and utilization of foreign exchange;
- they should be listed in the latest report of the WHO Expert Committee on Essential Drugs.

FORMED also covers the purchase of raw materials for the production of drugs that meet the above criteria. The selection is reviewed periodically by WHO/PAHO and the countries so that they can be adjusted to reflect changes in national morbidity and mortality profiles in order to meet real priority needs.

Significant savings...

A cost comparison of some of the products acquired through FORMED and the prices paid by the countries in 1985 demonstrates the Fund's ability to achieve significant savings (Table 1). These ranged from 26% to 75%, reflecting the varying efficiency and negotiating capacity of the different purchasing systems within the subregion.

FORMED was able to make these savings through: (1) competitive international bidding, (2) prompt payment in dollars, (3) purchases packaged in economical units, (4) bulk buying, and (5) selection of the most economical method of transportation.

Initial operational problems...

The first round of purchasing in 1986 revealed a number of specific operational problems, such as unacceptable expiry dates, inadequate external packaging, wrong language on the labels, delays in receiving analysis results from reference laboratories, and incorrect shipping documents. More important were the delays caused by long delivery times (which made programming difficult and necessitated emergency purchases) and by slow customs clearance. In addition, some countries had regulations limiting the procurement and importation of drugs through FORMED or hindering prompt reimbursement of the Fund. However, because they are motivated to make the FORMED mechanism work, the countries have succeeded in overcoming most of these obstacles. And WHO/PAHO — based on the experience of the first purchase — has adjusted its purchasing process, particularly the selection of suppliers, in order to ensure maximum compliance with the terms of the bidding process.

Will FORMED survive?

FORMED has undoubtedly met its goals of promoting regional cooperation. Its capacity to reduce the cost of procuring priority drugs has been widely documented, although this advantage was somewhat diminished by operational problems during the first round of purchases — problems that will be solved as PAHO and the countries acquire experience and better mastery of the processes and transactions involved. However, the rotation of the fund, and thus the future of the initiative, is threatened by the difficulties which participating countries face in obtaining foreign exchange for prompt reimbursement. In an attempt to overcome the problem, WHO/PAHO, early in 1989, initiated discussions with the Central American Bank for Economic Integration to explore alternative mechanisms that can be instituted through the Bank. FORMED participants are hopeful that solutions will be found and that this cooperative venture will become a permanent force in Central American drug purchasing.
LATIN AMERICA

Drug policy in Cuba

The fact that countries may not share the same social system does not preclude their working together to provide all their citizens with equal access to necessary and good quality drugs.

Prior to the Cuban revolution there was no national health plan and hence no supply plan. The pharmaceutical sector resembled that of any other market economy country, with about 500 private drug companies, 70% of which were foreign. About 80% of the drugs were imported and there was a huge variety - some 20,000 in all - many of which were duplicates with the same active principle and different brand names. Pharmaceutical activity was concentrated in the capital, which had more than 60% of the pharmacies and the professionals involved in pharmacy.

After the revolution, the pharmaceutical companies were nationalized. This enabled scattered production to be rationalized and units to specialize in different pharmaceutical forms. Year by year the industry has incorporated new plants, equipment and production technologies which have improved productivity and quality.

In 1968, the country decided to centralize the planning, production, distribution and importation of drugs under the sole management of the Ministry of Health (MINSAP). The Ministry regulates all aspects of production, circulation, distribution, importation, exportation, standardization and research in the field of drugs.

A comprehensive network of 11 national drug companies, 16 provincial laboratories, more than 500 dispensing pharmacies and 258 hospital pharmacies means that 93% of the drugs consumed in Cuba can be produced in the country from imported raw materials.

While rational use is a cornerstone of Cuba's national drug policy and in its broadest sense touches on every programme component, specific objectives are to:

- Increase the number of graduate pharmacists, improve the practical relevance of their training, and include basic knowledge of pharmacology and pharmacotherapy in the training of all medical and health personnel;
- Improve collaboration between pharmacists and doctors in clinical and community pharmacy and in research;
- Prevent the number of drugs with the same active principle;
- Evaluate the use of drugs through population surveys, monitoring and surveillance and the dissemination of information on drugs, and provide public education on appropriate drug use;
- Guarantee the quality of nationally produced and imported pharmaceuticals through the quality control system and drugs register;
- Improve the drug distribution system by linking the supply system with planning, health indicators, technological development, advanced technology and medical criteria;

After the first few years, the Ministry of Public Health (MINSAP) established a system of quality control for domestic production and of importation. The Cuba's most important health indicators - infant mortality and life expectancy - are 13.3 per 1000 live births and over 70 years of age respectively. These are comparable with those of the developed countries and show the value of an integrated health policy, not only in the field of drugs but in respect to all the factors which influence health.

But Cuba is now looking beyond national boundaries to the wider regional perspective. There are immense possibilities for industrial pharmaceutical development through cooperation, exchange and an integration of efforts by groups of developing countries. The fact that countries may not share the same social system does not preclude their working together to provide all their citizens with equal access to necessary and good quality drugs.

Abremex: a good example of regional cooperation?

Argentina, Brazil, Mexico and Spain have increased their collaboration in the field of pharmaceutical raw material manufacture through the Abremex project, which started in 1984. The long-term objective of the project is to rationalize pharmaceutical production, avoid duplication and favour inter-country trade.

Under the Abremex umbrella representatives from the ministries of health and industry, the local pharmaceutical companies of the participating countries, and WHO engage in open dialogue at regular meetings. Activities included under a first plan of action cover:

- Information sharing on raw materials and active ingredients produced in each country, essential drugs manufactured and export production capacity
- Identification of study topics, such as pricing policies, measures needed to facilitate regional integration, research and development
- Transfer of technology between participating countries

Young patient in the William Soler Pediatric Hospital, Cuba.

*creation of an tripartite private company - in which Argentina, Brazil and Mexico hold equal shares - to develop biotechnology and genetic engineering;

The national health and industrial authorities in each country are essentially acting as coordinators for the main participants in the scheme, who are the national producers. However, differences between national policies in areas such as customs, patents, and hard currency have limited the speed of implementation of this collaborative scheme although it must be appreciated that such a bold initiative requires time for maturation. One major lesson emerging from the project is that such initiatives cannot fully develop their potential unless accompanied by the development of consonant national policies.
Bolivia: a project to rationalize the essential drugs supply system

In 1977, the national authorities in Bolivia moved to develop a programme which would improve the supply of drugs in the rural parts of the country. The project, initiated at the time with the cooperation of USAID, did not meet its goals because of inadequate administrative control and the limited coverage it was able to achieve. In 1979, an attempt was made to revive it and broaden its scope, but the high cost and the inappropriate selection of drugs caused problems also with this project.

In 1982 a national formulary was compiled, originally containing 270 drugs, and now enlarged to 306 drugs in the most recent version. The following year the Government announced its aim of organizing and centralizing the pharmacies to supply drugs in order to eliminate intermediaries by direct importation, to free itself from the monopoly of the transnational corporations, to introduce generic drugs, and to provide incentives for the national production of drugs.

The result was the creation of the National Institute of Medical Supplies (INASME), which was to have responsibility for the procurement, supply, distribution, marketing, production and quality assurance of drugs and to cover both the public and the private sectors. The initial capital for INASME came partly from credit granted by the Central Bank of Bolivia, and partly from donations from the Netherlands and the United States to a value of approximately 1.4 million dollars.

"Popular pharmacies... a lack of public confidence"

The original idea was that the drugs imported by INASME should be distributed through the private pharmacies, but the resistance of these pharmacies, together with a selection of drugs which did not correspond to the country's needs, forced INASME to open "popular pharmacies" as a channel of distribution through which its products could move. Some of these pharmacies were under the direct control of INASME and others were operated as concessions, without there being any criteria of service to the public to determine where they should be located. The capital of INASME was gradually depleted through its inability to recover the revenue from the sales made in the pharmacies and problems with stock management. In 1986 the Government transformed INASME into the Department of Pharmaceutical and Medical Supplies, which now manages 40 pharmacies and 60 popular retail points. Some 20 generic drugs are offered at prices which may be as much as 50% lower than prices for similar brand products. In theory these drugs are only to be sold against prescription, a condition which is not respected. But in any case, the reputation of these pharmacies has slumped as many basic drugs are lacking.

The lack of a comprehensive national drug policy has adversely affected the drug supply system in both the public and private sectors. There is no basic list of essential drugs; supplies are inadequate; legislation does not meet today's needs, there are no incentives to stimulate local production of essential drugs; there is no effective system of quality assurance; hospital pharmacies play no part in the rational use of drugs, nor are there any programmes for the training of health personnel.

A new plan of action

It is against this background that the Government is once again considering how to rationalize the essential drugs supply system. A comprehensive proposal for action, with a budget of one and a half million dollars from external resources is now under active consideration and funding is being sought.

The overall goal of the proposed programme is to improve all components of the public sector supply system so as to increase the availability of essential drugs and to make them more accessible to the less income or economically marginal sectors of the population. The programme will have three principal thrusts:

- a comprehensive national drug policy, that will include legislative and administrative reforms, a national essential drugs list which will be compulsory in the public sector, a system of quality assurance, and promotion of the national use of drugs;
- structural changes needed to merge the present drug supply systems in the public sector into a single system, and improve each of its components, such as estimating requirements, centralized procurement, storage management, and a drug surveillance system;
- a pilot programme to supply essential drugs free of charge or at a nominal price to low income groups.

Venezuela: public and private sector collaborate on generic essential drugs initiative

The essential drugs concept already forms an integral part of Venezuela's public sector health services. But many in the population - the unemployed, the middle class, or those who for some reason or other have been marginalized by society - do not have access to public health care.

For these groups, who are particularly affected by the continuing economic crisis, the Government, working jointly with public health bodies and the private sector represented by the national pharmaceutical industry, is attempting to set up a generic essential drugs programme.

Key elements of the new programme will be:

- a list of 36 essential drugs marketed under their generic name;
- control of retail and wholesale prices;
- the requirement that manufacturers produce adequate quantities of the selected drugs;
- the requirement that distributors and retailers ensure that sufficient stocks are maintained to meet demand.
Peru: an essential drugs pioneer

Jose Chiñexe

Peru’s current approach to the provision of essential drugs is entrepreneurial and characterized by confrontation rather than confrontation.

During the first phase of the programme, which lasted three years, the drugs were made available by the Government through 2000 health posts, on the basis of the manufacture of the drugs, factoring in costs being reimbursed to the industry within 30 days. In general, this worked well although some problems were encountered due to underestimation of consumption, the building up of inventory stocks, and Government cash flow problems.

Resistance from pharmacists

In the second phase it was planned that the whole of the public through outlets sponsored by religious and social organizations but this policy met with resistance from the pharmaceutical profession (Colegio Químico Farmacéutico), which opposed the dispensing of drugs outside pharmacies. As a compromise, it was agreed that the 90 drugs should instead be distributed through more than 3500 private pharmacies and 2000 non-pharmaceutical outlets.

The implementation of this revised phase of the programme started in February 1989. Initial results are promising although prices have proved to be somewhat higher than those which the Government intended. However, they are in all cases at least 40% cheaper than the equivalent trademark product.

Concrete results

Peru’s experience shows that despite the grave economic crisis currently affecting the country and limiting the financial resources available for health care, it is still possible to improve access to essential drugs. The key has been flexibility, the willingness to learn from experience, and the development of a sound infrastructure. Peru’s current approach has been entrepreneurial and characterized by collaboration rather than confrontation.

The results are concrete: 10% of drug production now reaches the very poorest and most geographically isolated members of the population. Given the sustained national commitment to the provision of essential drugs, this figure can be expected to increase and the programme further evolve to meet the health care needs of the future.

* Mr J. Chiñempe is Director of the Laboratorio Farmacéutico de Vision, has worked closely with successive Peruvian essential drugs programmes.

The Mexican experience

The first list of essential drugs appeared in 1958, the first national drug formulary in 1966, and the national formulary (Cédula Basico de Medicamentos) for drugs in the public sector in 1977. An interministerial commission on the pharmaceutical industry was established in 1977, proposed a set of minimum standards for the facilities and equipment of the drug industry, and consolidated legislation for the procurement of drugs by the health sector. This became official practice in 1980.

The following are some conclusions arising from the implementation of the 1958 list:

Structural Weakness

Despite a shortage of drugs experienced in 1982 revealed structural weaknesses of the drug industry in the country. There was heavy dependence on foreign imports of basic intermediates; dependence also on the multinational companies; difficulty in obtaining appropriate technology; and lack of coordination in research and development. As a result, the Ministry of Health and other bodies instituted an emergency plan to deal with shortages. Legislation was enacted to control and rationalize the use of drugs and vaccines.

However, new policies met with strong opposition, mainly directed at the use of generic names without registered trademarks on all products sold to the health sector, the addition of generic names to registered trademarks in the private sector, the elimination of drugs from the register, and the ban on irrational combinations of drugs. In 1984, the Mexican Government decided to change these regulations, and in April 1985 a new set of rules for implementation of the decrees replaced the previous ones.

New policies

In the implementation of the new policies, the registration procedure was modernized and computerized, and all the products on the drug register are reviewed. Currently, combinations of drugs are being tackled by the Ministry of Health in its campaign to promote the rational use of drugs in the private sector. The quality control of both the manufacturing process and the products will be improved, good manufacturing practices will be enforced, and a Mexican pharmacopeia has been published. An adverse drug reaction information system was established in 1986.

Patent problems

1986 revisions to the patent law give process patents protection for pharmaceuticals produced through industrial processes. But drugs produced through technological processes will not be covered by process patents for 10 years after the amendments come into force. Product protection will be given to the chemico-pharmaceutical industry and the biotechnology industry in 10 years. For both process and product patents the period of protection will be 14 years.

There have been arguments about the impact of these changes on the industry. The multinational companies maintain that the introduction of product patents will benefit the whole industry, while national companies say they are not ready for such a change and that the Government should wait until they have further developed their own industry.

Procurement incentives for local producers

The procurement scheme for the public sector has been modified to make it more efficient and to create incentives for national producers. Under the new scheme the Government does not have to pick the company making the lowest bid but can choose one that bids within 15% of the lowest price if certain conditions are met. These conditions relate to performance in fulfilling previous orders, investment in manufacture of raw materials, Mexican share of capital, trade balance, and amount of locally manufactured ingredients.

Free essential drugs

Finally, a programme of free distribution of 60 essential drugs to the poor was instituted in 1987. These drugs may also be retailed at preferential prices.
HEALTH, as a basic social objective, is widely accepted by all nations despite an international reality marked by ideological differences and conflict. Health care should serve as a bridge to understanding, cooperation, solidarity, justice and peace. This is the philosophy which underlies a wide-reaching plan for joint action to solve common priority health needs agreed upon by the governments of Central America and Panama.

Economic crisis

The Central American Region is enduring the most profound social, economic and political crisis in its history. This has reached such proportions that the social sectors, including health, are having difficulty in maintaining past levels of social development. Resources for public health and for basic health services have decreased while mortality from infectious diseases and malnutrition is increasing.

The plan “Priority Health Needs in Central America and Panama” seeks to mobilize resources on behalf of the most vulnerable sectors of the population, particularly children, the rural and urban poor, and displaced persons. The Pan American Health Organization (PAHO), WHO’s Regional Office for the Americas, is coordinating the development of the Plan.

In conclusion, Mexico, like many other countries that are having to adjust to the economic crisis, has developed a strategy aimed at:

— strengthening its essential drugs policy by improvement of the national formulary, review of the drugs on the market, promotion of rational use of the public and private sector, rationalization of procurement, and increased coverage and distribution of drugs to the poor; and

— fostering the development of the national drug manufacturing industry.

The new policies have contributed to improved coverage of the population and to changes in the pharmaceutical market structure, in which Mexican firms have traditionally had a small share. The public sector purchasing policy is responsible for the increased share since Mexican firms are preferred as providers. As many of the measures described here have only recently been introduced, it is difficult at present to assess their full impact and progress.

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No! say Chilean manufacturers to stricter patent protection

In voicing its opposition to the introduction of stricter patent protection in Latin America, the Chilean National Pharmaceutical Companies Association, ASILFA, said it would be “contrary to the interests of every Latin American country”. ASILFA said this in response to calls for changes in legislation at the First Latin American Conference on Pharmaceutical Policies and Essential Drugs, held recently in Mexico City.

The implementation of such patent laws would cause an increase in pharmaceutical prices by giving the multinational companies a near-monopoly on the pharmaceutical market. Multinationals still make large profits despite the lack of patent protection in these countries.

It is understood that the US Pharmaceutical Manufacturers’ Association (PMA) had filed a trade petition against Chile in February 1989 but withdrew it when the Chilean Government hinted that it might be willing to change the law. Since then Chilean Government representatives have had some discussions with the PMA but with no agreement in sight. The PMA might submit another complaint if it does not obtain any concessions from Chile.

Access to essential drugs

Improving the supply and use of essential drugs is a major component of the Plan. The Central American countries and Panama annually invest close to US$250 million in drugs, of which more than US$100 million worth is purchased by the public sector. This amount will increase considerably as coverage is extended and a health system which reaches all population groups is developed.

Although there are pharmaceutical manufacturing plants of various levels of sophistication in the region, their present production does not satisfy current demand so a substantial portion of pharmaceutical products are imported and subject to world market variations. Moreover, national industries must import the main ingredients and other inputs, which means that both locally manufactured and imported products represent an important foreign currency drain. The Central American countries lack coherent pharmaceutical policies. A national policy which stresses coordination and cooperation among various sectors, such as health, commerce, industrial production, treasury and planning, is required to assure the availability of medicines that satisfy real needs. There are weaknesses in handling drugs at all levels of the system, from selection and acquisition to distribution and utilization. Among the most serious flaws are the inadequate infrastructure and the poor training systems.

Young lives to protect - life can be hard in the rural areas of Central America.

US and European Funding

The strategies are being implemented through five subregional projects which are complementary and that, as a whole, address the priority areas identified by the Central American Health Ministries. The projects are funded by grants provided by US and European donor agencies, who are also involved in the financial support of activities in other areas within the “Priority Health Needs” Plan, such as tropical diseases, child survival, and food and nutrition.

Many activities under an integrated plan

A single annual integrated workplan is developed for the five pharmaceutical projects at a coordination meeting attended by representatives of all participating countries. Since 1984, when the first project was funded, numerous activities have been carried out ranging from, for example, workshops and courses (on topics as varied as hospital pharmacy administration, development of national formularies, drug regulation, and Good Manufacturing Practices); the preparation of guidelines and manuals; and the establishment of storage and pharmacy facilities at hospitals and health centers; to the distribution of reference books to national drug information centers and drug control laboratories; the pool procurement of essential drugs through a revolving fund, and direct technical assistance to the participating countries.

It is too early to evaluate the impact of this large-scale effort. It is already clear, however, that Central America now has a core group of professionals who are knowledgeable in matters relating to the formulation of drug policies and the development of national essential drugs programmes.
Technical cooperation in the Americas: No more "reinventing the wheel"

Technical cooperation among Developing Countries (TCDC) means acquiring, adapting, transferring, and sharing knowledge and experience to achieve greater national and collective self-reliance - the cornerstone of social and economic development.

The availability, quality and use of pharmaceutical products developed and manufactured in Latin America and the Caribbean as in any other region of the world. Problems in these areas (such as the "disappearance" of an essential drug from the marketplace, the contamination of I.V. fluids, or the inappropriate prescribing of expensive or potent drugs) may assume crisis proportions for the authorities. The ensuing newspaper headlines and other pressures may push them to improvise and too-responses. Such symptomatic treatment will not prevent the recurrence of the underlying problem, on the contrary, it is almost certain to reappear, compounded by the distortions produced by the earlier measures.

Avoiding management by crisis

The need to avoid management by crisis and, more important, to take the initiative to minimise difficulties in this politically sensitive area, has been recognised by many governments in the Americas. They have launched various programmes, more comprehensive and better funded in some countries than others, but all aimed at improving the availability, quality and use of drugs. Frequently, these undertakings have been carried out by nations on their own, with their own resources - that is, the countries involved have utilized the knowledge, experience and the technical and managerial capabilities, as well as the funds available in their institutions, whether they be from the government, university or other sectors.

Of course, some countries have called on bilateral and multilateral development agencies for technical and financial assistance in implementing their pharmaceutical policies. The WHO Action Programme on Essential Drugs was set up precisely to respond to requests of this nature. And agencies such as DANIDA, SIDA and the World Bank, to mention a few, have become more supportive of activities in this area.

Yet, between each country independently developing its own programmes (and sometimes wasting valuable time in "reinventing the wheel") or relying on international expertise and funding (and becoming dependent on them) there is an alternative that can provide long-term benefits to all participating parties.

Increased technical capabilities

During the last decades, there has been a significant increase in the levels of political sophistication and technical capabilities of Latin American and Caribbean nations in matters relating to pharmaceuticals. The experience and expertise gained are relevant to circumstances in neighboring countries as well as in those at similar stages of socio-economic development.

Yet, we have become accustomed to bringing at great cost experts from far away lands, who are not fluent in the local language. We expect them to advise on national programmes and projects that take place within a social and cultural framework foreign to their background.

TCDC: knowledge sharing for self-reliance

The long-lasting economic crisis that burdens Latin America is forcing a re-evaluation of the traditional methods of providing technical assistance. Surely it is possible to develop schemes that are not only cost-effective but that also contribute to a long-term relationship and a better understanding between nations, thereby also contributing to the much sought after integration of Latin American and Caribbean countries.

Such a strategy already exists and is called Technical Cooperation among Developing Countries (TCDC). Organized by the interested governments concerned it can involve tech public and private sectors. It is aimed at acquiring, adapting, transferring and sharing knowledge and experience in order to achieve greater national and collective self-reliance, the cornerstone of social and economic development. In short, TCDC is an agreement of mutual cooperation to work together in a specific area of development.

TCDC does not replace technical cooperation from developed nations or international organizations. On the contrary, in WHO's Regional Office for the Americas the mobilization of national resources through TCDC is considered an effective strategy which expands the impact of the Organization's necessarily limited efforts, since AMRO regular staff and budget are but a fraction of those available in the countries.

In this manner the full range of resources available in developing and developed countries, as well as in multilateral organizations, are mobilized towards common goals, avoiding duplication of effort and contributing effectively to regional development in terms defined by the countries of the Region. This, after all, is the purpose of technical collaboration, regardless of its source.

Four initiatives to confront regional health problems

For this reason, high priority has been given to the establishment of TCDC programmes and the Regional Office has supported four special initiatives geared to sub-regional action:

- The Plan for Priority Health Needs in Central America and Panama;
- The Andean Cooperation in Health;
- The Plan for Health Infrastructure Development in the Southern Cone Countries;
- The Caribbean Cooperation in Health.

Each initiative has been developed to confront common health problems with priorities selected by joint decision of the health ministers of the countries involved. Each addresses five to seven common health priorities, and essential drugs was considered to be one of them in all but the Caribbean initiative.

The ministerial level decisions were followed by technical meetings of the government officials responsible for their national drug programmes to analyze in detail specific problems and to prepare joint projects with common workplans for their solution. The workplans developed to date cover a broad spectrum of activities which address the different components required for a comprehensive drug policy. These range from the preparation or updating of drug lists, through organizing courses on Good Manufacturing Practices, to improving pharmacy and storage facilities at hospitals and health centres.

Developed countries such as France, the Netherlands, Norway, Spain, Sweden and the USA have provided financial and/or technical cooperation to facilitate the process, while international agencies assist in the co-ordination of activities. As a result, joint programmes and projects are now underway throughout the region.